# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, DC 20549**

# FORM 10-K

☒ **ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the fiscal year ended December 31, 2020**

**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) |

1615 South Congress Avenue, Suite 103
Delray Beach, Florida 33445
(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 | Trading Symbol | Name of Each Exchange on Which Registered |
|---|---|---|
| Common stock, par value $0.0001 per share | AZRX | Nasdaq Capital Market |

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

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

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

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

Indicate by check mark 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 ☒ No ☐

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 | ☒ | Smaller reporting company | ☒ |
| | | Emerging growth company | ☒ |

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

The aggregate market value of common stock held by non-affiliates of the registrant, based on the closing price of a share of the registrant's common stock on June 30, 2020, 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 $25.2 million.

There were 74,439,377 shares of the registrant's common stock, par value $0.0001 per share (the ''*Common Stock*''), outstanding as of March 29, 2021.

**AZURRX BIOPHARMA, INC.**
**ANNUAL REPORT ON FORM 10-K**
**YEAR ENDED DECEMBER 31, 2020**

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## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

- statements regarding the impact of the COVID-19 pandemic and its effects on our operations, access to capital, research and development and clinical trials and potential disruption in the operations and business of third-party vendors, contract research organizations (''*CROs*''), contract development and manufacturing organizations (''*CDMOs*''), other service providers, and collaborators with whom we conduct business;
- the availability of capital to satisfy our working capital requirements;
- our current and future capital requirements and our ability to raise additional funds to satisfy our capital needs;
- the accuracy of our estimates regarding expense, future revenue and capital requirements;
- our ability to continue operating as a going concern;
- our plans to develop and commercialize our drug candidates, including MS1819, and niclosamide;
- our ability to initiate and complete our clinical trials and to advance our principal drug 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 vendor(s), CROs, CDMOs 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 drug candidates and our ability to serve those markets;
- the rate and degree of market acceptance of our drug candidates for any indication once approved;
- the success of competing products and drug 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.

Factors that may cause actual results to differ materially from current expectations include, among other things, those set forth in Part I, Item 1A, ''*Risk Factors*,'' herein and for the reasons described elsewhere in this Annual Report on Form 10-K. Any forward-looking statement in this Annual Report on Form 10-K reflects our current view with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our operations, results of operations, industry and future growth. Given these uncertainties, you should not rely on these forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business and the markets for certain drugs and consumer products, including data regarding the estimated size of those markets, their projected growth rates and the incidence of certain medical conditions. Information that is based on estimates, forecasts, projections or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained these industry, business, market and other data from reports, research surveys, studies and similar data prepared by third parties, industry, medical and general publications, government data and similar sources and we have not independently verified the data from third party sources. In some cases, we do not expressly refer to the sources from which these data are derived.

In this Annual Report on Form 10-K, unless otherwise stated or as the context otherwise requires, references to "*AzurRx*," the "*Company*," "*we*," "*us*," "*our*" and 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.

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## PART I

### ITEM 1. BUSINESS

#### Overview

We are engaged in the research and development of targeted, non-systemic therapies for the treatment of patients with gastrointestinal (''*GI*'') diseases. Non-systemic therapies are non-absorbable drugs that act locally, i.e. in the intestinal lumen, skin or mucosa, without reaching an individual's systemic circulation.

We are currently focused on developing our pipeline of gut-restricted GI clinical drug candidates. Our lead drug candidate is MS1819, a recombinant lipase for the treatment of exocrine pancreatic insufficiency (''*EPI*'') in patients with cystic fibrosis (''*CF*'') and chronic pancreatitis (''*CP*''), currently in two Phase 2 CF clinical trials. In 2021, we plan to launch two clinical programs using proprietary formulations of niclosamide, a pro-inflammatory pathway inhibitor; FW-1022, for Severe Acute Respiratory Syndrome Coronavirus 2 (''*SARS-CoV-2*,'' or ''*COVID-19*'') gastrointestinal infections, and FW-420, for Grade 1 Immune Checkpoint Inhibitor-Associated Colitis (''*ICI-AC*'') and diarrhea in oncology patients. Each drug candidate is described below.

*MS1819*

MS1819, a recombinant lipase enzyme for the treatment of EPI associated with CF and CP, is supplied as an oral non-systemic biologic capsule. MS1819 is derived from the *Yarrowia lipolytica* yeast lipase and breaks up fat molecules in the digestive tract of EPI patients so that they can be absorbed as nutrients. Unlike the standard of care, the MS1819 lipase does not contain any animal products.

EPI is a condition characterized by deficiency of exocrine pancreatic enzymes, primarily lipase, resulting in a patient's inability to digest food properly, or maldigestion. The deficiency of these enzymes can be responsible for greasy diarrhea, fecal urge, abdominal pain and weight loss. We believe that there are two principal therapeutic indications for EPI compensation by MS1819: (i) children and adults affected by CF, and (ii) adult patients with CP. There are more than 30,000 patients with EPI caused by CF according to the Cystic Fibrosis Foundation and there are approximately 90,000 patients in the U.S. with EPI caused by CP according to the National Pancreas Foundation. Patients are currently treated with porcine pancreatic enzyme replacement (''*PERT*'') pills.

We have determined to initially pursue the indication for adults in CF.

*Completed Phase 2 OPTION Bridging Dose Monotherapy Study*

In October 2018, the U.S. Food and Drug Administration (''*FDA*'') cleared our Investigational New Drug (''*IND*'') application for MS1819 in patients with EPI due to CF. In connection with the FDA's clearance of the IND, we initiated a multi-center Phase 2 bridging dose safety study in the fourth quarter of 2018 in the U.S. and Europe (the ''*OPTION Bridging Dose Study*''). We targeted enrollment of 30 to 35 patients and dosed the first patients in February 2019. In June 2019, we reached its enrollment target for the study and in September 2019, we announced positive results from the OPTION Bridging Dose Study.

Results showed that the primary efficacy endpoint of coefficient of fat absorption (''*CFA*'') was comparable to the CFA in a prior Phase 2a study in patients with CP, while using the same dosage of MS1819. The dosage used in the OPTION Bridging Dose 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 OPTION Bridging Dose Study was not powered for statistical significance, we believe the data demonstrated meaningful efficacy results, with approximately 50% of the patients showing CFA 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 Bridging Dose 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 Bridging Dose Study.

*Ongoing Phase 2b OPTION 2 Monotherapy Trial*

In October 2019, the Cystic Fibrosis Foundation Data Safety Monitoring Board (the ''*CFF DSMB*'') completed its review of our final results of the OPTION Bridging Dose Study. It found no safety concerns for MS1819, and supported our plan to proceed to a higher 4.4 gram dose of MS1819 with enteric (delayed release) capsules in

multi-center dose escalation Phase 2b clinical trial (the "*OPTION 2 Trial*"). In December 2019, we submitted the clinical trial protocol for the OPTION 2 Trial to the existing IND at the FDA. The clinical trial protocol was reviewed by the FDA with no comments. In April 2020, we received approval to conduct the OPTION 2 Trial in Therapeutics Development Network clinical sites in the U.S. as well as Institutional Review Board ("*IRB*") approval to commence the OPTION 2 Trial.

The OPTION 2 Trial was designed to investigate the safety, tolerability and efficacy of MS1819 (2.2 gram and 4.4 gram doses in enteric capsules) in a head-to-head manner versus the current standard of care, PERT pills. The OPTION 2 Trial was an open-label, crossover study, conducted in 15 sites in the U.S. and Europe. Enrollment included a total of 30 CF patients 18 years or older. MS1819 was administered in enteric capsules to provide gastric protection and test for optimal delivery of enzyme to the duodenum. Patients were initially randomized into two cohorts: to either the MS1819 arm, where they received a 2.2 gram daily oral dose of MS1819 for three weeks; or to the PERT arm, where they received their pre-study dose of PERT pills for three weeks. After three weeks, stools were collected for analysis of CFA. Patients were then crossed over for another three weeks of the alternative treatment. After three weeks of cross-over therapy, stools were again collected for analysis of CFA. A parallel group of patients were randomized and studied in the same fashion, using a 4.4 gram daily dose of MS1819. All patients were followed for an additional two weeks after completing both crossover treatments for post study safety observation. Patients were assessed using descriptive methods for efficacy, comparing CFA between MS1819 and PERT arms, and for safety.

In November 2020, we announced that we would submit protocol amendment request to the FDA for the OPTION 2 Trial to add a study arm utilizing immediate release MS1819 capsules. In January 2021, we announced that we had initiated the additional study arm. This extension phase tested patients 18 years or older, who had already completed the cross-over phase, with immediate release capsules at higher 4.4 and 6.6 gram doses relative to the 2.2 gram capsules previously used in the OPTION Bridging Dose Study. The purpose of the additional study arm was to allow us to compare data from the existing crossover arm using enteric (delayed release) capsules with data from the new extension arm, to help us identify the optimal dose and delivery method for MS1819.

In March 2021, we announced topline data results from the OPTION 2 Trial. The data demonstrated MS1819 to be safe and well-tolerated. In addition, we believe the data from the OPTION 2 Trial also demonstrates meaningful drug activity, as was also the case with our OPTION Bridging Dose Study and a prior Phase 2a study in patients with CP, and also with the interim data in our ongoing Combination Trial (as defined and discussed in further detail below). However, patients in the OPTION 2 Trial did not consistently meet the primary efficacy endpoint. Some patients were able to achieve CFA at levels beyond what is required to demonstrate non-inferiority with PERT therapies, but the majority did not. As such, we did not meet our primary endpoint for the trial.

We believe that the underlying cause of the MS1819's uneven efficacy performance in the OPTION 2 Trial lies with the enteric capsule formulation. While we believe the enteric coating protects the capsule from breaking down in the stomach acid, the trial data suggests it may dissolve too slowly in the small intestine to release the lipase enzyme in time to aid with proper digestion and nutrient absorption.

As a result, we have announced plans to develop a new formulation for MS1819, employing a capsule filled with acid-resistant granules, or microbeads, similar to what is used in CREON®, ZENPEP® and other PERT therapies. These beads will be placed into immediate release capsules that are intended to dissolve in the stomach, dispersing the beads, which should then pass through to the small intestine and break down, releasing the lipase enzyme so that it thoroughly mixes with food as it is being digested.

We are accelerating discussions with contract manufacturers to develop this new formulation. We believe we have sufficient capital on hand to fund this development and initiate a further Phase 2 study to evaluate the new formulation's efficacy, without substantially delaying our development efforts in other areas.

*Ongoing Phase 2 Combination Therapy Trial*

In addition to the CF monotherapy studies, we launched a Phase 2 multi-center clinical trial (the "*Combination Trial*") in Europe (Hungary and Turkey) to investigate the safety, tolerability and efficacy of escalating doses of MS1819, in combination with PERT, in order to increase CFA levels and relieve abdominal symptoms in CF patients who suffer from severe EPI but continue to experience clinical symptoms of fat malabsorption despite taking the maximum daily dose of PERTs.

Ideally, a stable daily dose of PERT will enable CF patients to eat a normal to high-fat diet and minimize unpleasant gastrointestinal symptoms. In practice, however, approximately 25-30% of CF patients do not achieve normal absorption of fat with PERTs. Achieving an optimal nutritional status, including normal fat absorption levels, in CF patients is important for maintaining better pulmonary function, physical performance and prolonging survival. Furthermore, a decline of body mass index around the age of 18 years predicts a substantial drop in lung function. We believe 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.

The Combination Trial enrolled 18 patients, 12 years of age or older, with severe EPI, with CFA levels less than 80%. Patients enrolled in the study receive escalating doses of 700mg, 1200mg, and 2240mg of MS1819 once daily for 15 days per dosing level, in addition to their standard PERT dose. Baseline CFA is established by measuring CFA levels while on standard of care therapy only, before beginning combination therapy. The primary efficacy endpoint of the trial is improvement in CFA; secondary endpoints of the study are improvements in the stool weight, stool consistency, number of bowel movements, the incidence of steatorrhea, and increase of body weight.

We dosed the first patients in the Combination Trial in Hungary in October 2019.

We announced positive interim data on the first five patients in the Combination Trial in August 2020. The primary efficacy endpoint was met, with CFAs greater than 80% for all patients across all visits. For secondary efficacy endpoints, we observed that stool weight decreased, the number of stools per day decreased, steatorrhea improved, and body weight increased. Additionally, no serious adverse events were reported. In October 2020, we opened a total of five clinical sites in Turkey and dosed the first patients in November 2020.

In March 2021, we announced that we completed enrollment of 18 patients and expect to report top-line data in the second quarter of 2021.

*Niclosamide*

Niclosamide, a pro-inflammatory pathway inhibitor, is a prescription small molecule drug that has been safely used on millions of patients. Niclosamide is listed as an essential medicine by the World Health Organization (WHO). In the U.S., niclosamide was approved by the FDA in 1982 for the treatment of intestinal tapeworm infections. Niclosamide's activity as an antihelminthic result from direct action in the intestinal lumen where it disrupts parasite oxidative metabolism, killing parasites. Niclosamide has been commercially available worldwide for more than 50 years as 500mg tablets intended for use in pediatric and adult populations, at a dose rate of 2g per adult or child over six years of age. No safety issues have ever been identified. In addition to its antihelminthic activity, niclosamide has novel anti- inflammatory and anti-viral properties.

We believe niclosamide, and more specifically the patented and proprietary micronized niclosamide formulation developed by First Wave, has the potential to be an ideal therapeutic to treat multiple GI indications due to the following favorable properties: (i) it has a reduced particle size (D(90) between 5 and 9 μM) as compared to regular non-micronized niclosamide (approximately D(90) ≥ 60μM) with greater surface to solvent ratio, (ii) low oral bio-availability with minimal systemic absorption / exposure, (iii) improved dissolution with broader distribution allowing for higher local GI concentrations (up to approximately 200 times based on preclinical study results), and (iv) it exhibits anti-inflammatory effects while avoiding steroid-related complications and adverse events.

*FW-1022: COVID-19 GI infections*

We are developing FW-1022, a small molecule medicinal product containing micronized niclosamide in an oral immediate release tablet formulation as treatment for SARS-CoV-2 intestinal infection in patients presenting with gastrointestinal symptoms of COVID-19 disease. The formulation to be used has been milled (micronized) to allow superior dissolution in the gut fluids. This in turn allows local niclosamide concentrations to reach anti-viral levels. Thus, FW-1022 has the potential to benefit COVID patients by decreasing viral load in the GI tract, treating infection symptoms and preventing transmission of the virus through fecal spread. Evidence of niclosamide's antiviral properties is sufficient to expect a clinical pharmacodynamic response against viral replication and clinical benefit, justifying the proposed clinical study in COVID-19 patients and favorable benefit-risk assessment.

An IND for FW-1022 micronized niclosamide for COVID-19 GI infections was cleared by the FDA in September 2020. We are currently preparing to initiate a two-part, two-arm, placebo-controlled Phase 2 clinical trial examining the safety and efficacy of niclosamide in patients with COVID-19 GI infections.

*FW-420: Immune Checkpoint Inhibitor Colitis (ICI-AC)*

Immune checkpoint inhibitors (''*ICIs*'') are monoclonal antibodies that target down-regulators of the anti-cancer immune response and have revolutionized the treatment of a variety of malignancies. The global market for ICIs in in 2019 was estimated to be over $22 billion and growing rapidly. Approximately 44% of patients with advanced cancer tumors, or about 260,000 patients, are eligible to receive ICIs

However, many immune-related adverse events, especially diarrhea and colitis, limit the use of ICIs. While Grade 1 colitis (less than four stools per day) is treated symptomatically as outpatients, about 30% or more of patients with Grade 1 colitis progress to Grade 2 or worse. Those patients must be taken off of the ICI being used for their cancer, risking relapse. Also, they receive aggressive immunosuppressive therapies, further aggravating their underlying cancer.

The incidence of immune-mediated colitis (''*IMC*'') ranges from 1% to 25% depending on the type of ICI and whether they are without interruption used in combination. Approximately 30% of ICI patients develop diarrhea, which can progress to colitis. The onset of diarrhea in ICI-AC patients occurs within six to seven weeks and progressively worsens, and the progression to colitis is rapid and unpredictable. For example, in patients taking ipilimumab (Yervoy), between 25% and 30% of patients developed diarrhea and approximately 8% to 12% developed colitis. Moreover, the trend is towards the use of combination ICI therapies (e.g. Yervoy and Opdivo) which may lead to a concomitant increase in both diarrhea and colitis.

Administration of corticosteroids, or treatment with certain immunosuppressive biologics, while withholding ICI therapy are recommended for Grade 2 or more severe colitis. The impact of this colitis complication and treatment may reduce the goal of progression free cancer survival. An oral, non-absorbed treatment, such as niclosamide, for Grade 1 colitis (diarrhea) may prevent progression to Grade 2 disease. There currently is no approved treatment for Grade 1 colitis.

FW-420 is a niclosamide based small molecule anti-inflammatory inhibitor therapy which we intend to use for the treatment of immune checkpoint inhibitor-associated colitis and diarrhea in metastatic cancer patients. FW-420 will be supplied in two formulations, as an oral immediate-release tablet and as a topical rectal enema foam. The standard care for treating inflammatory bowel diseases (IBD) such as ulcerative colitis and Crohn's Disease is corticosteroids and 5-ASAs, which can cause problems when used for check point inhibitor patients due to their immunosuppressant effects. FW-420 has the potential to safely treat Grade 1 ICI colitis and diarrhea and prevent its progression to more serious and potentially fatal later stages. The overall goal of early niclosamide treatment is to enable oncology patients to remain without interruption on, or spend minimal time off of, their ICI treatment programs.

The primary objective of our planned Phase 1b/2a trial of niclosamide is to monitor patients receiving ICI treatment, and to intervene with niclosamide treatment at the first signs of diarrhea. The primary objective is to compare niclosamide oral, versus niclosamide oral plus rectal, versus standard of care, and to prevent Grade 1 colitis progressing to Grade 2 or worse. We anticipate the trial will need about 100 patients to provide a signal of efficacy.

We plan to initiate the Phase 1b/2a clinical trial in the first half of 2021.

**Recent Developments**

*License Agreement with First Wave Bio, Inc.*

On December 31, 2020, we entered into a License Agreement (the ''*First Wave License Agreement*'') with First Wave Bio, Inc. (''*First Wave*''). Pursuant to the First Wave License Agreement, First Wave granted us a worldwide, exclusive right to develop, manufacture, and commercialize First Wave's proprietary immediate release and enema formulations of niclosamide for the fields of treating ICI-AC and COVID-19 in humans (the ''*Niclosamide Product*''). The Niclosamide Product uses First Wave's proprietary formulations of niclosamide, a pro-inflammatory pathway inhibitor. We plan to commence in 2021 both a Phase 2 trial of the Niclosamide Product for COVID-19 in GI and a Phase 1b/2a trial for ICI-AC.

In consideration of the license and other rights granted by First Wave, we paid First Wave a $9.0 million upfront cash payment and are obligated to make an additional payment of $1.25 million due on June 30, 2021. In addition, we are obligated to pay potential milestone payments to First Wave totaling up to $37.0 million for each indication, based upon the achievement of specified development and regulatory milestones. Under the First Wave License Agreement we are obligated to pay First Wave royalties as a mid-single digit percentage of net sales of the Product, subject to specified reductions.

In addition, on January 8, 2021, pursuant to the First Wave License Agreement we entered into a securities purchase agreement with First Wave (the "*First Wave Purchase Agreement*") pursuant to which we issued to First Wave, on that same day, 3,290.1960 shares of Series C 9.00% Convertible Junior Preferred Stock, par value $0.0001 (the "*Series C Preferred Stock*"), initially convertible into an aggregate of 3,290,196 shares of Common Stock, at an initial stated value of $750.00 per share and a conversion price of $0.75 per share, which was the equivalent of $3.0 million based upon the volume weighted average price of our Common Stock for the five-day period immediately preceding the date of the First Wave License Agreement, or $0.9118 per share. The First Wave Purchase Agreement contains demand and piggyback registration rights with respect to the Common Stock issuable upon conversion, which have not been requested by First Wave.

Pursuant to the First Wave Purchase Agreement, the shares of Series C Preferred Stock issued to First Wave were not convertible prior to us obtaining the approval of our stockholders to amend our certificate of incorporation to increase the number of authorized shares of Common Stock above 150,000,000 and to comply with the applicable stockholder approval rules and regulations of the Nasdaq Stock Market (the "*Stockholder Approval*"). Upon receiving Stockholder Approval on February 24, 2021, we issued an aggregate of 3,329,138 shares of Common Stock to First Wave upon conversion of the shares of Series C Preferred Stock, which included 38,942 shares of Common Stock for accrued dividends of approximately $29,000.

*Registered Direct Offering and Private Placement*

On December 31, 2020, we entered into a securities purchase agreement (the "*Series C Purchase Agreement*"), pursuant to which we agreed to sell in a registered direct offering 5,333.333 shares of Series C Preferred Stock, at a price of $750 per share, initially convertible into an aggregate of 5,333,334 shares of Common Stock, at an initial stated value of $750.00 per share and a conversion price of $0.75 per share (the "*Registered Direct Offering*"). The Registered Direct Offering closed on January 6, 2021.

Concurrently with the Registered Direct Offering, in a private placement offering pursuant to the Series C Purchase Agreement (the "*Private Placement*"), we agreed to sell an additional 5,333.3333 shares of Series C Preferred Stock at the same price as the Series C Preferred Stock offered in the Registered Direct Offering and convertible on the same terms and warrants (the "*Investor Warrants*") to purchase up to an aggregate of 10,666,668 shares of Common Stock, with an exercise price of $0.80 per share and an expiration term of five and one-half years from the date of issuance.

In connection with the Private Placement, we entered into a registration rights agreement, dated as of December 31, 2020, pursuant to which we filed a registration statement on Form S-1 (File No. 333-252087) to register the shares of Common Stock issuable upon the conversion of the Series C Preferred Stock sold in the Private Placement and the exercise of the Investor Warrants. The registration statement was declared effective by the SEC on January 21, 2021.

The aggregate gross proceeds from the Registered Direct Offering and the Private Placement, excluding the net proceeds, if any, from the exercise of the Investor Warrants, was approximately $8.0 million.

The net proceeds to us from the Registered Direct Offering and the Private Placement, after deducting the placement agent's fees and expenses and estimated offering expenses, was approximately $6.8 million. We used the net proceeds to fund the payment of cash consideration to First Wave under the First Wave License Agreement, and for other general corporate purposes.

We paid the placement agent a cash fee equal to 8.0% and a management fee equal to 1.0% of the aggregate gross proceeds received by us in the Registered Direct Offering and the Private Placement, or approximately $700,000. We also agreed to issue to the placement agent or its designees warrants (the "*December 2020 Placement Agent Warrants*") exercisable for up to 746,667 shares of Common Stock, which is equal to 7.0% of the amount determined by dividing the gross proceeds of the Registered Direct Offering and Private Placement by the offering price per share of Common Stock, or $0.75. The December 2020 Placement Agent Warrants have substantially the same terms as the Investor Warrants, except they are exercisable at $0.9375 per share, or 125% of the effective purchase price per share of the Series C Preferred Stock issued. We also reimbursed the placement agent $35,000 for non-accountable expenses, up to $125,000 for legal fees and expenses and other out-of-pocket expenses and $12,900 for clearing fees.

On February 24, 2021, our stockholders approved certain proposals related to the Registered Direct Offering and the Private Placement and all outstanding shares of Series C Preferred Stock were converted to Common Stock.

*Amendment to Charter and Approved Reverse Stock Split*

On February 24, 2021, at our Special Meeting of Stockholders (''*Special Meeting*''), our stockholders approved an amendment to our Amended and Restated Certificate of Incorporation (the ''*Charter*'') to increase the number of authorized shares of Common Stock by 100,000,000 shares to 250,000,000 shares, and to authorize our Board of Directors (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-five (1:5) to one-for-ten (1:10), any time prior to the one-year anniversary date of the Special Meeting, with the exact ratio to be determined by the Board.

We filed a Certificate of Amendment to our Charter with the Secretary of State of the State of Delaware on February 24, 2021, to increase the number of authorized shares of Common Stock to 250,000,000 shares.

*March 2021 Common Stock and Warrant Offering*

On March 7, 2021, we entered into a securities purchase agreement (the ''*March 2021 Purchase Agreement*'') with single institutional investor, pursuant to which we agreed to sell, in a registered direct offering (the ''*March 2021 Offering*'') priced at the market under Nasdaq rules, (i) 5,800,000 shares of Common Stock, (ii) pre-funded warrants (the ''*March 2021 Pre-Funded Warrants*'') to purchase up to 2,058,548 shares of Common Stock, with an exercise price of $0.01 per share and no expiration term and (iii) warrants (the ''*March 2021 Warrants*'') to purchase an aggregate of 3,929,274 shares of Common Stock with an exercise price of $1.21 per share and an expiration term of five years from the date of issuance. The aggregate price per of the March 2021 Offering share was $1.2725.

The aggregate gross proceeds from the March 2021 Offering, which closed on March 10, 2021 (the ''*March 2021 Closing Date*''), excluding the net proceeds, if any, from the exercise of the March 2021 Warrants was approximately $10.0 million.

The net proceeds to us from the March 2021 Offering, after deducting the placement agent's fees and expenses and estimated offering expenses, was approximately $9.1 million. We intend to use the net proceeds to initiate its two niclosamide clinical programs in the first half of 2021, a Phase 2 clinical trial for COVID-19 GI infections and a Phase 1b/2a trial for ICI-AC, respectively, and for other general corporate purposes.

We paid the placement agent a cash fee equal to 8.0% of the aggregate gross proceeds received by us in the March 2021 Offering, or approximately $800,000. We also agreed to issue to the placement agent or its designees warrants (the ''*March 2021 Placement Agent Warrants*'') exercisable for up to 550,099 shares of Common Stock, which is equal to 7.0% of the aggregate number of shares of Common Stock placed in the March 2021 Offering. The March 2021 Placement Agent Warrants have substantially the same terms as the March 2021Warrants, except they are exercisable at $1.5906 per share, or 125% of the effective purchase price per share of Common Stock issued in the March 2021 Offering. We also reimbursed the placement agent $35,000 for non-accountable expenses, up to $50,000 for legal fees and expenses and other out-of-pocket expenses and approximately $16,000 for clearing fees.

In the March 2021 Purchase Agreement, we have agreed not to issue, enter into any agreement to issue or announce the issuance or proposed issuance of, any shares of Common Stock or any securities convertible into or exercisable or exchangeable for shares of Common Stock or file any registration statement or prospectus, or any amendment or supplement thereto for 50 days after the March 2021 Closing Date. In addition, we have agreed not to effect or enter into an agreement to effect any issuance of Common Stock or any securities convertible into or exercisable or exchangeable for shares of Common Stock involving a variable rate transaction (as defined in the March 2021 Purchase Agreement) until the one-year anniversary of the date of the March 2021 Purchase Agreement, subject to certain exceptions.

*Series B Most Favored Nations (MFN) Exchanges*

Under the Certificate of Designations for the Series B Convertible Preferred Stock (the ''*Series B Certificate of Designations*''), in the event we effect any issuance of Common Stock or Common Stock equivalents for cash consideration, or a combination of units thereof (a ''*Subsequent Financing*''), each holder of the Series B Convertible Preferred Stock, par value $0.0001 per share (the ''*Series B Preferred Stock*''), has the right to exchange the stated value, plus accrued and unpaid dividends (the ''*Exchange Amount*''), of the Series B Preferred Stock for any securities issued in the Subsequent Financing, in lieu of any cash subscription payments therefor (the ''*Exchange Right*'').

On December 31, 2020, we entered into the Series C Purchase Agreement as part of the Registered Direct Offering and Private Placement, and the holders of our Series B Preferred Stock became entitled to exercise their Exchange

Right to exchange into the Series C Preferred Stock and related Investor Warrants. As of March 29, 2021, holders of approximately 1,266.92 shares of Series B Preferred Stock with an aggregate Exchange Amount of approximately $9.8 million had previously elected to exercise their Series B Exchange Rights into Series C Preferred Stock, convertible into an aggregate of 13,087,843 shares of Common Stock (which conversion we elected to make in full on February 24, 2021, upon receipt of certain stockholder approvals), and additional Investor Warrants exercisable for up to an aggregate of 13,087,843 shares of Common Stock.

As a result, as of March 29, 2021, we may be required to issue up to 13,028.698 additional shares of Series C Preferred Stock that are currently convertible up to 13,028,698 underlying shares of Common Stock, together with Investor Warrants to purchase up to an additional 13,028,698 shares of Common Stock, to any holders of Series B Preferred Stock who elect to exercise their Exchange Right. Any shares of Series C Preferred Stock to be issued pursuant to the Exchange Right would, upon issuance, be immediately converted into underlying shares of Common Stock.

*Exercises of Warrants*

From January 1, 2021 through March 29, 2021, we received gross proceeds of approximately $4.6 million from the exercise of warrants to purchase an aggregate of 6,640,588 shares of Common Stock, with exercise prices ranging from $0.001 to $1.42 per share. As of March 29, 2021, we had 44,930,105 shares of Common Stock issuable upon exercise of outstanding warrants, with a weighted average exercise price of $1.02 per share.

**Corporate History**

We were incorporated on January 30, 2014 in the State of Delaware. In May 2014, we entered into a stock purchase agreement 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. In June 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 in connection with MS1819. In October 2016, we completed an initial public offering (''*IPO*''), which allowed us to list our shares of Common Stock on the Nasdaq Capital Market.

**Product Programs**

Our current therapeutic product pipeline consists of three clinical-stage programs, each of which are described below.

*MS1819*

MS1819 is the active pharmaceutical ingredient (''*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 CF and CP. Lipases are enzymes that help with the digestion of lipids and fat.

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 Spindler SAS (''*Mayoly*'') under the JDLA (as defined below), which also granted us joint commercialization rights for Brazil, Italy, China and Japan. In March 2019, we purchased all rights, title and interest in and to MS1819 from Mayoly pursuant to the Mayoly APA (as defined below), *provided*, *however*, Mayoly retained exclusive commercial rights in France and Russia.

*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 protease (enzymes that break up carbohydrates (starches) and proteins, 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 U.S., 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 90,000 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, or 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. PERTs are typically comprised of three digestive enzymes; lipases, proteases, and amylases. The PERT market is well established with estimated sales of approximately $1.4 billion in 2019 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, or National Institute for Agricultural Research (“*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, 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.

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 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) children and adults affected by CF, and (ii) adult patients with CP. We have determined to initially pursue the indication for adults first in CF.

During 2010 and 2011, a phase 1/2a 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 (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.

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 2 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. In September 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 FDA cleared our IND application for MS1819 in patients with EPI due to CF. In December 2018, we initiated the Phase 2 OPTION Bridging Dose Study to investigate MS1819 in CF patients with EPI and in February 2019, we dosed the first patients. The Phase 2 OPTION Bridging Dose Study investigated the safety, tolerability and efficacy of MS1819 in a head-to-head comparison against the current PERT standard of care. The OPTION Bridging Dose Study employed a six-week non-inferiority CFA primary efficacy endpoint comparing MS1819 to PERTs.

In September 2019, we announced positive results from the OPTION Bridging Dose 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 Bridging Dose 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 CNA was comparable between the MS1819 and PERT arms, 93% vs. 97%, respectively, in the OPTION Bridging Dose 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 Bridging Dose Study.

In October 2019, the CFF DSMB completed its review of our final results of the OPTION Bridging Dose Study and found no safety concerns for MS1819 and supported our plan to proceed to the Phase 2b OPTION 2 Trial. In December 2019, we submitted the clinical trial protocol to the existing IND at the FDA, which has been reviewed

by the FDA with no comments. In April 2020, we received approval to conduct the OPTION 2 Trial in Therapeutics Development Network clinical sites in the U.S. as well as IRB approval to commence the OPTION 2 Trial.

The OPTION 2 Trial was designed to investigate the safety, tolerability and efficacy of MS1819 (2.2 gram and 4.4 gram doses in enteric capsules) in a head-to-head manner versus the current standard of care, PERT pills. The OPTION 2 Trial was an open-label, crossover study, conducted in 15 sites in the U.S. and Europe. Enrollment included a total of 30 CF patients 18 years or older ed. MS1819 was administered in enteric capsules to provide gastric protection and test for optimal delivery of enzyme to the duodenum. Patients will first be randomized into two cohorts: to either the MS1819 arm, where they receive a 2.2 gram daily oral dose of MS1819 for three weeks; or to the PERT arm, where they receive their pre-study dose of PERT pills for three weeks. After three weeks, stools will be collected for analysis of CFA. Patients will then be crossed over for another three weeks of the alternative treatment. After three weeks of cross-over therapy, stools will again be collected for analysis of CFA. A parallel group of patients will be randomized and studied in the same fashion, using a 4.4 gram daily dose of MS1819. All patients will be followed for an additional two weeks after completing both crossover treatments for post study safety observation. Patients will be assessed using descriptive methods for efficacy, comparing CFA between MS1819 and PERT arms, and for safety.

In January 2021, we announced an additional study arm in OPTION 2 Trial using an immediate release MS1819 capsules in order to identify the optimal dose and delivery method of MS1819. This extension phase tests patients 18 years or older, who have already completed the crossover phase, at higher doses relative to the previously conducted OPTION Bridging Dose Study, this allowing us to compare data from the existing crossover arm using enteric (delayed release) capsules with data from the new extension arm, and ultimately select the optimal delivery method for a pivotal Phase 3 clinical trial.

We launched the Phase 2 Combination Trial in Hungary in July 2019 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 (700 mg, 1120 mg and 2240 mg per day, respectively), in conjunction with a stable dose of PERTs, in order to increase CFA and relieve abdominal symptoms. In October 2020, we opened a total of five clinical sites in Turkey and dosed the first patients in November 2020. In March 2021, we reached targeted enrollment of 18 patents. Topline data for the Combination Trial is currently expected in the second quarter of 2021.

We announced positive interim data on the first five patients in the Combination Trial in August 2020. The primary efficacy endpoint was met, with CFAs greater than 80% for all patients across all visits. For secondary efficacy endpoints, we observed that stool weight decreased, the number of stools per day decreased, steatorrhea improved, and body weight increased. Additionally, no serious adverse events were reported.

We believe 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.

*Niclosamide*

Niclosamide, a pro-inflammatory pathway inhibitor, is a prescription small molecule drug that has been safely used on millions of patients. Niclosamide is listed as an essential medicine by the World Health Organization (WHO). In the U.S., niclosamide was approved by the FDA in 1982 for the treatment of intestinal tapeworm infections. Niclosamide's activity as an antihelminthic result from direct action in the intestinal lumen where it disrupts parasite oxidative metabolism, killing parasites. Niclosamide has been commercially available worldwide for more than 50 years as 500mg tablets intended for use in pediatric and adult populations, at a dose rate of 2g per adult or child over six years of age. No safety issues have ever been identified. In addition to its antihelminthic activity, niclosamide has novel anti- inflammatory and anti-viral properties.

We believe niclosamide, and more specifically the patented and proprietary micronized niclosamide formulation developed by First Wave, has the potential to be an ideal therapeutic to treat multiple GI indications due to the following favorable properties: (i) it has a reduced particle size ((D(90) between 5 and 9 μM) as compared to regular non-micronized niclosamide (approximately D(90) ≥ 60μM) with greater surface to solvent ratio, (ii) low oral bio-availability with minimal systemic absorption / exposure, (iii) improved dissolution with broader distribution allowing for higher local GI concentrations (up to approximately 200 times based on preclinical study results), and (iv) it exhibits anti-inflammatory effects while avoiding steroid-related complications and adverse events.

*Background*

*FW-1022: COVID-19 GI infections*

The COVID-19 pandemic is a global public health emergency caused by the SARS-CoV-2 virus. An increasing volume of convergent evidence indicates that GI infection and fecal-oral transmission of SARS-CoV-2 are important factors in the clinical presentation, virology and epidemiology of COVID-19. There is currently no etiological treatment for COVID-19 GI effects. We believe our FW-1022 micronized niclosamide formulation will be the only one being tested in clinical trials for a COVID-19 GI indication. Given the potentially critical role of COVID GI infections we believe there is a clear unmet therapeutic need.

Drug repurposing and/or repositioning aimed at identifying new therapeutic applications for existing clinically approved drugs is a critical strategy to accelerate drug discovery for the COVID-19 pandemic. Multiple companies and laboratories have identified and validated niclosamide to have potent antiviral activity against SARS-CoV-2.

A study published in July 2020 in *Antimicrobial Agents and Chemotherapy*, an American Society for Microbiology journal (Jeon *et. al*, 2020) examined a small set (n=49) of FDA-approved drugs that were selected based on either having known activity against SARS-CoV or being recommended by infectious disease experts for activity against the SARS-CoV-2 virus. Results from this study indicated that niclosamide was the most potent of all agents tested in a Vero cell cytopathic assay with an IC50 value of 0.28 μM. For comparison, in terms of potency, niclosamide out-performed reference compounds chloroquine, lopinavir, and remdesivir with IC50 values of 7.28, 9.12, and 11.41 μM, respectively. IC50 is a quantitative measure that indicates how much of a particular inhibitory substance (e.g. a drug) is needed to inhibit, *in vitro*, a given biological process or biological component by fifty percent. Thus, niclosamide is approximately 25-fold more potent in vitro than VEKLURY® (remdesivir), an antiviral drug marketed by Gilead Sciences Inc. that received FDA approval in October 2020 for use in adult and pediatric patients for the treatment of COVID-19 requiring hospitalization.

Following oral administration, niclosamide is poorly absorbed, which results in a majority of the administered dose remaining in the GI tract. We believe this basic property of niclosamide, when combined with FW-1022 the micronized niclosamide FW-1022 in the drug product developed by First Wave to accelerate dissolution, allows this drug product to achieve pharmacologically effective concentrations of niclosamide in the GI tract while having almost no bioavailability, potentially enhancing efficacy and safety. We believe these properties make our FW-1022 micronized niclosamide formulation an ideal and differentiated therapeutic for treating COVID-19 infections and GI symptoms.

There are multiple other late-stage clinical trials evaluating the standard (non-micronized) formulation of niclosamide in COVID-19. We believe this further indicates that available data on niclosamide's antiviral properties against SARS-CoV-2 is considered by others to be sufficient to proceed with clinical testing.

We are developing FW-1022, a medicinal product containing micronized niclosamide in an immediate release tablet formulation as treatment for SARS-CoV-2 intestinal infection in patients presenting with gastrointestinal symptoms of COVID-19 disease. Evidence of niclosamide's antiviral properties is sufficient to expect a clinical pharmacodynamic response against viral replication and clinical benefit, justifying the proposed clinical study in COVID-19 patients and favorable benefit -risk assessment.

*FW-420: Immune Checkpoint Inhibitor Colitis (ICI-AC)*

Immune checkpoint inhibitors (''*ICIs*'') are monoclonal antibodies that target down-regulators of the anti-cancer immune response and have gained increasing popularity and have revolutionized the treatment of a variety of malignancies. However, many immune-related adverse events, especially diarrhea and colitis, limit their use. A 2019 study titled, ''Immune checkpoint inhibitor-induced colitis: A comprehensive review,'' published in *World Journal of Clinical Cases* (Sol *et.al*, 2019) estimated the incidence of IMC ranges from 1% to 25% depending on the type of ICI and whether they are used in combination. A 2017 study titled ''Incidence of immune checkpoint inhibitor-related colitis in solid tumor patients: a systematic review and meta-analysis'' published in *Oncoimmunology* (Wang and Zhao *et.al*, 2017) estimated that approximately 44%, or 260,000 patients with advanced and metastatic tumors were eligible to receive ICIs. Further, approximately 30% of ICI patients develop diarrhea, which can progress to colitis. The onset of diarrhea in ICI-AC patients occurs within six to seven weeks and progressively worsens, and the progression to colitis is rapid and unpredictable.

In patients taking Yervoy® (ipilimumab) marketed by Bristol Myers Squibb, between 25% to 30% developed diarrhea and approximately 8% to 12% developed colitis, as reported in a peer-reviewed article, ''Immune-checkpoint

inhibitor-induced diarrhea and colitis in patients with advanced malignancies: retrospective review at MD Anderson'' published in the *Journal for ImmunoTherapy of Cancer* (Wang *et. al,*, 2018). Moreover, there is a treatment trend towards the use of combination ICI therapies (for example combining Yervoy® and Opdivo®), which is believed to lead to a concomitant increase in both diarrhea and colitis.

We believe there currently is no approved treatment for Grade-1 colitis. The recommended treatment for Grade 2 or more severe colitis is administration of corticosteroids, or treatment with certain immunosuppressive biologics, while withholding ICI therapy (National Cancer Institute, 2020). The impact of this colitis complication and treatment may reduce the goal of progression free cancer survival. We believe there is an unmet medical need and an oral, non-absorbed therapeutic, such as our FW-420 micronized niclosamide, for Grade-1 colitis (diarrhea) may prevent progression to Grade-2 disease.

*Clinical Development*

Recent discoveries in immune cell metabolism have opened up the possibility of selectively targeting disease-causing immune cells to treat inflammatory diseases without unwanted side effects such as broad immunosuppression. Prior to entering into the First Wave License Agreement, First Wave had developed a suite of drug candidates, gut-restricted small molecules that target the metabolism of disease- causing Th17 cells. First Wave's first clinical program, FW-424, had encouraging data from a study Phase 1b/2a study in patients with mild-to-moderate ulcerative colitis.

In addition, First Wave submitted an IND for FW-1022 micronized niclosamide for COVID-19 GI infections that was cleared by the FDA in September 2020.

Following the entry into the First Wave License Agreement, we plan to commence both a Phase 2 trial for COVID-19 GI infections as well as a Phase 1b/2a trial for ICI-AC.

**Agreements and Collaborations**

*License Agreement with First Wave Bio, Inc.*

On December 31, 2020, we entered into the First Wave License Agreement, pursuant to which First Wave granted us a worldwide, exclusive right to develop, manufacture, and commercialize First Wave's proprietary immediate release and enema formulations of niclosamide for the fields of treating ICI-AC and COVID-19 in humans (the ''*Niclosamide Product*''). We plan to commence in 2021 both a Phase 2 trial of the Niclosamide Product for COVID-19 in GI and a Phase 1b/2a trial for ICI-AC.

In consideration of the license and other rights granted by First Wave, we agreed to pay First Wave a $9.0 million upfront cash payment due within 10 days and are obligated to make an additional payment of $1.25 million due on June 30, 2021. In addition, we are obligated to pay potential milestone payments to First Wave totaling up to $37.0 million for each indication, based upon the achievement of specified development and regulatory milestones. Under the First Wave License Agreement we are obligated to pay First Wave royalties as a mid-single digit percentage of net sales of the Niclosamide Product, subject to specified reductions. We are also obligated to issue to First Wave junior convertible preferred stock, initially convertible into $3.0 million worth of common stock, par value $0.0001 per share (the ''*Common Stock*''), based upon the volume weighted average price of the Common Stock for the five-day period immediately preceding the date of the License Agreement, or $0.9118 per share. The preferred stock will convert automatically into Common Stock upon the stockholder approval.

In addition, on January 8, 2021, pursuant to the First Wave License Agreement we entered into a securities purchase agreement with First Wave (the ''*First Wave Purchase Agreement*'') pursuant to which we issued to First Wave 3,290.1960 shares of Series C Preferred Stock, initially convertible into an aggregate of 3,290,196 shares of Common Stock, at an initial stated value of $750.00 per share and a conversion price of $0.75 per share, which was the equivalent of $3.0 million at $0.9118 per share. The First Wave Purchase Agreement contains demand and piggyback registration rights with respect to the Common Stock issuable upon conversion.

We are now solely responsible, and has agreed to use commercially reasonable efforts, for all development, regulatory and commercial activities related to the Niclosamide Products in the ICI-AC and COVID-19 fields. We may sublicense its rights under the First Wave License Agreement and, if it does so, will be obligated to pay milestone payments and royalties to First Wave based on the sublicensee's development and commercialization of the licensed Niclosamide Products.

*Protea Stock Purchase Agreement and Asset Sale and Purchase Agreement*

In May 2014, we entered into a stock purchase agreement (the "*Protea SPA*") with Protea to acquire 100% of the outstanding capital stock of ProteaBio Europe SAS (the "*Protea Acquisition*"). In June 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.

In December 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 us to Protea now or in the future, arising from the Protea SPA (the "*Purchased Assets*"). In accordance with the terms of the Protea Purchase Agreement, we purchased the Purchased Assets from Protea for an aggregate purchase price of approximately $1.6 million. We paid approximately $0.3 million of the purchase price in cash, and the remaining approximately $1.3 million 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*

In March 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 between Mayoly and INRA, in charge of patent management acting for and on behalf of CNRS and INRA.

In January 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*

In March 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 we 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 us. In addition, the Company executed a Patent License Agreement with Mayoly pursuant to which we granted to Mayoly an exclusive, royalty- bearing right to revenue received from commercialization of MS1819 within France and Russia. We have exclusive rights to MS1819 in all other global territories.

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

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

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

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

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

(v) we agreed to pay to Mayoly an additional €1,500,000, payable in a mix of cash and shares of 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 14).

*TransChem Sublicense*

In August 2017, we 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. The Sublicense Agreement and the licenses granted therein may be terminated by us 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 allowed 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.

In March 2020, we 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 drug 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 drug candidates and any future drug 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 issued patents that we have licensed under the Mayoly Agreement:

- 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.

In addition, a provisional application was filed in 2020 directed to our proprietary formulation of MS1819. Any patent application claiming priority to this provisional application upon issuance will have an expected expiration in 2041.

*Niclosamide*

Our FW-420 and FW-1022 niclosamide programs are protected by patent filings licensed under the First Wave License Agreement that include the following:

- US10,912,746; US10,905,666; US10,292,951; US10,772,854; US10,744,103; US10,799,468; US10,849,867; and U.S. Patent Application Publication US20200276140 as well as corresponding worldwide patent filings all entitled ''Methods and Compositions for Treating Conditions Associated with an Abnormal Inflammatory Process.'' The expiration date of the issued patents is September 1, 2036;
- A series of provisional and yet unpublished applications all filed in 2020, including U.S. Application Serial No. 16/835,307, directed to the use of niclosamide for the treatment of COVID-19 gastrointestinal infections, which has been allowed and upon issuance will have an expiration date in 2040.

**Manufacturing**

We currently outsource all manufacturing, and we intend to use our collaborators and contract development and manufacturing organizations (CDMOs) for the foreseeable future. However, certain members of our team have broad experience in manufacturing, which we believe may provide a competitive advantage.

*MS1819*

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 SpA. MS1819 drug product is currently manufactured at a contract facilities located in Reims, France and Craigavon, United Kingdom owned by Delpharm and Almac Pharma Services. We believe there are multiple alternative contract manufacturers capable of producing the product we need for clinical trials. We are 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. In December 2020, we entered into a master service agreement with Asymchem to initiate the transfer of the manufacturing process for both drug substance and drug product.

*Niclosamide*

Niclosamide API is obtained by chemical synthesis and is currently manufactured by Olon SpA at a facility in Murcia, Spain. Niclosamide drug product is currently manufactured at a contract facility located in Milan, Italy owned by Monteresearch. We believe there are multiple alternative contract manufacturers capable of producing the product we need for clinical trials; 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.

*MS1819*

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.

*Niclosamide*

With respect to FW-1022, micronized niclosamide for COVID-19 GI infections, if approved, we will compete with currently approved antivirals, including VEKLURY® (remdesivir) marketed by Gilead Sciences, Inc. and vaccines, including those marketed by Pfizer Inc. and BioNTech SE, Moderna, Inc. Johnson & Johnson and AstraZeneca plc. There are also several therapeutic and vaccine candidates in various stages of development that may obtain regulatory approval for the treatment or prevention of COVID-19 infections. Additionally, there are currently ongoing clinical studies using niclosamide by ANA Therapeutics (acquired by NeuroBo Pharmaceuticals, Inc.), Daewoong Pharmaceuticals Co Ltd, and Union Therapeutics A/S, among others at various stages of development. We believe our approach to target COVID-19 GI infections is differentiated. We believe our ability to compete in this market, if we are successful in developing and obtaining regulatory approval to market FW-1022, will depend on our ability (or that of future corporate partners) to convince patients, their physicians, healthcare agencies and payors and the medical community of the benefits of using a GI restricted FW- 1022 to treat COVID-19 infections with GI symptoms.

With respect to FW-420, micronized niclosamide for ICI-AC, we will compete with both oral and intravenous administered steroids as well as hospital-based infusions of biologics, including infliximab and vedolizumab. We believe our ability to compete in this market, if we are successful in developing and obtaining regulatory approval to market FW-420, will depend on our ability (or that of future corporate partners) to convince patients, their physicians, healthcare agencies and payors and the medical community of the benefits of using a non-steroidal, non-biologic therapeutic option for the treatment of ICI-AC.

**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 drug 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 may 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, 2020, we had 12 full-time employees, of whom two were employed by AzurRx SAS and located in France and ten 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. 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.

### Summary of Risk Factors

- We have never generated any product revenues.
- We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.
- We will need substantial additional funding, and certain terms included in our financing transactions may restrict our ability to raise such capital at the times and in the manner we may require.
- To date, most of our development activities have been focused on our MS1819 product candidate, which is still under clinical development, and if MS1819 does not receive regulatory approval or is not successfully commercialized, our business will be harmed.
- The COVID-19 outbreak and global pandemic could adversely impact our business, including our clinical trials.
- We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of our product candidates.
- Clinical trials are very expensive, time-consuming, difficult to design and implement and involve an uncertain outcome.
- We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
- We do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of our product candidates.
- We intend to rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.
- If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.
- We are an emerging growth company within the meaning of the Securities Act and have taken advantage of certain exemptions from disclosure requirements available to emerging growth companies; this could make our securities less attractive to investors and may make it more difficult to compare our performance with other public companies.
- We do not currently intend to pay dividends on our Common Stock in the foreseeable future, and consequently, any gains from an investment in our Common Stock will likely depend on appreciation in the price of our Common Stock.

### 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 our lead drug candidate, MS1819 and our other drug candidates. We 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 drug 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, the acquisition of rights to niclosamide and our other drug candidates. These operations provide a limited basis for our stockholders and prospective investors to assess our ability to complete development of or commercialize MS1819, niclosamide or any other drug candidates and the advisability of investing in our securities.

We have incurred significant operating losses and negative cash flows from operations since inception. As of December 31, 2020, we had accumulated deficit of approximately $95.4 million and negative working capital of approximately $7.7 million. Based on our historical and anticipated rate of cash expenditures, we do not anticipate our working capital will be sufficient to sustain our business through the successful commercialization of our drug candidates. Therefore, 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. 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. MS1819, our lead drug candidate, and niclosamide , which we recently acquired, are in the early stages of clinical development and our other drug candidates are still in preclinical phase. Our drug 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 drug candidates will be successfully developed or commercialized. Our failure to develop, manufacture or receive regulatory approval for or successfully commercialize any of our drug 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 drug 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 drug 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 drug candidates depends on obtaining the final results of required non-clinical testing, including characterization of the manufactured components of our drug 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 drug 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 drug 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 drug candidates that are in the same therapeutic areas as our drug 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 drug 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 drug 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 drug candidate, MS1819, has only

completed two Phase 2 clinical trials in two separate indications (one Phase 2 in CF patients and one Phase 2 in CP patients). Niclosamide has completed a Phase 1b/2a study, conducted by First Wave, in patients with mild-to-moderate ulcerative colitis but has not completed a study in an indication that we intend on pursuing (ICI-AC and COVID-19 GI). Success in pre-clinical studies or early clinical trials does not mean that later clinical trials will be successful, as drug 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, niclosamide and our other drug 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 drug 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 drug candidates. If any of our drug 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 the ongoing Combination Trial in 2019 and 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 drug 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, changing clinical protocols, 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 drug 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, niclosamide and our other drug candidates.

***A pandemic, epidemic, or outbreak of an infectious disease, such as COVID-19, or coronavirus, may materially and adversely affect our business and our financial results.***

The spread of COVID-19 has affected segments of the global economy and may affect our operations, including the potential interruption of our clinical trial activities and our supply chain. Beginning in March 2020, the majority of our workforce began working from home. Disruptions caused by the continued spread of COVID-19, including the effects of stay-at-home orders and work-from-home policies, have impacted productivity and may result in further periods of business disruption, including delays in our clinical trials or delays or disruptions in our supply chain. In addition, there could be a potential effect of COVID-19 to the business at FDA or other health authorities, which could result in delays of reviews and approvals, including with respect to our drug candidates.

The continued spread of COVID-19 globally could adversely affect our clinical trial operations in the United States and Europe and other jurisdictions where we may decide to conduct clinical trials, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. We have already experienced certain delays of our clinical trials and may experience further delays as the pandemic continues. Disruptions in national or international shipments and deliveries could impede our ability to distribute product to trial sites in a timely manner. Any of the foregoing factors could delay our ability to conduct clinical trials or release clinical trial results. COVID-19 may also affect employees of third-party CROs located in affected geographies that we rely upon to carry out our clinical trials, which could result in inefficiencies due to reductions in staff and disruptions to work environments.

The spread of COVID-19, or another infectious disease, could also negatively affect the operations at our third-party manufacturers, which could result in delays or disruptions in the supply of our drug candidates. In addition, we have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring all employees to work remotely, suspending all non-essential travel worldwide for our employees, and discouraging employee attendance at industry events and in-person work-related meetings, which could negatively affect our business.

We have implemented business continuity plans designed to address and mitigate the impact of the ongoing COVID-19 pandemic on our employees and our business. We continue to operate normally with the exception of enabling all of our employees to work productively at home and abiding by travel restrictions issued by federal, state and local governments. Our current plans to return to the office remain fluid as federal, state and local guidelines, rules and regulations continue to evolve.

We cannot presently predict the scope and severity of any potential business shutdowns or disruptions. If we or any of the third parties with whom we engage, however, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operation and financial condition.

In addition, the global spread of COVID-19 has created significant volatility and uncertainty in global financial markets and may materially affect us economically and such conditions continue to persist. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. A recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our Common Stock.

***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 drug 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, niclosamide or of any other drug 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 drug candidates, and impair our ability to generate revenue from the commercialization of these drug 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 drug candidate in any jurisdiction and it is possible that none of our existing drug candidates or any drug candidates we may seek to develop in the future will ever obtain regulatory approval.

MS1819, niclosamide and our other drug 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 drug 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 drug 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, niclosamide or future drug 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, niclosamide and our other drug 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, niclosamide and our other drug 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, niclosamide and our other drug 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, niclosamide and our other drug 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, niclosamide and our other drug 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 drug 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, niclosamide and our other drug 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, niclosamide or any of our other drug candidates. Our drug 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 and niclosamide represent promising commercial opportunities, 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, niclosamide and our other drug 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, niclosamide or our other drug candidates. Our ability to successfully market our drug 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 drug 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 drug candidates provide clinical utility; and
- whether private health insurers, government health programs and other third-party payers will cover our drug candidates.

***We currently have no commercial organization. If we are unable to establish satisfactory sales and marketing capabilities or secure a sales and marketing partner, we may not successfully commercialize any of our product candidates.***

We have no commercial infrastructure. In order to commercialize products that are approved for marketing, we must either establish our own sales and marketing infrastructure or collaborate with third parties that have such commercial infrastructure.

We may not be able to enter into collaboration agreements on terms acceptable to us or at all. In addition, even if we enter into such relationships, we may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties. If we elect to establish a sales and marketing infrastructure, we may not realize a positive return on this investment. In addition, we will have to compete with established and well- funded pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize our drug candidates without strategic partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, or if we do not successfully enter into appropriate collaboration arrangements, we will have difficulty successfully commercializing our drug candidates and any we may develop or acquire, which would adversely affect our business, operating results and financial condition. Outside the United States, we may commercialize our drug candidates by entering into collaboration agreements with pharmaceutical partners. We may not be able to enter into such agreements on terms acceptable to us or at all. In addition, even if we enter into such relationships, we may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties.

***Because we license some of our product candidates from third parties, including First Wave, 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 drug candidates, including MS1819 and niclosamide, 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 royalties on net sales following commercialization 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, niclosamide and our other drug candidates and any future drug 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, niclosamide and our other drug candidates if we become dependent upon the other party and such other party does not prioritize the development of our drug 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 drug 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 drug 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 drug 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 drug candidates, including MS1819 and niclosamide. The proprietary yeast cell line from which the MS1819 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 SpA, and MS1819 drug product is currently manufactured at contract facilities located in Reims, France and Craigavon, United Kingdom owned by Delpharm and Almac Pharma Services, respectively. Niclosamide API is obtained by chemical synthesis and is currently manufactured by Olon SpA at a facility in Murcia, Spain. The drug substance manufacturing for niclosamide is currently conducted at a contract facility located in Milan, Italy owned by Monteresearch. We believe there are multiple alternative contract manufacturers capable of producing the MS1819 product we need for clinical trials. We are 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. In December 2020, we entered into a master service agreement with Asymchem to initiate the transfer of the manufacturing process for both drug substance and drug product.

We are completely dependent on these third parties for product supply and our MS1819 and niclosamide 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, niclosamide and our other drug 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 drug 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 drug candidates. In the case of niclosamide, we may also face competition from other companies developing different formulation of niclosamide for the same indications for which we intend to develop niclosamide, or from off-label uses of niclosamide approved for other indications.

***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, niclosamide and our other drug 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 drug candidates, our ability to develop and commercialize these drug 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 drug 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 drug 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, niclosamide, and our other drug 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 drug candidates, including MS1819 and niclosamide 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.

Because niclosamide is a small molecule it would be subject either to three or five year exclusivity, depending on the regulatory pathway of any clinical trials. niclosamide is not entitled to the same 12-year exclusivity as our biologic drug candidates.

***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 drug 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, niclosamide and our other drug candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of our drug 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 drug candidates over alternative treatments;

- the safety of drug 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.

***The First Wave License Agreement requires us to make significant developmental milestone and other payments which will require additional financing and, in the event we do commercialize niclosamide, we will be required to make royalty payments on net sales of the product which will decrease the revenues we may ultimately receive on sales. To the extent that such milestone, royalty and other payments are not timely made, First Wave, in certain cases, may terminate the First Wave License Agreement.***

Under the First Wave License Agreement, we must pay to First Wave significant milestone payments, and royalties on net sales (as defined in the First Wave Agreement). In order to make the various milestone payments that are required, we will need to raise additional funds. In addition, our royalty obligations will reduce the economic benefits to us of any future sales of niclosamide if we do receive regulatory approval and seek to commercialize niclosamide. To the extent that such milestone payments and royalties are not timely made, under the First Wave License Agreement, First Wave has certain termination rights relating to our license of niclosamide.

***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, niclosamide and our other drug 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 drug 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 drug 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, the "*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. We believe we are eligible to receive the CIR benefit through at least the end of 2021. If our research and development operations in France are terminated, we would no longer be eligible to receive the CIR. 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 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 EPI associated with CF and CP.

We have also recently entered into the First Wave License Agreement with First Wave pursuant to which we were granted a worldwide, exclusive right to develop, manufacture, and commercialize First Wave's proprietary immediate release and enema formulations of niclosamide for the fields of treating ICI-AC and COVID-19 gastrointestinal infections in humans. We are now solely responsible, and have agreed to use commercially reasonable efforts, for all development, regulatory and commercial activities related to the Products in the ICI-AC and COVID-19 fields.

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 drug 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 drug candidates or misread trends in the GI, CF, CP, COVID-19 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 drug 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 drug 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 drug 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 drug 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 drug candidates or proprietary technologies may infringe. Similarly, there may be issued patents relevant to our drug 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 drug 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 drug 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, niclosamide and our other drug 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, 2020, 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 drug 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 drug 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 drug 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 drug 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 $32.7 million and $15.2 million for the years ended December 31, 2020 and 2019, 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, niclosamide and our other drug 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. As of December 31, 2020, we had an accumulated deficit of approximately $95.4 million and negative working of approximately $7.7 million. Based on our historical and anticipated rate of cash expenditures, we do not anticipate our working capital will be sufficient to sustain our business through the successful commercialization of our drug candidates. Therefore, 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.

***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 drug candidates or grant licenses on terms that are not favorable to us.

In the event we effect any issuance, or any of our subsidiaries, of Common Stock or Common Stock equivalents for cash consideration, or a combination of units thereof (a "*Subsequent Financing*"), each holder of our Series B Preferred Stock has the right, subject to certain exceptions set forth in the Series B Certificate of Designations, at its option, to exchange (in lieu of cash subscription payments) all or some of the Series B Preferred Stock then held (with a value per share of Series B Preferred Stock equal to the Liquidation Preference) for any securities or units issued in a Subsequent Financing on dollar-for-dollar basis.

***We will need substantial additional capital and certain terms included in our financing transactions may prohibit us from raising 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, 2020 and 2019, we incurred research and development expense of approximately $19.1 million and $8.7 million, respectively. We expect to continue to spend substantial amounts on product development, including conducting clinical trials for MS1819, niclosamide and our other drug candidates and manufacturing 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.

Further, pursuant to the financing transaction documents we entered into in connection with the March 2021 Offering, we have agreed, not to issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of common stock or common stock equivalents or file any registration statement until April 29, 2021. In addition, we have agreed, subject to certain exceptions, for the one- year period commencing on the signing of the March 2021 Purchase Agreement, not to (i) issue or sell any debt or equity securities that are convertible into, exchangeable or exercisable for, or include the right to receive, additional common stock either (A) at a conversion price, exercise price or exchange rate or other price that is based upon, and/or varies with, the trading prices of or quotations for the common stock at any time after the initial issuance of such debt or equity securities or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such debt or equity security or upon the occurrence of specified or contingent events directly or indirectly related to our business or the market for the common stock or (ii) enter into, or effect a transaction under, any agreement, including, but not limited to, an equity line of credit, whereby we may issue securities at a future determined price. The March 2021 Purchase Agreement limits our ability to make sales of our Common Stock pursuant to our Equity Line Agreement (as defined below) with Lincoln Park Capital Fund, LLC until July 7, 2021.

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. If we are able to raise additional capital, our stockholders may experience additional dilution, and as a result, our stock price may decline.

***If we issue additional shares of Common Stock in the future, including issuances of shares upon conversion or exercise of our outstanding securities convertible and/or exercisable into shares of Common Stock, our existing stockholders will be diluted.***

The conversion or exercise, as applicable, of outstanding securities will dilute the voting interest of the owners of presently outstanding shares of Common Stock by adding a substantial number of additional shares of our Common Stock. As of March 29, 2021, we had:

- 3,932,506 shares of Common Stock issuable upon the exercise of stock options, at a weighted average exercise price of $1.20 per share under our 2014 Plan;
- 387,000 shares of granted, but unissued restricted stock and restricted stock units under our 2014 Plan;
- 353,685 shares of Common Stock issuable upon the exercise of stock options, at a weighted average exercise price of $1.01 per share under our 2020 Plan;
- 9,646,315 shares of Common Stock that are available for future issuance under our 2020 Plan;
- 44,930,105 shares of Common Stock issuable upon exercise of outstanding warrants, with a weighted average exercise price of $1.02 per share;
- 12,553,791 shares of Common Stock issuable upon conversion of Series B Preferred Stock, including accrued and unpaid dividends thereon in the aggregate amount of approximately $207,000;
- up to 347,461 shares of Common Stock issuable upon conversion of Series C Preferred Stock that may be issued pursuant to the Exchange Right, in excess of amounts currently underlying the Series B Preferred Stock;
- up to 13,376,159 shares of Common Stock issuable upon exercise of Investor Warrants that may be issued pursuant to the Exchange Right;

To the extent any of these convertible securities, warrants or options are converted or exercised and any additional options are granted and exercised, there will be further dilution to stockholders and investors.

**Risks Associated with our Capital Stock**

***Our failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our Common Stock.***

On March 23, 2020, we received a letter from the Listing Qualifications Department (the "*Staff*") of The Nasdaq Stock Market LLC ("*Nasdaq*") indicating that, based upon the closing bid price of our Common Stock for the prior 30 consecutive business days, we were not in compliance with the requirement to maintain a minimum bid price of $1.00 per share for continued listing on Nasdaq, as set forth in Nasdaq Listing Rule 5550(a)(2) (the "*Minimum Bid Price Requirement*"). The 180-day time period for us to regain compliance was subsequently extended to December 3, 2020, pursuant to certain COVID-19 related relief from price-based continued listing requirements issued by Nasdaq on April 16, 2020. On November 23, 2020, we submitted a request to Nasdaq for a 180-day extension to regain compliance with the Minimum Bid Price Requirement. On December 4, 2020, we received a letter from Nasdaq advising that we had been granted a 180-day extension to June 1, 2021 to regain compliance with the Minimum Bid Price Requirement, in accordance with Nasdaq Listing Rule 5810(c)(3)(A). If we do not regain compliance within the allotted compliance periods, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that our Common Stock will be subject to delisting. We would then be entitled to appeal that determination to a Nasdaq hearings panel. We will continue to monitor the closing bid price of our Common Stock and seek to regain compliance with the Minimum Bid Price Requirement within the allotted compliance period. If we do not regain compliance within the allotted compliance period, Nasdaq will provide notice that our Common Stock will be subject to delisting. We would then be entitled to appeal that determination to a Nasdaq hearings panel. There can be no assurance that we will regain compliance with the Minimum Bid Price Requirement during the 180-day extension.

On February 12, 2021, we received a letter from Nasdaq indicating that the Staff had determined that, from January 21 to February 12, 2021, the closing bid price of the Common Stock had been at $1.00 per share or greater. Accordingly, the Staff determined that we had regained compliance with the Minimum Bid Price Requirement and that the matter is now closed.

***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 on our Common Stock. 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. Our Series B Preferred Stock carries a cumulative dividend rate of 9.0% per year, which is cumulative and continues to accrue on a daily basis whether or not declared and whether or not we have assets legally available therefor. We may pay such dividends at our option either in cash or in kind in additional shares of preferred stock. We do not expect to pay any dividends in cash and have paid accrued dividends in kind in additional shares of preferred stock to date. 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

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.

***We currently have Series B Preferred Stock outstanding. Our certificate of incorporation authorizes our Board to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our Common Stock.***

Our Board has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board also has the authority to issue preferred stock without further stockholder approval.

We currently have approximately 1,248.89 shares of Series B Preferred Stock outstanding with a stated value of $7,700 per share, which are currently convertible at the holder's option at any time, together with any accrued but unpaid dividends thereon, into shares of Common Stock at a conversion price of $0.77, subject to certain adjustments.

Our Series B Preferred Stock gives its holders the preferred right to our assets upon liquidation and the right to receive dividend payments at 9.00% per annum before dividends are distributed to the holders of Common Stock, among other things. In addition, in the event we effect any issuance of Common Stock or Common Stock equivalents for cash consideration, or a combination of units thereof, the holders of the Series B Preferred Stock have the right, subject to certain exceptions, at their option, to exchange (in lieu of cash subscription payments) all or some of the Series B Preferred Stock then held (with a value per share of the Series B Preferred Stock equal to the Series B Stated Value plus accrued and unpaid dividends thereon) for any securities or units issued in such issuance on a dollar-for-dollar basis. The holders of the Series B Preferred Stock, voting as a separate class, also have customary consent rights with respect to certain corporate actions, including the issuance of an increased number of shares of Series B Preferred Stock, the establishment of any capital stock ranking senior to or on parity the Series B Preferred Stock as to dividends or upon liquidation, the incurrence of indebtedness, and certain changes to our Charter or Bylaws including other actions.

Our obligations to the holders of the Series B Preferred Stock and Series C Preferred Stock could limit our ability to obtain additional financing or increase our borrowing costs, which could have an adverse effect on our financial condition and hinder the accomplishment of our corporate goals.

In addition to the Series B Preferred Stock and Series C Preferred Stock, our Board could authorize the issuance of additional series of preferred stock with such rights preferential to the rights of our Common Stock, including the issuance of a series of preferred stock that has greater voting power than our Common Stock or that is convertible into our Common Stock, which could decrease the relative voting power of our Common Stock or result in dilution to our existing stockholders.

***As a result of the "most favored nation" in the Series B Certificate of Designations, we may be required to issue additional shares of Series C Preferred Stock and/or Investor Warrants which would be convertible for or exercisable into additional shares of Common Stock, to the investors who purchased shares of our Series B Preferred Stock and related warrants to purchase shares of our Common Stock in a private placement in July 2020.***

On July 16, 2020, we consummated a private placement offering (the "*Series B Private Placement*") in which we issued an aggregate of approximately 2,912.58 shares of Series B Preferred Stock, at a price of $7,700.00 per share,

initially convertible into an aggregate of 29,125,756 shares of Common Stock at $0.77 per share, together with warrants to purchase an aggregate of 14,562,826 shares of Common Stock at an exercise price of $0.85 per share. The Series B Preferred Stock carries a cumulative dividend at a rate of 9.0% per annum, payable at our option either in cash or in kind in additional shares of Series B Preferred Stock.

Under the Series B Certificate of Designations, in the event we effect any issuance of Common Stock or Common Stock equivalents for cash consideration, or a combination of units thereof (a "*Subsequent Financing*"), each holder of the Series B Preferred Stock has the right to exchange the stated value, plus accrued and unpaid dividends, of the Series B Preferred Stock for any securities issued in the Subsequent Financing, in lieu of any cash subscription payments therefor (the "*Exchange Right*"). As a result, as of March 29, 2021, we may be required to issue up to 13,376.159 additional shares of Series C Preferred Stock that are currently convertible up to 13,376,159 underlying shares of Common Stock, together with Investor Warrants to purchase up to an additional 13,376,159 shares of Common Stock, to any holders of Series B Preferred Stock who elect to exercise their Exchange Right. We anticipate that we would convert any shares of Series C Preferred Stock to be issued pursuant to the Exchange Right into underlying shares of Common Stock immediately upon issuance.

If the holders of our Series B Preferred Stock exercise their Exchange Rights, it will result in certain dilution to our stockholders, and would afford our stockholders a smaller percentage interest in our voting power, liquidation value and aggregate book value. The sale or resale of the Common Stock issued upon conversion of the preferred stock could cause the market price of our Common Stock to decline. In addition, the issuance of Common Stock upon the exercise of the Investor Warrants will result in similar dilution to our stockholders. This dilution, or the possibility that it may occur, may make it more difficult for us to sell equity securities in the future at a time and a price that we deem appropriate.

## ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

## ITEM 2. PROPERTIES

### Facilities

We lease the space for our principal executive offices at 1615 South Congress Avenue, Suite 103, Delray Beach, FL 33445 and an administrative office at 760 Parkside Avenue, Downstate Biotechnology Incubator, Suite 217, Brooklyn, NY 11226 on a month-to-month basis. 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, 2022. The operations of AzurRx SAS are conducted at office space located at 290 chemin de Saint Dionisy, Jardin des Entreprises, 30980 Langlade, France, that we occupy under a short-term lease. We believe that our facilities are adequate to meet our current needs.

## 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 of Record

At March 30, 2021, there were 74,439,377 shares of our Common Stock issued and outstanding and approximately 166 stockholders of record.

#### Dividends

We did not declare any dividends on our Common Stock for the years ended December 31, 2020 and 2019, respectively. Our board of directors does not intend to distribute dividends in the future. Instead, we plan to retain any earnings to finance the development of our drug candidates and expansion of our business. The declaration, payment and amount of any future dividends will be made at the discretion of the board of directors, and will depend upon, among other things, the results of our operations, cash flows and financial condition, operating and capital requirements, and other factors as the board of directors considers relevant. There is no assurance that future dividends will be paid, and if dividends are paid, there is no assurance with respect to the amount of any such dividend.

Future cash dividends, if any, will be at the discretion of our board of directors and will depend upon our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors as our board of directors may deem relevant. We can pay dividends only out of our profits or other distributable reserves and dividends or distribution will only be paid or made if we are able to pay our debts as they fall due in the ordinary course of business.

Cumulative dividends on the shares of Series B Preferred Stock accrue at the rate of 9% of the Stated Value per annum, payable semi- annually on June 30 and December 31 of each year, commencing on December 31, 2020. Dividends are payable in additional shares of Series B Preferred Stock valued at the Stated Value or in cash at our sole option.

#### Transfer Agent

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

#### Unregistered Sales of Equity Securities

In April 2020, we issued our non-executive Board members stock options to purchase an aggregate of 460,000 shares of Common Stock with a strike price of $0.97 per share, subject to time-based vesting, under the 2014 Plan as payment for services provided to the Board. Such issuance was exempt from registration under 4(a)(2) of the Securities Act of 1933, as amended (the ''Securities Act'').

In December 2020, we issued a consultant ten-year stock options to purchase 10,000 shares of Common Stock with a strike price of $0.97 per share, subject to performance-based milestone vesting related to clinical development of MS1819, under the 2020 Plan as payment for services rendered. Such issuance was exempt from registration under 4(a)(2) of the Securities Act.

During the year ended December 31, 2020, there were no other sales of our securities that were not reported in a Current Report on Form 8-K or our Quarterly Report on Form 10-Q.

### ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

## 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 consolidated 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.*

### Overview

We are engaged in the research and development of targeted, non-systemic therapies for the treatment of patients with gastrointestinal ("*GI*") diseases. Non-systemic therapies are non-absorbable drugs that act locally, i.e. in the intestinal lumen, skin or mucosa, without reaching an individual's systemic circulation.

We are currently focused on developing our pipeline of gut-restricted GI clinical drug candidates. Our lead drug candidate is MS1819, a recombinant lipase for the treatment of exocrine pancreatic insufficiency ("*EPI*") in patients with cystic fibrosis ("*CF*") and chronic pancreatitis ("*CP*"), currently in two Phase 2 CF clinical trials. In 2021, we plan to launch two clinical programs using proprietary formulations of niclosamide, a pro-inflammatory pathway inhibitor; FW-420, for Grade 1 Immune Checkpoint Inhibitor-Associated Colitis ("*ICI-AC*") and diarrhea in oncology patients, and FW-1022, for Severe Acute Respiratory Syndrome Coronavirus 2 ("*COVID-19*") GI infections.

### COVID-19 Update

In March 2020, the WHO declared the novel coronavirus disease, or COVID-19, outbreak a global pandemic. To limit the spread of COVID-19, governments have taken various actions including the issuance of stay-at-home orders and physical distancing guidelines. Accordingly, businesses have adjusted, reduced or suspended operating activities. Beginning in March 2020, the majority of our workforce began working from home. Disruptions caused by the COVID-19 pandemic, including the effects of the stay-at-home orders and work- from-home policies, have impacted productivity, including delayed enrollment of new patients at certain of our clinical trial sites, and may further disrupt our business and delay our development programs and regulatory timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct business in the ordinary course. As a result, our expenses may vary significantly if there is an increased impact from COVID-19 on the costs and timing associated with the conduct of our clinical trials and other related business activities.

We have implemented business continuity plans designed to address and mitigate the impact of the ongoing COVID-19 pandemic on our employees and our business. We continue to operate normally with the exception of enabling all of our employees to work productively at home and abiding by travel restrictions issued by federal, state and local governments. Our current plans to return to the office remain fluid as federal, state and local guidelines, rules and regulations continue to evolve.

### Financial Operations Overview

#### *Revenue*

To date, we have not generated any revenue from the sale of our drug candidates 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 drug candidates are at an early stage of development and may never be successfully developed or commercialized.

#### *Research and Development Expense*

Conducting research and development is central to our business. Historically, the majority of our research and development expenses have been focused on the development of our lead drug candidate, MS1819.

Research and development expenses consist primarily of internal and external costs incurred for our development activities, which include, among other things:

- personnel-related costs, which include salaries, benefits, and stock-based compensation expense;
- fees paid to third parties for services directly related to our drug development and regulatory efforts;
- Expenses 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 research activities;
- the cost of acquiring drug product, drug supply and clinical trial materials from contract development and manufacturing organization (CDMOs) and third-party contractors;
- costs associated with preclinical and non-clinical activities;
- payments and other costs in connection with the acquisition our drug candidates under licensing agreements; and
- amortization of intangible assets, including patents, in-process research and development and license agreements.

Costs incurred in connection with research and development activities are expensed as incurred.

We expect our research and development expenses to increase for the foreseeable future as we focus our efforts on the clinical development of our drug candidates, including MS1819, and niclosamide through late-stage clinical trials, as well as chemistry, manufacturing and controls (''*CMC*'') efforts. The process of conducting non-clinical studies and clinical trials necessary to obtain regulatory approval is costly and time-consuming. It is difficult to determine with certainty the duration and costs of any non-clinical study or clinical trial that we may conduct. In addition, if our product development efforts are successful, we expect to incur substantial costs to prepare for potential commercialization of any late-stage drug candidates and, in the event any of our drug candidates receives regulatory approval, to potentially fund the launch and sales and marketing efforts of the product.

The probability of success for any of our current or future drug candidates will depend on numerous factors, including competition, manufacturing capability and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each drug candidate, as well as an assessment of each drug candidate's commercial potential.

We do not record or maintain information regarding costs incurred in research and development on a program or project specific basis. Our research and development staff, outside consultants, contractors, CROs, and CDMOs 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 personnel does not accurately reflect the actual costs of a project.

***General and Administrative Expense***

General and administrative expenses consist primarily of personnel-related expenses, including salaries, benefits and stock-based compensation, related to our executive, finance, business development and support functions, legal fees relating to both intellectual property and corporate matters, insurance, costs associated with operating as a public company, including corporate communications and investor relations expense, information technology, professional fees for accounting, auditing and other professional services, and facility- related costs.

We anticipate our general and administrative expenses to increase for the foreseeable future to support of our expanded research and development activities, intellectual property, patent and corporate legal expense, insurance, and costs associated with operating as a public company, including corporate communications and investor relations expense. Additional increases in general and administrative expenses are expected in connection with increased business development efforts, including potential partnership and/or collaboration agreements and financing activities, expanding infrastructure, including information technology administration, and the hiring of additional personnel and consultants, among other expenses.

**Liquidity and Capital Resources**

To date, we have not generated any revenues and have experienced net losses and negative cash flows from our activities.

As of December 31, 2020, we had cash and cash equivalents of approximately $6.1 million, negative working capital of approximately $7.7 million, and had sustained cumulative losses attributable to common stockholders of approximately $95.4 million. Subsequent to December 31, 2020, we have raised aggregate gross proceeds of approximately $18.0 from the sale of preferred stock and Common Stock in public offerings and private placement transactions, and we have received gross cash proceeds of approximately $4.6 million from the exercise of warrants. 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 may raise substantial doubt about our ability to continue as a going concern.

Our primary sources of liquidity come from capital raises through additional equity and/or debt financings. This may be impacted by the COVID-19 pandemic, which is evolving and could negatively impact our ability to raise additional capital in the future.

We have funded our operations to date primarily through the issuance of debt, convertible debt securities, preferred stock, as well as the issuance of Common Stock in various public offerings and private placement transactions. We expect to incur substantial expenditures in the foreseeable future for the development of MS1819, niclosamide and any other drug candidates. We will require additional financing to develop our drug 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.

On December 31, 2020, to finance our entry into the First Wave License Agreement with First Wave, we entered into a purchase agreement to raise aggregate gross proceeds of $8.0 million from the sale of shares of Series C Preferred Stock and warrants, in a combined private placement and registered direct offering, which closed in January 2021. On March 7, 2021, we entered into a securities purchase agreement to raise aggregate gross proceeds of $10.0 million in a registered direct offering priced at the market under Nasdaq rules. Additionally, between January and March 2021, we received gross cash proceeds of approximately $4.6 million from the exercise of warrants.

Although, we are primarily focused on the development of our drug candidates, including MS1819 and niclosamide, we are also opportunely focused on expanding our product pipeline of clinical assets through collaborations, and also through acquisitions of products and companies. We are continually evaluating potential asset acquisitions business combinations, and other partnership opportunities. To finance such acquisitions, we might raise additional equity capital, incur additional debt, or both.

**Consolidated Results of Operations for the Years Ended December 31, 2020 and 2019**

The following table summarizes our consolidated results of operations for the periods indicated:

| | Year Ended December 31, | | Increase (decrease) |
|---|---|---|---|
| | 2020 | 2019 | |
| Operating expenses: | | | |
| Research and development expenses | $ 5,888,004 | $ 8,680,669 | $ (2,792,665) |
| Research and development expenses – license acquired | 13,250,000 | — | 13,250,000 |
| General and administrative expenses | 7,294,764 | 6,063,078 | 1,231,686 |
| Total operating expenses | 26,432,768 | 14,743,747 | 11,689,021 |
| Other expenses | 6,238,698 | 433,939 | 5,804,759 |
| Net loss | $32,671,466 | $15,177,686 | $17,493,780 |

*Revenues*

We have not yet achieved revenue-generating status from any of our drug candidates. Since inception, we have devoted substantially all of our time and efforts to developing our lead drug candidate, MS1819. As a result, we did not have any revenue during the years ended December 31, 2020 and 2019, respectively.

*Research and Development Expense*

Research and development expenses include cash and non-cash expenses primarily relating to the development of our lead drug candidate, MS1819 and the acquisition of our licensed niclosamide drug candidates.

Research and development expenses for the year ended December 31, 2020 totaled approximately $19.1 million, an increase of approximately $10.5 million, or 121% over the approximately $8.7 million recorded for the year ended December 31, 2019. Non-cash expenses, including stock-based compensation, stock expense and depreciation and amortization totaled approximately $0.5 million for the year ended December 31, 2020 and approximately $1.4 million for the year ended December 31, 2019. Cash research and development expenses for the year ended December 31, 2020 totaled approximately $5.4 million, a decrease of approximately $1.9 million, or 26% over the approximately $7.3 million recorded for the year ended December 31, 2019.

The increase in total research and development expenses was primarily attributable to the $13.3 million of expense related to the acquisition of our niclosamide drug candidates through the First Wave License Agreement entered into on December 31, 2020, and increases of approximately $1.1 million in CMC related costs, offset by decreases of approximately $2.9 million in clinical related expenses in connection with reduced clinical activity in 2020 as compared to 2019 partly due to COVID-19, and approximately $0.9 million in non-cash expenses.

*General and Administrative Expense*

General and administrative expenses include cash and non-cash expenses primarily consisting of costs associated with our overall operations and being a public company. These costs include personnel, legal and financial professional services, insurance, corporate communication and investor relations, compliance related fees, and expenses associated with obtaining and maintaining intellectual property and patents, among others.

General and administrative expenses for the year ended December 31, 2020 totaled approximately $7.3 million, an increase of approximately $1.6 million, or 27% over the approximately $5.7 million recorded for the year ended December 31, 2019. Non-cash expenses, including stock-based compensation, stock expense and depreciation and amortization totaled approximately $0.7 million for the year ended December 31, 2020, and approximately $0.7 million recorded for the year ended December 31, 2019. Cash general and administrative expenses for the year ended December 31, 2020 totaled approximately $6.6 million, an increase of approximately $1.6 million, or 32% over the approximately $5.0 million recorded for the year ended December 31, 2019.

The increase in total general and administrative expenses was due primarily to increases in legal expenses of approximately $0.7 million, personnel costs of approximately $0.4 million, business development related expense of approximately $0.3 million, directors and officer's insurance of approximately $0.3 million, and costs associated with being a publicly reporting company of approximately $0.1 million offset by decreases in travel and entertainment of $0.1 million, accounting and auditing of $0.1 million, and directors fees of approximately $0.1 million.

*Other Expense*

Other expenses for the year ended December 31, 2020 totaled approximately $6.3 million, an increase of approximately $5.5 million, or 686% over the approximately $0.8 million recorded for the year ended December 31, 2019. Interest expense was approximately $5.8 million and $0.4 million for the year ended December 31, 2020 and 2019, respectively. The increased interest expense is due to amortization of debt discount and accrued interest related to the convertible debt issued in December 2019 and January 2020.

*Net Loss*

As a result of the factors above, our net loss for the year ended December 31, 2020 totaled approximately $32.7 million, an increase of approximately $17.5 million, or 115% over the approximately $15.2 million recorded for the year ended December 31, 2019.

**Cash Flows for the Years Ended December 31, 2020 and 2019**

The following table summarizes our cash flows for the periods indicated:

| | Year Ended December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Net cash provided by (used in): | | |
| Operating activities | $(11,221,538) | $(14,033,502) |
| Investing activities | 87,350 | (24,098) |
| Financing activities | 17,046,121 | 13,144,979 |
| Net increase (decrease) in cash and cash equivalents | $ 5,911,933 | $ (912,621) |

***Operating Activities***

Net cash used in operating activities during the year ended December 31, 2020 of approximately $11.2 million was primarily attributable to our net loss of approximately $32.7 million adjusted for addbacks of non-cash expenses of approximately $7.3 million, which includes accretion of debt discount of approximately $4.6 million, loss on debt extinguishment of approximately $0.6 million, amortization of approximately $0.5 million, and stock-based compensation of approximately $0.5 million and a net increase of working capital of approximately $14.2 million.

Net cash used in operating activities during the year ended December 31, 2019 of approximately $14.0 million was primarily attributable to our net loss of approximately $15.2 million adjusted for addbacks of non-cash expenses of approximately $2.8 million, which includes amortization of approximately $1.0 million, stock expense of approximately $0.6 million, and stock-based compensation of approximately $0.6 million and a net decrease of working capital of approximately $1.7 million.

***Investing Activities***

Net cash provided by investing activities during the year ended December 31, 2020 of approximately 87,000 was primarily attributable to the and sale of equipment related to the closure of our laboratory in France.

Net cash used in investing activities during the year ended December 31, 2019 of approximately $24,000 was primarily attributable to the net purchase of property and equipment.

***Financing Activities***

Net cash provided by financing activities of approximately $17.0 million for the year ended December 31, 2020 was primarily due to the net proceeds from the issuance of convertible debt of approximately $3.2 million in January 2020 and the issuance of the preferred stock of approximately $13.2 million in the Series B Private Placement in July 2020 offset by repayments of approximately $0.5 million related to the ADEC Notes and approximately $0.7 million related to the note payable.

Net cash provided by financing activities of approximately $13.1 million for the year ended December 31, 2019 was primarily due to the net proceeds from our public offerings in April, May, and July 2019 of approximately $9.5 million, and issuance of the convertible debt of approximately $5.0 million from the ADEC Note Offering, and the December 2019 Promissory Note Offering offset by repayments of approximately $1.6 million related to the ADEC Notes and approximately $0.3 million related to the note payable.

**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 $2.9 million and $3.4 million at December 31, 2020, and 2019, 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, 2020 and 2019 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 SAS 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 was approximately $2.1 million and $1.9 million, at December 31, 2020 and 2019, respectively. If actual results are not consistent with our estimates or assumptions, we may be exposed to an impairment charge that could be material.

### Emerging Growth Company Status

We are an ‘‘emerging growth company,’’ as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company until December 31, 2022. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- reduced disclosure about our executive compensation arrangements ;
- no non-binding stockholder advisory votes on executive compensation or golden parachute arrangements; and
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We have taken advantage of reduced reporting requirements in this Annual Report on Form 10-K and may continue to do so until such time that we are no longer an emerging growth company. We will remain an ‘‘emerging growth company’’ until the earliest of (a) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more, (b) December 31, 2021, the last day of the fiscal year following the fifth anniversary of the completion of our IPO, (c) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years or (d) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period for complying with new or revised accounting standards. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

In addition, we are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

### Off-Balance Sheet Items

We had the following contractual obligations over the periods indicated:

| Contractual Obligations | Total | 2021 | 2022 | 2023 | 2024 | 2025 |
|---|---|---|---|---|---|---|
| Operating Leases[(1)] | $78,795 | $55,420 | $23,375 | $— | $— | $— |

(1) Only includes basic rent payments for our properties. Additional monthly payments under the lease agreements shall include tax payments and operational costs.

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

Not applicable.

## 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, our 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.**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the ''Exchange Act'') is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

As of December 31, 2020, our senior management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our senior management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of December 31, 2020 our disclosure controls and procedures were effective at the reasonable assurance level.

**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, management has concluded that, as of December 31, 2020, our internal control over financial reporting was effective based upon those criteria.

This report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting.

**Changes in Internal Controls over Financial Reporting.**

There were no significant 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 following section sets forth certain information regarding our directors. There are no family relationships between any of the directors and our Named Executive Officers.

| Director, Title | Age |
|---|---|
| James Sapirstein – President, Chief Executive Officer, Chairman and Non-Independent Director | 59 |
| Edward J. Borkowski – Lead Independent Director | 60 |
| Charles J. Casamento – Independent Director | 75 |
| Alastair Riddell, MSc., MBChB., DSc. – Independent Director | 71 |
| Vern L. Schramm, Ph.D. – Independent Director | 79 |
| Gregory Oakes –Independent Director | 52 |

***James Sapirstein*** was appointed to the Board on October 8, 2019 and as our President and Chief Executive Officer effective that same day. Mr. Sapirstein was appointed Chair of the Board effective February 19, 2021. Prior to joining us, Mr. Sapirstein served as Chief Executive Officer and as a director of ContraVir Pharmaceuticals, Inc. (now known as Hepion Pharmaceuticals, Inc.) from March 2014 to October 2018. Previously, Mr. Sapirstein was the Chief Executive Officer of Alliqua Therapeutics from October 2012 to February 2014. He founded and served as Chief Executive Officer of Tobira Therapeutics from October 2006 to April 2011 and served as Executive Vice President, Metabolic and Endocrinology for Serono Laboratories from June 2002 to May 2005. Mr. Sapirstein's earlier career included a number of senior level positions in the area of marketing and commercialization, including as Global Marketing Lead for Viread (tenofovir) while at Gilead Sciences and as Director of International Marketing of the Infectious Disease Division at Bristol Myers Squibb. Mr. Sapirstein is currently the Chair Emeritus of BioNJ, the New Jersey affiliate of the Biotechnology Innovation Organization, and also serves on the Emerging Companies and Health Section Boards of the Biotechnology Innovation Organization. Mr. Sapirstein received his bachelor's degree in pharmacy from Rutgers University and holds an MBA degree in management from Fairleigh Dickinson University.

Mr. Sapirstein's nearly 36 years of pharmaceutical industry experience which spans areas such as drug development and commercialization, including participation in 23 product launches, six of which were global launches led by him makes him a valuable asset to the Board and in his oversight and execution of our business plan.

***Edward J. Borkowski*** was appointed to the Board in May 2015, and currently serves as our Lead Independent Director. Mr. Borkowski served as Chair of the Board from 2015 through his resignation effective as of February 19, 2021. Mr. Borkowski is a healthcare executive who currently serves as Executive Vice President for Therapeutics MD. He served as Executive Vice President of MiMedx Group, Inc. (Nasdaq: MDGX) from April 2018 until December 2019. Mr. Borkowski also served as a director for Co-Diagnostics, Inc. (Nasdaq: CODX), from May 2017 until June 2019. Previously, he served as the Chief Financial Officer of Aceto Corporation (Nasdaq: ACET) from February 2018 to April 2018, and has held several executive positions with Concordia International, an international specialty pharmaceutical company, between May 2015 to February 2018. Mr. Borkowski has also served as Chief Financial Officer of Amerigen Pharmaceuticals, a generic pharmaceutical company with a focus on oral, controlled release products and as the Chief Financial Officer and Executive Vice President of Mylan N.V. In addition, Mr. Borkowski previously held the position of Chief Financial Officer with Convatec, a global medical device company focused on wound care and ostomy, and Carefusion, a global medical device company for which he helped lead its spin-out from Cardinal Health into an independent public company. Mr. Borkowski has also served in senior financial positions at Pharmacia and American Home Products (Wyeth). He started his career with Arthur Andersen & Co. after receiving his MBA in accounting from Rutgers University subsequent to having earned his degree in Economics and Political Science from Allegheny College. Mr. Borkowski is currently a Trustee and a member of the Executive Committee of Allegheny College.

Mr. Borkowski's extensive healthcare and financial expertise, together with his public company experience provides the Board and management with valuable insight in the growth of our business plan.

***Charles J. Casamento*** was appointed to the Board in March 2017. Since 2007, Mr. Casamento has been executive director and principal of The Sage Group, a health care advisory group. Prior to that, Mr. Casamento was president and Chief Executive Officer of Osteologix, a startup company which he oversaw going public, from October 2004 until April 2007. Mr. Casamento was the founder of Questcor Pharmaceuticals where he was President, Chief Executive Officer and Chair from 1999 through 2004. During his time at Questcor, the company acquired Acthar, a

product with sales that would eventually exceed $1.0 billion. Mr. Casamento also served as President, Chief Executive Officer and Chair of RiboGene Inc. until 1999 when RiboGene was merged another company to form Questcor. He was also the Co-Founder, President and Chief Executive Officer of Indevus (formerly Interneuron Pharmaceuticals) and has held senior management positions at Genzyme Corporation, where he was Senior Vice President, American Hospital Supply, where he was Vice President of Business Development for the Critical Care division, Johnson & Johnson, Hoffmann-LaRoche and Sandoz. He currently serves as Chairman of the Board of Directors of Relmada Therapeutics (OTCQB: RLMD) and also serves on the Board of Directors of Eton Pharmaceuticals (Nasdaq: ETON), and was previously a Director and Vice Chair of the Catholic Medical Missions Board, a large not for profit international organization. Mr. Casamento holds a bachelor's degree in Pharmacy from Fordham University and an MBA from Iona College.

Mr. Casamento's expertise and knowledge of the financial community combined with his experience in the healthcare sector makes him a valued member of the Board.

***Dr. Alastair Riddell*** was appointed to the Board in September 2015. Since June 2016, Dr. Riddell has served as Chair of Nemesis Biosciences Ltd and Chair of Feedback plc (LON: FDBK). He has also served as Chair of the South West Academic Health Science network in the UK since January 2016. Since his appointment in December 2015, Dr. Riddell has served as Non-Executive Director of Cristal Therapeutics in The Netherlands. From September 2012 to February 2016, he served as Chair of Definigen Ltd., and from November 2013 to September 2015 as Chair of Silence Therapeutics Ltd., and from October 2009 to November 2012 as Chair of Procure Therapeutics. Between 2007 to 2009, Dr. Riddell served as the Chief Executive Officer of Stem Cell Sciences plc. and between 2005 to 2007, served at Paradigm Therapeutics Ltd. as the Chief Executive Officer. Between 1998 to 2005, Dr. Riddell also served as the Chief Executive Officer of Pharmagene plc. Dr. Riddell began his career as a doctor in general practice in a variety of hospital specialties and holds a Master of Science and a Bachelor of Medicine and Surgery degrees. He was recently awarded a Doctorate of Science, Honoris Causa by Aston University.

Dr. Riddell's medical background coupled with his expertise in the life sciences industry, directing all phases of clinical trials, before moving to sales, marketing and general management, makes him a well-qualified member of the Board.

***Dr. Vern L. Schramm*** was appointed to the Board in October 2017. Dr. Schramm has served as Professor of the Albert Einstein College of Medicine since 1987 and Chair of the Department of Biochemistry from 1987 to 2015, and was awarded the Ruth Merns Endowed Chair in Biochemistry. His fields of interest include enzymatic transition state analysis, transition state inhibitor design, biological targets for inhibitor design, and mechanisms of N-ribosyltransferases. Dr. Schramm was elected to the National Academy of Sciences in 2007, and served as the Associate Editor for the *Journal of the American Chemical Society* between 2003 to 2012. A frequent lecturer and presenter in topics related to chemical biology, Dr. Schramm has been a consultant and advisor to Pico Pharmaceuticals, Metabolon Inc., Sirtris Pharmaceuticals, and BioCryst Pharmaceuticals. Dr. Schramm obtained his BS in Bacteriology with an emphasis in chemistry from South Dakota State College and holds a Master's Degree in Nutrition with an emphasis in biochemistry from Harvard University, a Ph.D. in Mechanism of Enzyme Action from the Australian National University and completed his postdoctoral training at NASA Ames Research Center, Biological Sciences, with an NSF-NRC fellowship.

Dr. Schramm's substantial experience in biochemistry and expertise in the chemistry related to non-systemic biologics makes him a respected member of the Board and an asset to us specifically in the development of our drug candidates.

***Gregory Oakes*** was appointed to the Board on April 13, 2020. Mr. Oakes brings over 25 years of pharmaceutical industry and leadership experience and currently serves as President, North America, Relypsa, Inc, Executive Vice President, Vifor Pharma. Mr. Oakes previously served as Corporate Vice President, Global Integration Lead for Otezla® (apremilast) at Amgen, Inc. where he was responsible for the integration and continued success of the brand with $2 billion in assets. Prior to Amgen from 2017 - 2019, Mr. Oakes served as Corporate Vice President and U.S. General Manager at Celgene Corp., a global biopharmaceutical company which develops and commercializes medicines for cancer and inflammatory disorders. Mr. Oakes also served as the Global Commercial Integration Lead at Celgene where he helped steer the $74 billion acquisition by Bristol-Myers Squibb and the $13.4 billion divestiture of Otezla®. From 2010 to 2017, Mr. Oakes held several positions at Novartis AG, the most recent as Head of Sandoz Biopharmaceuticals, North America. He began his career at Schering-Plough (Merck) where he held executive roles

in both the U.S. and Europe. Mr. Oakes holds a bachelor's degree in Marketing and Business Administration from Edinboro University and a M.B.A. from Clemson University. He currently sits on the Board of BioNJ and previously served on various Executive Committees at Celgene, Novartis, and Schering-Plough (Merck).

Mr. Oakes' background of over 25 years of pharmaceutical industry and leadership experience combined with broad experience in pharmaceutical commercialization and acquisitions makes him a qualified member of the Board.

**Non-Executive Director Compensation**

On October 1, 2020, our Board adopted a Non-Executive Director Compensation Policy under which each of our non-executive directors is entitled to receive the following cash compensation for their service on the Board (paid quarterly): (i) an annual retainer of $35,000; (ii) the chairman of the Board is entitled to receive an annual retainer in the amount of $20,000, (iii) the chair of the Audit Committee is entitled to receive an annual retainer in the amount of $10,000, (iv) each non-chairperson member of the Audit Committee is entitled to receive an annual retainer in the amount of $5,000, (v) the chair of the Compensation Committee is entitled to receive an annual retainer in the amount of $7,500, (vi) each non-chairperson member of the Compensation Committee is entitled to receive an annual retainer in the amount of $3,500, (vii) the chair of the Corporate Governance and Nominating Committee is entitled to receive an annual retainer in the amount of $5,000, and (viii) each non-chairperson member of the Corporate Governance and Nominating Committee is entitled to receive an annual retainer in the amount of $2,500. Additionally, under this policy, each of our non-executive directors is entitled to receive an annual grant of 80,000 stock options for their service on the Board which will vest in equal quarterly installments.

The following table provides information regarding compensation paid to non-employee directors for the year ended December 31, 2020. Mr. Sapirstein did not receive compensation for his service on the Board as employee director for the year ended December 31, 2020. Information regarding executive compensation paid to Messrs. Sapirstein during 2020 is reflected in the Summary Compensation table under "*Executive Compensation*."

| Name | Fees Earned or Paid in Cash[2] | Stock Awards | Option Awards [3] | All Other Compensation | Total |
|---|---|---|---|---|---|
| Edward J. Borkowski | $19,375 | $— | $35,968 | — | $55,343 |
| Charles J. Casamento | $11,500 | $— | $35,968 | — | $47,468 |
| Alastair Riddell | $11,500 | $— | $35,968 | — | $47,468 |
| Vern L. Schramm | $ 8,750 | $— | $35,968 | — | $44,718 |
| Gregory Oakes[1] | $ 8,750 | $— | $30,444 | — | $39,194 |

(1) Mr. Oakes was appointed to the board effective April 13, 2020.

(2) Represents amounts of accrued and unpaid cash compensation for board services through December 31, 2020. By agreement with each director, on January 4, 2021, an aggregate of 41,237 stock options were awarded to the directors in lieu of payment of such cash.

(3) Represents the aggregate grant date fair value of 80,000 stock options issued to each of Messrs. Borkowski, Casamento, Riddell and Schramm on April 6, 2020, and 60,000 stock options issued to Mr. Oakes on April 13, 2020, our non-employee directors, calculated in accordance with ASC Topic 718.

**Compensation Committee Interlocks and Insider Participation**

None of our executive officers currently serves, or has served during the last three years, on the Compensation Committee of any other entity that has one or more officers serving as a member of our Board.

**Board Leadership Structure**

Effective as of February 19, 2021, our President and Chief Executive Officer, Mr. James Sapirstein, was appointed to serve as Chair of our Board. Mr. Sapirstein has provided strong leadership to the Board and management, instilling a clear focus on our strategy and business plans. The Board has chosen this structure because it believes Mr. Sapirstein serves as a bridge between management and the Board, ensuring that both groups act with a common purpose. The Board believes that the combined role of Chair and Chief Executive Officer will better assist management in developing strategic direction and then holding management accountable for the execution of strategy once it is developed. The Board believes, at this time, the combined role of Chair and Chief Executive Officer, together with independent directors, is in the best interest of stockholders because it provides the appropriate balance between strategy development and independent oversight of management. As a result, all directors, other than Mr. Sapirstein, are independent as defined under Nasdaq and SEC rules, and all committees of the Board are comprised entirely of independent directors.

Following this change, Mr. Edward J. Borkowski, who previously served as Chair of our Board, now serves as lead independent director and has the following responsibilities:

- provides leadership to the Board in any situation where the Chair's role may be, or may be perceived to be, in conflict, and also chairs meetings when the chairman is absent;
- serving as liaison between the Chair and the independent directors;
- approving information sent to the Board; and;
- approving meeting agendas for the Board.

The Board believes that the lead independent director further strengthens the Board's independence and autonomous oversight of our business as well as Board communication and effectiveness. The role of lead independent director serves as a bridge between the independent directors and management.

**Director Independence**

The Board has determined that all of its members, other than Mr. Sapirstein, our President, Chief Executive Officer and Chair of our Board are ''independent'' within the meaning of Nasdaq Listing Rule 5605(a)(2) under the rules of the Nasdaq Stock Market (''*Nasdaq*''), and the Securities and Exchange Commission (''*SEC*'') rules regarding independence.

**Director Nomination Process**

The Corporate Governance and Nominating Committee identifies director nominees by first considering those current members of the Board who are willing to continue service. Current members of the Board with skills and experience that are relevant to our business and are willing to continue their service as a director are considered for re-election, balancing the value of continuity of service by existing members of the Board with that of obtaining a new perspective. Nominees for director are selected by a majority of the members of the Board. Although we do not have a formal diversity policy, in considering the suitability of director nominees, the Corporate Governance and Nominating Committee considers such factors as it deems appropriate to develop a Board and its committees that are diverse in nature and comprised of experienced and seasoned advisors. Factors considered by the Corporate Governance and Nominating Committee include sound judgment, knowledge, skill, diversity, integrity, experience with businesses and other organizations of comparable size, including experience in the biopharma industry, clinical studies, FDA compliance, intellectual property, business, finance, administration or public service, the relevance of a candidate's experience to our needs and experience of other Board members, experience with accounting rules and practices, the desire to balance the considerable benefit of continuity with the periodic injection of the fresh perspective provided by new members, and the extent to which a director candidate would be a desirable addition to the Board and its committees.

The Board may consider suggestions for persons to be nominated for director that are submitted by stockholders. The Corporate Governance and Nominating Committee will evaluate stockholder suggestions for director nominees in the same manner as it evaluates suggestions for director nominees made by management, then-current directors or other appropriate sources.

**The Role of the Board in Risk Oversight**

Our Board oversees a company-wide approach to risk management, determines our appropriate risk level in general, assesses the specific risks faced by us and reviews steps taken by management to manage those risks. Although our Board has ultimate oversight responsibility for the risk management process, specific areas of risk are overseen by designation of such duties and responsibilities to certain committees of the Board.

Specifically, the Board has designated certain fiduciary duties to its Compensation Committee, which is responsible for overseeing the management of risks relating to our executive compensation plans and arrangements, and the incentives created by the compensation awards it administers. The Board has also designated specific fiduciary duties to its Audit Committee, which is responsible for overseeing the management of enterprise risks and financial risks, as well as potential conflicts of interests. The Board is responsible for overseeing the management of risks associated with the independence of the Board.

### Code of Business Conduct and Ethics

The Board adopted a code of business conduct and ethics (the "*Code*") that applies to our directors, officers and employees. A copy of this Code is available on our website at www.azurrx.com/investors. We intend to disclose on our website any amendments to and waivers of the Code that apply to our principal executive officer, principal financial officer, principal accounting officer, controller, or persons performing similar functions.

### Stockholder Communications

If you wish to communicate with the Board, you may send your communication in writing to AzurRx BioPharma, Inc., Attention: Chief Financial Officer – 1615 South Congress Avenue, Suite 103, Delray Beach, Florida 33445.

You must include your name and address in the written communication and indicate whether you are a stockholder of the Company. The Chief Financial Officer will review any communication received from a stockholder, and all material and appropriate communications from stockholders will be forwarded to the appropriate director or directors or committee of the Board based on the subject matter.

### Meetings of the Board

Each of our directors who served during the year ended December 31, 2020 attended or participated in no less than 75% or more of the aggregate of (i) the total number of meetings of the Board; and (ii) the total number of meetings held by all committees of the Board on which such director served as a member during such year. Although directors are not required to attend our annual meeting of stockholders, they are encouraged to attend.

The following table represents the composition of each committee of the Board and meetings held as well as actions taken by unanimous written consent ("*UWC*") in lieu of holding a meeting, during the fiscal year ended December 31, 2020:

| | | Committees | | |
|---|---|---|---|---|
| **Director** | **Board** | **Audit** | **Compensation** | **Corporate Governance and Nominating** |
| Edward J. Borkowski[(1)] | C | CC | X | CC |
| Charles J. Casamento | X | X | X | X |
| Alastair Riddell | X | X | CC | X |
| Vern L. Schramm | X | | | |
| James Sapirstein[(1)] | X | | | |
| Gregory Oakes | X | | | |
| **Meetings Held During 2020** | 6 | 4 | 3 | — |
| **Actions Taken by UWC During 2020** | 9 | — | 1 | 2 |

**C – Chair of the Board**
**CC – Committee Chair**
**X – Member**

(1) Effective February 19, 2021, Mr. Borkowski resigned as Chair of the Board and Mr. Sapirstein was appointed Chair of the Board.

### Board Committees

The standing committees of the Board consist of the Audit Committee, Compensation Committee, and Corporate Governance and Nominating Committee. Our Board has adopted written charters for each of these committees, copies of which are available on our website at www.azurrx.com/investors. Our Board may establish other committees as it deems necessary or appropriate from time to time.

#### *Audit Committee*

The duties and responsibilities of the Audit Committee include but are not limited to:

- appointing, compensating, retaining, evaluating, terminating, and overseeing our independent registered public accounting firm;

- discussing with our independent registered public accounting firm the independence of its members from its management;
- reviewing with our independent registered public accounting firm the scope and results of their audit;
- approving all audit and permissible non-audit services to be performed by our independent registered public accounting firm;
- overseeing the financial reporting process and discussing with management and our independent registered public accounting firm the interim and annual financial statements that are filed with the SEC;
- reviewing and monitoring our accounting principles, accounting policies, financial and accounting controls, and compliance with legal and regulatory requirements;
- coordinating oversight of the Code and our disclosure controls and procedures on behalf of the Board;
- establishing procedures for the confidential and/or anonymous submission of concerns regarding accounting, internal controls or auditing matters; and
- reviewing and approving related-person transactions.

The rules of Nasdaq require our Audit Committee to consist of at least three directors, all of whom must be deemed to be independent directors under Nasdaq rules. The Board has affirmatively determined that Messrs. Borkowski and Casamento, and Dr. Riddell, each meet the definition of ''independent director'' for purposes of serving on an Audit Committee under Nasdaq rules. Additionally, the Board has determined that Messrs. Borkowski and Casamento each qualify as an ''audit committee financial expert,'' as such term is defined in Item 407(d)(5) of Regulation S-K.

***Compensation Committee***

The duties and responsibilities of the Compensation Committee include but are not limited to:

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

The rules of Nasdaq require our Compensation Committee to consist entirely of independent directors. The Board has affirmatively determined that Mr. Borkowski and Dr. Riddell meet the definition of ''independent director'' for purposes of serving on the Compensation Committee under Nasdaq rules.

***Corporate Governance and Nominating Committee***

The duties and responsibilities of the Corporate Governance and Nominating Committee include but are not limited to:

- assisting the Board in identifying qualified individuals to become members of the Board;
- determining the composition of the Board and monitoring the activities of the Board to assess overall effectiveness; and
- developing and recommending to our Board corporate governance guidelines applicable to the Company and advising our Board on corporate governance matters.

## ITEM 11. EXECUTIVE COMPENSATION

The following table sets forth information regarding our current executive officers as appointed by the Board, each to serve in such position until their respective successors have been duly appointed and qualified or until their earlier death, resignation or removal from office. Our executive officers are appointed by and serve at the discretion of the Board, subject to the terms of any employment agreements they may have with us. The following is a brief description of the qualifications and business experience of each of our current executive officers.

| Executive Officer | Age | Title |
|---|---|---|
| James Sapirstein | 58 | President, Chief Executive Officer and Director |
| Daniel Schneiderman | 42 | Chief Financial Officer |
| James E. Pennington | 78 | Chief Medical Officer |

Our executive officers are appointed by and serve at the discretion of the Board, subject to the terms of any employment agreements they may have with us. The following is a brief description of the qualifications and business experience of each of our current executive officers.

***James Sapirstein.*** Please see Mr. Sapirstein's biography under the ''Directors'' section of this Annual Report.

***Daniel Schneiderman*** was appointed as our Chief Financial Officer on January 2, 2020. Prior to joining us, from November 2018 through December 2019 Mr. Schneiderman served as Chief Financial Officer of Biophytis SA, (ENXTPA: ALBPS; Nasdaq: BPTS) and its U.S. subsidiary, Biophytis, Inc., a European-based, clinical-stage biotechnology company focused on the development of drug candidates for age-related diseases, with a primary focus on neuromuscular diseases. From February 2012 through August 2018, Mr. Schneiderman served as Vice President of Finance, Controller and Secretary of MetaStat, Inc. (OTCQB: MTST), a publicly traded biotechnology company with a focus on Rx/Dx precision medicine solutions to treat patients with aggressive (metastatic) cancer. From 2008 through February 2012, Mr. Schneiderman was Vice President of Investment Banking at Burnham Hill Partners LLC, a boutique investment bank providing capital raising, advisory and merchant banking services. From 2004 through 2008, Mr. Schneiderman served in various roles and increasing responsibilities, including as Vice President of Investment Banking at Burnham Hill Partners, a division of Pali Capital, Inc. Previously, Mr. Schneiderman worked at H.C. Wainwright & Co., Inc. in 2004 as an investment banking analyst. Mr. Schneiderman holds a bachelor's degree in economics from Tulane University.

***Dr. James E. Pennington*** was appointed as our Chief Medical Officer in May 2018. Prior to joining us, Dr. Pennington served as Senior Clinical Fellow from 2010 to 2018 and as Executive Vice President and Chief Medical Officer from 2007 to 2010 at Anthera Pharmaceuticals, Inc. (Nasdaq: ANTH). From 2004 to 2007, Dr. Pennington served as Executive Vice President and Chief Medical Officer at CoTherix, Inc., and has held various executive positions at a number of pharmaceutical companies, including InterMune Inc., Shaman Pharmaceuticals and Bayer Corporation. He has served on several editorial boards, and has authored numerous original research publications and reviews. Dr. Pennington is currently a Clinical Professor of Medicine with the University of California San Francisco, where he has taught since 1986. Prior to that, he was a professor at Harvard Medical School. Dr. Pennington received a Bachelor of Arts from the University of Oregon and a Doctor of Medicine from the University of Oregon School of Medicine, and is Board Certified in internal medicine and infectious diseases.

### Summary Compensation

The table set forth below reflects certain information regarding the compensation paid or accrued during the years ended December 31, 2020 and 2019 to our Chief Executive Officer and our executive officers, other than our Chief Executive Officer, who were serving as an executive officer as of December 31, 2020, and whose annual compensation exceeded $100,000 during such year (collectively the ''*Named Executive Officers*'').

As previously reported on our Current Report on Form 8-K filed on March 28, 2019, Dr. Dupret retired and resigned from his position as President of AzurRx SAS, a wholly owned French subsidiary of the Company effective July 1, 2019. Due to the resignation of Mr. Spoor as President and Chief Executive Officer effective October 8, 2019, Mr. Sapirstein was appointed as our President and Chief Executive Officer effective that same day. Compensation paid to Dr. Dupret and Mr. Spoor during the year ended December 31, 2019 is reflected in the table below.

**Executive Compensation**

| | Year | Salary | Bonus | Equity Awards | All Other Compensation | Total |
|---|---|---|---|---|---|---|
| **Current Named Executive Officers** | | | | | | |
| James Sapirstein | 2020 | $462,500 | $159,505[2] | $837,840[3] | | $1,459,845 |
| President and Chief Executive Officer | 2019 | 102,404 | — | 232,900[4] | — | 335,304 |
| James Pennington | 2020 | 260,000 | 64,799 | 209,460[3] | — | 534,259 |
| Chief Medical Officer | 2019 | 255,000 | 75,000[2] | 115,000[4] | — | 445,000 |
| Daniel Schneiderman | 2020 | 285,000 | 71,029[2] | 451,352[3] | — | 807,381 |
| Chief Financial officer | 2019 | — | — | —[5] | — | — |
| **Former Named Executive Officers[1]** | | | | | | |
| John M. (Thijs) Spoor | 2020 | — | — | — | — | — |
| Former President, Chief Executive Officer and Director[6] | 2019 | 340,177 | — | 157,500[4] | — | 497,677 |
| Maged Shenouda | 2020 | — | — | — | — | — |
| Former Chief Financial Officer[7] | 2019 | 308,035 | — | 105,000[4] | — | 413,035 |
| Daniel Dupret | 2020 | — | — | — | — | — |
| Former Chief Scientific Officer | 2019 | 151,393 | — | — | — | 151,393 |

(1) Mr. Spoor's employment with us as President and Chief Executive Officer terminated effective October 8, 2019 due to his resignation. In addition, Mr. Spoor resigned as a member of the Board on April 29, 2020.

Mr. Shenouda's employment with us as Chief Financial Officer terminated effective November 30, 2019 due to his resignation.

Dr. Dupret retired and resigned from his position as President of AzurRx SAS, a wholly owned French subsidiary of ours effective July 1, 2019.

(2) Represents accrued and unpaid bonuses during 2020, as of December 31, 2020.

(3) Represents the grant date fair value of restricted stock and stock options issued during the year ended December 31, 2020, calculated in accordance with ASC Topic 718. The assumptions used in the calculation of these amounts are included in Note 13 of the notes to the consolidated financial statements contained in our Annual Report, filed with the SEC on March 30, 2020.

(4) Represents the grant date fair value of restricted stock and stock options issued during the year ended December 31, 2019, calculated in accordance with ASC Topic 718. The assumptions used in the calculation of these amounts are included in Note 13 of the notes to the consolidated financial statements contained in the Company's Annual Report, filed with the SEC on March 30, 2020.

(5) Mr. Schneiderman received no compensation during this period or prior to his appointments as our Chief Financial Officer, which became effective January 2, 2020.

(6) On June 28, 2019, we 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 to Mr. Spoor, which determination is currently being challenged by Mr. Spoor. As a result of the Board's and management's determination, we reversed the accrual in the quarter ended December 31, 2019. This bonus has been excluded from the table.

In addition, all unvested shares of restricted stock and stock options subject to time and other performance-based vesting conditions have been forfeited in connection with Mr. Spoor's resignation as our President and Chief Executive Officer. Mr. Spoor also forfeited the right to receive 241,667 earned, but unissued shares of restricted stock in connection with his resignation from the Board on April 29, 2020.

On July 9, 2020, we and Mr. Spoor entered into a settlement and general release (the ''Spoor Settlement and Release''), effective July 9, 2020 (the ''Spoor Settlement Date''), of certain claims relating to Mr. Spoor's separation from the Company on October 8, 2019. In connection with the Spoor Settlement and Release, on July 14, 2020, we granted Mr. Spoor warrants to purchase an aggregate of 150,000 shares of Common Stock, which had a grant date fair value of $85,770. In addition, Mr. Spoor legally released all claims to a discretionary bonus in the amount of $255,000, which we originally accrued in June 2019 but was subsequently reversed during the quarter ended December 31, 2019, legally released all claims relating to $348,400 due to JIST Consulting, a company controlled by Mr. Spoor and we also paid Mr. Spoor's legal expenses in the amount of $51,200.

(7) On June 28, 2019, we 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 was not owed, and we reversed the accrual in the quarter ended December 31, 2019. This bonus has been excluded from the table.

On July 2, 2020, we and Maged Shenouda, entered into a settlement and general release (the ''Shenouda Settlement and Release''), of certain claims relating to Mr. Shenouda's s separation from the Company effective November 30, 2019. In connection with the Shenouda Settlement and Release, we paid a total of $15,000 to Mr. Shenouda, which amount includes $10,000 of accounts payable of the Company due to Mr. Shenouda for services provided and $5,000 for legal expenses, and Mr. Shenouda legally released all claims relating to a discretionary bonus in the amount of $100,000 we originally accrued in June 2019, but was subsequently reversed during the quarter ended December 31, 2019

**Employment Arrangements and Potential Payments upon Termination or Change of Control**

*Current Named Executive Officers*

***Sapirstein Employment Agreement.*** Effective October 8, 2019, we entered into an employment agreement with Mr. Sapirstein to serve as our 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 originally provided for a base salary of $450,000 per year, which was subsequently increased to $480,000 per year during the year ended December 31, 2020. In addition to the base salary, Mr. Sapirstein is eligible to receive (i) a 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 us 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 of our assets; (iii) a grant of 200,000 restricted shares of our Common Stock which are subject to vest as follows (a) 100,000 upon the first commercial sale of MS1819 in the U.S., and (b) 100,000 upon our total market capitalization exceeding $1.0 billion for 20 consecutive trading days; (iv) a grant of 300,000 10-year stock options to purchase shares of our Common Stock which are subject to vest as follows (a) 50,000 upon us initiating our next Phase 2 clinical trial in the U.S. for MS1819, (b) 50,000 upon us completing our next or subsequent Phase 2 clinical trial in the U.S. for MS1819, (c) 100,000 upon us initiating a Phase 2I clinical trial in the U.S. for MS1819, and (d) 100,000 upon us initiating a Phase 1 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 us.

In the event that Mr. Sapirstein's employment is terminated by us for Cause, as defined in his employment agreement, or by Mr. Sapirstein voluntarily, then 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 the 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.

***Schneiderman Employment Agreement.*** Effective January 2, 2020, we entered into an employment agreement with Mr. Schneiderman to serve as our 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 our Board or the Compensation Committee, (b) grants of stock options to purchase such number of shares equal to one and a quarter percent (1.25%) of the issued and outstanding Common Stock on January 2, 2020, or 335,006 shares of Common Stock with an exercise price of $1.03 per share, which shall vest in over a term of three years. 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 us. We may terminate Mr. Schneiderman's employment agreement at any time, with or without Cause, as such term is defined in his employment agreement. Effective July 16, 2020, our Board approved an amended and restated option grant to Mr. Schneiderman, amending and restating the grant previously made on January 2, 2020, to reduce the amount of shares issuable upon exercise of such option to be the maximum number of shares Mr. Schneiderman was eligible to receive under the Amended and Restated 2014 Omnibus Equity Incentive Plan (the ''2014 Plan'') on the original grant date (or 300,000 shares), due to the 2014 Plan provisions relating to Section 162(m) limitations.

In the event that Mr. Schneiderman's employment is terminated by us for Cause, as defined in Mr. Schneiderman's 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 we terminate his employment agreement without Cause, not in connection with a Change of Control, as such term is defined in Mr. Schneiderman's employment agreement, he 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 six months following the termination date or the remaining term of the employment agreement; (iv) payment of premiums to cover COBRA for a period of six 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 we terminate Mr. Schneiderman's employment agreement without Cause, in connection with a Change of Control, he will be entitled to the above and immediate accelerated vesting of any unvested options or other unvested awards.

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

*Former Named Executive Officers*

***Spoor Employment Agreement.*** On January 3, 2016, we entered into an employment agreement with our 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 expired, he remained employed as our President and Chief Executive Officer under the terms of his prior employment agreement through his resignation as President and Chief Executive Officer on October 8, 2019. In addition, Mr. Spoor resigned as a member of the Board on April 29, 2020.

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's employment agreement was terminable by either party at any time. In the event of termination by us without Cause or by Mr. Spoor for Good Reason not in connection with a Change of Control, as those terms are defined in Mr. Spoor's employment agreement, he was entitled to twelve months' severance payable over such period. In the event of termination by us without Cause or by Mr. Spoor for Good Reason in connection with a Change of Control, as those terms are defined in Mr. Spoor's employment agreement, he was eligible to receive eighteen months' worth of his base salary in a lump sum as severance.

Mr. Spoor resigned from his position as our President and Chief Executive Office effective October 8, 2019. 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. Mr. Spoor had a period of twelve months following his resignation to exercise all vested stock options.

***Shenouda Employment Agreement.*** On September 26, 2017, we entered into an employment agreement with Mr. Shenouda to serve as our Executive Vice-President of Corporate Development and Chief Financial Officer for a term of three years, during which time he received a base salary of $275,000. In addition to the base salary, Mr. Shenouda was eligible to receive an annual milestone cash bonus based on the achievement of certain financial, clinical development, and/or business milestones, which milestones were established annually at the sole discretion of our Board or the Compensation Committee. 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 an exercise price of $4.39 per share and a term of ten years. These stock options vested upon the achievement of certain strategic milestones during the year ended December 31, 2018.

Mr. Shenouda's employment agreement was terminable by us any time, with or without Cause, as such term is defined in the agreement. If we terminated the agreement without Cause, or if the agreement was terminated due to a Change of Control, as such term is defined in the agreement, Mr. Shenouda was 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 12 months following the termination date or the remaining term of his employment agreement; (iv) payment of premiums to cover COBRA for a period of 12 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; and (vi) immediate accelerated vesting of any unvested options or other unvested awards.

Mr. Shenouda resigned from his position as our 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 had a period of twelve months following his resignation to exercise all vested stock options.

### Outstanding Equity Incentive Awards at Fiscal Year-End

The following table sets forth information regarding unexercised options, stock that has not vested and equity incentive awards held by each of the Named Executive Officers outstanding as of December 31, 2020 and 2019:

| Name | Grant Date | Number of Securities underlying unexercised options (#) exercisable | Equity incentive plan awards: Number of underlying unexercised unearned options (#) | Option exercise price ($) | Option expiration date | Number of Shares or units of stock that have not vested (#) | Market value of shares or units of stock that have not vested ($) | Equity incentive plan awards: Number of Unearned shares, units or other rights that have not vested (#) | Equity incentive plan awards: market or payout value of unearned shares, units or other rights that have not vested ($) |
|---|---|---|---|---|---|---|---|---|---|
| **Current Named Executive Officers** | | | | | | | | | |
| James Sapirstein | 10/8/2019 | — | 300,000[1] | $0.56 | 10/7/2029 | — | — | — | $ — |
| | 10/8/2019 | — | — | $ — | — | — | — | 200,000[2] | $112,000 |
| | 7/16/2020 | — | 1,200,000[3] | $0.85 | 7/15/2030 | — | — | | $ — |
| Daniel Schneiderman | 1/2/2020 | — | 300,000[4] | $1.03 | 1/1/2030 | — | — | | $ — |
| | 7/16/2020 | — | 285,006 | $0.85 | 7/15/2030 | — | — | | $ — |
| | 7/16/2020 | | 35,006[4] | $0.85 | 7/15/2030 | | | | |
| James Pennington | 6/13/2019 | — | 110,000 | $1.75 | 6/13/2024 | — | — | — | $ — |
| | 7/16/2020 | — | 300,000 | $0.85 | 7/15/2030 | — | — | — | $ — |

(1) Represents stock options issued to Mr. Sapirstein on October 8, 2019 under the terms of his employment agreement, which options will vest as follows: (i) as to 50,000 shares upon initiating our next U.S. Phase 2 clinical trial for MS1819, (ii) as to 50,000 shares upon completing the next U.S. Phase 2 clinical trial for MS1819, (iii) as to 100,000 shares upon our initiating a Phase 3 clinical trial in the U.S. for MS1819, and (iv) as to 100,000 shares upon initiating a U.S. Phase 1 clinical trial for any product other than MS1819.

(2) Represents the restricted stock unit ("*RSU*") award issued to Mr. Sapirstein on October 8, 2019 under the terms of his employment agreement, which RSU will vest as follows: (i) as to 100,000 shares upon the first commercial sale in the U.S. of MS1819, and (ii) as to 100,000 shares upon our total market capitalization exceeding $1.0 billion for 20 consecutive trading days.

(3) Represents stock options issued to Mr. Sapirstein on July 16, 2020 under 2014 Plan, which options will vest as follows: (i) 50,000 upon initiating its next U.S. Phase 2 clinical trial MS1819, (ii) 50,000 upon completing the next U.S. Phase 2 clinical trial, (iii) 100,000 upon the Company initiating a Phase 3 clinical trial in the U.S. for MS1819, and (iv) 100,000 upon initiating a U.S. Phase 1 clinical trial for any product other than MS1819.

(4) During the three months ended September 30, 2020, the Board approved an amended and restated option grant to Mr. Schneiderman, amending and restating a grant previously made on January 2, 2020, to reduce the amount of shares issuable upon exercise of such option to be the maximum number of shares Mr. Schneiderman was eligible to receive under the 2014 Plan on the original grant date, or 300,000 shares, due to the 2014 Incentive Plan provisions relating to the Section 162(m) limitations described above. The Board also approved the issuance of a replacement option covering the balance of shares intended to be issued at that time, or 35,006 shares. The original stock option has an exercise price of $1.03, the closing sale price of Common Stock on January 2, 2020, which was the date of its original grant, and the replacement stock option has an exercise price of $0.85, the closing sale price of the Common Stock on its date of grant. Both the original stock option and the replacement stock option vest over a term of three years, in 36 equal monthly installments on each monthly anniversary of January 2, 2020.

**Securities Authorized for Issuance Under Equity Compensation Plans**

The following table provides information as of December 31, 2020 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 reflected in column (a)) |
|---|---|---|---|
| | (a) | (b) | (c ) |
| Equity compensation plans approved by security holders[1][2] | 4,298,691 | 1.23 | 9,783,815 |
| Equity compensation plans not approved by security holders | — | — | — |
| **Total** | **4,298,691** | **1.23** | **9,783,815** |

(1) Excludes 387,000 shares of Common Stock reserved under the 2014 Plan as of December 31, 2020, subject to the issuance of restricted stock and RSUs.

(2) Represents outstanding stock options granted to our current or former employees, directors and consultants pursuant to the 2014 Omnibus Equity Incentive Plan (the ''2014 Plan'' and 2020 Omnibus Equity Incentive Plan (the ''2020 Plan'').

***Summary of Amended and Restated 2014 Omnibus Equity Incentive Plan***

The Board and stockholders adopted and approved the 2014 Plan, which took effect on May 12, 2014, and the 2020 Plan, which took effect on September 11, 2020. From the effective date of the 2020 Plan, no new awards have been or will be made under the 2014 Plan.

***Stock Options.*** The 2014 Plan permitted the grant of ''incentive stock options'' (''ISOs''), which are intended to meet the requirements for special federal income tax treatment under the Code, and ''nonqualified stock options'' (''NQSOs'') that do not meet the requirements of Section 422 of the Code. No stock option may be transferred other than by will or by the laws of descent and distribution, and during a recipient's lifetime a stock option may be exercised only by the recipient. However, the Compensation Committee may permit the holder of a stock option, SAR or other award to transfer the stock option, right or other award to immediate family members or a family trust for estate planning purposes. The Compensation Committee will determine the extent to which a holder of a stock option may exercise the option following termination of service with us.

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

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

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

**Potential Limitation on Company Deductions**

Section 162(m) of the Code generally disallows a tax deduction for compensation in excess of $1 million paid in a taxable year by a publicly held corporation to its chief executive officer and certain other ''covered employees.''

Effective for taxable years beginning prior to January 1, 2018, an exception to this deduction limit applied to ''performance-based compensation'' that satisfied certain criteria. Under regulations issued by the Internal Revenue Service under Section 162(m), stock options and stock appreciation rights were treated as performance-based compensation if, among other things, an annual limit was placed on issuing such awards to a single individual. In order to comply with the foregoing exception to the $1 million deduction limit under Section 162(m), the 2014 Plan previously contained an annual limit on issuing awards of stock options and stock appreciation rights to a single individual, which was intended to allow us to deduct such awards granted as performance-based compensation. Pursuant to the Tax Cut and Jobs Act of 2017, however, the exception for performance-based compensation under Section 162(m) of the Code was repealed. As a result, the annual limit in the 2014 Plan was no longer effective to allow us to claim this deduction. Accordingly, effective July 16, 2020, our Board approved an amendment to the 2014 Plan that removed this annual limit.

***Summary of the 2020 Omnibus Equity Incentive Plan***

The Board and stockholders have adopted and approved the 2020 Plan, which is a comprehensive incentive compensation plan under which we can grant equity-based and other incentive awards to our officers, employees, directors, consultants and advisers. The purpose of the 2020 Plan is to help us attract, motivate and retain such persons with awards under the 2020 Plan and thereby enhance stockholder value.

***Administration.*** The 2020 Plan is administered by the Compensation Committee of the Board, which consists of three members of the Board, each of whom is a ''non-employee director'' within the meaning of Rule 16b-3 promulgated under the Securities Exchange Act of 1934, as amended (the ''*Exchange Act*''). The Compensation Committee may grant stock options, stock appreciation rights (''SARs''), performance stock awards, performance unit awards, dividend equivalent right awards, restricted stock awards, restricted stock unit awards, unrestricted stock awards, incentive bonus awards and other cash-based awards and other stock-based awards to our non- employee directors, officers, employees and nonemployee consultants or our affiliates. Among other things, the Compensation Committee has complete discretion, subject to the express limits of the 2020 Plan, to determine the directors, employees and individual consultants to be granted an award, the type of award to be granted, the terms and conditions of the award, the form of payment to be made and/or the number of shares of Common Stock subject to each award, the exercise price of each option and base price of each SAR, the term of each award, the vesting schedule for an award, whether to accelerate vesting, the value of the Common Stock underlying the award, and the required withholding, if any. Except as prohibited by applicable law or stock exchange rules, the Compensation Committee may delegate administrative functions under the 2020 Plan and may authorize a Reporting Person (as defined in the Exchange Act) to make certain awards under the 2020 Plan. Subject to the terms of the Plan, the Compensation Committee shall have the authority to amend the terms of an award in any manner that is not inconsistent with the Plan (including to extend the post-termination exercisability period of options and SARs), provided that no such action (except an action relating to a change of control) shall materially and adversely impair the rights of an award recipient with respect to such an outstanding award without the consent of the award recipient. The Compensation Committee is also authorized to construe the award agreements, and may prescribe rules relating to the 2020 Plan.

***Eligibility.*** Employees, directors and individual consultants of the Company or an affiliate as well as prospective employees, directors and individual consultants of the Company or an affiliate are eligible to participate in the 2020 Plan. The 2020 Plan allows for grants to employees, directors and individual consultants of the Company or an affiliate who are non-US persons. Currently, we have nine employees (including one executive director), five non-executive directors and approximately ten non-employee consultants.

***Shares Subject to the 2020 Plan.*** The maximum aggregate number of shares of Common Stock that may be issued under the 2020 Plan shall be 10,000,000 shares. The 2020 Plan allows for 100,000,000 shares to be issued as ''incentive stock options'' (''*ISOs*''). In addition, the 2020 Plan contains an ''evergreen provision'' providing for an annual increase in the number of shares of our Common Stock available for issuance under the 2020 Plan on January 1 of each year for a period of ten years, commencing on January 1, 2021 and ending on (and including) January 1, 2030, in an amount equal to the lesser of (i) ten percent of the total number of shares of Common Stock outstanding on December 31st of the preceding calendar year or (ii) such number of shares determined by the Board.

If any award expires, is cancelled, or terminates unexercised or is forfeited, the number of shares subject thereto is again available for grant under the 2020 Plan. The maximum number of shares of Common Stock that may be subject to awards to outside directors, in the aggregate, during any calendar year is 250,000.

The number of shares authorized for issuance under the 2020 Plan and each of the preceding share limitations are subject to customary adjustments for stock splits, stock dividends, recapitalization, reorganization, merger, combination, exchange or similar transactions.

***Stock Options.*** The 2020 Plan provides for either ISOs, which are intended to meet the requirements for special federal income tax treatment under the Code, or ''nonqualified stock options'' (''*NQSOs*'') that do not meet the requirements of Section 422 of the Code. Stock options may be granted on such terms and conditions as the Compensation Committee may determine; *provided, however*, that the per share exercise price under a stock option may not be less than the fair market value of a share of Common Stock on the date of grant and the term of the stock option may not exceed 10 years (110% of such value and five years in the case of an ISO granted to an employee who owns (or is deemed to own) more than 10% of the total combined voting power of all classes of our capital stock or our parent or subsidiary). ISOs may only be granted to employees. In addition, the aggregate fair market value of Common Stock covered by one or more ISOs (determined at the time of grant), which are exercisable for the first time by an employee during any calendar year may not exceed $100,000. Any excess is treated as a NQSO. Stock options granted under the 2020 Plan will be exercisable at such time or times as the Compensation Committee prescribes at the time of grant and recipients will be permitted to pay the exercise price as set forth by the Compensation Committee in the applicable option agreement. No stock option may be transferred other than by will or by the laws of descent and distribution, and during a recipient's lifetime a stock option may be exercised only by the recipient. However, the Compensation Committee may permit the holder of a stock option, SAR or other award to transfer the stock option, right or other award to immediate family members or a family trust for estate planning purposes. The Compensation Committee will determine the extent to which a holder of a stock option may exercise the option following termination of service with us.

***Stock Appreciation Rights.*** A SAR entitles the participant, upon exercise, to receive an amount, in cash or stock or a combination thereof, equal to the increase in the fair market value of the underlying Common Stock between the date of grant and the date of exercise. SARs may be granted in tandem with, or independently of, stock options granted under the 2020 Plan. A SAR granted in tandem with a stock option (i) is exercisable only at such times, and to the extent, that the related stock option is exercisable in accordance with the procedure for exercise of the related stock option; (ii) terminates upon termination or exercise of the related stock option (likewise, the Common Stock option granted in tandem with a SAR terminates upon exercise of the SAR); (iii) is transferable only with the related stock option; and (iv) if the related stock option is an ISO, may be exercised only when the value of the stock subject to the stock option exceeds the exercise price of the stock option. A SAR that is not granted in tandem with a stock option is exercisable at such times as the Compensation Committee may specify. The Compensation Committee will determine the other terms applicable to SARs. The exercise price per share of a SAR will be determined by the Compensation Committee, but will not be less than 100% of the fair market value of a share of our Common Stock on the date of grant, as determined by the Compensation Committee. The maximum term of any SAR granted under the 2020 Plan is ten years from the date of grant. Generally, each SAR will entitle a participant upon exercise to an amount equal to: (i) the excess of the fair market value on the exercise date of one share of our Common Stock over the exercise price, *multiplied by* (ii) the number of shares of Common Stock covered by the SAR. Payment may be made in shares of our Common Stock, in cash, or partly in Common Stock and partly in cash, all as determined by the Compensation Committee.

***Performance Shares and Performance Unit Awards.*** Performance share and performance unit awards entitle the participant to receive cash or shares of Common Stock upon the attainment of specified performance goals. In the case of performance units, the right to acquire the units is denominated in cash values. The Compensation Committee will determine the restrictions and conditions applicable to each award of performance shares and performance units.

***Dividend Equivalent Right Awards.*** A dividend equivalent right award entitles the participant to receive bookkeeping credits, cash payments and/or Common Stock distributions equal in amount to the distributions that would have been made to the participant had the participant held a specified number of shares of Common Stock during the period the participant held the dividend equivalent right. A dividend equivalent right may be awarded as a component of another award under the 2020 Plan, where, if so awarded, such dividend equivalent right will expire or be forfeited by the participant under the same conditions as under such other award.

***Restricted Stock Awards and Restricted Stock Unit Awards.*** A restricted stock award is a grant or sale of Common Stock to the participant, subject to our right to repurchase all or part of the shares at their purchase price (or to require forfeiture of such shares if issued to the participant at no cost) in the event that conditions specified by the Compensation Committee in the award are not satisfied prior to the end of the time period during which the shares

subject to the award may be repurchased by or forfeited to us. Restricted stock units entitle the participant to receive a cash payment equal to the fair market value of a share of Common Stock for each restricted stock unit subject to such restricted stock unit award, if the participant satisfies the applicable vesting requirement. The Compensation Committee will determine the restrictions and conditions applicable to each award of restricted stock award or restricted stock unit award, which may include performance-based conditions.

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

***Other Cash-Based Awards and Other Stock-Based Awards.*** The Compensation Committee may award other types of cash-based or equity-based awards under the 2020 Plan, including the grant or offer for sale of shares of unrestricted shares and the right to receive one or more cash payments subject to satisfaction of such conditions as the Compensation Committee may impose.

***Incentive Bonus Awards.*** Incentive bonus awards may be awarded to the participant based upon the attainment of specified levels of our performance as measured by pre-established, objective performance criteria determined at the discretion of the Compensation Committee.

***Change-of-Control Provisions.*** The Compensation Committee may, at the time of the grant of an award, provide for the effect of a change of control (as defined in the 2020 Plan) on an award, including (i) accelerating or extending the time periods for exercising, vesting in, or realizing gain from any award, (ii) eliminating or modifying the performance or other conditions of an award, or (iii) providing for the cash settlement of an award for an equivalent cash value, as determined by the Compensation Committee. The Compensation Committee may, in its discretion and without the need for the consent of any recipient of an award, also take one or more of the following actions contingent upon the occurrence of a change of control: (a) cause any or all outstanding stock options and SARs to become immediately exercisable, in whole or in part; (b) cause any other awards to become non-forfeitable, in whole or in part; (c) cancel any stock option or SAR in exchange for a substitute option; (d) cancel any award of restricted stock, restricted stock units, performance shares or performance units in exchange for a similar award of the capital stock of any successor corporation; (e) redeem any restricted stock, restricted stock unit, performance share or performance unit for cash and/or other substitute consideration with a value equal to the fair market value of an unrestricted share of our Common Stock on the date of the change of control; (f) cancel any stock option or SAR in exchange for cash and/or other substitute consideration based on the value of our Common Stock on the date of the change in control, and cancel any stock option or SAR without any payment if its exercise price exceeds the value of our Common Stock on the date of the change of control; or (g) make such other modifications, adjustments or amendments to outstanding awards as the Compensation Committee deems necessary or appropriate.

***Amendment and Termination.*** The Compensation Committee may adopt, amend and rescind rules relating to the administration of the 2020 Plan, and amend, suspend or terminate the 2020 Plan, provided, that (a) to the extent necessary and desirable to comply with any applicable law, regulation, or stock exchange rule, we shall obtain stockholder approval of any 2020 Plan amendment in such a manner and to such a degree as required, and (b) stockholder approval is required for any amendment to the 2020 Plan that (i) increases the number of shares available for issuance under the 2020 Plan, or (ii) changes the persons or class of persons eligible to receive awards.

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

The following table sets forth information regarding shares of our Common Stock beneficially owned as of March 29, 2021 by:

- each of our officers and directors;
- all officers and directors as a group; and
- each person known by us to beneficially own five percent or more of the outstanding shares of our Common Stock. Percentage of ownership is calculated based on 74,439,377 shares of Common Stock outstanding as of March 30, 2021.

| Name and Address of Beneficial Owner[1] | Number of Shares[2] | Percent Ownership of Class[3] |
|---|---|---|
| *Current Named Executive Officers and Directors* | | |
| James Sapirstein, President and Chief Executive Officer[4] | 341,883 | * |
| Daniel Schneiderman, Chief Financial Officer[5] | 150,862 | * |
| James E. Pennington, Chief Scientific Officer[6] | 120,833 | * |
| Edward J. Borkowski, Chair of the Board of Directors[7] | 1,380,274 | 1.9% |
| Charles J. Casamento, Director[8] | 226,998 | * |
| Alastair Riddell, Director[9] | 272,049 | * |
| Vern L. Schranmm, Director[10] | 200,498 | * |
| Gregory Oakes, Director[11] | 60,000 | * |
| All directors and executive officer as a group (8 persons) | **2,753,397** | **3.7%** |

(1) Unless otherwise indicated, the address of such individual is c/o AzurRx BioPharma, Inc., 1615 South Congress Avenue, Suite 103, Delray Beach, FL 33445.

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

(3) Percentages are rounded to nearest tenth of a percent. Percentages are based on 74,439,377 shares of Common Stock outstanding. Warrants, options or other derivative securities that are presently exercisable or exercisable within 60 days are deemed to be beneficially owned by the person holding such securities for the purpose of computing the percentage ownership of that person, but are not treated as outstanding for the purpose of computing the percentage of any other person.

(4) Includes (i) 141,667 shares of Common Stock issuable upon exercise of vested options, (ii) 135,281 shares of Common Stock issuable upon conversion of approximately 13.53 shares of Series B Preferred Stock, which includes issued PIK dividends through December 31, 2020, and (iii) 64,935 shares of Common Stock issuable upon exercise of warrants. Excludes (i) 1,358,333 shares of Common Stock issuable upon exercise of unvested options, and (ii) 200,000 shares of Common Stock issuable upon unvested Restricted Stock Units (RSUs). Pursuant to the Exchange Right, Mr. Sapirstein has the right to exchange the stated value, plus accrued and unpaid dividends, of the shares of Series B Preferred Stock beneficially owned by him for shares of Series C Preferred Stock and Investor Warrants on a dollar-for-dollar basis.

(5) Includes (i) 1,000 shares of Common Stock and (ii) 149,862 shares of Common Stock issuable upon exercise of vested options. Excludes 435,144 shares of Common Stock issuable upon exercise of unvested options.

(6) Includes 120,833 shares of Common Stock issuable upon exercise of vested options. Excludes 364,167 shares of Common Stock issuable upon exercise of unvested options.

(7) Includes (i) 409,773 shares of Common Stock; (ii) 336,397 shares of Common Stock issuable upon the exercise of warrants; (iii) 140,000 shares of Common Stock issuable upon exercise of vested options; (iv) 480,423 shares of Common Stock issuable upon conversion of approximately 48.043 shares of Series B Preferred Stock, which includes issued PIK dividends through December 31, 2020, and (v) 13,680 shares of Common Stock held by Mr. Borkowski's spouse. Excludes (i) 45,000 unvested and unissued restricted shares of Common Stock; and (ii) 41,237 shares of Common Stock issuable upon exercise of unvested options. Pursuant to the Exchange Right, Mr. Borkowski has the right to exchange the stated value, plus accrued and unpaid dividends, of the shares of Series B Preferred Stock beneficially owned by him for shares of Series C Preferred Stock and Investor Warrants on a dollar-for- dollar basis.

(8) Includes (i) 107,998 shares of Common Stock; (ii) 110,000 shares of Common Stock issuable upon exercise of vested options; and (iii) 9,000 shares of Common Stock held by La Jolla Lenox Trust, a family trust of which the Trustee is someone other than Mr. Casamento. Mr. Casamento and members of his immediate family are the sole beneficiaries of the trust. Excludes 75,000 shares of Common Stock issuable upon exercise of unvested options. Excludes 41,237 shares of Common Stock issuable upon exercise of unvested options.

(9) Includes (i) 132,049 shares of Common Stock and (ii) 140,000 shares of Common Stock issuable upon exercise of vested options. Excludes (i) 30,000 unvested restricted shares of Common Stock; and (ii) 41,237 shares of Common Stock issuable upon exercise of unvested options.

(10) Includes (i) 90,498 shares of Common Stock and (ii) 110,000 shares of Common Stock issuable upon exercise of vested options. Excludes 41,237 shares of Common Stock issuable upon exercise of unvested options.

(11) Includes 60,000 shares of Common Stock issuable upon exercise of vested options. Excludes 41,237 shares of Common Stock issuable upon exercise of unvested options.

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

***Johan (Thijs) Spoor***

During the year ended December 31, 2015, we employed the services of JIST Consulting (''*JIST*''), a company controlled by Johan (Thijs) Spoor, our former Chief Executive Officer and President, as a consultant for business strategy, financial modeling, and fundraising. Included in accounts payable at December 31, 2020 and 2019, is $0 and approximately $348,000, respectively, for JIST relating to Mr. Spoor's services. The approximately $348,000 included in the accounts payable at December 31, 2019 has since been waived by Mr. Spoor, pursuant to a settlement and general release, effective July 9, 2020. Mr. Spoor received no other compensation from us other than as specified in his employment agreement. On October 8, 2019, Mr. Spoor resigned as our Chief Executive Officer and President, and on April 29, 2020, Mr. Spoor resigned as a member of the Board.

In June 2019, we 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, we reversed the accrual in the quarter ended December 31, 2019. As part of a settlement and general release effective July 9, 2020, Mr. Spoor waived all claims to the incentive bonus in the amount of

$255,000 and also waived all claims to the amount of approximately $348,000 due to JIST Consulting, a company controlled by Mr. Spoor. Also in connection with the settlement and general release, Mr. Spoor received warrants to purchase an aggregate of 150,000 shares of Common Stock and we agreed to pay Mr. Spoor's legal expenses in the amount of approximately $51,000.

As of December 31, 2019, Mr. Spoor was entitled to an aggregate of 241,667 shares of restricted Common Stock with an aggregate grant date fair value of approximately $856,000 that have vested but not been issued. Mr. Spoor forfeited the right to receive these shares on April 29, 2020 in connection with his resignation from the Board.

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.

***Maged Shenouda***

From October 1, 2016 until his appointment as our Chief Financial Officer on September 25, 2017, we employed the services of Maged Shenouda as a financial consultant. Included in accounts payable at December 31, 2020 and 2019 is $0 and $10,000, respectively, for Mr. Shenouda's services. On November 1, 2019, Mr. Shenouda submitted his resignation as our Chief Financial Officer, effective November 30, 2019.

In June 2019, we 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 was not owed, and we reversed the accrual in the quarter ended December 31, 2019. As part of a settlement and general release entered into on July 2, 2020, Mr. Shenouda waived all claims to the incentive bonus in the amount of $100,000 and we agreed to pay Mr. Shenouda a settlement sum of $15,000, which includes $10,000 due to Mr. Shenouda reflected in our accounts payable as of June 30, 2020.

Mr. Shenouda resigned from his position as our 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.

***Promissory Notes, Series B Private Placement and Series B Exchange***

On December 20, 2019, Edward J. Borkowski, a Director, purchased a Promissory Note (the ''*Borkowski Promissory Note*'') for an original principal amount of $100,000, together with related warrants exercisable for 51,547 shares of Common Stock at an exercise price of $1.07, pursuant to a Note Purchase Agreement by and between us and certain accredited investors. The Borkowski Promissory Note accrued interest at a rate of 9% per annum and was convertible at the option of the holder into shares of Common Stock at a price of $0.97 per share. On July 16, 2020, in connection with the Series B Private Placement and the Series B Exchange, Mr. Borkowski purchased $250,000 worth of Series B Preferred Stock and related Series B Warrants for cash, and Mr. Borkowski also exchanged the balance of his outstanding Borkowski Promissory Note of $105,128 (including outstanding principal amount and accrued and

unpaid interest thereon) for approximately 13.65 shares of Series B Preferred Stock convertible into 136,531 shares of Common Stock, Series B Warrants for 68,266 shares of Common Stock and Exchange Warrants for 25,774 shares of Common Stock.

On January 3, 2020, Edmund Burke Ross, Jr., a stockholder that beneficially owned greater than 5% of our outstanding shares, purchased a Promissory Note for an original amount of $750,000, together with related warrants exercisable for 375,000 shares of Common Stock at an exercise price of $1.07, pursuant to a Note Purchase Agreement by and between us and certain accredited investors. The Promissory Note accrued interest at a rate of 9% per annum and was convertible at the option of the holder into shares of Common Stock at a price of $0.97 per share. On July 16, 2020, in connection with the Private Placement and the Exchange, Mr. Ross exchanged the balance of his outstanding Promissory Note of approximately $786,000 (including outstanding principal amount and accrued and unpaid interest thereon) for 102.06191 shares of Series B Preferred Stock convertible into 1,020,620 shares of Common Stock, Series B Warrants for 510,310 shares of Common Stock and Exchange Warrants for 193,299 shares of Common Stock.

On July 16, 2020, in connection with the Series B Private Placement and the Exchange, James Sapirstein, President, Chief Executive Officer and Director purchased $100,000 worth of Series B Preferred Stock and related Series B Warrants for cash. Mr. Sapirstein received approximately 12.99 shares of Series B Preferred Stock convertible into 129,871 shares of Common Stock and Series B Warrants for 64,936 shares of Common Stock.

**Policy and Procedures Governing Related Party Transactions**

The Board is committed to upholding the highest legal and ethical conduct in fulfilling its responsibilities and recognizes that related party transactions can present a heightened risk of potential or actual conflicts of interest.

The SEC rules define a related party transaction to include any transaction, arrangement or relationship which: (i) we are a participant; (ii) the amount involved exceeds $120,000; and (iii) executive officer, director or director nominee, or any person who is known to be the beneficial owner of more than 5% of our Common Stock, or any person who is an immediate family member of an executive officer, director or director nominee or beneficial owner of more than 5% of our Common Stock had or will have a direct or indirect material interest.

Although we do not maintain a formal written procedure for the review and approval of transactions with such related persons, it is our policy for the disinterested members of our Board to review all related party transactions on a case-by-case basis. To receive approval, a related-party transaction must have a legitimate business purpose for us and be on terms that are fair and reasonable to us and our stockholders and as favorable to us and our stockholders as would be available from non-related entities in comparable transactions.

All related party transactions must be disclosed in our applicable filings with the SEC as required under SEC rules.

## ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Set forth below are fees billed or expected to be billed to us by our independent registered public accounting firm Mazars USA LLP for the years ended December 31, 2020 and 2019 for the professional services performed for us.

### Audit Fees

The following table presents fees for professional services billed by Mazars USA LLP for the fiscal years ended December 31, 2020 and 2019.

| | For the years ended December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Audit fees[1] | $165,766 | $124,640 |
| Audit-related fees[2] | 34,700 | 71,500 |
| Tax fees[3] | 27,055 | 31,087 |
| All other fees[4] | — | — |
| Total | $227,521 | $227,227 |

(1) Professional services rendered by the Mazars USA LLP for the audit of our annual financial statements and review of financial statements included in our Form 10-Q's.

(2) The aggregate fees billed for assurance and related services by Mazars USA LLP that are reasonably related to the performance of the audit or review of our financial statements and are not reported under Note 1 above, principally related to registration statement filings.

(3) The aggregate fees billed for professional services rendered by Mazars USA LLP for tax compliance, tax advice, and tax planning.

(4) The aggregate fees billed for products and services provided by Mazars USA LLP other than the services reported in Notes 1 through 3 above.

### Audit Committee Pre-Approval Policies and Procedures

The Audit Committee has the sole authority for the appointment, compensation and oversight of the work of our independent auditors. The Audit Committee has established a policy regarding pre-approval of all auditing services and the terms thereof and non-audit services (other than non-audit services prohibited under Section 10A(g) of the Exchange Act or the applicable rules of the SEC or the Public Company Accounting Oversight Board) to be provided to us by the independent auditor. However, the pre-approval requirement may be waived with respect to the provision of non-audit services for us if the ''de minimus'' provisions of Section 10A(i)(1)(B) of the Exchange Act are satisfied.

The Audit Committee has considered whether the provision of audit-related fees, tax fees, and all other fees as described above is compatible with maintaining Mazars USA LLP's independence and has determined that such services for fiscal year 2020 were compatible. All such services were approved by the Audit Committee pursuant to Rule 2-01 of Regulation S-X under the Exchange Act to the extent that rule was applicable.

The Audit Committee is responsible for reviewing and discussing the audited financial statements with management, discussing with the independent registered public accountants the matters required in Auditing Standards No. 16, receiving written disclosures from the independent registered public accountants required by the applicable requirements of the Public Company Accounting Oversight Board regarding the independent registered public accountants' communications with the Audit Committee concerning independence and discussing with the independent registered public accountants their independence, and recommending to our board of directors that the audited financial statements be included in our annual report on Form 10-K.

## PART IV

### ITEM 15. EXHIBITS

| Exhibit No. | Description |
|---|---|
| 3.1 | Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 of the Company's Registration Statement on Form S-1, filed July 13, 2016). |
| 3.2 | Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 of the Company's Registration Statement on Form S-1, filed with the SEC July 13, 2016). |
| 3.3 | Certificate of Amendment to Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K, filed with the SEC December 30, 2019). |
| 3.4 | Certificate of the Designations, Powers, Preferences and Rights of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the SEC on July 20, 2020.) |
| 3.5 | Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the SEC on August 5, 2020.) |
| 3.6 | Certificate of the Designations, Powers, Preferences and Rights of Series C 9.00% Convertible Junior Preferred Stock (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the SEC on January 8, 2021). |
| 3.7 | Certificate of Amendment to the Certificate of Incorporation of the Registrant (incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on February 25, 2021). |
| 4.1 | Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 of the Company's Registration Statement on Form S-1, filed with the SEC on July 29, 2016). |
| 4.2 | Form of Investor Warrant (incorporated by reference to Exhibit 4.2 of the Company's Registration Statement on Form S-1 filed with the SEC on July 13, 2016). |
| 4.3 | Form of Underwriter Warrant (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1, filed with the SEC on July 29, 2016). |
| 4.4 | Form of Series A Warrant, dated April 11, 2017 between the Company and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.3 filed with the Company's Current Report on Form 8-K filed with the SEC on April 12, 2017). |
| 4.5 | Form of Series A Warrant, dated June 5, 2017 (incorporated by reference to Exhibit 10.3 filed with the Company's Current Report on Form 8-K filed with the SEC on June 9, 2017). |
| 4.6 | Form of Series A-1 Warrant, dated June 5, 2017 (incorporated by reference to Exhibit 10.4 filed with the Company's Current Report on Form 8-K filed with the SEC on June 9, 2017). |
| 4.7 | Form of Underwriter Warrant (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on May 4, 2018). |
| 4.8 | Form of Selling Agent Warrant (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on April 3, 2019). |
| 4.9 | Form of Selling Agent Warrant (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on May 14, 2019). |
| 4.10 | Form of Wainwright Warrant (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on July 22, 2019). |
| 4.11 | Form of Warrant (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on July 20, 2020). |
| 4.12 | Form of Warrant for Convertible Notes Offering (incorporated by reference to Exhibit 4.2 of the Company's Registration Statement on Form S-3 filed with the SEC on July 27, 2020). |
| 4.13 | Form of Pre-funded Warrant (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on January 4, 2021). |
| 4.14 | Form of Private Placement Warrant (incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K filed with the SEC on January 4, 2021). |
| 4.15 | Form of Wainwright Warrant (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on January 8, 2021). |

| Exhibit No. | Description |
|---|---|
| 4.16 | Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on March 10, 2021). |
| 4.17 | Form of Warrant (incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K filed with the SEC on March 10, 2021). |
| 4.18 | Form of Wainwright Warrant (incorporated by reference to Exhibit 4.3 of the Company's Current Report on Form 8-K filed with the SEC on March 10, 2021). |
| 4.19* | Description of Capital Stock. |
| 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 to Exhibit 10.1 of the Company's Registration Statement on Form S-1 filed with the SEC on July 13, 2016). |
| 10.2† | Amended and Restated AzurRx BioPharma, Inc. 2014 Omnibus Equity Incentive Plan (incorporated by reference to Exhibit 10.3 of the Company's Registration Statement on Form S-1 filed with the SEC on July 13, 2016). |
| 10.3 | Securities Purchase Agreement dated April 11, 2017 between the Registrant and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on April 12, 2017). |
| 10.4 | Registration Rights Agreement dated April 11, 2017 between the Registrant and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.4 of the Company's Current Report on Form 8-K filed with the SEC on April 12, 2017). |
| 10.5 | Form of Securities Purchase Agreement dated June 5, 2017 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on June 9, 2017). |
| 10.6 | Form of Registration Rights Agreement dated June 5, 2017 (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on April 12, 2017). |
| 10.7 | Sublicense Agreement dated August 7, 2017 by and between the Registrant and TransChem, Inc. (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on August 11, 2017). |
| 10.8 | 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 to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on December 13, 2018). |
| 10.9 | Registration Rights Agreement, dated February 14, 2019 (incorporated by reference to Exhibit 10.6 of the Company's Current Report on Form 8-K filed with the SEC on February 20, 2019). |
| 10.10 | Asset Purchase Agreement, by and between AzurRx BioPharma, Inc., AzurRx BioPharma SAS and Laboratoires Mayoly Spindler SAS, dated March 27, 2019 (incorporated by reference to Exhibit 10.25 of the Company's Annual Report on Form 10-K filed with the SEC on April 1, 2019). |
| 10.11 | Patent License Agreement, by and between AzurRx BioPharma, Inc. and Laboratoires Mayoly Spindler SAS, dated March 27, 2019 (incorporated by reference to Exhibit 10.26 of the Company's Annual Report on Form 10-K filed with the SEC on April 1, 2019). |
| 10.12† | Employment Agreement by and between AzurRx BioPharma, Inc. and James Sapirstein, dated October 8, 2019 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on October 11, 2019). |
| 10.13 | Securities Purchase Agreement, dated November 13, 2019 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on November 14, 2019). |
| 10.14 | Registration Rights Agreement, dated November 13, 2019 (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on November 14, 2019). |
| 10.15 | Form of Note Purchase Agreement (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on December 30, 2019). |

| Exhibit No. | Description |
|---|---|
| 10.16 | Form of Warrant (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed with the SEC on December 30, 2019). |
| 10.17 | Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.4 of the Company's Current Report on Form 8-K filed with the SEC on December 30, 2019). |
| 10.18† | Employment Agreement by and between AzurRx BioPharma, Inc. and Daniel Schneiderman, dated January 1, 2020 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on January 6, 2020). |
| 10.19 | Form of Purchase Agreement, by and among the Company and the investors set forth on the signature pages thereto, including the form of Exchange Addendum (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on July 20, 2020). |
| 10.20 | Form of Registration Rights Agreement, by and among the Company and the investors set forth on the signature page thereto (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on July 20, 2020). |
| 10.21† | First Amendment to 2014 Omnibus Equity Incentive Plan (incorporated by reference as Exhibit 10.3 of the Company's Current Report on Form 8-K filed with the SEC on July 20, 2020). |
| 10.22† | 2020 Omnibus Equity Incentive Plan (incorporated by reference to Exhibit 10.4 of the Company's Quarterly Report on Form 10-Q filed with the SEC on November 16, 2020). |
| 10.23 | Form of Purchase Agreement (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on January 4, 2021). |
| 10.24 | Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on January 4, 2021). |
| 10.25 | First Wave Purchase Agreement (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8- K filed with the SEC on January 8, 2021). |
| 10.26# | First Wave License Agreement (incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed with the SEC on January 13, 2021). |
| 10.27 | Form of Purchase Agreement (incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed with the SEC on March 10, 2021). |
| 21.1 | Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 filed with the Company's Registration Statement on Form S-1 filed with the SEC on July 13, 2016). |
| 23.1* | Consent of Mazars USA LLP. |
| 31.1* | Certification of CEO as Required by Rule 13a-14(a) or Rule 15d-14(a). |
| 31.2* | Certification of CFO as Required by Rule 13a-14(a) or Rule 15d-14(a). |
| 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. |
| 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 |

* Filed herewith.

\# Certain portions of this exhibit (indicated by "[*****]") have been omitted as we have determined (1) it is not material and (2) is the type that the Company treats as private or confidential.

† Indicates a management contract or compensation plan, contract or arrangement.

## ITEM 16: FORM 10-K SUMMARY

None.

## SIGNATURES

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

**AZURRX BIOPHARMA, INC.**

March 31, 2021

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<br>James Sapirstein | President, Chief Executive Officer and Chair of the Board of Directors (principal executive officer) | March 31, 2021 |
| /s/ Daniel Schneiderman<br>Daniel Schneiderman | Chief Financial Officer (principal financial officer and accounting officer) | March 31, 2021 |
| /s/ Edward J. Borkowski<br>Edward J. Borkowski | Director | March 31, 2021 |
| /s/ Charles J. Casamento<br>Charles J. Casamento | Director | March 31, 2021 |
| /s/ Alastair Riddell<br>Alastair Riddell | Director | March 31, 2021 |
| /s/ Vern L. Schramm<br>Vern L. Schramm | Director | March 31, 2021 |
| /s/ Gregory Oakes<br>Gregory Oakes | Director | March 31, 2021 |

**AzurRx BioPharma, Inc.**
**Index to Consolidated Financial Statements**

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

### Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of AzurRx BioPharma, Inc. (the ''Company'') as of December 31, 2020 and 2019, 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, 2020 and 2019, 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 $95.4 million at December 31, 2020. 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 31, 2021

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

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| **ASSETS** | | |
| Current Assets: | | |
| Cash and cash equivalents | $ 6,062,141 | $ 175,796 |
| Other receivables | 551,489 | 2,637,303 |
| Prepaid expenses | 1,256,154 | 595,187 |
| Total Current Assets | 7,869,784 | 3,408,286 |
| Property, equipment, and leasehold improvements, net | 18,329 | 77,391 |
| Other Assets: | | |
| Patents, net | 2,879,536 | 3,407,084 |
| Goodwill | 2,054,048 | 1,886,686 |
| Operating lease right-of-use assets | 74,238 | 82,386 |
| Deposits | 27,920 | 41,047 |
| Total Other Assets | 5,035,742 | 5,417,203 |
| Total Assets | $ 12,923,855 | $ 8,902,880 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current Liabilities: | | |
| Accounts payable and accrued expenses | $ 1,685,603 | $ 1,754,682 |
| Accounts payable and accrued expenses - related party | — | 533,428 |
| Payables related to license agreement | 13,250,000 | — |
| Note payable | 552,405 | 444,364 |
| Convertible debt | — | 1,076,938 |
| Other current liabilities | 57,417 | 476,224 |
| Total Current Liabilities | 15,545,425 | 4,285,636 |
| Other liabilities | 19,123 | — |
| Total Liabilities | 15,564,548 | 4,285,636 |
| Stockholders' Equity: | | |
| Common stock - Par value $0.0001 per share; 150,000,000 shares authorized; 31,150,309 and 26,800,519 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively | 3,115 | 2,680 |
| Series B preferred stock- Par value $0.0001 per share; 5,194.81 shares authorized; 2,773.62 and 0 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively | — | — |
| Additional paid-in capital | 93,834,936 | 68,575,851 |
| Accumulated deficit | (95,366,198) | (62,694,732) |
| Accumulated other comprehensive loss | (1,112,546) | (1,266,555) |
| Total Stockholders' Equity | (2,640,693) | 4,617,244 |
| Total Liabilities and Stockholders' Equity | $ 12,923,855 | $ 8,902,880 |

The accompanying notes are an integral part of these Consolidated Financial Statements.

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

| | For the Years Ended December 31, | |
|---|---|---|
| | **2020** | **2019** |
| Operating expenses: | | |
| Research and development expenses | $ 5,888,004 | $ 8,680,669 |
| Research and development expenses - license acquired | 13,250,000 | — |
| General and administrative expenses | 7,294,764 | 6,063,078 |
| Total operating expenses | 26,432,768 | 14,743,747 |
| Loss from operations | (26,432,768) | (14,743,747) |
| Other income (expenses): | | |
| Interest expense | (5,840,614) | (433,939) |
| Interest income | 484 | — |
| Gain on settlement | 211,430 | — |
| Loss on debt extinguishment | (609,998) | — |
| Total other income (expenses) | (6,238,698) | (433,939) |
| Loss before income taxes | (32,671,466) | (15,177,686) |
| Income taxes | — | — |
| **Net loss** | **$(32,671,466)** | **$(15,177,686)** |
| Other comprehensive loss: | | |
| Foreign currency translation adjustment | (154,009) | (116,443) |
| Total comprehensive loss | $(32,825,475) | $(15,294,129) |
| Net loss | $(32,671,466) | $(15,177,686) |
| Deemed dividend of preferred stock | (8,155,212) | — |
| Series B preferred stock dividends | (905,660) | — |
| Net loss applicable to common stockholders | (41,732,338) | (15,177,686) |
| Basic and diluted weighted average shares outstanding | 28,436,292 | 22,425,564 |
| Net loss per share - basic and diluted | $ (1.15) | $ (0.68) |

The accompanying notes are an integral part of these Consolidated Financial Statements.

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

| | Series B Preferred Stock | | Common Stock | | Additional Paid In Capital | Accumulated Deficit | Accumulated Other Comprehensive Loss | Total |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | | | | |
| **Balance, January 1, 2019** | **—** | **$—** | **17,704,925** | **$1,771** | **$53,139,259** | **$(47,517,046)** | **$(1,150,112)** | **$ 4,473,872** |
| Common stock issued from public offering | | | 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 for warrant exercises | | | 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 stock granted to employees/directors | | | 120,000 | 12 | 607,579 | | | 607,591 |
| Convertible debt converted into common stock | | | | | 325,320 | | | 325,320 |
| Warrant modification | | | | | 61,590 | | | 61,590 |
| Foreign currency translation adjustment | | | | | | | (116,443) | (116,443) |
| Net loss | | | | | | (15,177,686) | | (15,177,686) |
| **Balance, December 31, 2019** | **—** | **$—** | **26,800,519** | **$2,680** | **$68,575,851** | **$(62,694,732)** | **$(1,266,555)** | **$ 4,617,244** |
| **Balance, January 1, 2020** | **—** | **$—** | **26,800,519** | **$2,680** | **$68,575,851** | **$(62,694,732)** | **$(1,266,555)** | **$ 4,617,244** |
| Issuance of Series B preferred stock and warrants for cash, conversion of promissory notes, net | 2,912 | — | — | — | 14,460,155 | — | — | 14,460,155 |
| Warrants issued in connection with Series B preferred stock offering | — | — | — | — | 5,952,516 | — | — | 5,952,516 |
| Warrants issued as inducement to exchange promissory notes into Series B preferred stock offering | — | — | — | — | 986,526 | — | — | 986,526 |
| Series B Preferred Stock | — | — | — | — | 8,155,212 | — | — | 8,155,212 |
| Deemed dividend of preferred stock | — | — | — | — | (8,155,212) | — | — | (8,155,212) |
| Deemed dividend related to exchange of promissory notes into Series B preferred stock | — | — | — | — | (1,129,742) | — | — | (1,129,742) |
| Issuance of Series B preferred PIK shares for accrued dividends | 118 | — | — | — | — | — | — | — |
| Common stock issued upon conversion of Series B preferred stock | (256) | — | 2,565,813 | 257 | (257) | — | — | — |
| Common stock issued to settle accounts payable | — | — | 105,937 | 11 | 131,126 | — | — | 131,137 |
| Common stock issued to Lincoln Park for equity purchase agreement | — | — | 1,495,199 | 149 | 988,199 | — | — | 988,348 |
| Warrants issued in association with convertible debt issuances | — | — | — | — | 1,252,558 | — | — | 1,252,558 |
| Beneficial conversion feature on convertible debt issuances | — | — | — | — | 1,838,422 | — | — | 1,838,422 |
| Common stock issued to consultants | — | — | 182,841 | 18 | 144,387 | — | — | 144,405 |
| Settlement with former chief executive officer | — | — | — | — | 85,770 | — | — | 85,770 |
| Stock-based compensation | — | — | — | — | 549,425 | — | — | 549,425 |
| Foreign currency translation adjustment | — | — | — | — | — | — | 154,009 | 154,009 |
| Net loss | — | — | — | — | — | (32,671,466) | — | (32,671,466) |
| **Balance, December 31, 2020** | **2,774** | **$—** | **31,150,309** | **$3,115** | **$93,834,936** | **$(95,366,198)** | **$(1,112,546)** | **$ (2,640,693)** |

The accompanying notes are an integral part of these Consolidated Financial Statements.

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

| | Year Ended December 31, | |
|---|---|---|
| | **2020** | **2019** |
| Cash flows from operating activities: | | |
| Net loss | $(32,671,466) | $(15,177,686) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 37,797 | 63,096 |
| Amortization | 527,548 | 956,950 |
| Non-cash lease expense | (4,855) | — |
| Fixed assets written off | 10,950 | 7,296 |
| Stock-based compensation | 522,133 | 574,335 |
| Restricted stock granted to employees/directors | 27,292 | 607,591 |
| Common stock granted to consultants | 166,905 | 210,000 |
| Accreted interest on convertible debt | 234,074 | 112,543 |
| Accretion of debt discount | 4,580,168 | 313,364 |
| Loss on debt extinguishment | 609,998 | — |
| Gain on settlement | (211,430) | — |
| Beneficial conversion feature related to promissory note exchange | 798,413 | — |
| Net changes in assets and liabilities: | | |
| Other receivables | 2,083,270 | (749,859) |
| Prepaid expenses | (660,845) | (85,681) |
| Right of use assets | (110,835) | (82,234) |
| Deposits | (15,412) | 3,900 |
| Accounts payable and accrued expenses | (750,027) | (420,788) |
| Payables related to license agreement | 13,250,000 | — |
| Accrued dividends payable | — | — |
| Other liabilities | 354,784 | (366,329) |
| Net cash used in operating activities | (11,221,538) | (14,033,502) |
| Cash flows from investing activities: | | |
| Purchase of property and equipment, net | (4,167) | (24,098) |
| Proceeds from sale of property and equipment, net | 91,517 | — |
| Net cash used in investing activities | 87,350 | (24,098) |
| Cash flows from financing activities: | | |
| Proceeds from issuance of note payable, net | 799,772 | 498,783 |
| Proceeds from issuance of common stock, net | 988,348 | 9,476,749 |
| Proceeds from issuance of convertible debt, net | 3,227,002 | 4,967,308 |
| Proceeds from issuance of preferred stock, net | 13,197,740 | — |
| Received from stockholder in relation to warrant modification | — | 61,590 |
| Repayments of note payable | (691,741) | (309,451) |
| Repayments of convertible debt | (475,000) | (1,550,000) |
| Net cash provided by financing activities | 17,046,121 | 13,144,979 |
| Increase in cash and cash equivalents | 5,911,933 | (912,621) |
| Effect of exchange rate changes on cash | (25,588) | (25,926) |
| Cash and cash equivalents, beginning balance | 175,796 | 1,114,343 |
| **Cash and cash equivalents, ending balance** | **$ 6,062,141** | **$ 175,796** |
| Supplemental disclosures of cash flow information: | | |
| Cash paid for interest | $ 105,460 | $ 8,032 |
| Non-cash investing and financing activities: | | |
| Common stock issued for patents purchased from Mayoly | $ — | $ 1,740,959 |
| Warrant modification related to convertible debt issuance | $ — | $ 325,320 |
| Deemed dividend on preferred stock | $ 8,155,212 | $ — |
| Accrued dividends on preferred stock | $ 905,660 | $ — |
| Exchange of promissory notes into preferred stock and warrants | $ 609,998 | $ — |
| Payables related to license agreement | $ 13,250,000 | $ — |

The accompanying notes are an integral part of these 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 targeted, non-systemic therapies for the treatment of patients with gastrointestinal (''*GI*'') diseases. Non-systemic therapies are non-absorbable drugs that act locally, i.e. in the intestinal lumen, skin or mucosa, without reaching an individual's systemic circulation.

The Company is currently focused on developing its pipeline of gut-restricted GI clinical drug candidates. Our lead drug candidate is MS1819, a recombinant lipase for the treatment of exocrine pancreatic insufficiency (''*EPI*'') in patients with cystic fibrosis (''*CF*'') and chronic pancreatitis (''*CP*''), currently in two Phase 2 CF clinical trials. In 2021, we plan to launch two clinical programs using in-licensed proprietary formulations of niclosamide, a pro-inflammatory pathway inhibitor; FW-1022, for Severe Acute Respiratory Syndrome Coronavirus 2 (''*COVID-19*'') GI infections, and FW-420, for Grade 1 Immune Checkpoint Inhibitor-Associated Colitis (''*ICI-AC*'') and diarrhea in oncology patients.

Since its inception, the Company has devoted substantially all of its efforts to research and development, business development, and raising capital, and has financed its operations through issuance of common stock, convertible preferred stock, convertible debt and other debt/equity instruments. The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development and regulatory success, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, and ability to secure additional capital to fund operations.

Historically, the Company's major sources of cash have been comprised of proceeds from various public and private offerings of its capital stock. As of December 31, 2020, the Company had approximately $6.1 million in cash and cash equivalents. The Company has incurred recurring losses, has experienced recurring negative operating cash flows and requires significant cash resources to execute its business plans. The Company has an accumulated deficit of approximately $95.4 million as of December 31, 2020.

We have implemented business continuity plans designed to address and mitigate the impact of the COVID-19 pandemic on our business. The extent to which the ongoing COVID-19 pandemic impacts our business, our clinical development and regulatory efforts, our corporate development objectives and the value of and market for our Common Stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the U.S., Europe and other countries, and the effectiveness of actions taken globally to contain and treat the disease. The global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition, we are subject to other challenges and risks specific to our business and our ability to execute on our strategy, as well as risks and uncertainties common to companies in the pharmaceutical industry with development and commercial operations, including, without limitation, risks and uncertainties associated with: obtaining regulatory approval of our drug candidates; delays or problems in the manufacture and supply of our drug candidates, loss of single source suppliers or failure to comply with manufacturing regulations; identifying, acquiring or in-licensing additional products or drug candidates; pharmaceutical product development and the inherent uncertainty of clinical success; and the challenges of protecting and enhancing our intellectual property rights; complying with applicable regulatory requirements. In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties discussed above.

***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*'') and 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. At December 31, 2020, we had an accumulated deficit of approximately $95.4 million and had negative working capital of approximately $4.7 million. The Company is dependent on obtaining additional working capital funding from the sale of equity securities and/or debt in order to continue to execute its development plan and continue operations.

Subsequent to December 31, 2020, we have raised aggregate gross proceeds of approximately $18.0 million from the sale of preferred stock and Common Stock in public offerings and private placement transactions. Net proceeds from our 2021 offerings are intended to be used for the cash consideration to First Wave under the First Wave License Agreement, to initiate our two niclosamide programs in 2021, and for other general corporate purposes. Additionally, we have received gross cash proceeds of approximately $4.6 million from the exercise of warrants, which proceeds are intended to be used for general corporate purposes.

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. 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 and cash equivalent balances were highly liquid at December 31, 2020 and 2019, 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, 2020 and 2019, the Company had approximately $2.7 million and $0, 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***

In August 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 approximately $420,000. 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 December 31, 2020, the Company had recovered approximately $50,000 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 approximately $370,000 which is included in general and administrative expense. As a result of the cyber-related fraud, the Company has instituted additional controls and procedures and all employees 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, 2020.

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, 2020.

***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, 2020 and 2019, 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 costs are charged to operations when incurred and are included in operating expense. Research and development costs consist principally of compensation of employees and consultants that perform the Company's research activities, the fees paid for and to maintain the Company's licenses, and the payments to third parties for clinical trials and manufacturing, and amortization of intangible assets related to the acquisition of MS1819.

***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 (the ''*2014 Plan*'') which took effect on May 12, 2014, and the 2020 Omnibus Equity Incentive Plan, which took effect on September 11, 2020 (the ''*2020 Plan*''). From the effective date

of the 2020 Plan, no new awards have been or will be made under the 2014 Plan. 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.

***License Agreements***

As more fully discussed in Note 14, the Company entered into a license agreement (the "*First Wave License Agreement*") with First Wave Bio, Inc. ("*First Wave*"), pursuant to which First Wave granted the Company an exclusive license to certain patents and patent applications related to a proprietary formulation of niclosamide for use in the fields of ICI-AC and COVID-19 GI infections. The acquisition of intellectual property and patents for the worldwide, exclusive right to develop, manufacture, and commercialize proprietary formulations of niclosamide for the fields of treating ICI-AC and COVID-19 in humans was accounted for as an asset acquisition and initial liabilities of approximately $13.3 million in connection with the license acquisition were recorded as research and development expense, because it was determined to have no alternative future uses and therefore no separate economic value, which included cash payments totaling approximately $10.3 million and the issuance of approximately $3.0 million of preferred stock.

As more fully discussed in Note 14, 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. Payments made to TransChem in connection with this sublicence agreement were recorded as research and development expense. The Company terminated the sublicence agreement with TransChem during the year ended December 31, 2020.

***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 ASU 2017-04, Intangibles - Goodwill and Other, Simplifying the Accounting for Goodwill Impairment. ASU 2017-04 removes Step 2 of the goodwill impairment test, which requires a hypothetical purchase price allocation. A goodwill impairment will now be the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the carrying amount of goodwill. All other goodwill impairment guidance will remain largely unchanged. Entities will continue to have the option to perform a qualitative assessment to determine if a quantitative impairment test is necessary. This new guidance will be applied prospectively and is effective for annual or any interim goodwill impairment tests in fiscal years beginning after December 15, 2019. This ASU, which the Company adopted as of January 1, 2020, did not have a material effect on the Company's consolidated financial statements.

In August 2020, the FASB issued accounting pronouncement (ASU 2020-06) related to the measurement and disclosure requirements for convertible instruments and contracts in an entity's own equity. The pronouncement simplifies and adds disclosure requirements for the accounting and measurement of convertible instruments and the settlement assessment for contracts in an entity's own equity. As a smaller reporting company, as defined by the U.S. Securities and Exchange Commission (the *"SEC"*), this pronouncement is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2023. The Company is currently evaluating the impact of this ASU on the financial statements.

**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.

The fair value of the Company's financial instruments are as follows:

| | Fair Value Measured at Reporting Date Using | | | | |
|---|---|---|---|---|---|
| | Carrying Amount | Level 1 | Level 2 | Level 3 | Fair Value |
| At December 31, 2020: | | | | | |
| Cash and cash equivalents | $6,062,141 | $3,000,184 | $3,061,957 | $ — | $6,062,141 |
| Other receivables | $ 551,489 | $ — | $ — | $ — | $ 551,489 |
| Note payable | $ 552,405 | $ — | $ — | $ — | $ 552,405 |
| At December 31, 2019: | | | | | |
| Cash and cash equivalents | $ 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, 2020, cash and cash equivalents included approximately $3.0 million held in high-quality money market funds quoted in an active market and included in level 1 in the table above.

The fair value of other receivables approximates carrying value as these consist primarily of French research and development tax credits that are normally received the following year.

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**

Other receivables consisted of the following:

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Research and development tax credits | $493,906 | $2,566,281 |
| Other | 57,583 | 71,022 |
| Total other receivables | $551,489 | $2,637,303 |

At December 31, 2020, research and development tax credits was comprised of the 2020 refundable tax credits for research conducted in France and Europe. At December 31, 2019, the research and development tax credits were comprised of the 2017, 2018, and 2019 refundable tax credits for research conducted in France and Europe. During the year ended December 31, 2020, the Company received the 2017, 2018 and 2019 refundable tax credits.

At December 31, 2020 and 2019, other consisted of amounts due from U.S. research and development tax credits.

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

Property, equipment and leasehold improvements consisted of the following:

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Laboratory equipment | $ 2,410 | $ 193,661 |
| Computer equipment | 19,676 | 74,836 |
| Office equipment | 5,483 | 36,703 |
| Leasehold improvements | 29,163 | 35,711 |
| Total property, plant and equipment | 56,732 | 340,911 |
| Less accumulated depreciation | (38,403) | (263,520) |
| Property, plant and equipment, net | $ 18,329 | $ 77,391 |

Depreciation expense was approximately $48,000 and $63,000 for the years ended December 31, 2020 and 2019, respectively. Approximately $10,000 of write-offs of fixed assets was included in depreciation for the year ended December 31, 2020.

For the year ended December 31, 2020, approximately $33,000 of depreciation was included in research and development expense and approximately $15,000 of depreciation was included in general and administrative expense.

For the year ended December 31, 2019, approximately $42,000 of depreciation was reclassified to research and development expense and approximately $13,000 of depreciation remained in general and administrative expense.

**Note 6 - Intangible Assets and Goodwill**

*Patents*

Pursuant to the Mayoly APA entered into in March 2019 (see Note 14), in which the Company purchased all remaining rights, title and interest in and to MS1819 from Mayoly, the Company recorded Patents in the amount of approximately $3.8 million 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 |

Intangible assets are as follows:

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Patents | $3,802,745 | $3,802,745 |
| Less accumulated amortization | (923,209) | (395,661) |
| Patents, net | $2,879,536 | $3,407,084 |

Amortization expense was approximately $528,000 and $780,000 for the years ended December 31, 2020, and 2019, respectively.

For the year ended December 31, 2019, approximately $780,000 of amortization was included research and development expense. Amortization expense for the year ended December 31, 2019 included approximately $385,000 from in process research and development and license agreements written off as a result of the Mayoly APA.

As of December 31, 2020, amortization expense related to patents is expected to be approximately $528,000 for each of the next five years (2021 through 2025).

| | |
|---|---|
| 2021 | $527,548 |
| 2022 | $527,548 |
| 2023 | $527,548 |
| 2024 | $527,548 |
| 2025 | $527,548 |

Goodwill is as follows:

| | Goodwill |
|---|---|
| Balance at January 1, 2019 | $1,924,830 |
| Foreign currency translation | (38,144) |
| Balance at December 31, 2019 | 1,886,686 |
| Foreign currency translation | 167,362 |
| Balance at December 31, 2020 | $2,054,048 |

**Note 7 - Accounts Payable and Accrued Expense**

Accounts payable and accrued expense consisted of the following:

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Trade payables | $1,558,591 | $1,683,505 |
| Accrued expense | 127,012 | 71,177 |
| Total accounts payable and accrued expense | $1,685,603 | $1,754,682 |

**Note 8 - Note Payable**

*Directors and Officer's Liability Insurance*

On November 30, 2020, the Company entered into a 9-month financing agreement for its directors and officer's liability insurance in the amount of approximately $620,000 that bears interest at an annual rate of 4.250%. Monthly payments, including principal and interest, of approximately $70,000 per month. The balance due under this financing agreement was approximately $552,000 at December 31, 2020.

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 approximately $500,000 that bears interest at an annual rate of 5.461%. Monthly payments, including principal and interest, were approximately $57,000 per month. The balance due under this financing agreement was approximately $444,000 at December 31, 2019.

*CARES ACT PPP Loan*

In April 2020, the Company applied for and received a CARES Act Paycheck Protection Program ("*PPP*") loan of approximately $179,000 through the Small Business Administration (SBA). In May 2020, the Company returned the loan in full after analysis of the updated guidance from the U.S. Department of Treasury and the SBA regarding the eligibility for such loans.

**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 $1.0 million per ADEC Note, resulting in gross proceeds to the Company of $2.0 million (the "*ADEC Note Offering*").

The ADEC Notes accrued interest at a rate of 10% per annum; provided, however, that in the event the Company should elect to repay the full balance due under the terms of both ADEC Notes prior to December 31, 2019, then the interest rate would be reduced to 6% per annum. Interest would be payable at the time all outstanding principal amounts owed under each ADEC Note were repaid. The ADEC Notes were scheduled to 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 was 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 could 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 did not alter any other terms of the ADEC Warrants. The ADEC Warrant Amendment resulted in a debt discount of approximately $325,000 that was accreted to additional interest expense over the lives of the ADEC Notes.

In December 2019, the Company repaid $1,550,000 principal amount of the ADEC Notes and on January 2, 2020 repaid the remaining principal balance of $450,000 plus outstanding accrued interest of approximately $104,000. As of December 31, 2020, no ADEC Notes were outstanding.

***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 Note Investors (the "*Promissory* NPAs") (the "*Promissory Note Offering*").

In December 2019, the Company issued Promissory Notes to the Note Investors in the aggregate principal amount of approximately $3.4 million. The Promissory Notes were scheduled to mature on September 20, 2020, accrue interest at a rate of 9% per annum, and were 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 could be prepaid by the Company at any time prior to the maturity date in cash without penalty or premium (the "*Prepayment Option*").

On January 2, 2020, January 3, 2020, and January 9, 2020, the Company issued Promissory Notes to the Note Investors in the aggregate principal amount of approximately $3.5 million.

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 "*Note Warrant Shares*"). The Note Warrants have an exercise price of $1.07 per share and expire five years from the date of issuance. In addition, all of the Note Warrants, other than those issued in the December 20, 2019 closing (covering an aggregate of 2,374,345 shares of Common Stock) contain a provision prohibiting exercise until the expiration of six months 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 Note Warrant Shares, but that registration statement was not declared effective and was subsequently withdrawn by the Company. On July 27, 2020, the Company filed a separate registration statement in connection with the Series B Private Placement and the Exchange described in Note 11, which also covers the Note Warrant Shares. That registration statement was declared effective on September 21, 2020.

In connection with the four closings in December 2019 of the Promissory Note Offering, the Company paid aggregate placement agent fees of approximately $339,000, 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.

In connection with the three closings in January 2020 of the Promissory Note Offering, the Company paid aggregate placement agent fees of approximately $277,000, 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 January Placement Agent Warrants, to purchase an aggregate of 199,732 shares of Common Stock. 41,495 of these January Placement Agent Warrants have an exercise price of $1.21 per share and 158,237 of these January Placement Agent Warrants have an exercise price of $1.42 per share.

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 approximately $3.4 million 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 approximately $913,000. Then the beneficial conversion feature was calculated, which amounted to approximately $1.4 million. The Company incurred debt issuance costs of approximately $0.6 million related to the offering. The initial carrying value of the Promissory Notes issued amounted to approximately $0.5 million.

Pursuant to the January 2020 closings of the Promissory Note Offering, the principal amount of approximately $3.5 million 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 approximately $2.4 million. Then the beneficial conversion feature was calculated, which amounted to approximately $1.8 million. The Company incurred debt issuance costs of approximately $0.5 million related to the offering. The initial carrying value of the Promissory Notes issued amounted to approximately $0.1 million.

On June 1, 2020, the Company entered into an amendment to a certain Promissory Note in the principal amount of $100,000 issued on December 20, 2019 to Edward J. Borkowski, the chairman of the Board, to increase the Conversion Price to $1.07 per share (the "*Note Amendment*"). The Company evaluated the Note Amendment transaction in accordance with ASC 470-50 and determined the Note Amendment did not constitute a substantive modification of the Promissory Note and that the transaction should be accounted for as a debt modification with no accounting treatment required.

During the year ended December 31, 2020, the Company recognized approximately $4.9 million of interest expense related to these Promissory Notes, including amortization of debt discount related to the value of the Note Warrants of approximately $1.5 million, amortization of the beneficial conversion feature of approximately $2.3 million, amortization of debt discount related to debt issuance costs of approximately $0.8 million, and accrued interest expense of approximately $0.3 million.

During the year ended December 31, 2019, the Company recognized approximately $115,000 of interest expense related to these Promissory Notes, including amortization of debt discount related to the value of the Note Warrants of approximately $34,000, amortization of the beneficial conversion feature of approximately $52,000, amortization of debt discount related to debt issuance costs of approximately $21,000, and accrued interest expense of approximately $8,000.

*Exchange of Promissory Notes into Series B Convertible Preferred Stock*

As more fully discussed in Note 11, on July 16, 2020, in connection with the Series B Private Placement, approximately 937.00 shares of Series B Preferred Stock, Series B Warrants to purchase 4,684,991 shares of Common Stock, and Exchange Warrants to purchase 1,772,937 shares of Common Stock were issued to certain holders of the Promissory Notes in exchange for such Promissory Notes for aggregate consideration of approximately $7.2 million consisting of approximately $6.9 million aggregate outstanding principal amount, together with accrued and unpaid interest thereon through the date of the Series B Private Placement of approximately $0.3 million.

The Company prepaid the remaining outstanding balance of $25,000 aggregate principal amount of Promissory Notes, together with accrued and unpaid interest thereon through the prepayment date of approximately $1,000, held by those holders who did not participate in the Exchange. Following these transactions, no Promissory Notes remain outstanding.

*Accounting for the Exchange of Promissory Notes into Series B Private Placement*

The Company determined the Exchange of the Promissory Notes into Series B Preferred Stock and related warrants should be recognized as an extinguishment of the Promissory Notes, which resulted in a loss on extinguishment of approximately $0.6 million. Additionally, the Company recorded interest expense of approximately $0.8 million related to the remaining unamortized discount resulting from initial beneficial conversion feature of the Promissory Notes on closing date of the Exchange.

Convertible debt consisted of the following:

| | Total December 31, 2020 | Promissory Notes December 31, 2020 | ADEC Notes December 31, 2020 | Total December 31, 2019 |
|---|---|---|---|---|
| Convertible debt | $— | $— | $— | $ 3,836,300 |
| Unamortized debt discount - revalued warrants | — | — | — | (118,356) |
| Unamortized debt discount - warrants | — | — | — | (878,979) |
| Unamortized debt discount - BCF | — | — | — | (1,307,755) |
| Unamortized debt discount - debt issuance costs | — | — | — | (566,815) |
| Accrued interest | — | — | — | 112,543 |
| Total convertible debt | $— | $— | $— | $ 1,076,938 |

**Note 10 – Other Liabilities**

Other liabilities consisted of the following:

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| **Current** | | |
| Due to Mayoly | $ — | $392,989 |
| Lease liabilities | 57,417 | 83,235 |
| Total current liabilities | $57,417 | $476,224 |

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| **Long-term** | | |
| Lease liabilities | $19,123 | $— |
| Total long-term liabilities | $19,123 | $— |

**Note 11 – Equity**

Our certificate of incorporation, as amended and restated on December 20, 2019 (the ''*Charter*'') authorized the issuance of up to 150,000,000 shares of Common Stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share.

On February 24, 2021 the Company held a Special Meeting of Stockholders (the ''*Special 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 250,000,000 shares from 150,000,000 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- five (1:5) to one-for-ten (1:10), any time prior to the one-year anniversary date of the Special Meeting, with the exact ratio to be determined by the Board (the ''*Reverse Split*''). As of the date hereof, the Board had not elected to effect a Reverse Split. The authorization for the Reverse Split will expire on February 24, 2022.

***Common Stock***

The Company had 31,150,309 and 26,800,519 shares of its Common Stock issued and outstanding at December 31, 2020 and 2019, respectively.

Each holder of Common Stock is entitled to one vote for each share of Common Stock held on all matters submitted to a vote of the stockholders. Our Charter and Amended and Restated Bylaws (the ''*Bylaws*'') do not provide for cumulative voting rights.

In addition, the holders of our Common Stock will be entitled to receive ratably such dividends, if any, as may be declared by the 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.

Holders of our Common Stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to the Common Stock. The rights, preferences and privileges of the holders of Common Stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

***Preferred Stock***

We have 10,000,000 shares of preferred stock, par value $0.0001 per share, authorized and available for issuance in one or more series. The Board is authorized to divide the preferred stock into any number of series, fix the designation and number of each such series, and determine or change the designation, relative rights, preferences, and limitations of any series of preferred stock. The Board of may increase or decrease the number of shares initially fixed for any series, but no decrease may reduce the number below the shares then outstanding and duly reserved for issuance.

On July 16, 2020, we authorized 5,194.805195 shares as Series B Preferred Stock and issued approximately 2,912.58 shares of Series B Preferred Stock, with approximately 2,282.22 shares of Series B Preferred Stock remaining authorized but unissued. At December 31, 2020, the Company had approximately 2,773.62 shares of preferred stock issued and outstanding with approximately 9,997,226.38 shares of preferred stock remaining authorized but unissued.

***Series B Convertible Preferred Stock***

Pursuant to the Certificate of Designation of Rights and Preferences of the Series B Preferred Stock (the ''*Series B Certificate of Designation*''), the terms of the Series B Preferred Stock are as follows:

*Ranking*

The Series B Preferred Stock will rank senior to the Common Stock with respect to distributions of assets upon the liquidation, dissolution or winding up of the Company.

*Stated Value*

Each share of Series B Preferred Stock has a stated value of $7,700, subject to adjustment for stock splits, combinations and similar events (the ''*Series B Stated Value*'').

*Dividends*

Each holder of shares of Series B Preferred Stock, in preference and priority to the holders of all other classes or series of stock of the Company, is entitled to receive dividends, commencing from the date of issuance. Such dividends may be paid by the Company only when, as and if declared by the Board, out of assets legally available therefor, semiannually in arrears on the last day of June and December in each year, commencing December 31, 2020, at the dividend rate of 9.0% per year, which is cumulative and continues to accrue on a daily basis whether or not declared and whether or not the Company has assets legally available therefor. The Company may pay such dividends at its option either in cash or in kind in additional shares of Series B Preferred Stock (rounded down to the nearest whole share), provided the Company must pay in cash the fair value of any such fractional shares in excess of $100.00. During the year ended December 31, 2020, the Company issued a total of approximately 117.62 shares of Series B Preferred Stock for payment of dividends amounting to approximately $906,000.

*Liquidation Preference; Liquidation Rights*

Under the Certificate of Designations, each share of Series B Preferred Stock carries a liquidation preference equal to the Series B Stated Value (as adjusted thereunder) plus accrued and unpaid dividends thereon (the "*Liquidation Preference*").

If the Company voluntarily or involuntarily liquidates, dissolves or winds up its affairs, each holder of the Series B Preferred Stock will be entitled to receive out of the Company's assets available for distribution to stockholders, after satisfaction of liabilities to creditors, if any, but before any distribution of assets is made on the Common Stock or any of the Company's shares of stock ranking junior as to such a distribution to the Series B Preferred Stock, a liquidating distribution in the amount of the Stated Value of all such holder's Series B Preferred Stock plus all accrued and unpaid dividends thereon. At December 31, 2020, the value of the liquidation preference of the Series B Preferred stocks aggregated to approximately $21.4 million.

*Conversion*

Each share of Series B Preferred Stock will be convertible at the holder's option at any time, into Common Stock at a conversion rate equal to the quotient of (i) the Series B Stated Value divided by (ii) the initial conversion price of $0.77, subject to specified adjustments for stock splits, cash or stock dividends, reorganizations, reclassifications other similar events as set forth in the Series B Certificate of Designations. In addition, at any time after the six month anniversary of the Series B Closing Date, if the closing sale price per share of Common Stock exceeds 250% of the initial conversion price, or $1.925, for 20 consecutive trading days, then all of the outstanding shares of Series B Preferred Stock will automatically convert (the "*Automatic Conversion*") into such number of shares of Common Stock as is obtained by multiplying the number of shares of Series B Preferred Stock to be so converted, plus the amount of any accrued and unpaid dividends thereon, by the Series B Stated Value per share and dividing the result by the then applicable conversion price. The Series B Preferred Stock contains limitations that prevent the holder thereof from acquiring shares of Common Stock upon conversion (including pursuant to the Automatic Conversion) that would result in the number of shares beneficially owned by such holder and its affiliates exceeding 9.99% of the total number of shares of Common Stock outstanding immediately after giving effect to the conversion, which percentage may be increased or decreased at the holder's election not to exceed 19.99%.

*Most Favored Nations Exchange Right*

In the event the Company effects any issuance by the Company or any of its subsidiaries of Common Stock or Common Stock equivalents for cash consideration, or a combination of units thereof (a "*Subsequent Financing*"), each holder of the Series B Preferred Stock has the right, subject to certain exceptions set forth in the Series B Certificate of Designations, at its option, to exchange (in lieu of cash subscription payments) all or some of the Series B Preferred Stock then held (with a value per share of Series B Preferred Stock equal to the stated value, plus accrued and unpaid dividends thereon, of the Series B Preferred Stock (the "*Exchange Amount*")) for any securities or units issued in a Subsequent Financing on dollar-for-dollar basis (the "*Exchange Right*").

As of March 30, 2021, holders of approximately 1,266.92 shares of Series B Preferred Stock with an aggregate Exchange Amount of approximately $9.8 had previously elected to exercise their Series B Exchange Rights into Series C Preferred Stock, convertible into an aggregate of 13,087,843 shares of Common Stock (which conversion the Company has elected to make in full), and additional Investor Warrants exercisable for up to an aggregate of 13,087,843 shares of Common Stock.

In addition, as of March 30, 2021, approximately 1,248.89 shares of Series B Preferred Stock with an aggregate Exchange Amount of approximately $9.7 million currently remain outstanding, which are currently exchangeable for Series C Preferred Stock convertible into an aggregate of up to 13,168,280 shares of Common Stock and additional Investor Warrants exercisable for up to an aggregate of 13,168,280 shares of Common Stock. Any shares of Series C Preferred Stock to be issued pursuant to the Exchange Right would, upon issuance, be immediately converted into underlying shares of Common Stock.

*Voting*

The holders of the Series B Preferred Stock, voting as a separate class, will have customary consent rights with respect to certain corporate actions of the Company. The Company may not take the following actions without the prior consent of the holders of at least a majority of the Series B Preferred Stock then outstanding: (a) authorize, create, designate, establish, issue or sell an increased number of shares of Series B Preferred Stock or any other class or series of capital stock ranking senior to or on parity with the Series B Preferred Stock as to dividends or upon liquidation; (b) reclassify any shares of Common Stock or any other class or series of capital stock into shares having any preference or priority as to dividends or upon liquidation superior to or on parity with any such preference or priority of Series B Preferred Stock; (c) amend, alter or repeal the Certificate of Incorporation or Bylaws of the Company and the powers, preferences, privileges, relative, participating, optional and other special rights and qualifications, limitations and restrictions thereof, which would adversely affect any right, preference, privilege or voting power of the Series B Preferred Stock; (d) issue any indebtedness or debt security, other than trade accounts payable, insurance premium financings and/or letters of credit, performance bonds or other similar credit support incurred in the ordinary course of business, or amend, renew, increase, or otherwise alter in any material respect the terms of any such indebtedness existing as of the date of first issuance of shares of Series B Preferred Stock; (e) redeem, purchase, or otherwise acquire or pay or declare any dividend or other distribution on (or pay into or set aside for a sinking fund for any such purpose) any capital stock of the Company; (f) declare bankruptcy, dissolve, liquidate, or wind up the affairs of the Company; (g) effect, or enter into any agreement to effect, a Change of Control (as defined in the Certificate of Designations); or (h) materially modify or change the nature of the Company's business.

***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. From the adoption and approval of the 2020 Plan on September 11, 2020, no new awards have been or will be made under the 2014 Plan.

The 2014 Plan allowed 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 could 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 included all shares of Common Stock and all shares of Common Stock issuable upon the conversion of outstanding preferred stock and other convertible securities but did 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 was automatically be increased concurrently with the Company's issuance of fully paid and non-assessable shares of As Converted Shares. Shares were deemed to have been issued under the 2014 Plan solely to the extent actually issued and delivered pursuant to an award.

On July 16, 2020, the Board approved an amendment to the 2014 Plan. The amendment eliminates individual grant limits under the 2014 Plan that were intended to comply with the exemption for "performance-based compensation" under Section 162(m) of the Internal Revenue Code, which section has been repealed.

The Company issued an aggregate of 2,870,012 and 1,193,500 stock options, during the years ended December 31, 2020 and 2019, respectively, under the 2014 Plan (see Note 13). As of December 31, 2020, there were an aggregate of 5,888,632 total shares available under the 2014 Plan, of which 4,060,284 are issued and outstanding, and 387,000 shares are reserved subject to issuance of restricted stock and RSUs. Upon adoption of the 2020 Omnibus Equity Incentive Plan on September 11, 2020, the Company will no longer make grants under the 2014 Plan.

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.

***2020 Equity Incentive Plan***

The Company's Board and stockholders adopted and approved the 2020 Omnibus Equity Incentive Plan (the ''*2020 Plan*''), which took effect on September 11 ,2020. The 2020 Plan allows for the issuance of securities, including stock options to employees, Board members and consultants. The initial number of shares of Common Stock available for issuance under the 2020 Plan is 10,000,000 shares, which will, on January 1 of each calendar year, unless the Board decides otherwise, automatically increase to equal ten percent (10%) of the total number of shares of Common Stock outstanding on December 31 of the immediately preceding calendar year, calculated on an As Converted Basis. As Converted Shares include all outstanding shares of Common Stock and all shares of Common Stock issuable upon the conversion of outstanding preferred stock, warrants and other convertible securities, but will not include any shares of Common Stock issuable upon the exercise of options and other convertible securities issued pursuant to either the 2014 Plan or the 2020 Plan. The number of shares permitted to be issued as ''incentive stock options'' (''*ISOs*'') from is 15,000,000 under the 2020 Plan.

The Company issued an aggregate of 10,000 stock options under the 2020 Plan during the year ended December 31, 2020. As of December 31, 2020, 10,000,000 total shares were available under the 2020 Plan, of which 10,000 were issued and outstanding and 9,990,000 shares were available for potential issuances.

***Equity Line with Lincoln Park***

In November 2019, the Company entered into a purchase agreement (the ''*Equity Line Agreement*''), together with a registration rights agreement (the ''*Lincoln Park Registration Rights Agreement*''), with Lincoln Park. Under the terms of the Equity Line Agreement, Lincoln Park has committed to purchase up to $15,000,000 of our Common Stock (the ''*Equity Line*''). Upon execution of the Equity Line Agreement, the Company issued Lincoln Park 487,168 shares of Common Stock (the ''*Commitment Shares*'') as a fee for its commitment to purchase shares of our Common Stock under the Equity Line Agreement. The Commitment Shares had a grant date fair value of approximately $297,000 and had no effect on expenses or stockholders' equity.

The remaining shares of our Common Stock that may be issued under the Equity Line Agreement may be sold by the Company to Lincoln Park at our discretion from time-to-time over a 30-month period commencing after the satisfaction of certain conditions set forth in the Equity Line Agreement, subject to the continued effectiveness of a registration statement covering such shares of Common Stock sold to Lincoln Park by the Company. The registration statement was filed with the SEC on December 31, 2019 and was declared effective on January 14, 2020.

Under the Equity Line Agreement, on any business day over the term of the Equity Line Agreement, the Company has the right, in its sole discretion, to present Lincoln Park with a purchase notice (each, a ''*Purchase Notice*'') directing Lincoln Park to purchase up to 150,000 shares of Common Stock per business day (the ''*Regular Purchase*''). In each case, Lincoln Park's maximum commitment in any single Regular Purchase may not exceed $1,000,000. The Equity Line 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 Lincoln Park, the Company also has the right, in its sole discretion, to present Lincoln Park with an accelerated purchase notice (each, an ''*Accelerated Purchase Notice*'') directing Lincoln Park 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 Equity Line 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 Lincoln Park will not be required to buy shares pursuant to an Accelerated Purchase Notice that was received by Lincoln Park 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 Lincoln Park 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 Lincoln Park in accordance with the Equity Line 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; and;
- the closing sale price of Common Stock on the applicable Additional Accelerated Purchase.

Pursuant to the terms of the Equity Line Agreement, without first obtaining stockholder approval, the aggregate number of shares that the Company is permitted to sell to Lincoln Park thereunder, when aggregated with certain other private offerings of Common Stock, as applicable, may not exceed 19.99% of the Common Stock outstanding immediately prior to the execution of the Equity Line Agreement on November 13, 2019, unless the average price of all applicable sales thereunder exceeds $0.70 per share calculated by reference to the "Minimum Price" under Nasdaq Listing Rule 5635(d). On September 11, 2020, the Company received stockholder approval for the issuances of the full $15 million available under the Equity Line Agreement. There is approximately $14.0 million of availability left for issuance pursuant to the Equity Line Agreement.

The Company issued an aggregate of 1,495,199, and 0 shares of Common Stock, during the years ended December 31, 2020 and 2019, respectively, in connection with the Equity Line Agreement, resulting in net proceeds to the Company of approximately $1.0 million, and $0, respectively.

***Common Stock Issuances***

*2020 Issuances*

During the year ended December 31, 2020, holders of shares of Series B Preferred Stock converted approximately 254.54 shares of Series B Preferred Stock into an aggregate of 2,565,813 shares of Common Stock at the stated conversion price of $0.77 per share.

During the year ended December 31, 2020, the Company issued an aggregate of 182,841 shares of its Common Stock to consultants with a total grant date fair value of approximately $144,000 for investor relations services provided, which was recorded as stock-based compensation and included as part of general and administrative expense.

During the year ended December 31, 2020, the Company issued 62,518 restricted shares of Common Stock to a consultant as payment of $135,000 of accounts payable for investor relations services.

During the year ended December 31, 2020, the Company issued an aggregate of 105,937 shares of its Common Stock to outside Board members as payment of Board fees with an aggregate grant date fair value of approximately $131,000 that was recorded as stock-based compensation, included as part of general and administrative expense. 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.

*2019 Issuances*

During the year ended December 31, 2019, pursuant to the Asset Purchase Agreement and associated Assignment Agreement and Delegation and Set-off Agreement by and between the Company and Mayoly (together, the "*Mayoly APA*"), the Company issued Mayoly 400,481 shares of Common Stock as part of the closing payment in March 2019 with a grant date fair value of approximately $917,000, that was recognized as part of stockholders' equity.

During the year ended December 31, 2019, pursuant to the Mayoly APA, the Company issued 200,240 shares of Common Stock to be released form escrow on December 31, 2019, and 175,210 shares of restricted Common Stock to be released form escrow on December 31, 2020. During the year ended December 31, 2019, the Company recognized approximately $824,000 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 approximately $173,000, that was recorded as part of general and administrative expense.

During the year ended December 31, 2019, the Company issued an aggregate of 7,522,097 shares of its Common Stock in our public offerings of Common Stock that occurred in April 2019, May 2019, and July 2019 for aggregate net proceeds of approximately $9.5 million.

During the year ended December 31, 2019, the Company issued 487,168 of Common Stock as a commitment fee pursuant to entering into the Equity Line Agreement with grant date fair value of approximately $297,000 and had no effect on expenses or stockholders' equity.

***Restricted Stock and Restricted Stock Units***

Restricted stock refers to shares of Common Stock subject to vesting based on certain service, performance, and market conditions. Restricted stock unit awards (''*RSUs*'') refer to an award under the 2014 Plan, which constitutes a promise to grant shares of Common Stock at the end of a specified restriction period.

During the year ended December 31, 2020, an aggregate of 10,080 restricted shares of Common Stock, subject to service conditions, vested with a total grant date fair value of approximately $36,000 and was recorded as stock-based compensation, included as part of general and administrative expense.

During the year ended December 31, 2020, an aggregate 4,000 unvested restricted shares of Common Stock were forfeited.

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 U.S. 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 vesting of the milestones becomes 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 $500,000 due to their resignations from the Company.

During the year ended December 31, 2019, an aggregate of 223,417 restricted shares of Common Stock vested with a total grant date fair value of approximately $557,000. 33,334 of these restricted shares with a total grant date fair value of approximately $101,000 vested due to the Company achieving certain clinical milestones. 41,250 of these restricted shares with a total grant date fair value of approximately $135,000 vested due to the satisfaction of service conditions. 30,000 of these restricted shares were issued to certain our directors as a part of Board compensation with a total grant date fair value of approximately $142,000.

During the year ended December 31, 2019, an aggregate of 48,668 shares of restricted Common Stock, subject to time-based vesting, vested with a total grant date fair value of approximately $154,000 and was recorded as stock-based compensation, included as part of general and administrative expense.

As of December 31, 2020, the Company had an aggregate unrecognized restricted Common Stock expense of approximately $393,000, which will be recognized when vesting of certain milestones will be become probable.

***The Series B Private Placement and the Exchange***

On July 16, 2020 (the ''*Series B Closing Date*''), the Company consummated a private placement offering (the ''*Series B Private Placement*'') whereby the Company entered into a Convertible Preferred Stock and Warrant Securities Purchase Agreement (the ''*Series B Purchase Agreement*'') with certain accredited and institutional investors (the ''*Series B Investors*''). Pursuant to the Series B Purchase Agreement, the Company issued an aggregate of 2,912.583005 shares of Series B Convertible Preferred Stock, par value $0.0001 per share (the ''*Series B Preferred Stock*''), at a price of $7,700.00 per share, initially convertible into an aggregate of 29,125,756 shares of Common

Stock at $0.77 per share, together with warrants (the "*Series B Warrants*") to purchase an aggregate of 14,562,826 shares of Common Stock at an exercise price of $0.85 per share. The amount of the Series B Warrants is equal to 50% of the shares of Common Stock into which the Series B Preferred Stock is initially convertible

In connection with the Series B Private Placement, an aggregate of approximately 1,975.58 shares of Series B Preferred Stock initially convertible into 19,755,748 shares of Common Stock and related 9,877,835 Series B Warrants were issued for cash consideration, resulting in aggregate gross proceeds of approximately $15.2 million and aggregate net proceeds to the Company of approximately $13.2 million after deducting placement agent compensation and offering expenses.

An aggregate of approximately 937.00 shares of Series B Preferred Stock initially convertible into 9,370,008 shares of Common Stock and related Series B Warrants to purchase 4,684,991 shares of Common Stock were issued to certain Series B Investors (the "*Exchange Investors*") in exchange for consideration consisting of approximately $6.9 million aggregate outstanding principal amount, together with accrued and unpaid interest thereon through the Series B Closing Date of approximately $0.3 million, of certain Senior Convertible Promissory Notes (the "*Promissory Notes*") issued between December 20, 2019 and January 9, 2020 (the "*Exchange*"), pursuant to an Exchange Addendum (the "*Exchange Addendum*") executed by the Company and the Exchange Investors. As additional consideration to the Exchange Investors, the Company also issued certain additional warrants (the "*Exchange Warrants*") to purchase an aggregate of 1,772,937 shares of Common Stock at an exercise price of $0.85 per share. The amount of the Exchange Warrants is equal to 25% of the shares of Common Stock into which such Promissory Notes were originally convertible upon the initial issuance thereof.

Pursuant to the Series B Private Placement and the Series B Purchase Agreement, for purposes of complying with Nasdaq Listing Rule 5635(c) and 5635(d), the Company was required to hold a meeting of its stockholders not later than 60 days following the Series B Closing Date to seek approval (the "*Stockholder Approval*") for, among other things, the issuance of shares of Common Stock upon (i) full conversion of the Series B Preferred Stock; and (ii) full exercise of the Series B Warrants and the Exchange Warrants. In the event the Stockholder Approval was not received on or prior to the 90th day following the Series B Closing Date, subject to extension upon the prior written approval of the holders of at least a majority of the Series B Preferred Stock then outstanding, the Company would have been required to repurchase all of the then outstanding shares of Series B Preferred Stock at a price equal to 150% of the stated value thereof plus accrued and unpaid dividends thereon, in cash. On September 11, 2020, the Company received Stockholder Approval.

The Company prepaid the remaining outstanding balance of $25,000 aggregate principal amount of Promissory Notes, together with accrued and unpaid interest thereon through the prepayment date of approximately $1,000, held by those holders who did not participate in the Exchange. Following these transactions, no Promissory Notes remain outstanding.

In connection with the Series B Private Placement, the Company paid the placement agent 9.0% of the gross cash proceeds received by the Company from investors introduced by the placement agent and 4.0% of the gross cash proceeds received by the Company for all other investors, or approximately $1.3 million. The Company also paid the placement agent a non-accountable cash fee equal to 1.0% of the gross cash proceeds and a cash financial advisory fee equal to 3.0% of the outstanding principal balance of the Promissory Notes that were submitted in the Exchange, or approximately $0.3 million in additional cash fees in the aggregate. In addition, the Company issued to the placement agent warrants to purchase up to 1,377,458 shares of Common Stock (the "*July Placement Agent Warrants*"). The July Placement Agent Warrants have substantially the same terms as the Series B Warrants, except the July Placement Agent Warrants have an exercise price of $0.96 per share, are not callable, provide for cashless exercise and are not exercisable until the earlier of stockholder approval of the Series B Private Placement and the date that is six months following the issuance thereof.

*Accounting for the Series B Private Placement*

Upon receiving Shareholder Approval on September 11, 2020, the Company classified the Series B Preferred Stock as permanent equity because no features provide for redemption by the holders of the Series B Preferred Stock or conditional redemption, which is not solely within the Company's control, and there are no unconditional obligations in that (1) the Company must or may settle in a variable number of its equity shares and (2) the monetary value is predominantly fixed, varying with something other than the fair value of the Company's equity shares or varying inversely in relation to the Company's equity shares.

Because the Series B Preferred Stock contain certain embedded features that could affect the ultimate settlement of the Series B Preferred Stock, the Company analyzed the instrument for embedded derivatives that require bifurcation. The Company's analysis began with determining whether the Series B Preferred Stock is more akin to equity or debt. The Company evaluated the following criteria/features in this determination: redemption, voting rights, collateral requirements, covenant provisions, creditor and liquidation rights, dividends, conversion rights and exchange rights. The Company determined that the Series B Preferred Stock was more akin to equity than to debt when evaluating the economic characteristics and risks of the entire Series B Preferred Stock, including the embedded features. The Company then evaluated the embedded features to determine whether their economic characteristics and risks were clearly and closely related to the economic characteristics and risks of the Series B Preferred Stock. Since the Series B Preferred Stock was determined to be more akin to equity than debt, and the underlying that causes the value of the embedded features to fluctuate would be the value of the Company's common stock, the embedded features were considered clearly and closely related to the Series B Preferred Stock. As a result, the embedded features would not need to be bifurcated from the Series B Preferred Stock.

Any beneficial conversion features related to the exercise of the Most Favored Nation exchange right or the application of the Mandatory Conversion provision will be recognized upon the occurrence of the contingent events based on its intrinsic value at the commitment date.

The Company concluded the freestanding Series B Warrants did not contain any provision that would require liability classification and therefore should be classified in stockholder's equity, based on their relative fair value.

The proceeds from the Series B Private Placement were allocated to the Series B Preferred Stock and Series B Warrants based on their relative fair values. The total proceeds of approximately $22.4 million were allocated as follows: approximately $16.5 million to the Series B Preferred Stock, and approximately $5.9 million to the Series B Warrants. After allocation of the proceeds, the effective conversion price of the Series B Preferred Stock was determined to be beneficial and, as a result, the Company recorded a deemed dividend of approximately $8.2 million equal to the intrinsic value of the beneficial conversion feature and recognized on the closing date and recorded as a reduction of income available to common stockholders in computing basic and diluted loss per share. The total offering costs of approximately $2.0 million were recognized in equity.

*Registered Direct Offering and Private Placement*

On December 31, 2020, the Company entered into a securities purchase agreement (the "*Series C Purchase Agreement*"), pursuant to which the Company agreed to sell in a registered direct offering 5,333.333 shares of Series C Preferred Stock, at a price of $750 per share, initially convertible into an aggregate of 5,333,334 shares of Common Stock, at an initial stated value of $750.00 per share and a conversion price of $0.75 per share (the "*Registered Direct Offering*").

Concurrently with the Registered Direct Offering, in a private placement offering pursuant to the Series C Purchase Agreement (the "*Private Placement*"), the Company agreed to sell an additional 5,333.3333 shares of Series C Preferred Stock at the same price as the Series C Preferred Stock offered in the Registered Direct Offering and convertible on the same terms and warrants (the "*Investor Warrants*") to purchase up to an aggregate of 10,666,668 shares of Common Stock, with an exercise price of $0.80 per share and an expiration term of five and one-half years from the date of issuance.

In connection with the Private Placement, we entered into a registration rights agreement, dated as of December 31, 2020, pursuant to which we filed a registration statement on Form S-1 (File No. 333-252087) to register the shares of Common Stock issuable upon the conversion of the Series C Preferred Stock sold in the Private Placement and the exercise of the Investor Warrants. The registration statement was declared effective by the SEC on January 21, 2021.

The aggregate gross proceeds from the Registered Direct Offering and the Private Placement, excluding the net proceeds, if any, from the exercise of the Investor Warrants, was approximately $8.0 million.

The net proceeds to the Company from the Registered Direct Offering and the Private Placement, after deducting the placement agent's fees and expenses and estimated offering expenses, was approximately $6.8 million. The Company used the net proceeds to fund the payment of cash consideration to First Wave under the First Wave License Agreement, and for other general corporate purposes.

The Company paid the placement agent a cash fee equal to 8.0% and a management fee equal to 1.0% of the aggregate gross proceeds received by the Company in the Registered Direct Offering and the Private Placement, or

approximately $700,000. The Company also agreed to issue to the placement agent or its designees warrants (the "*December 2020 Placement Agent Warrants*") exercisable for up to 746,667 shares of Common Stock, which is equal to 7.0% of the amount determined by dividing the gross proceeds of the Registered Direct Offering and Private Placement by the offering price per share of Common Stock, or $0.75. The December 2020 Placement Agent Warrants have substantially the same terms as the Investor Warrants, except they are exercisable at $0.9375 per share, or 125% of the effective purchase price per share of the Series C Preferred Stock issued. The Company also reimbursed the placement agent $35,000 for non-accountable expenses, up to $125,000 for legal fees and expenses and other out-of-pocket expenses and $12,900 for clearing fees.

On February 24, 2021, the Company's stockholders approved certain proposals related to the Registered Direct Offering and the Private Placement and all outstanding shares of Series C Preferred Stock were converted to Common Stock.

**Note 12 - Warrants**

For the year ended December 31, 2020, in connection with the January 2020 closings of the Promissory Note Offering, the Company issued Note Warrants to investors to purchase an aggregate of 1,813,257 shares of Common Stock with the issuance of the Promissory Notes (See Note 9). These Note Warrants were issued in January 2020, became exercisable commencing six (6) months following issuance 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 $1.6 million, as calculated using the Black-Scholes model, and were recorded as a debt discount based on their relative fair value.

Additionally, in connection with the January 2020 closings of the Promissory Note Offering, the Company issued the placement agent warrants to purchase an aggregate of 199,732 shares of Common Stock to the placement agent and/or their designees (See Note 9). These warrants were issued in January 2020, were immediately exercisable, and expire five years from issuance. 41,495 of these warrants are exercisable at $1.21 per share and 158,237 of these warrants are exercisable at $1.42 per share. The total grant date fair value of these warrants was determined to be approximately $174,000, as calculated using the Black-Scholes model, and was charged to debt discount and amortized over the life of the debt.

For the year ended December 31, 2020, in connection with the closing of the Exchange (See Note 11), the Company issued Exchange Warrants to certain investors to purchase an aggregate of 1,772,937 shares of Common Stock with the issuance of the Series B Preferred Stock as referenced in Note 11. These Exchange Warrants were issued on July 16, 2020, are exercisable commencing six (6) months following the issuance date at $0.85 per share and expire five years from issuance. The total grant date fair value of the Exchange warrants was determined to be approximately $987,000, as calculated using the Black-Scholes model, and were recorded as part of the loss on extinguishment (See Note 9).

For the year ended December 31, 2020, in connection with the closing of the Series B Private Placement, the Company issued placement agent warrants to purchase an aggregate of 1,377,458 shares of Common Stock to the placement agent and/or their designees. These warrants were issued in July 2020, became exercisable commencing six (6) months following issuance at $0.96 per share and expire five years from issuance. The total grant date fair value of these warrants was determined to be approximately $745,000, as calculated using the Black-Scholes model, and were recorded as equity.

For the year ended December 31, 2020, in connection with the Spoor Settlement and Release in July 2020, the Company granted Mr. Spoor warrants to purchase an aggregate of 150,000 shares of Common Stock. The warrants were immediately exercisable, have an exercise price equal to $1.00 per share, a five-year term and may be exercised pursuant to a cashless exercise provision commencing six months from the issuance date. The total grant date fair value of these warrants was determined to be approximately $86,000, as calculated using the Black-Scholes model, and were included in the gain on settlement (See Note 18).

During year ended December 31, 2020, warrants to purchase an aggregate of 80,750 shares of Common Stock expired with exercise prices ranging between $3.25 and $7.37 per share.

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 (See Note 9). These Note Warrants were issued in December 2019,

became exercisable commencing six (6) months following issuance 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 $1.3 million, as calculated using the Black-Scholes model, and were recorded as a debt discount based on their relative fair value.

Additionally, 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 in December 2019, were immediately exercisable, 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 $169,000, 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 public offerings in April 2019, and May 2019, the Company issued selling agent warrants to purchase an aggregate of 75,663 shares of Common Stock. These selling agent warrants will become exercisable one year following issuance, expire five years from issuance, and have an exercise prices of ranging from $2.55 to $2.82 per share. The total grant date fair value of these investment banking warrants was determined to be approximately $117,000, 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 public offerings July 2019, the Company issued the underwriting warrants to purchase an aggregate of 200,000 shares of Common Stock. These underwriting warrants are exercisable immediately, expire five years from issuance, 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).

Warrant transactions for the years ending December 31, 2020 and 2019 were as follows:

| | Warrants | Exercise Price Per Share | Weighted Average Exercise Price |
|---|---|---|---|
| **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** | **$1.07 - 7.37** | **$2.53** |
| **Warrants outstanding and exercisable at January 1, 2020** | **5,378,288** | **$1.07 - 7.37** | **$2.53** |
| Granted during the period | 19,881,654 | $0.85 - 1.42 | $0.88 |
| Expired during the period | (80,750) | $3.25 - 7.37 | $4.11 |
| Exercised during the period | — | — | — |
| **Warrants outstanding and exercisable at December 31, 2020** | **25,179,192** | **$0.85 - 7.37** | **$1.22** |

Warrants exercisable at December 31, 2020 were as follows:

| Exercise Price | Number of Shares Under Warrants | Weighted Average Remaining Contract Life in Years | Weighted Average Exercise Price |
|---|---|---|---|
| $0.00 - 0.99 | 17,718,665 | 4.54 | |
| $1.00 - 1.99 | 5,362,464 | 3.41 | |
| $2.00 - 2.99 | 320,063 | 2.56 | |
| $3.00 - 3.99 | 635,019 | 1.32 | |
| $4.00 - 4.99 | 164,256 | 1.27 | |
| $5.00 - 5.99 | 778,116 | 1.18 | |
| $6.00 - 6.99 | 187,750 | 0.76 | |
| $7.00 - 7.37 | 12,859 | 0.18 | |
| **Totals** | **25,179,192** | **4.04** | **$1.22** |

The weighted average fair value of warrants granted during the years ended December 31, 2020 and 2019, was $0.59 and $0.71 per share, respectively. The grant date fair values were calculated using the Black-Scholes model with the following weighted average assumptions:

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Expected life (in years) | 5 | 5 |
| Volatility | 81 - 85% | 71 - 80% |
| Risk-free interest rate | 0.28 - 1.67% | 1.64 - 2.37% |
| Dividend yield | —% | —% |

**Note 13 – Stock Options**

Under the 2014 Plan and the 2020 Plan, the fair value of options granted is estimated on the grant date using the Black-Scholes option valuation model. This valuation model for stock-based compensation expense requires the Company to make assumptions and judgments about the variables used in the calculation, including the expected term (weighted-average period of time that the options granted are expected to be outstanding), the volatility of the common stock price and the assumed risk-free interest rate. The Company recognizes stock-based compensation expense for only those shares expected to vest over the requisite service period of the award. No compensation cost is recorded for options that do not vest and the compensation cost from vested options, whether forfeited or not, is not reversed.

During the year ended December 31, 2020, the Company issued stock options under the 2014 Plan to purchase an aggregate of 335,006 shares of Common Stock with a strike price of $1.03 per share and a term of ten years to its chief financial officer that vest in equal monthly installments over three years. These options had a total grant date fair value of approximately $281,000, as calculated using the Black-Scholes model.

During the year ended December 31, 2020, the Board approved an amended and restated option grant to its chief financial officer, amending and restating a grant previously made on January 2, 2020, to reduce the amount of shares issuable upon exercise of such option to be the maximum number of shares Mr. Schneiderman was eligible to receive under the 2014 Plan on the original grant date, or 300,000 shares, due to the 2014 Plan provisions relating to the individual grant limits that were intended to comply with the exemption for ‘‘performance-based compensation’’ under Section 162(m) of the Internal Revenue Code, which section has been repealed. The Board also approved the issuance of a replacement option covering the balance of shares intended to be issued at that time, or 35,006 shares. The original stock option has an exercise price of $1.03, the closing sale price of Common Stock on January 2, 2020, which was the date of its original grant, and the replacement stock option has an exercise price of $0.85, the closing sale price of the Common Stock on its date of grant. Both the original stock option and the replacement stock option vest over a term of three years, in 36 equal monthly installments on each monthly anniversary of January 2, 2020. On the issuance date, 6,336 shares had vested, and 28,670 shares were unvested with approximately $24,000 of unrecognized expense. The Company determined the cancellation and reissue of these stock options resulted in an effective repricing of the stock options and modification accounting should be applied under ASC 718. The fair value

of the original stock options immediately prior to the modification was approximately $23,000 and the grant date fair value of the replacement stock options was approximately $24,000. The Company will recognize a total of approximately $25,000 over the remaining requisite service period through January 1, 2023.

During the year ended December 31, 2020, the Company issued stock options under the 2014 Plan to purchase an aggregate of 460,000 shares of Common Stock with a strike price of $0.97 per share and a term of ten years to certain Board members that vested in equal installments over 2020. These options had a total grant date fair value of approximately $210,000, as calculated using the Black-Scholes model.

During the year ended December 31, 2020, the Company issued stock options under the 2014 Plan to purchase an aggregate of 2,040,000 shares of Common Stock with a strike price of $0.85 per share and a term of ten years to its employees. 600,000 of these stock options are subject to performance-based milestone vesting conditions and 1,440,000 of these stock options vest in equal monthly installments over three years. These options had a total grant date fair value of approximately $1.4 million, as calculated using the Black-Scholes model.

During the year ended December 31, 2020, the Company issued stock options under the 2020 Plan to purchase an aggregate of 10,000 shares of Common Stock with a strike price of $0.97 per share and a term of ten years to a consultant that are subject to performance- based milestone vesting conditions. These options had a total grant date fair value of approximately $8,000, as calculated using the Black- Scholes model.

During the year ended December 31, 2020, stock options under the 2014 Plan to purchase an aggregate of 600,086 shares of Common Stock, subject to service-based milestone vesting conditions, vested with a total grant date fair value of approximately $361,000 and recorded as stock-based compensation, of which approximately $341,00 was included as part of general and administrative expense and approximately $20,000 was included as part of research and development expense.

During the year ended December 31, 2020, stock options under the 2014 Plan to purchase an aggregate of 50,000 shares of Common Stock, subject to performance-based vesting conditions, vested with a total grant date fair value of approximately $20,000 and were recorded as stock-based compensation, and included as part of general and administrative expense due to the Company achieving clinical milestones.

During the year ended December 31, 2020, stock options under the 2014 Plan to purchase an aggregate of 487,228 shares of Common Stock were cancelled with strike prices ranging between $0.85 and $4.48 per share.

The weighted average fair value of stock options granted during the year ended December 31, 2020 was $0.89 per share.

During the year ended December 31, 2019, the Company issued stock options under the 2014 Plan 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 vested 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, and included as part of general and administrative expense.

During the year ended December 31, 2019, the Company issued stock options under the 2014 Plan to purchase an aggregate of 250,000 shares of Common Stock with a strike price of $1.75 per share and a term of five years to its former chief executive officer and former chief financial officer, and were subject to performance-based milestone vesting conditions. These stock options had a grant date fair value of approximately $253,000, as calculated using the Black-Scholes model. These unvested stock options were cancelled as a result of the former executives' resignations.

During the year ended December 31, 2019, the Company issued stock options under the 2014 Plan to purchase an aggregate of 300,000 shares of Common Stock with a strike price of $0.56 per share and a term of 10 years to its chief executive officer with performance-based milestone vesting conditions. These options had a total grant date fair value of approximately $121,000, as calculated using the Black- Scholes model. The Company will recognize the expense related to these performance-based milestones when the milestones become probable.

During the year ended December 31, 2019, the Company issued stock options under the 2014 Plan 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 performance-based milestone vesting conditions. These options had a total grant date fair value of approximately $550,000, as calculated using the Black- Scholes model. The Company will recognize the expense related to these performance-based milestones when the milestones become probable.

During the year ended December 31, 2019, stock options under the 2014 Plan to purchase an aggregate of 304,500 shares of Common Stock, subject to performance-based vesting conditions, vested with a total grant date fair value of approximately $574,000 and recorded as stock-based compensation.

During the year ended December 31, 2019, stock options under the 2014 Plan 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.

The weighted average fair value of stock options granted during the year ended December 31, 2019 was $0.89 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, | |
|---|---|---|
| | 2020 | 2019 |
| Contractual term (in years) | 5 - 10 | 5 - 10 |
| Volatility | 81 - 85% | 72 - 75% |
| Risk-free interest rate | 0.62 - 1.88% | 1.54 - 1.84% |
| 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, 2020 and 2019, stock option activity under the 2014 Plan and 2020 Plan was as follows:

| | Number of Shares | Average Exercise Price | Remaining Contract Life in Years | Intrinsic Value |
|---|---|---|---|---|
| **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** | **$1.33** | **6.26** | **$—** |

| | Number of Shares | Average Exercise Price | Remaining Contract Life in Years | Intrinsic Value |
|---|---|---|---|---|
| **Stock options outstanding at January 1, 2020** | **1,667,550** | **$2.17** | **5.37** | **$—** |
| Granted during the period | 2,880,012 | $0.89 | 9.06 | $— |
| Expired during the period | — | — | | |
| Canceled during the period | (487,228) | $2.77 | | $— |
| Exercised during the period | — | — | | |
| **Stock options outstanding at December 31, 2020** | **4,070,284** | **$1.38** | **7.94** | **$—** |
| **Exercisable at December 31, 2020** | **1,329,627** | **$1.78** | **6.67** | **$—** |
| **Non-vested stock options outstanding at January 1, 2020** | **883,500** | **$1.33** | **6.26** | **$—** |
| Granted during the period | 2,880,012 | $0.89 | 9.06 | $— |
| Vested during the period | (840,627) | $0.98 | | $— |
| Expired during the period | — | — | | |
| Canceled during the period | (182,228) | $1.75 | | $— |
| Exercised during the period | — | — | | |
| **Non-vested stock options outstanding at December 31, 2020** | **2,740,657** | **$0.99** | **8.42** | **$—** |

As of December 31, 2020, the Company had unrecognized stock-based compensation expense of approximately $2.0 million. Approximately $1.0 million of this unrecognized expense will be recognized over the average remaining vesting term of the stock options of 8.42 years.

Approximately $440,000 of this unrecognized expense will vest upon enrollment completion of the ongoing OPTION 2 Trial. Approximately $41,000 of this unrecognized expense will vest upon enrollment completion of the ongoing Combination Trial. Approximately $168,000 of this unrecognized expense will vest upon the public release of topline data of the complete OPTION 2 Trial results . Approximately $40,000 of this unrecognized expense will vest upon initiating a Phase 3 clinical trial in the U.S. for MS1819. Approximately $40,000 of this unrecognized expense will vest upon initiating a U.S. Phase 1 clinical trial for any product other than MS1819. Approximately, $140,000 of this unrecognized expense will vest upon the public release of topline data of the complete Combination Trial results. Approximately, $140,000 of this unrecognized expense will vest upon signing of a definitive term sheet with Board approval for either (i) a strategic licensing, distribution or commercialization agreement for MS1819 with a bona fide partner, or (ii) the substantial sale of the Company or the MS1819 asset, on or before December 31, 2021. The Company will recognize the expense related to these milestones when the milestones become probable.

**Note 14 – Agreements**

***License Agreement with First Wave Bio, Inc.***

On December 31, 2020, we entered into the First Wave License Agreement, pursuant to which First Wave granted us a worldwide, exclusive right to develop, manufacture, and commercialize First Wave's proprietary immediate release and enema formulations of niclosamide (the "*Niclosamide Product*") for the fields of treating ICI-AC and COVID-19 in humans.

In consideration of the license and other rights granted by First Wave, we agreed to pay First Wave a $9.0 million upfront cash payment due within 10 days, which was paid in January 2021 and are obligated to make an additional payment of $1.25 million due on June 30, 2021. In addition, we are obligated to pay potential milestone payments to First Wave totaling up to $37.0 million for each indication, based upon the achievement of specified development and regulatory milestones. Under the First Wave License Agreement we are obligated to pay First Wave royalties as a mid-single digit percentage of net sales of the Niclosamide Product, subject to specified reductions. We are also obligated to issue to First Wave junior convertible preferred stock, initially convertible into $3.0 million worth of Common Stock based upon the volume weighted average price of the Common Stock for the five-day period

immediately preceding the date of the First Wave License Agreement, or $0.9118 per share, convertible into an aggregate of 3,290,196 shares of Common Stock. This was classified as a liability in the consolidated balance sheet because of certain NASDAQ restrictions and the requirement to obtain stockholder approval.

On January 8, 2021, we entered into a securities purchase agreement with First Wave (the "*First Wave Purchase Agreement*") to issue the junior convertible preferred stock to the First Wave License Agreement. Pursuant to the First Wave Purchase Agreement, we issued to First Wave 3,290.1960 shares of Series C Preferred Stock, at an initial stated value of $750.00 per share and a conversion price of $0.75 per share, which is convertible into an aggregate of 3,290,196 shares of Common Stock. The shares of Series C Preferred Stock automatically converted into Common Stock upon the stockholder approval on February 24, 2021.The First Wave Purchase Agreement contains demand and piggyback registration rights with respect to the Common Stock issuable upon conversion.

The Company is now solely responsible, and has agreed to use commercially reasonable efforts, for all development, regulatory and commercial activities related to the Niclosamide Products in the ICI-AC and COVID-19 fields. The Company may sublicense its rights under the First Wave License Agreement and, if it does so, will be obligated to pay milestone payments and royalties to First Wave based on the sublicensee's development and commercialization of the licensed Niclosamide Products.

Pursuant to the First Wave License Agreement, First Wave retains rights to develop and commercialize the licensed niclosamide formulations outside the ICI-AC and COVID-19 fields, and to develop and commercialize other niclosamide formulations that are not licensed to Company. However, if prior to April 30, 2021, First Wave seeks to outlicense, sell to or otherwise grant rights to a third party related to any products containing niclosamide for use outside the ICI-AC or COVID-19 fields to develop or commercialize a product containing niclosamide for use outside of the Field then First Wave shall provide to AzurRx written notice of such proposal, in reasonable detail and AzurRx shall have the right and option to negotiate with First Wave with respect to a definitive agreement for the acquisition of First Wave. Pursuant to the First Wave License Agreement, the Company grants First Wave a worldwide, non-exclusive, royalty-free, perpetual, irrevocable license for use outside the ICI-AC and COVID-19 fields, with the right to grant sublicenses, under any Program IP and other intellectual property owned by the Company and incorporated into the Niclosamide Product.

The First Wave License Agreement terminates on a country-by-country basis and product-by-product basis upon the expiration of the royalty term for such product in such country. Each royalty term begins on the date of the first commercial sale of the licensed product in the applicable country and ends on date of expiration of the last to expire royalty term with respect to the country. The First Wave License Agreement may be terminated earlier in specified situations, including termination for uncured material breach of the First Wave License Agreement by either party, termination by the Company in specified circumstances, termination by First Wave in specified circumstances, termination by the Company for convenience with advance notice, and termination upon a party's insolvency or bankruptcy. After expiration of the royalty term, the Company shall have a non-exclusive, fully-paid, perpetual, royalty-free right and irrevocable license with respect to any Product in any country within the territory.

In certain circumstances set forth in the First Wave License Agreement, in the event that First Wave seeks to outlicense, sell or otherwise grant to a third party rights relating to its proprietary formulations of niclosamide (or any products containing niclosamide) for use outside the ICI-AC and the COVID-19 field, then First Wave must provide the Company written notice and engage in good faith negotiations with the Company for a period of time to try to reach agreement on the terms of an acquisition of First Wave by the Company. In the event that First Wave and the Company fail to reach an agreement, then First Wave shall be free to negotiate a transaction, and the right of first refusal shall be of no further force or effect.

The First Wave License Agreement also contains customary representations, warranties and covenants by both parties, as well as customary provisions relating to indemnification, confidentiality and other matters.

***Mayoly Agreement***

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

During the year ended December 31, 2019, the Company charged approximately $403,000 to Mayoly under the JDLA that was in effect during such period.

***TransChem Sublicense***

In August 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 allowed 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, 2020 and 2019 were approximately $0 and $50,000, respectively, and were included in research and development expense.

In March 2020, the Company provided TransChem with sixty (60) days prior written notice of its intent to terminate the TransChem Sublicense Agreement. As of December 31, 2020, this agreement has been terminated.

***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 originally provided for a base salary of $450,000 per year, which was subsequently increased to $480,000 per year during the year ended December 31, 2020. 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) an award grant of 200,000 restricted stock units (''*RSUs*'') which are scheduled 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 an exercise price equal to $0.56 per share, which are scheduled to vest as follows (a) 50,000 shares upon the Company initiating its next Phase 2 clinical trial in the U.S. for MS1819, (b) 50,000 shares upon the Company completing its next or subsequent Phase 2 clinical trial in the U.S. for MS1819, (c) 100,000 shares upon the Company initiating a Phase 3 clinical trial in the U.S. for MS1819, and (d) 100,000 shares upon the Company initiating a Phase 1 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 (as such term is defined in Mr. Sapirstein's employment agreement) for a period of twelve months following the termination date; (ii) payment of Mr. Sapirstein's premiums to cover COBRA for a period of twelve 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 an exercise price of $1.03 per share, which shall vest in three equal portions on each anniversary date of the execution of Mr. Schneiderman's employment agreement, commencing on January 2, 2021, 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 Mr. Schneiderman's 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 Mr. Schneiderman's employment agreement, he 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 six months following the termination date or the remaining term of the employment agreement; (iv) payment of premiums to cover COBRA for a period of six 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 Mr. Schneiderman's employment agreement without Cause, in connection with a Change of Control, he 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 Dr. 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 Dr. Pennington's employment agreement at any time, with or without Cause, as such term is defined in Dr. Pennington's 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 Dr. Pennington's employment agreement, Dr. Pennington will receive six months' severance payable over such period.

**Note 15 - 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 offices and research facilities under operating leases which are subject to various rent provisions and escalation clauses.

During the year ended December 31, 2020, the Company entered into a month-to-month lease for office space in Delray Beach, FL, a one- year residential lease in Delray Beach, FL and a two-year lease extension (amendment) to is Hayward, CA office. During the year ended December 31, 2020, the Company's lease for its research laboratory in France expired and was not renewed.

The Company determined that the modification to the Hayward, CA lease did not grant an additional right of use and concluded that the modification was not a separate new lease, but rather that it should reassess and remeasure the entire modified lease on the effective date of the modification. The Company accounted for the lease amendment prospectively.

The Company's leases expire at various dates through 2022. The escalation clauses are indeterminable and considered not material and have been excluded from minimum future annual rental payments.

Lease expense amounted to approximately $205,000 and $198,000 for the years ended December 31, 2020 and 2019, respectively.

The weighted-average remaining lease term and weighted-average discount rate under operating leases at December 31, 2020 were:

| | December 31, 2020 |
|---|---|
| **Lease term and discount rate** | |
| Weighted-average remaining lease term | 1.42 years |
| Weighted-average discount rate | 6.0% |

Maturities of operating lease liabilities at December 31, 2020 were as follows:

| | |
|---|---|
| 2021 | 55,420 |
| 2022 | 23,375 |
| Total lease payments | 78,795 |
| Less imputed interest | — |
| Present value of lease liabilities | $78,795 |

**Note 16 - 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, 2020 and 2019, the Company had no tax provision for either jurisdictions.

At December 31, 2020 and 2019, the Company had gross deferred tax assets of approximately $26.1 million and $16.4 million, 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 $26.1 million and $16.4 million has been established at December 31, 2020 and 2019, respectively. The change in the valuation allowance was approximately $9.7 million and $3.9 million in 2020 and 2019, respectively.

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

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Gross deferred tax assets: | | |
| Net operating loss carry-forwards | $ 24,269,000 | $ 16,197,000 |
| Temporary differences: | | |
| Stock compensation | 1,408,000 | 199,000 |
| Accruals | 76,000 | 136,000 |
| Other | 639,000 | 131,000 |
| Amortization | (319,000) | (291,000) |
| Deferred tax asset valuation allowance | (26,073,000) | (16,372,000) |
| 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, | |
|---|---|---|
| | 2020 | 2019 |
| Income taxes benefit (expense) at statutory rate | 21% | 21% |
| State income tax | 14% | 14% |
| Non-deductible expense | (12%) | (6%) |
| Change in valuation allowance | (23%) | (29%) |
| | 0% | 0% |

The Company has gross net operating loss (''*NOL*'') carryforwards for U.S. federal and state income tax purposes of approximately $51.4 million and $29.3 million, at December 31, 2020 and 2019, 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.

The Company had approximately $23.0 million and $19.5 million in net operating losses, at December 31, 2020 and 2019, respectively, which it can carryforward indefinitely to offset against future French income.

The Company had taken no uncertain tax positions that would require disclosure under ASC 740, Accounting for Income Taxes, at December 31, 2020 and 2019, respectively.

**Note 17 - 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, 2020, diluted net loss per share did not include the effect of 27,736,019 shares of Common Stock issuable upon the conversion of Series B preferred stock, 25,179,192 shares of Common Stock issuable upon the exercise of outstanding warrants, 112,000 shares of restricted stock not yet issued, and 4,070,284 shares of Common Stock issuable upon the exercise of outstanding options as their effect would be antidilutive during the periods prior to conversion. Also excluded from the diluted net loss per are the potentially dilutive effect of 3,290,196 shares of Common Stock from the First Wave License Agreement, and the potentially dilutive effect 10,666,668 shares of Common Stock underlying the Series C Preferred Stock and 10,666,668 shares of Common Stock issuable upon exercise of Investor Warrants potentially issuable pursuant the Registered Direct Offering and Private Placement entered into on December 31, 2020.

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.

**Note 18 - 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. Approximately $348,000 was included in accounts payable at December 31, 2019 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. In addition, Mr. Spoor resigned as a member of the Board on April 29, 2020.

In June 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 by the Company, 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.

All unvested shares of restricted stock and stock options subject to time and other performance-based vesting conditions have been forfeited in connection with Mr. Spoor's resignation as the Company's President and Chief Executive Officer. Mr. Spoor also declined the right to receive 241,667 earned, but unissued shares of restricted stock on April 29, 2020 in connection with his resignation from the Board.

The Company and Mr. Spoor entered into a settlement and general release (the ''*Spoor Settlement and Release*''), effective July 9, 2020 (the ''*Spoor Settlement Date*''), of certain claims relating to Mr. Spoor's separation from the

Company on October 8, 2019. In connection with the Spoor Settlement and Release, on July 14, 2020 the Company granted Mr. Spoor warrants to purchase an aggregate of 150,000 shares of Common Stock, which had a grant date fair value of $85,770 (See Note 12). In addition, Mr. Spoor legally released all claims to a discretionary bonus in the amount of $255,000, which was originally accrued by the Company in June 2019 but was subsequently reversed during the quarter ended December 31, 2019, legally released all claims to $348,400 due to JIST Consulting, a company controlled by Mr. Spoor and the Company also paid Mr. Spoor's legal expenses in the amount of approximately $51,000. During the year ended December 31, 2020, the Company recognized a gain on settlement of approximately $211,000 in connection with the Spoor Settlement and Release.

*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. Approximately $50,000 was included in accounts payable at December 31, 2019 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.

In June 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.

On July 2, 2020, the Company and Mr. Shenouda, also entered into a settlement and general release (the "*Shenouda Settlement and Release*"), of certain claims relating to Mr. Shenouda's s separation from the Company effective November 30, 2019. In connection with the Shenouda Settlement and Release, the Company paid a total of $15,000 to Mr. Shenouda, which amount included $10,000 of accounts payable of the Company due to Mr. Shenouda for services provided and $5,000 for legal expenses, and Mr. Shenouda legally released all claims to a discretionary bonus in the amount of $100,000 originally accrued by the Company in June 2019, but was subsequently reversed during the quarter ended December 31, 2019.

*Insider Participation in the Private Placement and Exchange*

On July 16, 2020, in connection with the Private Placement and the Exchange, James Sapirstein, President, Chief Executive Officer and Chair of the Board purchased $100,000 worth of Series B Preferred Stock and related Series B Warrants for cash. Mr. Sapirstein received 12.987013 shares of Series B Preferred Stock convertible into 129,871 shares of Common Stock and Series B Warrants for 64,936 shares of Common Stock. Edward J. Borkowski, lead independent director, purchased $250,000 worth of Series B Preferred Stock and related Series B Warrants for cash and exchanged $105,129 of Promissory Notes (including outstanding principal amount and accrued and unpaid interest thereon) for Series B Preferred Stock and related Series B Warrants and Exchange Warrants in the Exchange.

**Note 19 - Employee Benefit Plans**

***401(k) Plan***

Since 2015, the Company has sponsored 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 approximately $92,000 and $92,000 for the years ended December 31, 2020 and 2019, respectively.

**Note 20 – Subsequent Events**

*Amendment to Charter and Approved Reverse Stock Split*

On February 24, 2021, at the Special Meeting of Stockholders ("*Special Meeting*"), the stockholders approved an amendment to the Amended and Restated Certificate of Incorporation (the "*Charter*") to increase the number of authorized shares of Common Stock by 100,000,000 shares to 250,000,000 shares, and to authorize the Board of Directors (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-five (1:5) to one-for-ten (1:10), any time prior to the one-year anniversary date of the Special 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 February 24, 2021, to increase the number of authorized shares of Common Stock to 250,000,000 shares.

*March 2021 Common Stock and Warrant Offering*

On March 7, 2021, the Company entered into a securities purchase agreement (the "*March 2021 Purchase Agreement*") with a single institutional investor, pursuant to which the Company agreed to sell, in a registered direct offering (the "*March 2021 Offering*") priced at the market under Nasdaq rules, (i) 5,800,000 shares of Common Stock, (ii) pre-funded warrants (the "*March 2021 Pre-Funded Warrants*") to purchase up to 2,058,548 shares of Common Stock, with an exercise price of $0.01 per share and no expiration term and (iii) warrants (the "*March 2021 Warrants*") to purchase an aggregate of 3,929,274 shares of Common Stock with an exercise price of $1.21 per share and an expiration term of five years from the date of issuance. The aggregate price per of the March 2021 Offering share was $1.2725.

The aggregate gross proceeds from the March 2021 Offering, which closed on March 10, 2021 (the "*March 2021 Closing Date*"), excluding the net proceeds, if any, from the exercise of the March 2021 Warrants was approximately $10.0 million.

The net proceeds to the Company from the March 2021 Offering, after deducting the placement agent's fees and expenses and estimated offering expenses, was approximately $9.1 million. The Company intends to use the net proceeds to initiate the two niclosamide clinical programs in the first half of 2021, a Phase 2 clinical trial for COVID-19 GI infections and a Phase 1b/2a trial for ICI-AC, respectively, and for other general corporate purposes.

The Company paid the placement agent a cash fee equal to 8.0% of the aggregate gross proceeds received by us in the March 2021 Offering, or approximately $800,000. The Company also agreed to issue to the placement agent or its designees warrants (the "*March 2021 Placement Agent Warrants*") exercisable for up to 550,099 shares of Common Stock, which is equal to 7.0% of the aggregate number of shares of Common Stock placed in the March 2021 Offering. The March 2021 Placement Agent Warrants have substantially the same terms as the March 2021 Warrants, except they are exercisable at $1.5906 per share, or 125% of the effective purchase price per share of Common Stock issued in the March 2021 Offering. The Company also reimbursed the placement agent $35,000 for non-accountable expenses, up to $50,000 for legal fees and expenses and other out-of-pocket expenses and approximately $16,000 for clearing fees.

In the March 2021 Purchase Agreement, the Company agreed not to issue, enter into any agreement to issue or announce the issuance or proposed issuance of, any shares of Common Stock or any securities convertible into or exercisable or exchangeable for shares of Common Stock or file any registration statement or prospectus, or any amendment or supplement thereto for 50 days after the March 2021 Closing Date. In addition, the Company agreed not to effect or enter into an agreement to effect any issuance of Common Stock or any securities convertible into or exercisable or exchangeable for shares of Common Stock involving a variable rate transaction (as defined in the March 2021 Purchase Agreement) until the one-year anniversary of the date of the March 2021 Purchase Agreement, subject to certain exceptions

*Series B Most Favored Nations (MFN) Exchanges*

Under the Certificate of Designations for the Series B Convertible Preferred Stock (the "*Series B Certificate of Designations*"), in the event the Company effects any issuance of Common Stock or Common Stock equivalents for cash consideration, or a combination of units thereof (a "*Subsequent Financing*"), each holder of the Series B Convertible Preferred Stock, par value $0.0001 per share (the "*Series B Preferred Stock*"), has the right to exchange the stated value, plus accrued and unpaid dividends (the "*Exchange Amount*"), of the Series B Preferred Stock for any securities issued in the Subsequent Financing, in lieu of any cash subscription payments therefor (the "*Exchange Right*").

On December 31, 2020, the Company entered into the Series C Purchase Agreement as part of the Registered Direct Offering and Private Placement, and the holders of the Series B Preferred Stock became entitled to exercise their Exchange Right to exchange into the Series C Preferred Stock and related Investor Warrants. As of March 30, 2021, holders of approximately 1,266.92 shares of Series B Preferred Stock with an aggregate Exchange Amount of approximately $9.8 million had previously elected to exercise their Series B Exchange Rights into Series C Preferred Stock, convertible into an aggregate of 13,087,843 shares of Common Stock (which conversion the Company has elected to make in full on February 24, 2021, upon receipt of certain stockholder approvals), and additional Investor

Warrants exercisable for up to an aggregate of 13,087,843 shares of Common Stock. As a result, as of March 30, 2021, the Company may be required to issue up to 13,168.280 additional shares of Series C Preferred Stock that are currently convertible up to 13,168,280 underlying shares of Common Stock, together with Investor Warrants to purchase up to an additional 13,168,280 shares of Common Stock, to any holders of Series B Preferred Stock who elect to exercise their Exchange Right. Any shares of Series C Preferred Stock to be issued pursuant to the Exchange Right would, upon issuance, be immediately converted into underlying shares of Common Stock.

*Exercises of Warrants*

From January 1, 2021 through March 29, 2021, the Company received gross proceeds of approximately $4.6 million from the exercise of warrants to purchase an aggregate of 6,640,588 shares of Common Stock, with exercise prices ranging from $0.001 to $1.42 per share. As of March 29, 201, the Company had 44,930,105 shares of Common Stock issuable upon exercise of outstanding warrants, with a weighted average exercise price of $1.02 per share.