

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 10-K

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

For the fiscal year ended: **December 31, 2019**

OR

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

Commission file number: 000-38418

Cocrystal Pharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware

*(State or Other Jurisdiction of
Incorporation or Organization)*

35-2528215

*(I.R.S. Employer
Identification No.)*

19805 North Creek Parkway Bothell, WA

(Address of Principal Executive Office)

98011

(Zip Code)

Registrant's telephone number, including area code: **(786) 459-1831**

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

| <u>Title of Each Class</u> | <u>Trading Symbol(s)</u> | <u>Name of each exchange on which registered</u> |
|--|--------------------------|--|
| Common Stock, par value \$0.001 per share | COCP | The Nasdaq Stock Market LLC (The Nasdaq Capital Market) |

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 Exchange 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 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 or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

| | | | |
|-------------------------|-------------------------------------|---------------------------|-------------------------------------|
| Large accelerated filer | <input type="checkbox"/> | Accelerated filer | <input type="checkbox"/> |
| Non-accelerated filer | <input checked="" type="checkbox"/> | Smaller reporting company | <input checked="" type="checkbox"/> |
| Emerging growth company | <input type="checkbox"/> | | |

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the closing price as of the last business day of the registrant's most recently completed second fiscal quarter, June 28, 2019, was approximately \$38,555,201.

The number of shares outstanding of the registrant's common stock, as of March 30, 2020, was approximately 52,140,699 shares.

Documents Incorporated by Reference

Portions of the registrant's definitive proxy statement for its 2020 Annual Meeting of Stockholders are incorporated by reference in Items 10, 11, 12, 13, and 14 of Part III of this Annual Report on Form 10-K.

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PART I

Item 1. Business.

Overview

Cocrystal Pharma, Inc. (the “Company” or “Cocrystal”) is a biotechnology company seeking to discover and develop novel antiviral therapeutics as treatments for serious and/or chronic viral diseases. We employ unique structure-based technologies and Nobel Prize winning expertise to create first- and best-in-class antiviral drugs. These technologies are designed to efficiently deliver small molecule therapeutics that are safe, effective and convenient to administer. We have identified promising preclinical and early clinical stage antiviral compounds for unmet medical needs including Hepatitis C virus (“HCV”), influenza virus, coronavirus, and norovirus infections.

The Company operates in one segment. Management uses cash flows as the primary measure to manage its business and does not segment its business for internal reporting or decision-making.

Cocrystal Technology

We are developing antiviral therapeutics that inhibit the essential viral replication function of several viruses. One of our goals is to decrease the duration of HCV therapy by advancing drug candidates targeting the HCV RNA-dependent RNA polymerase enzyme. Additional goals include treating human and avian (bird) influenza virus, coronavirus and norovirus infections by discovering and developing drug candidates targeting the viral replication complex. In the case of coronavirus, we target the protease enzyme that produces the active form of the viral enzymes. To discover and design these inhibitors, we use a proprietary platform comprising computation, medicinal chemistry, X-ray crystallography, and our extensive know-how. We determine the structures of cocrystals containing the inhibitors bound to the enzyme or protein to guide our design. We also use advanced computational methods to screen and design product candidates using proprietary cocrystal structural information. In designing the candidates, we seek to anticipate and avert potential viral mutations leading to resistance. By designing and selecting drug candidates that interrupt the viral replication process and also have specific binding characteristics, we seek to develop drugs that are not only effective against both the virus and possible mutants of the virus, but which also have reduced off-target interactions that cause undesirable clinical side effects. This successful application of our approach requires an extensive knowledge of viruses and drug targets. In addition, knowledge and experience in the fields of structural biology, and enzymology are required. We developed our proprietary structure-based drug design under the guidance of Dr. Roger Kornberg, our Chief Scientist and recipient of the Nobel Prize in Chemistry in 2006. Our drug discovery process focuses on those parts of the enzymes to which drugs bind and on drug-enzyme interactions at the atomic level. Additionally, we have developed proprietary targeted in-house chemical libraries of non-nucleoside inhibitors, metal-binding inhibitors, and drug-like fragments. Our drug discovery process is different from traditional, empirical, medicinal chemistry approaches that often require iterative high-throughput compound screening and lengthy hit-to-lead processes. We continue developing preclinical and clinical drug candidates using our proprietary drug discovery technology.

The Company’s proprietary technology integrates several powerful and specialized techniques:

- (1) Selection of viral drug targets amenable to broad-spectrum antiviral drug development and essential for viral genome replication;
- (2) Atomic resolution 3-D structure determination of drug binding pockets;
- (3) In-depth computational analysis of conservation of drug-binding pockets and critical molecular interactions between antiviral inhibitors and amino acid residues of the target molecule’s drug-binding pocket;
- (4) Cocrystal structure determinations to inform hit identification, hit-to-lead, and lead optimization processes;
- (5) Molecular modeling and computer-guided lead discovery to support rational chemical modifications based on structure-activity relationships, or SAR, of candidate inhibitor compounds;

- (6) Knowledge of enzymatic mechanisms to guide the design of drugs with exceptional affinity, specificity, and broad-spectrum activity; and
- (7) Platforms for rapid identification of antiviral enzyme inhibitors showing broad-spectrum antiviral capability.

We have applied these techniques to develop antiviral inhibitors of four important viruses: HCV, influenza virus, coronavirus and norovirus.

Market-Driven Product Profiles

In all of our programs our goal is to develop best-in-class broad-spectrum antiviral drugs with high-barrier-to-drug resistance. An ideal product for an antiviral therapy would have at least the following characteristics:

- (1) High barrier to viral resistance;
- (2) Effective against all viral subtypes that cause disease;
- (3) Fast onset of action and/or shortened therapeutic time;
- (4) Good safety and tolerability profile; and
- (5) Ease of administration, for example, a pill.

Even at the discovery stage of drug development, we select compounds with these factors in mind. Furthermore, our technology is capable of delivering therapies that satisfy all of these key factors, as detailed below.

High barrier to drug resistance: Drug resistance is a major obstacle to developing effective antiviral therapies. Viruses can reproduce rapidly and in enormous quantities in infected human cells. During viral replication, random changes in the viral genome, called mutations, develop. If such a mutation occurs in a region of the viral genome that is targeted by a given antiviral therapy, that therapy may no longer be effective against the mutated virus. These mutated or “resistant” viruses can freely infect and multiply even in individuals who have received drug treatment. In some cases, resistant virus strains may even predominate. For example, in the 2009 swine influenza pandemic, the predominant strain was resistant to the best available therapies.

The Company’s focus on viral replication proteins can overcome the obstacle of viral resistance. We identify and target critical components of viral replication proteins that are essential for function, therefore, sensitive to change. A mutation in these critical components is likely to inactivate the replication protein and, in turn, render the virus incapable of replicating. Because such mutations cannot propagate, the virus cannot effectively develop resistance to the enzyme inhibitors we employ. We test the effectiveness of our compounds against potential viral mutations and select compounds with the highest barrier to resistance.

Broadly effective against major strains responsible for a viral disease: For any given viral disease, there are different strains of viruses that cause the disease. For example, there are six major strains of the virus known to cause HCV. These strains are termed “genotypes.” Each HCV genotype is common in some parts of the world and rare in others. Also, there are three types of influenza viruses, A, B, and C. Influenza A and B viruses are significant human respiratory pathogens that cause seasonal flu. Influenza A viruses can also cause an influenza pandemic. Influenza C is a subtype of the influenza virus that tends to cause only mild illness and is not responsible for seasonal or pandemic infections. Our goal is to design and develop drug candidates that will be effective on the broadest possible range of viruses causing the disease.

Many antiviral drugs available today are effective only against certain strains of viruses and less effective or not effective at all against other strains. To address this problem, we are developing drug candidates that specifically target viral proteins involved in viral replication. Despite the various strains of virus that may exist, these replication enzymes are essentially identical (highly conserved) among all strains of a given virus. By targeting these conserved replication enzymes, our antiviral compounds are designed and tested to be effective against major virus strains. Replication enzymes are generally conserved not only among subtypes of a given virus but also among many different viruses, creating an opportunity for the development of broad-spectrum antiviral drugs.

Fast onset of action: In order to improve patient care and penetrate the HCV marketplace, drugs are needed with faster onset of viral load reduction resulting in shorter treatment time. Current and known future influenza treatments shorten symptoms by only about 24 hours.

Coronavirus and norovirus spread readily among the affected population and both are in need of a fast-acting therapeutic intervention. During the discovery and development phases we focus on this important clinical variable.

Safety and tolerability: All drugs have side effects, also referred to as adverse effects. These usually result from a drug's ability to bind to human molecules (usually proteins). When this interaction is intentional (i.e., part of the drug's mechanism of action), the adverse effects are classified as on-target effects. When this interaction is unintentional (i.e., resulting from the drug's interaction with an unintended human molecule), the effects are called off-target effects. Our inhibitors target viral replication enzymes, which are generally unique to viruses. Because the targets are viral, not human, minimal adverse effects are possible. During the discovery phase, we evaluate candidate compounds for potential cross-reactivity with human replication enzymes and attempt to eliminate those compounds that are cross-reactive with humans.

Ease of administration: We select compounds for development that can be administered orally, preferably once daily in pill-form.

Research and Development Update

During the year ended December 31, 2019 the Company focused its research and development efforts primarily in three areas:

Hepatitis C

CC-31244, our HCV Non-Nucleoside Polymerase Inhibitor ("NNI"), is a potential best-in-class pan-genotypic inhibitor of NS5B polymerase for the treatment of HCV infection. It has the potential to be an important component in an all-oral ultra-short HCV combination therapy. The Company filed an Investigational New Drug ("IND") application with the U.S. Food and Drug Administration ("FDA") on February 28, 2018 and received notice from the FDA on March 29, 2018 that its IND was now open and the Company was cleared to initiate its Phase 2a clinical study evaluating CC-31244 for the treatment of HCV infected individuals.

In June 2018, the Company began enrollment in and initiation of patient dosing in its Phase 2a clinical study evaluating CC-31244 for the treatment of HCV infected individuals and completed the enrollment in September 2018. The Phase 2a open-label study was designed to evaluate the safety, tolerability and preliminary efficacy of CC-31244 in combination with Eplclusa, an approved HCV drug. Patients are treated with CC-31244 and Eplclusa for two weeks and then Eplclusa alone for an additional four weeks.

On January 22, 2019 the Company announced safety and preliminary efficacy data for the Phase 2a study. All subjects had completed the six-week treatment regimen. The treatment was well tolerated with no study discontinuations due to adverse events. Eight of 12 subjects achieved the primary efficacy endpoint of sustained virologic response at 12 weeks after completion of treatment (SVR12). SVR12 is defined as undetectable virus in blood 12 weeks after completion of treatment and is considered a virologic cure. The trial is completed at the Institute of Human Virology, University of Maryland School of Medicine and the final study report is completed.

In addition, in October 2018, the Company signed a Clinical Trial Agreement for an investigator-initiated study with the Humanity & Health Research Centre ("HHRC") in Hong Kong, China. Due to unrest in Hong Kong and the coronavirus pandemic, the clinical trial agreement has been terminated effective March 24, 2020.

In December 2018, the Company voluntarily terminated a license agreement with Emory University covering the patents and patent applications for HCV inhibitors, which are not essential to our HCV program. See “Item 1 - Business – Collaborations – Emory University Collaboration” for further information.

The Company is in partnership discussions for further clinical development of CC-31244.

Influenza infections

We have several preclinical candidates under development for the treatment of influenza infection. CC-42344, a novel PB2 inhibitor, has been selected as a preclinical lead. This candidate binds to a highly conserved PB2 site of influenza polymerase complex (PB1: PB2: PA) and exhibits a novel mechanism of action. CC-42344 showed excellent antiviral activity against influenza A strains, including avian pandemic strains and Tamiflu resistant strains, and has favorable pharmacokinetic and drug resistance profiles. We are currently conducting additional preclinical IND enabling studies and plan to initiate a Phase 1 study during 2021.

In addition, novel inhibitors effective against both strains A and B have been identified and are in the preclinical stage. Several of these have potencies approaching single digit nanomolar. On January 2, 2019, the Company entered into an Exclusive License and Research Collaboration Agreement (the “Collaboration Agreement”) with Merck Sharp & Dohme Corp. (“Merck”) to discover and develop certain proprietary influenza A/B antiviral agents. See “Item 1 – Business – Collaborations – Merck Collaboration” for more information.

Coronavirus infections

On February 24, 2020 the Company announced that it had entered into a license agreement with Kansas State University Research Foundation (“KSURF”) to further develop certain proprietary broad-spectrum antiviral compounds for the treatment of Norovirus and Coronavirus infections.

Under the terms of the agreement, Cocystal has been granted an exclusive, royalty-bearing right and license to certain antiviral compounds for humans covered by KSURF’s patents. Cocystal intends to pursue research and development of these antiviral compounds, including preclinical and clinical development. This license advances the Company’s antiviral programs significantly by providing potent compounds for further development.

Norovirus Infections

We continue to identify and develop non-nucleoside polymerase inhibitors using the Company’s proprietary structure-based drug design technology platform. In addition, we now have exclusive rights to norovirus protease inhibitors for use in humans obtained in the license from Kansas State University Research Foundation (see under Collaborations below).

Therapeutic Targets

Hepatitis C: A large competitive market with opportunity for shorter treatment regimens

HCV is a highly competitive and changing market. Currently, the standard treatment varies with the genotype of the HCV infection. Prior to late 2013, treatment included peginterferon alpha and ribavirin, along with a protease inhibitor (either telaprevir, boceprevir, or simeprevir). In late 2013, sofosbuvir, a drug belonging to a new class of drugs called “nucleoside analogs” or “Nucs,” was approved to treat HCV. In patients infected with HCV genotype 1 (the most common HCV genotype in the US), sofosbuvir was administered in combination with peginterferon alpha and ribavirin. In patients with HCV genotypes 2 and 3, however, sofosbuvir could be effectively administered in combination with ribavirin, without the need for peginterferon alpha. Since 2014, several new combinations of direct-acting antiviral agents (“DAAs”) have been approved for the treatment of HCV infection. These include Harvoni (sofosbuvir/ledipasvir) 12 weeks of treatment, Viekira Pak (ombitasvir/paritaprevir/ritonavir, dasabuvir) 12 weeks of treatment, Epclusa (sofosbuvir/velpatasvir) 12 weeks of treatment, Zepatier (elbasvir/grazoprevir) 12 weeks of treatment and Mavyret (glecaprevir/pibrentasvir) 8 weeks of treatment. We believe the next improvements in HCV treatment will be ultra-short treatments of four to six weeks, the goal of our program.

We anticipate a significant global HCV market opportunity that will persist through at least 2036, given the large prevalence of HCV infection worldwide. The 2017 World Health Organization Global Hepatitis Report estimates that 71 million people worldwide have chronic HCV infections.

We are targeting the NS5B polymerase with an NNI, which could be developed as part of an all-oral, pan-genotypic combination regimen. Our focus is on developing what is now called ultrashort treatment regimens from 4 to 6 weeks in length. Such a combination treatment CC-31244 with different classes of approved DAAs has the potential to change the paradigm of treatment for HCV with a shorter duration of treatment. Combination strategies with approved drugs could allow us to expand CC-31244 into the HCV antiviral therapeutic area globally and could lead to a high and fast cure rate, to improved compliance, and to reduced treatment duration. To our knowledge no competing company has yet developed a short HCV treatment of less than 8 weeks with a high (>95%) sustained virologic response (SVR) at week 12.

CC-31244, an HCV NNI, is a potential best in class pan-genotypic inhibitor of NS5B polymerase for the treatment of HCV. The Company completed a Phase 1a/b study in Canada in September 2016, with favorable safety results in a randomized, double-blinded, Phase 1a/b study in healthy volunteers and HCV-infected subjects. The Company has completed a Phase 2a study in HCV genotype 1 subjects in the United States. Cocrystal presented the interim results from the Phase 1a/b study at the APASL in February 2017. HCV-infected subjects treated with CC-31244 had a rapid and marked decline in HCV RNA levels, and slow viral rebound after treatment. Results of this study suggest that CC-31244 could be an important component in a shortened duration all-oral HCV combination therapy. Patient enrollment has been completed in the Phase 2b. See “Item 1 – Business – Research and Development Update – Hepatitis C” for more information.

The Company is seeking a partner for further clinical development of CC-31244.

Influenza: A worldwide public health problem, including the potential for pandemic disease

Influenza is a severe respiratory illness, caused primarily by influenza A or B virus. The Centers for Disease Control and Prevention (the “CDC”) estimates that influenza was linked to approximately 79,000 deaths and 960,000 hospitalizations in the United States during the 2017-2018 flu season. According to the report published by BCC Research in May 2018, the worldwide market for antiviral drugs to treat influenza was valued at approximately \$5.6 billion in 2017 and is expected to grow to \$6.5 billion by 2022.

Currently, approved antiviral treatments for influenza are effective, but burdened with significant viral resistance. Strains of influenza virus that are resistant to the approved treatments oseltamivir phosphate (Tamiflu(R)) and zanamavir (Relenza(R)) have appeared, and in some cases predominate. For example, the predominant strain of the 2009 swine influenza pandemic was resistant to Tamiflu. These drugs target viral neuraminidase enzymes, which are not highly conserved between viral strains. In fact, different influenza virus strains such as H1N1 and H5N1 are named according to their respective differences in hemagglutinin (H) and neuraminidase (N).

In addition, the Company has several preclinical candidates under development for the treatment of influenza infection. CC-42344, a novel PB2 inhibitor, has been selected as a preclinical lead. This candidate binds to a highly conserved PB2 site of the influenza polymerase complex (PB1: PB2: PA), and exhibits a novel mechanism of action. CC-42344 showed excellent antiviral activity against influenza A strains, including avian pandemic strains and Tamiflu-resistant strains, and has a favorable pharmacokinetic profile. Antiviral product candidates that are competitors for the Company’s influenza programs are, VX-787, being developed by Janssen, and S-033188, being developed by Shionogi/Roche. S-033188 was approved as Xofluza in Japan on February 23, 2018, and in the US as baloxavir marboxil (trade name Xofluza®) on October 24, 2018. See “Item 1 – Business – Research and Development Update – Influenza” for more information.

Coronavirus: The World Health Organization (WHO) has recently declared COVID-19 a pandemic.

On March 11, 2020 the World Health Organization classified the coronavirus disease 2019 (COVID-19), a pandemic. This announcement followed the rapid worldwide rise of infected individuals after the initial identification of pneumonia associated with an unknown virus in China in December 2019, later determined to be caused by infection with the virus named SARS-CoV-2.

Coronaviruses (CoV) are a large family of viruses that historically have been associated with illness ranging from mild symptoms similar to the common cold to more severe respiratory disease. Infection with the novel SARS-CoV-2 has been associated with a wide range of responses, from no symptoms to more severe disease that has included pneumonia, severe acute respiratory syndrome, kidney failure, and death. The incubation period for SARS-CoV-2 is believed to be within 14 days after exposure, with most illness occurring within about 5 days after exposure. The ability of someone with no symptoms to transmit infection to another person has heightened the public health challenge of COVID-19.

There is currently no treatment recommended for COVID-19 or shown to be effective against other coronaviruses. We are aggressively pursuing the development of novel antiviral compounds for the treatment of coronavirus infections using our established proprietary drug discovery platform. By targeting the viral replication enzymes and protease, we believe it is possible to develop an effective treatment for all coronavirus diseases including COVID-19, Severe Acute Respiratory Syndrome (SARS), and Middle East Respiratory Syndrome (MERS) - coronaviruses.

Norovirus: A worldwide public health problem responsible for close to 90% of epidemic, non-bacterial outbreaks of gastroenteritis around the world

Norovirus is a very common and highly contagious virus that causes symptoms of acute gastroenteritis including nausea, vomiting, stomach pain and diarrhea. Other symptoms include fatigue, fever and dehydration. Noroviruses are a major cause of gastrointestinal illness in closed and crowded environments, having become notorious for their common occurrence in hospitals, nursing homes, child care facilities, and cruise ships. In the United States alone, noroviruses are the most common cause of acute gastroenteritis, and are estimated to cause 20 million illnesses each year and contribute to 70,000 hospitalizations and 800 deaths. Noroviruses are responsible for up to 1.1 million hospitalizations and 218,000 deaths annually in children in the developing world. In immunosuppressed patients, chronic norovirus infection can lead to a debilitating illness with extended periods of nausea, vomiting and diarrhea. There is currently no effective treatment or effective vaccine for norovirus, and the ability to curtail outbreaks is limited. A few companies, including Chimerix, are developing antiviral treatments for this disease and three candidate vaccines are currently in early stages of clinical testing by GlaxoSmithKline, Ligocyte and Takeda Pharmaceuticals.

By targeting viral replication enzymes and a viral protease, we believe it is possible to develop an effective treatment for all genogroups of norovirus. Also, because of the significant unmet medical need and the possibility of chronic norovirus infection in immunocompromised individuals, new antiviral therapeutic approaches may warrant an accelerated path to market. The Company is developing inhibitors of the RNA-dependent RNA polymerase of norovirus. Similar to the HCV polymerases, this enzyme is essential to viral replication and is highly conserved between all noroviral genogroups. Therefore, an inhibitor of this enzyme might be an effective treatment or short-term prophylactic agent, when administered during a cruise or nursing home stay, for example. We have developed X-ray quality norovirus polymerase and protease crystals and have identified promising inhibitors. We are implementing the platform and approaches that have proven successful in our other antiviral programs.

Possible Effects of COVID-19

While our administrative and finance activities are fully functional by our providing services from remote locations, our research laboratory is located in Bothell, Washington. In his latest State of Emergency Proclamation, the Washington Governor issued a “Stay Home Stay Healthy Order”, the effect of which includes shutting all non essential businesses until April 6th. Our research laboratory is not an essential business which means our team of scientists can not access our laboratory. While they can continue to work from home and carry out other duties, we estimate that by some time shortly after April 6th without access to our laboratory, our ongoing research will be suspended. This will affect our research programs if the Order is extended. For further information on COVID-19 risks, see Item 1A. “Risk Factors.”

Intellectual Property

Our success depends, in part, upon our ability to protect our core technology. To establish and protect our proprietary rights, we rely on a combination of patents, patent applications, trademarks, copyrights, trade secrets and know-how, license agreements, confidentiality procedures, non-disclosure agreements with third parties, employee disclosure and invention assignment agreements, and other contractual rights.

Our patent portfolio consists of issued patents and pending applications in the areas primarily related to the treatment of disease associated with HCV, Influenza A, Influenza B, and Norovirus/Coronavirus.

In our HCV program, our patent portfolio consists of various patent families, with granted patents in the U.S. and Europe, as well as China, Canada, Eurasia, Japan, and Singapore. Applications are pending in numerous other jurisdictions, including a pending PCT application.

In our Influenza A program, our patent portfolio consists of various patent families, including pending international (PCT) applications and one family of pending applications in the U.S. and various foreign countries. Aspects of this program are developed in collaboration with Merck.

In our Influenza A/B program, our patent portfolio consists of a number of patent families pending, variously, as international (PCT) applications and in Taiwan.

In our Norovirus and Coronavirus programs, our patent portfolio consists of a pending U.S. provisional application, and patent families licensed from Kansas State University Research Foundation.

Collaborations

Merck Collaboration

On January 2, 2019, we entered into an Exclusive License and Research Collaboration Agreement (the “Collaboration Agreement”) with Merck to discover and develop certain proprietary influenza A/B antiviral agents.

Under the terms of the Collaboration Agreement, Merck is funding research and development for the program at Cocrystal and Merck, including clinical development at Merck, and Merck is responsible for worldwide commercialization of any products derived from the collaboration. The Company received an upfront payment of \$4,000,000 and is eligible to receive milestone payments related to designated development, regulatory and sales milestones with the potential to earn up to \$156,000,000, as well as royalties on product sales. The Collaboration Agreement operates under a Research Operating Plan (ROP) which includes goals for both organizations. The Company has achieved anticipated goals in 2019.

See “Item 1A. Risk Factors - If our research collaboration with Merck is terminated or is otherwise unsuccessful, including failure to reach milestones, we could lose the research program funding, and would not receive milestone payments or royalties, which could materially and adversely affect our business, our ability to successfully develop and commercialize influenza A/B product candidates and our future financial condition” for the discussion of termination provisions of the Collaboration Agreement.

Kansas State University Research Foundation

On February 18, 2020, Cocrystal Pharma, Inc. (the “Company”) entered into a License Agreement (the “Agreement”) with Kansas State University Research Foundation (the “Foundation”) effective February 12, 2020.

Pursuant to the terms of the Agreement, the Foundation granted the Company an exclusive royalty bearing license for human use to practice under certain patent rights, including a patent and a patent application covering antivirals against coronaviruses and norovirus, and related know-how, to make and sell therapeutic, diagnostic and prophylactic products.

The Company agreed to pay the Foundation a one-time non-refundable license initiation fee of \$80,000 and an annual license maintenance fee of \$20,000 per year, and agreed to reimburse the Foundation for third party expenses associated with the filing, prosecution and maintenance of the patent rights in question. The Company also agreed to make certain future milestone payments up to \$3.1 million, dependent upon the progress of clinical trials, regulatory approvals, and initiation of commercial sales in the United States and certain countries outside the United States.

The Agreement will remain in effect until the expiration of the patent rights covered by the Agreement, unless earlier terminated pursuant to customary terms.

Emory University Collaboration

On December 6, 2018, we notified Emory University (“Emory”) of the termination of our License Agreement with Emory, dated March 7, 2013 (the “License Agreement”). The License Agreement covered patents and patent applications for HCV inhibitors, which we no longer consider essential to our HCV program. As part of our HCV program, we continue to focus our efforts on CC-31244, our HCV NNI. See “Item 1 – Business – Research and Development Update – Hepatitis C.” The Company had the right to terminate the License Agreement at its sole discretion upon 90 days’ prior written notice and upon payment of all amounts due Emory under the License Agreement through the date of termination. As of the date of this Annual Report on Form 10-K, the License Agreement has been terminated, no amounts were due under the License Agreement and none will be owed in the future.

Competition

The biotechnology and pharmaceutical industries are subject to intense and rapidly changing competition as companies seek to develop new technologies and proprietary products. We know of several companies that have marketed or are developing products for the treatment of HCV or influenza, including Roche, Gilead Sciences, Inc. (“Gilead”), Merck & Co., Janssen Pharmaceuticals, Inc., Bristol-Myers Squibb, Toyama Chemical Co., Shionogi/Roche and Abbvie, Inc. In particular, Gilead and Abbvie dominate the market for HCV with an estimated combined market share greater than 85%. Their products are widely considered effective. Many of the companies developing products for the other viral diseases that are of interest to us have substantially greater financial resources, expertise and capabilities than we do.

Government Regulation

Government authorities extensively regulate the research, development, testing, manufacturing and commercialization of drug products. Any product candidates we develop must be approved by the U.S. Food and Drug Administration (“FDA”) before they may be legally marketed in the U.S., and by the appropriate foreign regulatory agencies before they may be legally marketed in other countries. The clinical testing of product candidates to establish their safety and efficacy in humans is subject to substantial statutory and regulatory requirements with which we must comply.

Employees

As of December 31, 2019, we employed 11 full-time employees. Of these full-time employees, eight are engaged in research and development activities. In addition, we have contracts with Clinical Research Organizations (“CROs”), Contract Manufacturing Organizations (“CMOs”) and consultants to provide chemistry, toxicology, preclinical, clinical, and regulatory work on our programs.

Corporate History

The Company was formerly incorporated in Nevada under the name Biozone Pharmaceuticals, Inc. (“Biozone”). On January 2, 2014, Biozone sold substantially all of its assets to MusclePharm Corporation, and, on the same day, merged with Cocrystal Discovery, Inc. (“Discovery”) in a transaction accounted for as a reverse merger. Following the merger, the Company assumed Discovery’s business plan and operations. On March 18, 2014, the Company reincorporated in Delaware under the name Cocrystal Pharma, Inc.

On November 25, 2014, a subsidiary of the Company and affiliated entities completed a series of merger transactions. As a result, a subsidiary of the Company merged with RFS Pharma, LLC, a Georgia limited liability company (RFS Pharma”).

Available Information

Our corporate website is www.cocrystalpharma.com. We make available on our website under “Investors – SEC Filings” access to 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 amendments to those materials filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), free of charge.

Item 1A. Risk Factors.

You should consider carefully the following risk factors, together with all of the other information included or incorporated in this Annual Report. Each of these risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, and adversely affect the value of an investment in our common stock. There may be additional risks that we do not know of or that we believe are immaterial that could also impair our business and financial position.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors before deciding whether to invest in the Company. If any of the events discussed in the risk factors below occur, our business, financial condition, results of operations or prospects could be materially and adversely affected. In such case, the value and marketability of our common stock could decline.

RISKS RELATED TO OUR FINANCIAL CONDITION AND NEED FOR ADDITIONAL CAPITAL

We have never generated revenue from product sales and expect that due to the regulatory constraints on a drug development company with products in the pre-clinical and early clinical stages, we may never generate revenue from product sales and may continue to incur significant losses for the foreseeable future.

We are a pre-clinical and early stage clinical, biopharmaceutical discovery and development company. From inception until 2016, our operations were limited to organizing and staffing the Company, acquiring and developing intellectual property rights, developing our technology platform, undertaking basic research on viral replication enzyme targets and conducting preclinical studies for our initial programs. We currently have only one product candidate which has completed a Phase 2a clinical trial. Because of the need to complete clinical trials, establish safety and efficacy and obtain regulatory approval, which is an expensive and time-consuming process, we do not anticipate generating revenue from product sales for at least five years and will continue to sustain considerable losses. We may develop a partnership that could generate income sooner, but there is no guarantee that will be achievable.

To date, we have devoted the majority of our financial resources to research and development. We have financed our operations primarily through the sale of equity securities and entering into research collaborations. The results of our operations will depend, in part, on the rate of future expenditures and our ability to obtain funding through equity or debt financings, strategic alliances or grants. We anticipate our expenses will increase substantially if and as we continue our research and clinical and preclinical development of our product candidates. We anticipate that if we continue to undertake clinical studies our expenses will increase even further.

We have lost \$235 million from inception through December 31, 2019 and expect to continue losing money in the future. We may never achieve income from operations or have positive cash flow from operations.

As an early stage drug development company, our focus is on developing product candidates, obtaining regulatory approvals and commercializing pharmaceutical products. As a result, we have lost \$235 million from inception through December 31, 2019, expect losses to continue, and have never generated revenue from product sales. It is likely that we will need to raise money again in the future. We cannot assure you that we will ever generate income from operations or have positive cash flow from operations.

Because we have yet to generate any revenue from product sales on which to evaluate our potential for future success and to determine if we will be able to execute our business plan, it is difficult to evaluate our future prospects and the risk of success or failure of our business.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with partners, to successfully complete the development of, obtain the regulatory approvals for and commercialize pharmaceutical product candidates. We have no pharmaceutical product candidates that have generated any commercial revenue, do not expect to generate revenues from the commercial sale of pharmaceutical products for many years, and might never generate revenues from the sale of pharmaceutical products. Our ability to generate revenue and achieve profitability will depend on, among other things, the following:

- identifying and validating new therapeutic strategies;

- entering into collaborations with large pharmaceutical or biotechnology companies, similar to our recently announced Collaboration Agreement with Merck;
- completing our research and preclinical development of pharmaceutical product candidates;
- initiating and completing clinical trials for pharmaceutical product candidates;
- seeking and obtaining regulatory marketing approvals for pharmaceutical product candidates that successfully complete clinical trials;
- establishing and maintaining supply and manufacturing relationships with third parties;
- launching and commercializing pharmaceutical product candidates for which we obtain regulatory marketing approval, with a partner or, if launched independently, successfully establishing a sales force, marketing and distribution infrastructure;
- maintaining, protecting, enforcing, defending and expanding our intellectual property portfolio; and
- attracting, hiring and retaining qualified personnel.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we cannot predict the timing or amount of increased expenses and when we will be able to achieve or maintain profitability, if ever. Our expenses could increase beyond expectations if we are required by regulatory agencies to perform unanticipated studies and trials.

Even if one or more pharmaceutical product candidates we independently develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved pharmaceutical product candidate. Moreover, even if we can generate revenues from the sale of any approved pharmaceutical products, we may not become profitable and may need to obtain additional funding to continue operations.

Because early stage drug development requires major capital investment, as we continue to incur operating losses, we will need to raise additional capital or form strategic partnerships to support our research and development activities in the future.

We are still in the early stages of development of our product candidates and have no products approved for commercial sale. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is capital-intensive. As a rule, research and development expenses increase substantially as we advance our product candidates toward clinical programs. We currently have one hepatitis C product candidate that has completed a Phase 2a clinical trial and have secured funding of the research and development of influenza A/B product candidates under our Collaboration Agreement with Merck. See “Item 1 – Business – Collaborations – Merck Collaboration.” However, in order to conduct trials for our other product candidates, we will need to raise additional capital to support our operations or form partnerships, in addition to our existing collaborative alliances, which may give substantial rights to a partner. Such funding or partnerships may not be available to us on acceptable terms, or at all. Moreover, any future financing may be very dilutive to our existing stockholders.

As we move lead compounds through toxicology and other preclinical studies, also referred to as nonclinical studies, we have and we will be required to file an Investigational New Drug application (“IND”) or its equivalent in foreign countries, and as we conduct clinical development of product candidates, we may have adverse results that may cause us to consume additional capital. Our partners may not elect to pursue the development and commercialization of our product candidates subject to our respective agreements with them. These events may increase our development costs more than we expect. We may need to raise additional capital or otherwise obtain funding through strategic alliances if we initiate clinical trials for new product candidates other than programs currently partnered. We will require additional capital to obtain regulatory approval for, and to commercialize, product candidates.

In securing additional financing, such additional fundraising efforts may divert our management's attention from our day-to-day activities, which may adversely affect our ability to develop and commercialize product candidates. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we cannot raise additional capital when required or on acceptable terms, we may be required to:

- significantly delay, scale back or discontinue the development or commercialization of any product candidates;
- seek strategic alliances for research and development programs at an earlier stage than otherwise would be desirable or on terms less favorable than might otherwise be available; or
- relinquish or license on unfavorable terms, our rights to technologies or any product candidates we otherwise would seek to develop or commercialize ourselves.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing development and commercialization efforts, which will have a material adverse effect on our business, operating results and prospects or may render the Company unable to continue operations.

Because, we are unable to rely on certain exemptions from registration under the federal securities laws, as the result of a “disqualifying event” involving a director of the Company, it could materially and adversely affect our ability to obtain future financing.

On January 10, 2019, Dr. Frost, one of our directors, was permanently enjoined from violating a certain anti-fraud provision of the Securities Act of 1933, future violations of Section 13(d) of the Exchange Act and Rule 13d-1(a) thereunder, and participating in penny stock offerings with certain exceptions. So long as Dr. Frost is a director, the Company will be unable to rely on certain exemptions from registration including the exemptions under Regulation A and Rule 506 promulgated under the Securities Act absent a waiver issued by the Securities and Exchange Commission (the “SEC”). We have not applied for a waiver, and even if we do, the SEC may choose not to grant us a waiver. While there is a statutory exemption for private placements under Section 4(a)(2) of the Securities Act, the absence of the Rule 506 safe harbor under Regulation D could adversely affect our ability to raise necessary financing in the future on terms favorable to us, or at all.

Because of the unknown impact from the COVID-19 virus, it may have unanticipated material adverse effects upon us.

The United States and global impact from the COVID-19 virus may have a material adverse effect on us in a number of ways including:

- If our scientists and other personnel (or their family members) are infected with the virus, it may hamper our ability to engage in ongoing research activities;
- Similarly, we rely on third parties who can be similarly impacted;
- If these third parties are affected by COVID-19, they may focus on other activities which they may devote their limited time to other priorities rather than to our joint research;
- We may experience a shortage of laboratory materials which would impact our research activities;
- As a result of the continuing impact of the virus, we may fail to get access to third party laboratories which would impact our research activities; and
- We may sustain problems due to the serious short-term and possible longer term serious economic disruptions as our economy faces unprecedented uncertainty.

RISKS RELATED TO OUR RELIANCE ON THIRD PARTIES

We will depend substantially on Merck for the successful research, development and commercialization of our influenza A/B product candidates.

In January 2019, we entered into the Collaboration Agreement with Merck to research, develop, and commercialize certain proprietary influenza A/B antiviral agents. See “Item 1 – Business – Collaborations – Merck Collaboration” for more information on the Collaboration Agreement. The success of this collaborative alliance will depend substantially on the efforts and activities of Merck. Pursuant to the Collaboration Agreement, in case the joint research committee overseeing the research program cannot reach an agreement, the ultimate decision-making authority is vested in Merck as to most matters. Furthermore, Merck will be solely responsible for the development and commercialization of any products derived from the collaboration.

In addition, during the term of the research program and for a period of 12 months following the expiration or termination of the research program under the Collaboration Agreement, we have agreed to work exclusively with Merck on the research and development of influenza A/B antiviral agents. During the term of the Collaboration Agreement, we will be unable to conduct, or enable third parties to conduct, research, development and commercialization activities related to such agents. These restrictions may impair our ability to pursue research, development and commercialization opportunities that we would otherwise deem to be beneficial to our business.

If our research collaboration with Merck is terminated or is otherwise unsuccessful, including failure to reach milestones, we could lose the research program funding, and would not receive milestone payments or royalties, which could materially and adversely affect our business, our ability to successfully develop and commercialize influenza A/B product candidates and our future financial condition.

Pursuant to the terms of the Collaboration Agreement, Merck agreed to, among other things, (i) fund the research and development collaboration, including clinical development and commercialization; (ii) make certain milestone payments up to a total of \$156 million, including payments associated with the successful product development and attainment of certain U.S. and EU regulatory approvals for the developed products and sales volume; and (iii) pay royalties on net sales of the products.

Merck can terminate the Collaboration Agreement at any time prior to the first commercial sale of the first product developed under the Collaboration Agreement, in its sole discretion, without cause. Furthermore, research collaborations, including the Collaboration Agreement, may turn out to be unsuccessful and are subject to certain risks, including the following risks:

- disagreements with Merck resulting in delays or termination of the research, development or commercialization of product candidates, or litigation;
- change the focus by Merck of its development and commercialization efforts;
- failure by Merck to commit sufficient resources to the testing, marketing, distribution or development of product candidates; and
- development by Merck of alternative products either on its own or in collaboration with others, or conflicts of interest or changes in business strategy or other business issues, which could adversely affect its willingness or ability to fulfill their obligations to us.

If our collaboration with Merck is unsuccessful for these or other reasons, or is otherwise terminated for any reason, we may lose the research program funding, and would not receive the milestone payments or royalties under the Collaboration Agreement.

Further, pursuant to the Collaboration Agreement Merck will only be obligated to make many of the milestone payments if our influenza A/B product receives required regulatory approvals, is commercialized and net sales exceed the thresholds set forth in the Collaboration Agreement. Achieving the milestones may be difficult and time-consuming. If some or all of these goals are not achieved, we may not receive some or all of the milestone payments under the Collaboration Agreement.

Any of the foregoing could have a material adverse effect on our business, our ability to successfully develop and commercialize influenza A/B product candidates and our future financial condition.

If we form strategic alliances which are unsuccessful or are terminated, we may be unable to develop or commercialize certain product candidates and we may be unable to generate revenues from our development programs.

In addition to the Collaboration Agreement with Merck, we are likely to use third-party alliance partners for financial, scientific, manufacturing, marketing and sales resources for the clinical development and commercialization of certain of our product candidates. These strategic alliances will likely constrain our control over development and commercialization of our product candidates, especially once a candidate has reached the stage of clinical development. Our ability to recognize revenues from successful strategic alliances may be impaired by several factors including:

- a partner may shift its priorities and resources away from our programs due to a change in business strategies, or a merger, acquisition, sale or downsizing of its company or business unit;
- a partner may cease development in therapeutic areas which are the subject of our strategic alliances;
- a partner may change the success criteria for a program or product candidate delaying or ceasing development of such program or candidate;
- a significant delay in initiation of certain development activities by a partner could also delay payment of milestones tied to such activities, impacting our ability to fund our own activities;
- a partner could develop a product that competes, either directly or indirectly, with an alliance product;
- a partner with commercialization obligations may not commit sufficient financial or human resources to the marketing, distribution or sale of a product;
- a partner with manufacturing responsibilities may encounter regulatory, resource or quality issues and be unable to meet demand requirements;
- a partner may exercise its rights under the agreement to terminate a strategic alliance, including termination without cause;
- a dispute may arise between us and a partner concerning the research, development or commercialization of a program or product candidate resulting in a delay in milestones, royalty payments or termination of a program and possibly resulting in costly litigation or arbitration which may divert management attention and resources; and
- a partner may use our proprietary information or intellectual property to invite litigation from a third-party or fail to maintain or prosecute intellectual property rights possibly jeopardizing our rights in such property.

Termination of a strategic alliance may require us to seek out and establish alternative strategic alliances with third-party partners. This may not be possible, including due to restrictions under the terms of our existing collaborations, or we may not be able to do so on terms acceptable to us. See “Item 1A – Risk Factors – We will depend substantially on Merck for the successful research, development and commercialization of our influenza A/B product candidates.” If we fail to establish alternative strategic alliances with third-party partners on terms acceptable to us, or at all, we may be required to limit the size or scope of one or more of our programs or decrease our expenditures and seek additional funding by other means. Such events would likely have a material adverse effect on our results of operations and financial condition.

We expect to rely on third parties to conduct some or all aspects of our compound formulation, research and preclinical testing, and those third parties may not perform satisfactorily.

We do not expect to independently conduct most and certainly not all aspects of our drug discovery activities, compound formulation research or preclinical testing of product candidates. We rely and expect to continue to rely on third parties to conduct some aspects of our preclinical testing and on third-party Clinical Research Organizations (“CROs”) to conduct clinical trials.

If these third parties terminate their engagements, we will need to enter into alternative arrangements which would delay our product development activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. If in the future, we elect to develop and commercialize any product candidates on our own, we will remain responsible for ensuring that each of our IND-enabling preclinical studies and clinical trials are conducted under the respective study plans and trial protocols. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies under regulatory requirements or our stated study plans and protocols, we will not be able to complete, or may experience delays in completing, the necessary clinical trials and preclinical studies to enable us or our partners to select viable product candidates for IND submissions and will not be able to, or may be delayed in our efforts to, successfully develop and commercialize such product candidates.

Because we intend to rely on third-party manufacturers to produce our preclinical and clinical supplies, and commercial supplies of any approved product candidates, we will be subject to a variety of risks.

Our reliance on third-party manufacturers to develop products and our anticipated reliance on third-party manufacturers to produce products we may develop in the future entail risks to which we would not be subject if we supplied the materials needed to develop and manufacture our product candidates ourselves, including:

- the inability to meet any product specifications and quality requirements consistently;
- a delay or inability to procure or expand sufficient manufacturing capacity;
- discontinuation or recall of reagents, test kits, instruments, and other items used by us in the development, testing, and potential commercialization of products;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- a failure to comply with cGMP and similar foreign standards;
- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or that is costly or damaging to us;
- the reliance on a few sources, and sometimes, single sources for raw materials, such that if we cannot secure a sufficient supply of these product components, we cannot manufacture and sell product candidates in a timely fashion, in sufficient quantities or under acceptable terms;
- the lack of qualified backup suppliers for any raw materials currently purchased from a single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier;
- carrier disruptions or increased costs beyond our control;

- misappropriation of our proprietary technology for the purpose of manufacturing a “generic” version of our product or sale of our product to organizations that distribute and sell counterfeit goods, including drugs; and
- failing to deliver products under specified storage conditions and in a timely manner.

These events could lead to clinical study delays or failure to obtain regulatory approval or impact our ability to successfully commercialize future products. Some of these events could be the basis for regulatory actions, including injunction, recall, seizure or total or partial suspension of production.

Because we expect to rely on limited sources of supply for the drug substance and drug product of product candidates, any disruption in the chain of supply may cause a delay in developing and commercializing these product candidates.

We intend to establish manufacturing relationships with a limited number of suppliers to manufacture raw materials, the drug substance, and the drug product of any product candidate for which we are responsible for preclinical or clinical development. Each supplier may require licenses to manufacture such components if such processes are not owned by the supplier or in the public domain. As part of any marketing approval, a manufacturer and its processes must be qualified by the FDA or foreign regulatory authorities prior to commercialization. If supply from the approved vendor is interrupted, there could be a significant disruption in commercial supply. An alternative vendor would need to be qualified through an NDA or marketing authorization supplement, which could cause further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if a new supplier is relied upon for commercial production.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of drug substance or drug product on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

Manufacturing issues may arise that could increase product and regulatory approval costs or delay commercialization.

As third parties scale up manufacturing of product candidates and conduct required stability testing, product, packaging, equipment and process-related issues may require refinement or resolution to proceed with any clinical trials and obtain regulatory approval for commercial marketing. We or the manufacturers may identify significant impurities or stability problems, which could cause discontinuation or recall by us or our manufacturers, increased scrutiny by regulatory agencies, delays in clinical programs and regulatory approval, significant increases in our operating expenses, or failure to obtain or maintain approval for product candidates or any approved products.

We rely and expect to continue 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.

We rely and expect to continue to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials. While we have agreements governing the activities of such CROs and clinical trial sites, we or our partners will have limited influence over their actual performance. Nevertheless, we or our partners will be responsible for ensuring that each of our clinical trials is conducted in accordance with its protocol, and that all legal, regulatory and scientific standards are met. Our reliance on the CROs does not relieve us of our regulatory responsibilities.

We, our partners and our CROs must comply with current Good Clinical Practices (“cGCPs”), as defined by the FDA and the International Conference on Harmonization, for conducting, recording and reporting the results of IND-enabling preclinical studies and clinical trials, to ensure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA enforces these cGCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulators may require us to perform additional clinical trials before approving any marketing applications. Our clinical trials will require a sufficiently large number of test subjects to evaluate the safety and effectiveness of a product candidate. If our CROs fail to comply with these regulations or fail to recruit a sufficient number of patients, fail to recruit properly qualified patients or fail to properly record or maintain patient data, we may be required to repeat such clinical trials, which would delay the regulatory approval process.

Our contracted CROs will not be our employees, and we cannot control whether they devote sufficient time and resources to our clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities that could harm our competitive position. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to failing to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not obtain regulatory approval for, or successfully commercialize our product candidates. Our financial results and the commercial prospects for such products and any product candidates we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

We also expect to rely on other third parties to store and distribute drug products for any clinical trials we may conduct. Any performance failure by our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, if approved, producing additional losses and depriving us of potential product revenue.

RISKS RELATED TO THE DISCOVERY AND DEVELOPMENT OF PRODUCT CANDIDATES

Because the approach we are taking to discover and develop drugs is novel, it may never lead to marketable products.

We are concentrating our antiviral therapeutic product research and development efforts using our proprietary technology, and our future success depends on the continued successful development of this technology and the products derived from it. We have no drug products commercialized. The scientific discoveries that form the basis for our efforts to discover and develop drug product candidates are relatively new and unproven. The scientific evidence to support the feasibility of developing product candidates based on our approach is limited. If we do not successfully develop and commercialize drug product candidates based upon our technological approach, we may not become profitable and the value of our stock may decline.

Further, our focus on the Company's technology for developing drugs, as opposed to relying entirely on more standard technologies for drug development, increases the risks associated with the ownership of our stock. If we are unsuccessful in developing any product candidates using the Company's technology, we may be required to change the scope and direction of our product development activities. We may not successfully identify and implement an alternative product development strategy and may as a result cease operations.

If we do not succeed in our efforts to identify or discover potential product candidates, your investment may be lost.

The success of our business depends primarily upon our ability to identify, develop and commercialize antiviral drug products, an extremely risky business. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for several reasons, including:

- our research methodology or that of our partners may be unsuccessful in identifying potential product candidates;
- potential product candidates may have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval; and
- we or our partners may change their development profiles for potential product candidates or abandon a therapeutic area.

Such events may force us to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

Because our future commercial success depends on gaining regulatory approval for our products, we cannot generate revenue without obtaining approvals

Our long-term success and generation of revenue will depend upon the successful development of new products from our research and development activities, including those licensed or acquired from third parties. Product development is very expensive and involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. The process for obtaining regulatory approval to market a product like our hepatitis C or influenza products is expensive, takes many years, and can vary substantially based on the type, complexity, and novelty of the product candidates involved. Our ability to generate revenues would be adversely affected if we are delayed or unable to successfully develop our products.

We cannot guarantee that any marketing application for our product candidates will be approved. If we do not obtain regulatory approval of our products or we are significantly delayed or limited in doing so, we cannot generate revenue, and we may need to significantly curtail operations.

If we are unable to successfully complete preclinical testing and clinical trials of our product candidates or experience significant delays in doing so, our business will be materially harmed.

We intend to invest a significant portion of our efforts and financial resources in the identification and preclinical development of product candidates that target viral replication enzymes. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates.

The commercial success of our product candidates will depend on several factors, including:

- successful completion of preclinical studies and clinical trials;
- receipt of marketing and pricing approvals from regulatory authorities;
- obtaining and maintaining patent and trade secret protection for product candidates;
- establishing and maintaining manufacturing relationships with third parties or establishing our own manufacturing capability; and
- commercializing our products, if and when approved, whether alone or in collaboration with others.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully complete development of, or to successfully commercialize, our product candidates, which would materially harm our business. Most pharmaceutical products that do overcome the long odds of drug development and achieve commercialization still do not recoup their cost of capital. If we are unable to design and develop each drug to meet a commercial need far in the future, the approved drug may become a commercial failure and our investment in those development and commercialization efforts will have been commercially unsuccessful.

We may be unable to demonstrate safety and efficacy of our product candidates to the satisfaction of regulatory authorities or we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining marketing approval from regulatory authorities for the sale of product candidates, we or our partners must conduct extensive preclinical studies and clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical trials are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

Events that may cause a delay or unsuccessful completion of clinical development include, as examples:

- delays in agreeing with the FDA or other regulatory authorities on final clinical trial design;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in agreeing on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- delays in obtaining required institutional review board approval at each clinical trial site;
- delays in recruiting suitable patients to participate in a trial;
- delays in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- delays caused by patients dropping out of a trial due to product side effects or disease progression;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new clinical sites; or
- delays by our contract manufacturers in producing and delivering sufficient supply of clinical trial materials.

If we or our partners must conduct additional clinical trials or other testing of any product candidates beyond those that are contemplated, or are unable to successfully complete clinical trials or other testing of any of our product candidates, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we or our partners may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- remove the product from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or in obtaining marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, if at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. Any inability to successfully complete preclinical and clinical development, whether independently or with our partners, could cause additional costs to us or impair our ability to generate revenues from our product candidates, including product sales, milestone payments, profit sharing or royalties.

Our product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events (“AEs”) or serious adverse events (SAEs”), that may be observed during clinical trials of our product candidates could cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt such trials and could cause denial of regulatory approval. If AEs or SAEs are observed in any clinical trials of our product candidates, including those our partners may develop under alliance agreements, our or our partners’ ability to obtain regulatory approval for product candidates may be negatively impacted.

Serious or unexpected side effects caused by an approved product could result in significant negative consequences, including:

- regulatory authorities may withdraw prior approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy;
- we may be required to add labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

These events could prevent us or our partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our products and impair our ability to generate revenues from the commercialization of these products either by us or by our partners.

Following regulatory approval for a product candidate, we will still face extensive regulatory requirements and the approved product may face future development and regulatory difficulties.

Even if we obtain regulatory approval in the United States or elsewhere, the applicable regulators may still impose significant restrictions on the indicated uses or marketing of our product candidates or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. The following discussion is based on United States law. Similar types of regulatory provision apply outside of the United States.

The holder of an approved New Drug Application (“NDA”), must monitor and report AEs and SAEs and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and other applicable federal and state laws and are subject to FDA review.

Drug product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current Good Manufacturing Practices (“cGMP”), and adherence to commitments made in the NDA. If we or a regulatory agency discover previously unknown problems with a product such as AEs or SAEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we or our partners fail to comply with regulatory requirements following approval of our product candidates, a regulatory agency may:

- issue a warning letter asserting we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or supplements to an NDA submitted by us;
- seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Our defense of any government investigation of alleged violations of law, or any lawsuit alleging such violations, could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may prevent or inhibit our ability to commercialize our products and generate revenues.

We may not succeed in obtaining or maintaining necessary rights to drug compounds and processes for our development pipeline through acquisitions and in-licenses.

We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and more established companies are also pursuing strategies to license or acquire third-party intellectual property rights we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

Companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

Because third parties may be developing competitive products without our knowledge, we may later learn that competitive products are superior to our product candidates which may force us to terminate our research efforts of one or more product candidates.

We face potential competition from companies, particularly privately-held companies and foreign companies that may be developing competitive products that are superior to one or more of our product candidates. If in the future, we learn of the existence of one or more competitive products, we may be required to:

- cease our development efforts for a product candidate;
- cause a partner to terminate its support of a product candidate; or
- cause a potential partner to terminate discussions about a potential license.

Any of these events may occur after we have spent substantial sums in connection with the clinical research of one or more product candidates.

Compliance with governmental regulations regarding the treatment of animals used in research could increase our operating costs, which would adversely affect the commercialization of our technology.

The Animal Welfare Act (“AWA”), is the United States federal law that covers the treatment of certain animals used in research. The AWA imposes a wide variety of specific regulations that govern the humane handling, care, treatment and transportation of certain animals by producers and users of research animals, most notably relating to personnel, facilities, sanitation, cage size, feeding, watering and shipping conditions. Third parties with whom we contract are subject to registration, inspections and reporting requirements. Some states have their own regulations, including general anti-cruelty legislation, which establish certain standards for handling animals. If we or our contractors fail to comply with United States and foreign laws and regulations, as applicable, concerning the treatment of animals used in research, we may be subject to fines and penalties and adverse publicity, and our operations could be adversely affected.

Public perception of ethical and social issues may limit or discourage the type of research we conduct.

Our clinical trials will involve people, and we and third parties with whom we contract also conduct research using animals. Governmental authorities could, for public health or other reasons, limit the use of human or animal research or prohibit the use of our technology. In addition, animal rights activists may protest or make threats against our facilities, which may cause property damage and delay our research. Ethical and other concerns about our methods, including our use of human subjects in clinical trials and our use of animal testing, could adversely affect our market acceptance.

We have limited experience in conducting and managing the preclinical development activities and clinical trials necessary to obtain approvals for marketing our product candidates, including approval by the FDA.

Our efforts to develop our product candidates are at an early stage. To date, with one exception, we have not entered a compound into human clinical trials. We may be unable to progress our other product candidates undergoing preclinical testing into clinical trials. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will succeed, and favorable initial results from a clinical trial do not determine outcomes in subsequent clinical trials. The indications of use for which we are pursuing development may have clinical effectiveness endpoints not previously reviewed or validated by the FDA or foreign regulatory authorities, which may complicate or delay our effort to obtain marketing approval. We cannot guarantee that our clinical trials will succeed. In fact, most compounds fail in clinical trials, even at companies far larger and more experienced than us.

We have not obtained marketing approval or commercialized any of our product candidates. We may not successfully design or implement clinical trials required for marketing approval to market our product candidates. If we are unsuccessful in conducting and managing our preclinical development activities or clinical trials or obtaining marketing approvals, we might not be able to commercialize our product candidates, or might be significantly delayed in doing so, which will materially harm our business.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

If we cannot obtain or protect intellectual property rights related to our future products and product candidates, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our future products and product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications we own or in-license may fail to result in patents with claims that cover the products in the United States or in other countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found; such prior art can invalidate a patent or prevent a patent from issuing based on a pending patent application. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may cause such patents to be narrowed or invalidated. Even if unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims.

If the patent applications we hold or have in-licensed regarding our programs or product candidates fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize products. Patents may not issue and issued patents may be found invalid and unenforceable or challenged by third parties. Since patent applications in the United States and most other countries are confidential for a period after filing, and some remain so until issued, we cannot be certain that we were the first to invent a patent application related to a product candidate. In certain situations, if we and one or more third parties have filed patent applications in the United States and claiming the same subject matter, an administrative proceeding can be initiated to determine which applicant is entitled to the patent on that subject matter. Patents have a limited lifespan. In the United States, the natural expiration of a patent is 20 years after it is filed, although various extensions may be available. The life of a patent, and the protection it affords, is limited. When the patent life has expired for a product, we will become vulnerable to competition from generic medications attempting to replicate that product. Further, if we encounter delays in regulatory approvals, the time during which we will be able to market and commercialize a product candidate under patent protection could be reduced.

In addition to patent protection, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology not covered by patents. Each of our employees agrees to assign their inventions to us through an employee inventions agreement. In addition, as a general practice, our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology enter into confidentiality agreements. Nonetheless, our trade secrets and other confidential proprietary information may be disclosed and competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. In addition, in January 2018 the FDA as part of its Transparency Initiative, launched a voluntary pilot program calling on biopharmaceutical research companies to release clinical study reports summarizing clinical trial data. However, with a low response rate to this initiative thus far, the FDA may consider making release of clinical study reports mandatory and may consider making additional information publicly available on a routine basis in response to concerns expressed by the academic community, including information we may consider to be trade secrets or other proprietary information. If the FDA takes these measures, we may be forced to disclose propriety information about our product candidates and research, which could materially harm our business.

The laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. We may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Third-party intellectual property infringement claims may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement on the patents and proprietary rights of third parties. There is substantial litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, and reexaminations and other post-grant proceedings before the U.S. Patent and Trademark Office, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our partners are pursuing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be patent applications currently pending that may later result in patents that our product candidates may infringe. Third parties may obtain patents in the future and claim that use of our technologies infringes on these patents. If any third-party patents were to be held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patents were to be held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making intellectual property claims against us may obtain injunctive or other equitable relief, which could block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, involves substantial litigation expense and would be a substantial diversion of our management's attention from our business. If a claim of infringement against us succeeds, we may have to pay substantial damages, possibly including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may need to obtain licenses to intellectual property rights from third parties.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist that might be enforced against our products, resulting in either an injunction prohibiting our sales, or, with respect to our sales and other activities, an obligation on our part to pay royalties and/or other forms of compensation to third parties. Because of the costs involved in defending patent litigation, we currently lack and may in the future lack the capital to defend our intellectual property rights.

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.

Competitors may infringe our patents or the patents of our licensors. To counter such infringement or unauthorized use, we may be required to file infringement claims, or we may be required to defend the validity or enforceability of such patents, which can be expensive and time-consuming. In an infringement proceeding, a court may decide that either one or more of our patents or our licensors' patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue because our patents do not cover that technology. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions regarding our patents or patent applications or those of our partners or licensors. An unfavorable outcome could require us to cease using the related technology or to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may cause us to incur substantial costs and distract the attention of our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Because of the substantial amount of discovery required in intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our securities.

We may be subject to claims our that employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims asserting that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we succeed, litigation could cause substantial cost and be a distraction to our management and other employees.

Because we face significant competition from other biotechnology and pharmaceutical companies, our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. This enables them, among other things, to make greater research and development investments and efficiently utilize their research and development costs. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may cause even more resources being concentrated in our competitors. Competition may increase further because of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may develop, acquire or license drug products that are more effective or less costly than any product candidate we may develop.

With the exception of one product candidate, all of our programs are in a preclinical development stage and are targeted toward indications for which there are approved products on the market or product candidates in clinical development. We will face competition from other drugs that are or will be approved for the same therapeutic indications. Our ability to compete successfully will depend largely on our ability to leverage our experience in drug discovery and development to:

- discover and develop therapeutics superior to other products in the market;
- attract qualified scientific, product development and commercial personnel;
- obtain patent and/or other proprietary protection for our technology platform and product candidates;
- obtain required regulatory approvals; and
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new therapeutics.

The availability of our competitors' products could limit the demand, and the price we can charge, for any products we may develop and commercialize. We will not achieve our business plan if the acceptance of these products is inhibited by price competition or the reluctance of physicians to switch from existing drug products to our products, or if physicians switch to other new drug products or reserve our products for use in limited circumstances. Additionally, the biopharmaceutical industry is characterized by rapid technological and scientific change, and we may not be able to adapt to these rapid changes to the extent necessary to keep up with competitors or at all. The inability to compete with existing or subsequently introduced drug products would have a material adverse impact on our business, financial condition and prospects.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. Any new product that competes with an approved product must typically demonstrate advantages, such as in efficacy, convenience, tolerability or safety, to overcome price competition and to succeed. Our competitors may obtain patent protection, receive approval by FDA and/or foreign regulatory authorities or discover, develop and commercialize product candidates before we do, which would have a material adverse impact on our business.

The commercial success of our product candidates will depend upon the acceptance of these product candidates by the medical community, including physicians, patients and healthcare payors.

Assuming one or more product candidates achieve regulatory approval and we commence marketing such products, the market acceptance of any product candidates will depend on several factors, including:

- demonstration of clinical safety and efficacy compared to other products;
- the relative convenience, ease of administration and acceptance by physicians, patients and healthcare payors;
- the prevalence and severity of any AEs or SAEs;
- limitations or warnings in the label approved by FDA and/or foreign regulatory authorities for such products;
- availability of alternative treatments;
- pricing and cost-effectiveness;
- the execution and effectiveness of our or any collaborators' sales and marketing strategies;
- our ability to obtain hospital formulary approval; and
- our ability to obtain and maintain sufficient third-party payor coverage or reimbursement.

If our current product candidates are approved, we expect sales to generate substantially all of our product revenues for the foreseeable future, and as such, the failure of these products to find market acceptance would harm our business.

If insurance and/or government coverage and adequate reimbursement are not available for our product candidates, it could impair our ability to achieve and maintain profitability.

Market acceptance and sales of any product candidates we develop will depend on coverage and reimbursement policies of third-party payors. Government authorities and third-party payors, such as private health insurers, hospitals and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. Coverage and adequate reimbursement may not be available for some or all of our product candidates. As patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment, inadequate reimbursement amounts may reduce the demand for, or the price of, our future products. Thus, the availability of adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process, and no uniform policy of coverage and reimbursement for products exists among third-party payors in the United States. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptable. If reimbursement is not available, or is available at limited levels, we may not be able to successfully commercialize product candidates we develop.

Pricing pressures on our drug candidates, including as the result of proposed legislative changes, may negatively impact our future results of operations.

There have been numerous legislative and regulatory proposals to change the healthcare system in the United States and in some foreign jurisdictions that could affect our ability to sell products profitably. For example, in May 2018, the Trump administration issued a plan to lower drug prices, including among other things the disclosure of list prices in television ads, increasing negotiated discounts in Medicare, banning pharmacy gag clauses, adopting real-time prescription benefit tools, and boosting low-cost generic and biosimilar competition. In January 2019, the Trump administration proposed a rule to lower prescription drug prices and out-of-pocket costs by banning rebates on prescription drugs paid by manufacturers to pharmacy benefit managers, Part D plans and Medicaid managed care organizations to increase the use and sales of their products.

Further, in February 2019, President Trump expressed concern that prescription drug prices in Canada are approximately 50% of prescription drug prices in the United States. At the same time, the current Democratic Presidential candidate is advocating for a Medicare-for-all approach. While expanding Medicare would increase the demand for prescription drugs, there is a likelihood that Medicare will be required to negotiate drug prices, which could adversely affect our future prospects.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control drug pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. These measures could reduce the ultimate demand for our products, if approved, or put pressure on our product pricing. The availability of generic treatments may also substantially increase pricing pressures on, and reduce reimbursement for, our future products. The potential application of user fees to generic drug products may expedite approval of additional generic drug treatments. We expect to experience additional pricing pressures in connection with sale of any of our products, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes.

In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. The European Union, or EU, 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. 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 our products. Historically, products launched in the EU do not follow price structures of the U.S. and tend to be priced significantly lower.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenues from product sales.

We do not have an organization for the sales, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. To market any products that may be approved, we must build our sales, marketing, managerial and other non-technical capabilities or arrange with third parties to perform these services.

Our current and future partners may not dedicate sufficient resources to the commercialization of our product candidates or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective alliances to enable the sale of our product candidates to healthcare professionals and in geographical regions, including the United States, that will not be covered by our own marketing and sales force, or if our potential future strategic partners do not successfully commercialize the product candidates, our ability to generate revenues from product sales will be adversely affected.

If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with many companies that have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third-party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If any of our product candidates are approved for commercialization, we may enter into agreements with third parties to market them on a worldwide basis or in more limited geographical regions. We expect we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could cause increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is endemic;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

RISKS RELATED TO OUR BUSINESS OPERATIONS AND INDUSTRY

If we lose key management or scientific personnel, cannot recruit qualified employees, directors, officers, or other personnel or experience increases in our compensation costs, our business may materially suffer.

We depend on principal members of our executive and research teams; the loss of whose services may adversely impact the achievement of our objectives. We are highly dependent on our Chairman of the Board and Chief Executive Officer, Dr. Gary Wilcox, our President, Dr. Sam Lee and our Chief Financial Officer, James Martin. We do not carry “key-man” life insurance on any of our employees or advisors. Furthermore, our future success will also depend in part on the continued service of our key scientific and management personnel and our ability to identify, hire, and retain additional personnel. We may not be able to attract and retain personnel on acceptable terms, as there is significant competition among numerous pharmaceutical companies for individuals with similar skill sets. Because of this competition, our compensation costs may increase significantly. If we lose key employees, our business may suffer.

If we expand our organization, we may experience difficulties in managing growth, which could disrupt our operations.

As of March 30, 2020, we have 11 full-time employees. As our company matures, we expect to expand our employee base to increase our managerial, scientific and operational, commercial, financial and other resources and to hire more consultants and contractors. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may cause weaknesses in our infrastructure, and give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as developing additional product candidates. If our management cannot effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to manage our future growth.

Any relationships with customers and third-party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

If we obtain FDA approval for any of our product candidates and commercialize those products in the United States, our operations may be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may impact, among other things, our proposed sales, marketing and education programs. We may be subject to patient privacy regulation by the federal government and by the U.S. states and foreign jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

If our operations are found to violate any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, possible exclusion from Medicare, Medicaid and other government healthcare programs, and curtailment or restructuring of our operations, which could adversely affect our ability to operate our business and our results of operations.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs.

Using our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. Regardless of merit or eventual outcome, product liability claims may cause:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

Insurance coverage is becoming increasingly expensive and we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. Occasionally, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Business interruptions resulting from pandemics, natural disasters and adverse weather events could cause delays in research and development of our product candidates.

Our principal offices are in Bothell, Washington where we conduct our scientific research. We also maintain a small finance and accounting office in Miami, Florida. We are vulnerable to natural disasters such as earthquakes and tornados as well as other events that could disrupt our operations and cause delays in research and development of our product candidates. We do not carry insurance for natural disasters, and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our operations. The recent coronavirus pandemic has the potential to impact our business in both the short and long run. At the moment there is uncertainty to both the extent and duration of the effect on employees and supply lines. See the Risk Factor in this Report concerning the COVID-19 virus.

If our information technology systems are compromised, the information we store and process, including our intellectual property, could be accessed, publicly disclosed, lost or stolen, which could harm our business, relationships with strategic partners and future results of operations.

Companies are increasingly suffering damage from attacks by hackers. In the ordinary course of business, we store sensitive information, such as our intellectual property, including trade secrets and results of our clinical and preclinical research, and that of our suppliers and business partners, on a central server, and such information is transmitted via email correspondence. The secure maintenance and processing of this information is critical to our research and development activities and future operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breaches due to employee error, malfeasance or other disruptions. Any such breach could compromise our information technology systems and the information stored there could be accessed by third parties, publicly disclosed, lost or stolen. Any such access, disclosure, misappropriation or other loss of information could result in disruption of our operations, including our existing and future research collaborations, and damage our reputation, which in its turn could harm our business and future results of operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve using hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. If contamination occurs or injury results from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

The Federal Occupational Safety and Health Administration has established extensive requirements relating to workplace safety for health care employers, including clinical laboratories, whose workers may be exposed to blood-borne pathogens such as the hepatitis C virus. These requirements, among other things, require work practice controls, protective clothing and equipment, training, medical follow-up, vaccinations and other measures designed to minimize exposure to, and transmission of, blood-borne pathogens. In addition, the Needlestick Safety and Prevention Act requires, among other things, that we include in our safety programs the evaluation and use of engineering controls such as safety needles if found to be effective at reducing the risk of needlestick injuries in the workplace.

Although our workers' compensation insurance may cover us for costs and expenses, we may incur additional costs due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, and this insurance may not provide adequate coverage against other potential liabilities. We may incur substantial costs 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 cause substantial fines, penalties or other sanctions.

RISKS RELATED TO OUR COMMON STOCK

Because we believe the recent volatility of our stock price was caused by our announcement of our License Agreement and our acquisition of rights to use the licensed patents to seek a treatment for coronavirus as well as norovirus, the increase in our stock price may be temporary for a number of reasons.

After we announced our entry into the License Agreement with the Kansas State University Research Foundation, the price of our common stock surged from \$0.49 as of February 21 to the closing price of \$1.77 on February 26 and our daily trading volume also increased substantially during that time. Additionally, after our March 6, 2020 announcement regarding the initiation of our coronavirus program, our trading volume remained extremely high relative the prior 12-month period. Since then, our stock price has fallen to a closing price of \$0.68 per share on March 26, 2020. Our common stock may continue to be volatile and could materially fall for a number of reasons including:

- Announcements by competitors that they are initiating human trials of drugs to treat the coronavirus or with respect to a possible vaccine;
- Public announcement that the rapid spread of the coronavirus has receded;
- Our disclosure that the use of our technology and the patents we licensed do not appear promising for the treatment of this virus;
- The continued large declines in major stock market indexes which causes investors to sell our common stock; or
- The termination of any other factors which may have created the unusual volatility and spike in volume;

We cannot assure you that our stock price and volume will stabilize, in which case investors may sustain large losses

Due to factors beyond our control, our common stock price may be volatile, or may decline regardless of our operating performance, and you may not be able to resell your shares.

The market price of our common stock will depend on a number of factors, many of which are beyond our control and may not be related to our operating performance. These fluctuations could cause you to lose all or part of your investment in our common stock since you might be unable to sell your shares at or above the price you paid. Factors that could cause fluctuations in the market price of our common stock include the following:

- price and volume fluctuations in the overall stock market from time to time;
- volatility in the market prices and trading volumes of biotechnology stocks generally, or those in our peer group in particular;
- our announcements concerning the initiation and results of clinical trials;
- changes in operating performance and stock market valuations of other biotechnology companies generally, or those in our industry in particular;
- sales of shares of our stock by us or our stockholders;
- the failure of securities analysts to maintain coverage of us, changes in financial estimates by securities analysts who follow our company or our failure to meet these estimates or the expectations of investors;
- the financial projections we may provide to the public, any changes in those projections or our failure to meet those projections.
- announcements by us or our competitors of new novel medicines;
- the public's reaction to our earnings releases, other public announcements and filings with the SEC;
- rumors and market speculation involving us or other companies in our industry;
- actual or anticipated developments in our business, our competitors' businesses or the competitive landscape generally;
- actual or anticipated changes in our operating results or fluctuations in our operating results;
- litigation involving us, our current or former officers and directors, our stockholders, our industry, or investigations by regulators into our operations or those of our competitors;
- developments or disputes concerning our intellectual property or other proprietary rights;
- new laws or regulations or new interpretations of existing laws or regulations applicable to our business;
- changes in accounting standards, policies, guidelines, interpretations or principles;
- any significant change in our management; and
- general economic conditions and slow or negative growth in any of our significant markets.

In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources. See Item 3. "Legal Proceedings" for a description of certain pending litigation.

Any future impairment in the carrying value of goodwill and in-process research and development assets could depress our stock price.

Historically, we had a significant amount of goodwill and indefinite-lived intangible assets for in-process research and development (“IPR&D”) on our balance sheet. Goodwill and indefinite-lived intangible assets must be evaluated for impairment annually or more frequently if events indicate it is warranted. If the carrying value of a reporting unit or IPR&D asset exceeds its current fair value, the goodwill or IPR&D asset is considered impaired. Events and conditions that could result in impairment in the value of our indefinite-lived assets and goodwill include, but are not limited to, significant negative industry or economic trends, significant decline in the Company’s stock price for a sustained period of time, significant decline in market capitalization relative to net book value, limited funding that could delay development efforts, significant changes in the manner of use of the assets or the strategy for the Company’s overall business, safety or efficacy issues that surface during development efforts, or preclinical and clinical outcomes that reduce the probability for technical and regulatory success of our product candidates.

We have fully written-off our IPR&D, and we no longer have an IPR&D asset as of December 31, 2018; refer to “Item 7 – Management’s Discussion and Analysis – Critical Accounting Policies and Estimates – Business Combinations and Intangible Assets.”

At December 31, 2019 and 2018, the Company had goodwill of \$19,092,343 and \$65,195,000 respectively. Based on the fair value of its reporting unit, measured by the Company’s Nasdaq market capitalization and an income based approach analysis, which exceeded the carrying value at December 31, 2019; we have incurred an impairment charge of approximately \$46,100,000 from our goodwill as of December 31, 2019.

We may in the future be required to record additional impairment charges to write-off goodwill which is also related to our merger with RFS Pharma in 2014. Our stock price could be negatively impacted should future impairments of our goodwill occur.

Because certain of our stockholders control a significant number of shares of our common stock, they may have effective control over our actions requiring stockholder approval.

As of March 13, 2020, our directors, executive officers and principal stockholders (those beneficially owning in excess of 5%), and their respective affiliates, beneficially own approximately 29.2% of our outstanding shares of common stock. As a result, these stockholders, acting together, would have the ability to control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets.

Dr. Raymond Schinazi, our former Board Chairman, and Dr. Philip Frost, a director and certain other stockholders entered into a Stockholders Rights Agreement in November 2014 when we acquired another company headed by Dr. Schinazi. This Agreement gives each of Dr. Schinazi and Dr. Frost (and certain other stockholders) the right to designate three directors to a seven-person board of directors and together agree upon the seventh designee. In addition, our principal stockholders, acting together, would have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership might harm the market price of our common stock by:

- delaying, deferring or preventing a change in corporate control;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

Further, the Stockholder Rights Agreement provides Dr. Schinazi and Dr. Frost and certain other Company stockholders with rights including the right to approve future financings and a right of first refusal, which have not been impediments to date. However, in the event of any future disagreements between Dr. Schinazi and Dr. Frost, we may be unable to raise future capital we need or make concessions to one of these directors, which may adversely affect us or result in added expenses. Dr. Schinazi did not consent to our most recent financing in March 2020. We are uncertain what impact this may have upon us.

Future sales and issuances of our common stock or rights to purchase common stock, including under our equity incentive plan, could cause additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

In November 2019 and February and March 2020 we conducted public offerings in which we issued a total of approximately 17.03 million shares of common stock and raised a total of approximately \$20.8 million in gross proceeds. While we expect that these financings will be sufficient to fund our operations for more than the 12 months, significant additional capital may be needed in the future to continue our planned operations. To the extent we have raised and continue to raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Under our Equity Incentive Plans, our management may grant stock options and other equity-based awards to our employees, directors and consultants. Approximately 3,588,377 million shares of common stock are available for future grant.

We are currently involved in a class action lawsuit, a related derivative action, and other litigation, and may in the future be involved in other legal proceedings, which may be expensive and time consuming to defend, and, if resolved adversely, could harm our business and financial condition.

We and certain current and former executive officers and directors of the Company are currently defendants in a class action lawsuit filed with the U.S. District Court for the District of New Jersey alleging violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, and a related derivative action lawsuit filed with the U.S.

District Court for the Western District of Washington and may become involved in additional legal proceedings in the future.

These proceedings can be time consuming, divert management's attention and resources and cause us to incur significant expenses. While we believe we have insurance coverage for the class action suit and the derivative action, our insurance carrier has initially declined to cover the lawsuits. While we are seeking to reverse this decision, even if we can do so the amount of insurance may be insufficient. Furthermore, because litigation is inherently unpredictable, the results of any such actions may have a material adverse effect on our business, and financial condition, and cause our stock price to decrease.

See "Item 3 – Legal Proceedings" for more information.

Failure to meet the continued listing requirements of The Nasdaq Capital Market, could result in delisting of our common stock, which in its turn would negatively affect the price of our common stock and limit investors' ability to trade in our common stock.

Our common stock trades on The Nasdaq Capital Market ("Nasdaq"). Nasdaq rules impose certain continued listing requirements, including the minimum \$1 bid price, corporate governance standards and number of public stockholders. On December 13, 2019, we were notified by Nasdaq that we were not compliant with its closing bid price requirement because the closing bid price of our common stock was below \$1.00 per share for 30 consecutive trading days. While we have regained compliance and this matter has since been resolved, if we fail to meet these continued listing requirements in the future, Nasdaq may take steps to delist our common stock. If our common stock is delisted from The Nasdaq Capital Market, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our common stock;
- reduced liquidity with respect to our common stock;

- a determination that our shares of common stock are a “penny stock” which will require broker-dealers trading in our common stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our common stock;
- a limited amount of news and analyst coverage for our company; and
- a limited ability to issue additional securities or obtain additional financing in the future.

Our ability to use our net operating loss carry forwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986 if a corporation undergoes an “ownership change,” generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carry forwards (“NOLs”), and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. We believe that, with the RFS Pharma and Discovery mergers and other transactions that have occurred over the past three years, we may have triggered an “ownership change” limitation. We may also experience ownership changes in the future because of subsequent shifts in our stock ownership. If we earn net taxable income, our ability to use our pre-change net operating loss carry forwards to offset U.S. federal taxable income may be subject to limitations, which could result in increased future tax liability to us. At the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our common stock. We anticipate we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

Because we may not attract the attention of major brokerage firms, it could have a material impact upon the price of our common stock.

It is possible that securities analysts of major brokerage firms will not provide research coverage for our common stock. The absence of such coverage limits the likelihood that an active market will develop for our common stock. It may also make it more difficult for us to attract new investors when we acquire additional capital.

Future sales of our common stock could cause the market price for our common stock to decline, even if our business is performing well.

As of March 28, 2020, we had approximately 52.1 million shares of common stock outstanding, approximately 36.9 million of which are either free trading or may be sold without volume or manner of sale limitations under Rule 144. The remainder of our shares, because they are held by affiliates, are subject to additional restrictions as described below.

In general, Rule 144 provides that any person who is not an affiliate of the Company and has not been an affiliate for 90 days, and who has held restricted common stock for at least six months, is entitled to sell their restricted stock freely, provided that we stay current in our SEC filings. After one year, a non-affiliate may sell without any restrictions.

Our largest stockholder, Dr. Raymond Schinazi, who beneficially owned 19.7% of our common stock as of March 29, 2020, resigned as our Board Chairman in February 2019. However, a Stockholder Rights Agreement he signed in 2014, in which another principal shareholder is a party, requires that we continue to treat him as an affiliate.

The shares of common stock outstanding which are held by affiliates of the Company are subject to additional restrictions. An affiliate may sell after a six-month holding period with the following restrictions:

- (i) we are current in our filings;

- (ii) certain manner of sale provisions; and
- (iii) filing of Form 144.

Future sales of substantial amounts of shares of our common stock in the public market, or the perception that those sales will occur, could cause the market price of our common stock to decline significantly, even if our business is performing well.

We may issue preferred stock which could make it more difficult for a third-party to acquire us and could depress our stock price

In accordance with the provisions of our Certificate of Incorporation and the Stockholder Rights Agreement described above, our Board may issue one or more additional series of preferred stock that have more than one vote per share, so long as the Board obtains the majority approval of each of the groups of stockholders who formerly held our Series A and Series B. This could permit our Board to issue preferred stock to investors who support our management and give effective control of our business to our management. Issuance of preferred stock could block an acquisition resulting in both a drop in our stock price and a decline in interest of our common stock. This could make it more difficult for stockholders to sell their common stock. This could also cause the market price of our common stock shares to drop significantly, even if our business is performing well.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We have operating facilities in Bothell, Washington and Miami, Florida.

We lease approximately 9,400 square feet of office and laboratory space in Bothell, Washington. In June 2018, we signed an amendment to the Bothell, Washington lease agreement to extend the term through January 2024.

On September 1, 2018, the Company relocated its accounting and finance offices from Tucker, Georgia to Miami, Florida, where it leases a total of 1,280 square feet of office space. In connection with the relocation, the Company entered into a lease agreement with a limited liability company controlled by Dr. Phillip Frost, a director and a principal stockholder of the Company. The lease term is three years with an optional three-year extension. Following the relocation, the Company closed down its office in Tucker, Georgia and terminated the respective month-to-month lease agreement with the limited liability company owned by our former Chairman and a principal stockholder, Dr. Raymond Schinazi.

Item 3. Legal Proceedings

From time to time, the Company is a party to, or otherwise involved in, legal proceedings arising in the normal course of business. As of the date of this report, except as described below, the Company is not aware of any proceedings, threatened or pending, against it which, if determined adversely, would have a material effect on its business, results of operations, cash flows or financial position.

On September 20, 2018, Anthony Pepe, individually and on behalf of a class, filed with the United States District Court for the District of New Jersey a complaint against the Company, certain current and former executive officers and directors of the Company and the other defendants named therein for violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. The class consists of the persons and entities who purchased the Company's common stock during the period from September 23, 2013 through September 7, 2018. Pepe also alleges violation of other sections of the Exchange Act by the defendants named in the complaint other than the Company. Pepe seeks damages, pre-judgment and post-judgment interest, reasonable attorneys' fees, expert fees and other costs.

On January 16, 2019, Ms. Susan Church, a stockholder of the Company, filed with the United States District Court for the Western District of Washington a derivative suit against certain current and former executive officers and directors of the Company alleging breach of fiduciary duties, unjust enrichment, waste of corporate assets, and violations of the rules governing proxy solicitation. Church seeks, among other things, money damages, disgorgement of profits from alleged wrongful conduct, including cash bonuses, pre-judgment and post-judgment interest, reasonable attorneys' fees, expert fees and other costs.

Liberty Insurance Underwriters Inc. filed suit against us in federal court in Delaware seeking a declaratory judgment that it is not liable to defend us in the class and derivative litigation. The insurance company also is claiming it is entitled to recover \$1 million it advanced to us in connection with the SEC investigation. We have retained counsel to defend us which has filed an answer to the complaint.

On September 7, 2018, the SEC filed with the United States District Court for the Southern District of New York a complaint against Dr. Philip Frost, a director and principal stockholder of the Company, a trust Dr. Frost controls and OPKO Health, Inc., a stockholder of the Company, of which Dr. Frost is the Chief Executive Officer, as well as other defendants named therein. On January 10, 2019, the District Court entered final judgments against these defendants on their consent without admitting or denying the allegations set forth in the complaint. Dr. Frost was permanently enjoined from violating a certain anti-fraud provision of the Securities Act of 1933, future violations of Section 13(d) of the Exchange Act and Rule 13d-1(a) thereunder and participating in penny stock offerings subject to certain exceptions.

November 2017, Lee Pederson, a former Biozone lawyer, filed a lawsuit in Minnesota against co-defendants the Company, Dr. Phillip Frost, OPKO Health, Inc. and Brian Keller for various allegations. On September 13, 2018, the United States District Court granted the Company and its co-defendants' motion to dismiss Pederson's amended complaint. Subsequent to September 30, 2018, Pederson filed a notice of appeal with the United States Court of Appeals for the Eighth Circuit on October 11, 2018. The plaintiff's appeal was denied and the dismissal affirmed.

While the Company intends to defend itself vigorously from the claims in the aforementioned disputes, it is unable to predict the outcome of these legal proceedings. Any potential loss as a result of these legal proceedings cannot be reasonably estimated. As a result, the Company has not recorded a loss contingency for any of the aforementioned claims.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock has been traded on The Nasdaq Capital Market ("Nasdaq") under the symbol "COCP" since March 12, 2018. Prior to March 12, 2018, our common stock was quoted on OTCQB under the same symbol "COCP". As of December 31, 2019, there were approximately 213 holders of record of our common stock.

The last reported sales price of our Common stock on Nasdaq on December 31, 2019 was \$0.50 per share.

Dividend Policy

We have not declared nor paid any cash dividend on our common stock, and we currently intend to retain future earnings, if any, to finance the expansion of our business, and we do not expect to pay any cash dividends in the foreseeable future. The decision whether to pay cash dividends on our common stock will be made by our board of directors, in their discretion, and will depend on our financial condition, results of operations, capital requirements and other factors that our board of directors considers significant. Our ability to pay cash dividends is governed by applicable provisions of Delaware law.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Unregistered sales of equity securities

All unregistered sales of our equity securities during the period covered by this Annual Report on Form 10-K have been previously reported.

Item 6. Selected Financial Data

As a smaller reporting company as defined in Rule 12b-2 of the Exchange Act, we are not required to include information otherwise required by this item.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read in conjunction with the Consolidated Financial Statements included elsewhere in this report.

Company Overview

Our primary business going forward is to develop novel medicines for use in the treatment of human viral diseases. Discovery has been developing novel technologies and approaches to create first-in-class and best-in-class antiviral drug candidates since its initial funding in 2008. Our focus is to pursue the development and commercialization of broad-spectrum antiviral drug candidates that will transform the treatment and prophylaxis of viral diseases in humans. By concentrating our research and development efforts on viral replication inhibitors, we plan to leverage our infrastructure and expertise in these areas.

During fiscal year ended December 31, 2019, the following key aspects of our business advanced:

- We signed exclusive license and collaboration agreement with Merck and Co., Inc. to discover and develop certain proprietary influenza A/B antiviral agents.
- We secured a total of \$13,230,000 million gross proceeds over the past 12 months; \$6,564,000 million from Merck payments and \$6,666,000 million gross proceeds from common-stock only financings.
- We reported encouraging safety and preliminary efficacy data for its U.S. Phase 2a study evaluating CC-31244 for the ultra-short treatment of HCV infected individuals showing no drug-drug interactions and substantial efficacy. The data obtained from this trial used 2 weeks of CC-31244 in combination with Eplusa followed by 4 weeks of Eplusa alone.
- We presented preclinical characterization data of CC-42344 at the 6th ISIRV-AVG Conference demonstrating excellent antiviral activity against influenza A strains and favorable pharmacokinetic and safety profile.

Results of Operations

As stated above, we are focused on research and development of novel medicines for use in the treatment of human viral diseases. We had revenue of \$6,564,000 and \$0 for the years ended December 31, 2019 and 2018, respectively. We had a net loss of \$48,169,000 for the year ended December 31, 2019 primarily due to a \$46,103,000 goodwill impairment, compared to a net loss of \$49,048,000 for the year ended December 31, 2018 primarily due to a \$53,905,000 IPR&D impairment. These 2019 and 2018 impairments are non-cash impairments of intangible assets. Our operating loss for the year ended December 31, 2019 was \$48,406,000 compared to an operating loss of \$62,924,000 in 2018. The operating loss for 2019 included the non-cash impairment charge of \$46,103,000 on our intangible goodwill asset and 2018 operating loss included the non-cash impairment charge of \$53,905,000 on our intangible IPR&D asset. Other income was \$256,000 for the year ended December 31, 2019, which is primarily due to a \$256,000 gain on the fair value of derivative liabilities. Under accounting principles generally accepted in the United States, we record other income or expense for the change in fair value of our outstanding warrants that are accounted for as liabilities during each reporting period. If the value of the warrants decreases during a period, which occurred during the year ended December 31, 2019, we record other income. The fair value of our outstanding warrants is inversely related to the fair value of the underlying common stock; as such, a decrease in the fair value of our common stock during a given period generally results in other income while an increase in the fair value of our common stock generally results in other expense.

Research and Development Expense

Research and development expenses consist primarily of compensation-related costs for our 7 employees dedicated to research and development activities and for our Scientific Advisory Board members, as well as lab supplies, lab services, and facilities and equipment costs. We expect research and development expenses to increase in future periods as we expand our pre-clinical development activities.

Total research and development expenses were \$4,004,000 for the year ended December 31, 2019, compared with \$4,667,000 for the year ended December 31, 2018. This year over year decrease in research and development expenditures was primarily due to the completion of our HCV phase 2 clinical trial and expense reimbursements resulting from our Collaboration Agreement with Merck. We expect research and development expenses to increase in 2020 due to advancing our coronavirus and norovirus programs.

General and Administrative Expense

General and administrative expense includes compensation-related costs for our employees dedicated to general and administrative activities, legal fees, audit and tax fees, consultants and professional services, and general corporate expenses.

General and administrative expenses were \$4,863,000 for the year ended December 31, 2019, compared with \$4,352,000 for the year ended December 31, 2018. This increase of \$511,000 was primarily due to professional fees associated with litigation matters and insurance increases.

In the ordinary course of business, the Company entered into non-cancelable related party leases for its facilities and convertible debt (see Note 16 – Transactions with Related Parties in the following Consolidated Financial Statements).

Interest Income/Expense

Interest income (expense) was (\$19,000) for the year ended December 31, 2019, compared to (\$58,000) for the year ended December 31, 2018. The interest expense in 2019 is related to lease agreements and in 2018 is primarily a result of the convertible promissory notes we entered into in November 2017 which were all converted to common stock in May 2018.

Other Income/Expense

Other income, net, was \$237,000 for the year ended December 31, 2019 compared with \$294,000 for the year ended December 31, 2018. Other income, net for the year ended December 31, 2019 and 2018 primarily consisted of gains of \$256,000 and \$306,000, respectively, recognized from decreases in the fair value of our derivative liabilities as our stock price decreased.

Income Taxes

For the year ended December 31, 2019, we did not record an income tax benefit despite of our goodwill impairment which is reversed for tax purposes as a permanent difference. For the year ended December 31, 2018, we recorded an income tax benefit of \$13,582,000 primarily as a result of reduction of our deferred tax liability which was caused by recent tax law changes lowering the corporate tax rate to 21%.

Liquidity and Capital Resources

For the year ended December 31, 2019, net cash used in operating activities was \$1,563,000, compared to net cash used in operating activities of \$8,290,000 for the year ended December 31, 2018. The decrease in cash used in operating activities in 2019 as compared to 2018 was attributable to the revenue flow from our influenza A/B license agreement with Merck of \$6,564,000. For the year ended December 31, 2019, net cash used in investing activities netted to \$145,000, which consisted of capital expenditures for lab equipment, software, and networking for our Lab located in Bothell, Washington. For the year ended December 31, 2018, our net cash provided by investing activities consisted of \$1,372,000 primarily from settlement of our mortgage note receivable of \$1,400,000 offset by capital expenditures for lab equipment in our R&D facilities and relocation to Miami of our finance office. For the year ended December 31, 2019, net cash provided by financing activities was \$6,424,000, compared to net cash provided by financing activities of \$8,893,000 for the year ended December 31, 2019. Net cash generated by financing activities in 2019 and 2018 was the result of issuance common stock, net of finance lease payments.

The Company had approximately \$7,418,000 cash on hand at December 31, 2019. Subsequently, the Company raised gross proceeds of approximately \$20,000,000, before deducting fees payable to the placement agent and other estimated offering expenses payable by the Company, as described below. Based upon our estimated cash balance of \$22 million as of March 26, 2020, we estimate we have enough working capital to meet or needs for approximately the next two years. Of course, the uncertainties caused by COVID-19 could impact our research activities and affect our Merck collaboration which would reduce this estimate. Regardless we have more than enough cash to meet our working capital needs for the next 12 months.

On January 29, 2020, the Company entered into a securities purchase agreement with certain institutional investors, pursuant to which the Company agreed to sell and issue, in a registered direct offering, 3,492,063 of the Company's shares of common stock, par value \$0.001 at a purchase price per share of \$0.63 for aggregate gross proceeds to the Company of approximately \$2.2 million, before deducting fees payable to the placement agent and other estimated offering expenses payable by the Company. The Company closed the offering on January 31, 2020.

On February 27, 2020, the Company entered into a securities purchase agreement with certain institutional investors, pursuant to which the Company agreed to sell and issue, in a registered direct offering, 8,461,540 of the Company's shares of common stock, par value \$0.001 at a purchase price per share of \$1.30 for aggregate gross proceeds to the Company of approximately \$11.0 million, before deducting fees payable to the placement agent and other estimated offering expenses payable by the Company. The Company closed the offering on February 28, 2020.

On March 9, 2020, the Company entered into a securities purchase agreement with certain institutional investors, pursuant to which the Company agreed to sell and issue, in a registered direct offering, 5,037,038 of the Company's shares of common stock, par value \$0.001 at a purchase price per share of \$1.35 for aggregate gross proceeds to the Company of approximately \$6.8 million, before deducting fees payable to the placement agent and other estimated offering expenses payable by the Company. The Company closed the offering on March 10, 2020.

The Company's consolidated financial statements are prepared using generally accepted accounting principles in the United States of America applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred net losses and negative operating cash flows since inception. For the year ended December 31, 2019, the Company recorded a net loss of approximately \$48,169,000 and used approximately \$1,544,000 of cash in operating activities.

Cautionary Note Regarding Forward Looking Statements

This Annual Report includes forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, including statements regarding the expected timing of initiation of our Phase 1 influenza study, our collaboration with Merck pursuant to the Collaboration Agreement, and our liquidity.

The words "believe," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "could," "target," "potential," "is likely," "will," "expect" and similar expressions, as they relate to us, are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs.

The results anticipated by any or all of these forward-looking statements might not occur. Important factors, uncertainties and risks that may cause actual results to differ materially from these forward-looking statements include continued collaboration with Merck, the availability of products manufactured by third parties, and the ability of clinical research organizations to recruit subjects, favorable results of planned research and, if successful, clinical trials, and receipt of regulatory approvals. Further information on such uncertainties and risks is contained in the “Risk Factors” in Item 1A of this this Annual Report. We undertake no obligation to publicly update or revise any forward-looking statements, whether as the result of new information, future events or otherwise. For more information regarding some of the ongoing risks and uncertainties of our business, see “Item 1A – Risk Factors” and our other filings with the SEC.

Critical Accounting Policies and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. Generally Accepted Accounting Principles, or GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate these estimates and judgments, including those described below. We base our estimates on our 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 and experiences may differ materially from these estimates. While our significant accounting policies are more fully described in the accompanying notes to the consolidated financial statements included in this Annual Report on Form 10-K for the year ended December 31, 2019, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our consolidated financial statements.

Stock-Based Compensation

We account for stock options related to our equity incentive plans under the provisions of Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) 718 which requires the recognition of the fair value of stock-based compensation. The fair value of stock options is estimated using a Black-Scholes option valuation model. This model requires the input of subjective assumptions including expected stock price volatility, expected life and estimated forfeitures of each award. The fair value of equity-based awards is amortized ratably over the requisite service period of the award. Due to the limited amount of historical data available to us, particularly with respect to stock-price volatility, employee exercise patterns and forfeitures, actual results could differ from our assumptions.

Fair Value of Warrants

Warrants are recorded either as equity instruments or derivative liabilities. In the case of warrants recorded as liabilities, they are recorded at their estimated fair value at the date of issuance. Subsequent changes in estimated fair value are recorded in other income (expense) in the Company’s statement of operations in each subsequent period. The warrants are measured at estimated fair value using the Black Scholes valuation model, which is based, in part, upon inputs for which there is little or no observable market data, requiring the Company to develop its own assumptions. Inherent in this model are assumptions related to expected stock price volatility, expected life, risk-free interest rate and dividend yield. We estimate the volatility of our common stock at the date of issuance, and at each subsequent reporting period, based on a combination of the historical implied volatility of our own stock price and that of a group of comparable companies, that matches the expected remaining life of the warrants. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the measurement date for a maturity similar to the expected remaining life of the warrants. The expected life of the warrants is assumed to be equivalent to their remaining contractual term. The dividend rate is based on our historical rate, which we anticipate to remain at zero. The assumptions used in calculating the estimated fair value of the warrants represent our best estimates. However, these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the warrant liability and the change in estimated fair value could be materially different.

Business Combinations and Intangible Assets

In connection with our acquisition of RFS Pharma in November 2014, we acquired a substantial amount of intellectual property. We have accounted for the intellectual property acquired as an in-process research and development (IPR&D) asset and have determined that asset to have an indefinite life based on the stage of development of the research projects of RFS Pharma at the date of acquisition. This intangible asset, which we recorded at its estimated fair value of \$184,966,000 as of the acquisition date, will continue to have an indefinite life until the associated research and development activities are complete, at which point a determination of the asset's useful life will be made. Prior to completion of these research and development activities, the intangible asset will be subject to annual impairment tests, or more frequent tests in the event of any impairment indicators occurring. These impairment tests require significant judgment regarding the status of the research activities, the potential for future revenues to be derived from any products that may result from those activities, and other factors.

The Company conducts its annual impairment test related to the in-process research and development asset as of November 30 each year. The initial valuation recorded in November 2014 at the time of the RFS Pharma acquisition represented the fair value of the acquired hepatitis C program acquired from RFS Pharma. We perform our impairment test using the income approach (also known as the discounted cash flow ("DCF") method, which utilizes the present value of future cash flows to estimate fair value). The future cash flows for our hepatitis C assets are projected based upon our estimates of future revenues, operating income and other factors (such as working capital and capital expenditures). We take into account market conditions for hepatitis C therapies, anticipated new competitive therapies and anticipated market prices of our potential future products as we model future cash flows.

Late in 2015, the Company received reports from ongoing pre-clinical studies that indicated higher than acceptable toxicity related to its hepatitis C lead molecule, CC-1845. As a result, in 2015 we lowered our forecasts of future cash flows, which caused a reduction in value of our hepatitis C assets and which led to an impairment charge recorded in the amount of \$38,665,000 in 2015 related to our IPR&D asset.

In November 2016, due to industry reports forecasting patient volume decreasing and the average price of treatment trending downward, as well as due to increased competition in the hepatitis C market, and partially the result of further data defining the scientific and commercial potential of Company HCV compounds, we further lowered our forecasted cash flows, which resulted in an impairment of our IPR&D asset in the amount of \$92,396,000 in 2016. In late 2018, the Company concluded that given the success of CC-31244 in clinical trials, the Hepatitis C program would move forward solely with CC-31244 without any of the compounds acquired from RFS Pharma. As part of this decision, the Company abandoned all remaining in process research and development intangible assets recognized by the Company and thereafter, we executed our right to terminate the license with Emory on December 6, 2018 (see Note 11 – Licenses and Collaborations). This resulted in a \$53,905,000 impairment in 2018.

We also recorded \$65,195,000 of goodwill in the RFS Pharma acquisition that is subject to impairment testing. This goodwill primarily represents the amount initially recorded as a deferred tax liability in the RFS Pharma acquisition, which was required as the goodwill recorded for book purposes is not tax deductible based on the structure of the acquisition. Impairment tests of goodwill are done annually on November 30 requiring substantial judgment and estimates. We completed our annual goodwill impairment tests for November 30, 2019 and determined that there was a \$46,103,000 impairment of goodwill. There was no impairment of goodwill for November 13, 2018.

Recently Issued Accounting Standards

See discussion in Note 2 to the consolidated financial statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 8. Financial Statements

The consolidated financial statements of Cocrystal Pharma, Inc. required by this Item are described in Item 15 of this Annual Report on Form 10-K and are presented beginning on page F-1.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures

Not applicable.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, have evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2019. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms of the Securities and Exchange Commission. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on this evaluation, management concluded that our disclosure controls and procedures were effective as of December 31, 2019.

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 Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined effective could provide only reasonable assurance with respect to financial statement preparation and presentation.

Our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2019, based on the framework in the Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "2013 Internal Control-Integrated Framework"). Based on our evaluation under the 2013 Internal Control-Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2019.

Changes in Internal Control Over Financial Reporting

With input and oversight from the Audit Committee, management implemented a remediation plan to ensure that control deficiencies contributing to the material weaknesses for the year ended December 31, 2018 were remediated such that these controls now operate effectively. These remediation actions included:

- (i) the implementation of additional review procedures designed to enhance the control owner's execution of controls activities, including entity level controls, through the implementation of improved documentation standards evidencing execution of these controls, oversight, and training;
- (ii) improvement of the control activities and procedures associated with the review of complex accounting areas, including proper segregation of duties and assigning personnel with the appropriate experience as preparers and reviewers over analyses relating to such accounting areas;
- (iii) educating and re-training control owners regarding internal control processes to mitigate identified risks and maintaining adequate documentation to evidence the effective design and operation of such processes; and
- (iv) implementing enhanced controls to monitor the effectiveness of the underlying business process controls that are dependent on the data and financial reports generated from the relevant information systems.

Item 9B. Other Information

None.

COCRYSTAL PHARMA, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Cocrystal Pharma, Inc.
Bothell, Washington

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Cocrystal Pharma, Inc. (the “Company”) and subsidiaries as of December 31, 2019 and 2018, the related consolidated statements of operations, 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 at December 31, 2019 and 2018, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

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 Company Accounting Oversight Board of the 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.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated 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/ Weinberg & Company

We have served as the Company’s auditor since 2019.
Los Angeles, California
March 27, 2020

COCRYSTAL PHARMA, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except per share data)

| | December 31, 2019 | December 31, 2018 |
|--|-------------------|-------------------|
| Assets | | |
| Current assets: | | |
| Cash | \$ 7,418 | \$ 2,723 |
| Restricted cash | 50 | 29 |
| Accounts receivable | 644 | - |
| Prepaid expenses and other current assets | 169 | 191 |
| Total current assets | 8,281 | 2,943 |
| Property and equipment, net | 431 | 384 |
| Deposits | 50 | 40 |
| Operating lease right-of-use assets, net (including \$40 to related party) | 677 | - |
| Goodwill | 19,092 | 65,195 |
| Total assets | \$ 28,531 | \$ 68,562 |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | \$ 1,999 | \$ 1,080 |
| Current maturities of finance lease liabilities | 103 | 214 |
| Current maturities of operating lease liabilities (including \$59 to related party) | 177 | - |
| Derivative liabilities | 7 | 263 |
| Total current liabilities | 2,286 | 1,557 |
| Long-term liabilities: | | |
| Finance lease liabilities | 14 | 117 |
| Operating lease liabilities (including \$40 to related party) | 523 | - |
| Total long-term liabilities | 537 | 117 |
| Total liabilities | 2,823 | 1,674 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Common stock, \$.001 par value; 100,000 and 100,000 shares authorized as of December 31, 2019 and December 31, 2018; 35,150 and 29,938 shares issued and outstanding as of December 31, 2019 and December 31, 2018, respectively | | |
| | 36 | 30 |
| Additional paid-in capital | 260,932 | 253,949 |
| Accumulated deficit | (235,260) | (187,091) |
| Total stockholders' equity | 25,708 | 66,888 |
| Total liabilities and stockholders' equity | \$ 28,531 | \$ 68,562 |

See accompanying notes to consolidated financial statements.

COCRYSTAL PHARMA, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

| | December 31, | |
|---|--------------|-------------|
| | 2019 | 2018 |
| Revenues: | | |
| Collaboration revenue | \$ 6,564 | \$ - |
| Operating expenses: | | |
| Research and development | 4,004 | 4,667 |
| General and administrative | 4,863 | 4,352 |
| Impairments | 46,103 | 53,905 |
| Total operating expenses | 54,970 | 62,924 |
| Loss from operations | (48,406) | (62,924) |
| Other (expense) income: | | |
| Interest expense, net | (19) | (58) |
| Gain on settlement of mortgage note receivable | - | 106 |
| Loss on disposal of property and equipment | - | (60) |
| Change in fair value of derivative liabilities | 256 | 306 |
| Total other income, net | 237 | 294 |
| Loss before income taxes | (48,169) | (62,630) |
| Income tax benefit | - | 13,582 |
| Net loss | \$ (48,169) | \$ (49,048) |
| Net loss per common share: | | |
| Loss per share, basic and diluted | \$ (1.51) | \$ (1.75) |
| Weighted average number of common shares outstanding, basic and diluted | 31,859 | 28,009 |

See accompanying notes to consolidated financial statements.

COCRYSTAL PHARMA, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)

| | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Total Stockholders' Equity |
|--|---------------|--------------|----------------------------------|------------------------|----------------------------------|
| | Shares | Amount | | | |
| Balance as of December 31, 2017 | 24,275 | \$ 24 | \$ 243,419 | \$ (138,043) | \$ 105,400 |
| Stock-based compensation | - | - | 562 | - | 562 |
| Exercise of common stock options | 144 | - | 228 | - | 228 |
| Sale of common stock, net of transaction costs | 4,435 | 5 | 7,679 | - | 7,684 |
| Convertible debt instruments | 1,085 | 1 | 2,061 | - | 2,062 |
| Net loss | - | - | - | (49,048) | (49,048) |
| Balance as of December 31, 2018 | <u>29,939</u> | <u>\$ 30</u> | <u>\$ 253,949</u> | <u>\$ (187,091)</u> | <u>\$ 66,888</u> |

| | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Total Stockholders' Equity |
|--|---------------|--------------|----------------------------------|------------------------|----------------------------------|
| | Shares | Amount | | | |
| Balance as of December 31, 2018 | 29,938 | \$ 30 | \$ 253,949 | \$ (187,091) | \$ 66,888 |
| Stock-based compensation | - | - | 351 | - | 351 |
| Sale of common stock, net of transaction costs | 5,212 | 6 | 6,632 | - | 6,638 |
| Net loss | - | - | - | (48,169) | (48,169) |
| Balance as of December 31, 2019 | <u>35,150</u> | <u>\$ 36</u> | <u>\$ 260,932</u> | <u>\$ (235,260)</u> | <u>\$ 25,708</u> |

See accompanying notes to consolidated financial statements.

COCRYSTAL PHARMA, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

| | 2019 | 2018 |
|--|-------------|-------------|
| Operating activities: | | |
| Net loss | \$ (48,169) | \$ (49,048) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization expense | 98 | 50 |
| Amortization of right of use assets | 156 | - |
| Stock-based compensation | 351 | 562 |
| Interest expense, net | - | 58 |
| Loss on impairment goodwill | 46,103 | - |
| Loss on impairment of in process research and development | - | 53,905 |
| Gain on settlement of mortgage note receivable | - | (106) |
| Loss on disposal of property and equipment | - | 60 |
| Payments on operating lease liabilities | (133) | - |
| Change in fair value of derivative liabilities | (256) | (306) |
| Gain on mortgage note receivable | - | (106) |
| Deferred income tax benefit | - | (13,582) |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (644) | - |
| Prepaid expenses and other current assets | 22 | (86) |
| Deposits | (10) | (9) |
| Accounts payable and accrued expenses | 919 | 240 |
| Deferred rent | - | (28) |
| Net cash used in operating activities | (1,563) | (8,290) |
| Investing activities: | | |
| Purchases of property and equipment | (145) | (28) |
| Proceeds from settlement of mortgage note receivable | - | 1,400 |
| Net cash (used in) provided by investing activities | (145) | 1,372 |
| Financing activities: | | |
| Payments of finance lease obligations | (214) | (19) |
| Proceeds from sale of common stock, net of transaction costs | 6,638 | 7,684 |
| Proceeds from issuance of convertible notes | - | 1,000 |
| Proceeds from exercise of stock options | - | 228 |
| Net cash provided by financing activities | 6,424 | 8,893 |
| Net increase in cash and restricted cash | 4,716 | 1,975 |
| Cash and restricted cash at beginning of period | 2,752 | 777 |
| Cash and restricted cash at end of period | \$ 7,468 | \$ 2,752 |
| SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING ACTIVITIES: | | |
| Purchases of property and equipment under capital leases | \$ - | 347 |
| Recognition of operating lease right-of-use assets and operating lease liabilities upon adoption of ASC Topic 842, <i>Leases</i> | \$ 833 | \$ - |
| Issuance of commons stock upon conversion of notes payable | \$ - | \$ 2,062 |

See accompanying notes to consolidated financial statements.

COCRYSTAL PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Business

Cocrystal Pharma, Inc. (“we”, the “Company” or “Cocrystal”), a biopharmaceutical company, has been developing novel technologies and approaches to create first-in-class and best-in-class antiviral drug candidates since its initial funding in 2008. Our focus is to pursue the development and commercialization of broad-spectrum antiviral drug candidates that will transform the treatment and prophylaxis of viral diseases in humans. By concentrating our research and development efforts on viral replication inhibitors, we plan to leverage our infrastructure and expertise in these areas.

The Company was formerly incorporated in Nevada under the name Biozone Pharmaceuticals, Inc. (“Biozone”). On January 2, 2014, Biozone Pharmaceuticals, Inc. sold substantially all of its assets to MusclePharm Corporation (“MusclePharm”), and, on the same day, merged with Cocrystal Discovery, Inc. in a transaction accounted for as a reverse merger. Following the merger, the Company assumed Cocrystal Discovery, Inc.’s business plan and operations. On March 18, 2014, the Company reincorporated in Delaware under the name Cocrystal Pharma, Inc.

Effective November 25, 2014, Cocrystal Pharma, Inc. and affiliated entities completed a series of merger transactions as a result of which Cocrystal Pharma, Inc. merged with RFS Pharma, LLC, a Georgia limited liability company (“RFS Pharma”). We refer to the surviving entity of this merger as “Cocrystal” or the “Company.”

On January 18, 2018, the Company’s Board of Directors (the “Board”) filed an amendment (the “Amendment”) with the Delaware Secretary of State to affect a one-for-thirty reverse split (the “Reverse Stock Split”) of the Company’s class of common stock. The Amendment took effect on January 24, 2018. The Reverse Stock Split did not change the authorized number of shares of common stock. Pursuant to the terms of the Company’s then outstanding convertible notes (see Note 8 – Convertible Notes Payable), its options and warrants have been proportionately adjusted to reflect the Reverse Stock Split. A proportionate adjustment was made to the per share exercise price, number of shares issued, and shares reserved for issuance under all of the Company’s equity compensation plans.

All per share amounts and number of shares in the consolidated financial statements and related notes presented have been retroactively restated to reflect the Reverse Stock Split.

The Company’s activities since inception have principally consisted of acquiring product and technology rights, raising capital, and performing research and development. Successful completion of the Company’s development programs, obtaining regulatory approvals of its products and, ultimately, the attainment of profitable operations is dependent on future events, including, among other things, its ability to access potential markets, secure financing, develop a customer base, attract, retain and motivate qualified personnel, and develop strategic alliances. Through December 31, 2018, the Company has primarily funded its operations through equity offerings.

The Company has no pharmaceutical products approved for sale, has not generated any revenues to date from pharmaceutical product sales, and has incurred significant operating losses since inception. The Company has never been profitable and has incurred losses from operations of \$48,406,000 and \$62,924,000 in the years ended December 31, 2019 and 2018, respectively.

In July 2018, the Company entered into an Equity Distribution Agreement (the “Distribution Agreement”) with Ladenburg Thalmann & Co. Inc. (“Ladenburg”), Barrington Research Associates, Inc. (“Barrington”), and Alliance Global Partners (“AGP” and together the “Sales Agents”), pursuant to which, and at the Company’s sole discretion, may issue and sell over time, and from time to time, to or through the Sales Agents, up to \$10,000,000 worth of shares of the Company’s common stock. On December 14, 2018, Ladenburg terminated its engagement as a sales agent under the Distribution Agreement. As of December 31, 2018, we had not sold any shares of common stock under the Distribution Agreement.

On March 20, 2019, the Company by written notice suspended at-the-market sales of its common stock pursuant to the Distribution Agreement. The Company also terminated the agreement with Barrington effective March 21, 2019. The Distribution Agreement remains in place with respect to AGP, subject to the suspension of sales discussed above until further notice is provided by the Company to AGP.

On October 30, 2019, the Company and AGP amended and restated its Distribution Agreement to reduce the amount to be raised under the Agreement from \$10,000,000 to \$6,000,000 (inclusive of the \$351,576 which has been raised to date).

On January 29, 2020, the Company and AGP amended and restated its Distribution Agreement to reduce the amount to be raised under the Agreement from \$6,000,000 to \$551,576 (inclusive of the \$351,576 which has been raised to date).

During the year ended December 31, 2019, the Company received an upfront non-refundable payment of \$4,000,000 and employees and research expense reimbursements of approximately \$2,400,000, and anticipates future payments for employees and research expense reimbursements over the term of our collaboration with Merck Sharp & Dohme Corp. (“Merck”), which became effective January 2, 2019 (refer to Note 11, Licenses and Collaborations).

Subsequent to December 31, 2019, the Company sold 16,990,641 shares of its common stock for net proceeds of \$18.2 million

Liquidity

The Company’s consolidated financial statements are prepared using generally accepted accounting principles in the United States of America applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred net losses and negative operating cash flows since inception. For the year ended December 31, 2019, the Company recorded a net loss of approximately \$48,169,000 and used approximately \$1,544,000 of cash in operating activities.

At December 31, 2019, the Company had cash and cash equivalents of approximately \$7.4 million. During the first three months of 2020 we raised approximately \$20.0 million, net \$18.3 million after deducting placement agent fees and offering expenses. We believe that our current resources will be sufficient to fund our operations for the foreseeable future. This estimate is based, in part, upon our currently projected expenditures for 2020 and 2021.

The Company will need to continue obtaining adequate capital to fund operating losses until it becomes profitable. The Company can give no assurances that the additional capital it is able to raise, if any, will be sufficient to meet its needs, or that any such financing will be obtainable on acceptable terms. If the Company is unable to obtain adequate capital, it could be forced to cease operations or substantially curtail its drug development activities. The Company expects to continue incurring substantial operating losses and negative cash flows from operations over the next several years during its pre-clinical and clinical development phases.

2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”), and pursuant to the rules and regulations of the Securities and Exchange Commission (“SEC”) for reporting of annual financial information.

Principles of Consolidation

The consolidated financial statements include the accounts of Cocrystal Pharma, Inc. and its wholly owned subsidiaries: RFS Pharma, LLC, Cocrystal Discovery, Inc., Cocrystal Merger Sub, Inc., Baker Cummins Corp. and Biozone Laboratories, Inc. Intercompany transactions and balances have been eliminated.

Segments

The Company operates in only one segment. Management uses cash flows as the primary measure to manage its business and does not segment its business for internal reporting or decision-making.

Use of Estimates

Preparation of the Company's consolidated financial statements in conformance with U.S. GAAP requires the Company's management to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities in the Company's consolidated financial statements and accompanying notes. The significant estimates in the Company's consolidated financial statements relate to the valuation of equity awards and derivative liabilities, recoverability of deferred tax assets, estimated useful lives of fixed assets, and forecast assumptions used in the valuation of intangible assets and goodwill. The Company bases estimates and assumptions on historical experience, when available, and on various factors that it believes to be reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis, and its actual results may differ from estimates made under different assumptions or conditions.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash deposited in accounts held at two U.S. financial institutions, which may, at times, exceed federally insured limits of \$250,000 for each institution accounts are held. At December 31, 2019 and 2018, our primary operating account held approximately \$7,418,000 and \$2,723,000, respectively, and our collateral account balance was \$50,000 at a different institution. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risks thereof.

As of December 31, 2019, 100% of our revenue and receivables are from one customer.

Risks and Uncertainties

The Company's future results of operations involve a number of risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, rapid technological change, ability to obtain regulatory approvals, competition from currently available treatments and therapies, competition from larger companies, effective protection of proprietary technology, maintenance of strategic relationships, and dependence on key individuals.

Products developed by the Company will require clearances from the U.S. Food and Drug Administration (the "FDA") and other international regulatory agencies prior to commercial sales in their respective markets. The Company's products may not receive the necessary clearances and if they are denied clearance, clearance is delayed, or the Company is unable to maintain clearance, the Company's business could be materially, adversely impacted.

Cash and Restricted Cash

The Company considers all highly liquid investments with an original maturity from the date of purchase of three months or less to be cash equivalents, and the Company held no cash equivalents as of December 31, 2019 and 2018.

The following table provides a reconciliation of cash and restricted cash reported within the consolidated balance sheets that sum to the total of the same such amounts shown in the consolidated statements of cash flows (in thousands):

| | December 31, 2019 | December 31, 2018 |
|--|-------------------|-------------------|
| Cash | \$ 7,418 | \$ 2,723 |
| Restricted cash | 50 | 29 |
| Total cash and restricted cash shown in the statements of cash flows | <u>\$ 7,468</u> | <u>\$ 2,752</u> |

Restricted cash represents amounts pledged as collateral for financing arrangements that are currently limited to the issuance of business credit cards. The restriction will end upon the conclusion of these financing arrangements.

Property and Equipment

Property and equipment, which consists of lab equipment (including lab equipment under capital lease), computer equipment, and office equipment, is recorded at cost and depreciated over the estimated useful lives of the underlying assets (three to five years) using the straight-line method.

Leases

Prior to January 1, 2019, the Company accounted for leases under Accounting Standards Codification (“ASC”) 840, Accounting for Leases. Effective from January 1, 2019, the Company adopted the guidance of ASC 842, Leases, which requires an entity to recognize a right-of-use asset and a lease liability for virtually all leases. The Company adopted ASC 842 using a modified retrospective approach. As a result, the comparative financial information has not been updated and the required disclosures prior to the date of adoption have not been updated and continue to be reported under the accounting standards in effect for those periods. The adoption of ASC 842 on January 1, 2019 resulted in the recognition of operating lease right-of-use assets and lease liabilities of approximately \$833,000 and did not result in a cumulative-effect adjustment to accumulated deficit.

Fair Value Measurements

FASB Accounting Standards Codification (“ASC”) 820 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined under ASC 820 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value under ASC 820 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

Level 1 — quoted prices in active markets for identical assets or liabilities.

Level 2 — other significant observable inputs for the assets or liabilities through corroboration with market data at the measurement date.

Level 3 — significant unobservable inputs that reflect management’s best estimate of what market participants would use to price the assets or liabilities at the measurement date.

The Company categorizes its cash and restricted cash as Level 1 fair value measurements. The Company categorizes its warrants potentially settleable in cash as Level 3 fair value measurements. The warrants potentially settleable in cash are measured at fair value on a recurring basis and are being marked to fair value at each reporting date until they are completely settled or meet the requirements to be accounted for as component of stockholders’ equity. The warrants are valued using the Black-Scholes option pricing model as discussed in Note 10 – Warrants.

At December 31, 2019 and 2018, the carrying amounts of financial assets and liabilities, such as cash, accounts receivable, other assets, and accounts payable and accrued expenses approximate their fair values due to their short-term nature. The carrying values of notes payable approximate their fair values due to the fact that the interest rates on these obligations are based on prevailing market interest rates.

The Company has not transferred any financial instruments into or out of Level 3 classification during the years ended December 31, 2019 and 2018. A reconciliation of the beginning and ending Level 3 liabilities for is as follows (in thousands):

| | Fair Value Measurements Using Significant Unobservable Inputs (Level 3) | |
|---|--|--------|
| | 2019 | 2018 |
| Balance, January 1, | \$ 263 | \$ 569 |
| Change in fair value of warrants potentially settleable in cash (Note 10) | (256) | (306) |
| Balance at December 31, | \$ 7 | \$ 263 |

Goodwill and In-Process Research and Development

We account for business combinations using the acquisition method, recording the acquisition-date fair value of total consideration over the acquisition-date fair value of net assets acquired as goodwill. Acquisition-related costs, including banking, legal, accounting, valuation, and other similar costs, are expensed in the periods in which the costs are incurred and included in loss from operations in the consolidated financial statements. The results of operations of the acquired business are included in the consolidated financial statements from the acquisition date.

In November 2014, goodwill and intangible assets for in-process research and development were recorded in connection with the acquisition of RFS Pharma, and have represented a series of awarded patents, filed patent applications and an in-process research program acquired related to Hepatitis C compound development.

We evaluate indefinite-lived intangible assets and goodwill for impairment annually, as of November 30, or more frequently when events or circumstances indicate that impairment may have occurred. As part of the impairment evaluation, we may elect to perform an assessment of qualitative factors. If this qualitative assessment indicates that it is more likely than not that the fair value of the indefinite-lived intangible asset or the reporting unit (for goodwill) is less than its carrying value, we then would proceed with the quantitative impairment test to compare the fair value to the carrying value and record an impairment charge if the carrying value exceeds the fair value.

Beginning January 1, 2019, the Company early adopted ASU No. 2017-04, "Intangibles-Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment." The standard eliminates the second step in the goodwill impairment test which requires an entity to determine the implied fair value of the reporting unit's goodwill. Instead, an entity should recognize an impairment loss if the carrying value of the net assets assigned to the reporting unit exceeds the fair value of the reporting unit, with the impairment loss not to exceed the amount of goodwill allocated to the reporting unit. Such early adoption did not have a material effect on the Company's financial statements and related disclosures.

Fair value is typically estimated using an income approach based on the present value of future discounted cash flows. The significant estimates in the discounted cash flow model primarily include the discount rate, and rates of future revenue and expense growth and/or profitability of the acquired assets. In performing the impairment test, the Company considered, among other factors, the Company's intention for future use of acquired assets, analyses of historical financial performance and estimates of future performance of Cocrystal's product candidates.

In-process research and development assets are accounted for as indefinite-lived intangible assets and maintained on the balance sheet until either the underlying project is completed, or the asset becomes impaired. If the project is completed, the carrying value of the related intangible assets are amortized to cost of sales over the remaining estimated life of the asset(s), beginning in the period in which the project is completed. If the intangible asset becomes impaired or the related project is abandoned, the carrying value of the underlying intangible asset is written down to its fair value and an impairment charge is recorded in the period in which the impairment occurs and included in operating expenses under research and development within the relative consolidated statement of operations.

As of December 31, 2017, the Company had recorded Goodwill of \$65,195,000 and In Process Research and Development costs of 53,905,000.

The Company has a lead compound, CC-31244, for its Hepatitis C program, which was created at the Company's labs in Bothell, Washington, and not part of the acquisition from RFS Pharma. In 2016, the Company initiated and completed a Phase 1A trial with compound CC-31244, and began a Phase 1B trial with CC-31244 that was completed in 2017. In 2018, the Company began a Phase 2A clinical trial with CC-31244 and released interim results in January 2019. In late 2018, the Company concluded that given the success of CC-31244 in clinical trials, the Hepatitis C program would move forward solely with CC-31244 without any of the compounds acquired from RFS Pharma. As part of this decision, the Company abandoned all remaining in process research and development intangible assets recognized by the Company and thereafter, terminated its license with Emory University on December 6, 2018 (see Note 11 – Licenses and Collaborations). This resulted in a \$53,905,000 impairment in 2018.

At December 31, 2018, the Company had goodwill of \$65,195,000. The Company completed its annual impairment test in November 2019, and at that time determined the fair value of its reporting unit, under both the Company's Nasdaq market capitalization and an income approach analysis; both methods did not exceed the carrying value as of December 31, 2019; therefore, management considered goodwill to be impaired. This resulted in a \$46,103,000 impairment in 2019.

Long-Lived Assets

The Company regularly reviews the carrying value and estimated lives of its long-lived assets, including property and equipment, to determine whether indicators of impairment may exist which warrant adjustments to carrying values or estimated useful lives. The determinants used for this evaluation include management's estimate of the asset's ability to generate positive income from operations and positive cash flow in future periods as well as the strategic significance of the assets to the Company's business objective. Should an impairment exist, the impairment loss would be measured based on the excess of the carrying amount over the asset's fair value.

Mortgage Note Receivable

The Company records its mortgage note receivable at the amount advanced to the borrower, which includes the stated principal amount and certain loan origination and commitment fees that are recognized over the term of the mortgage note. Interest income is accrued as earned over the term of the mortgage note. The Company evaluates the collectability of both interest and principal of the note to determine whether it is impaired. The note is considered impaired if, based on current information and events, the Company determines that it is probable that it would be unable to collect all amounts due according to the existing contractual terms. Upon determination that the note is impaired, the amount of loss is calculated by comparing the recorded investment to the value determined by discounting the expected future cash flows at the note's effective interest rate or to the fair value of the Company's interest in the underlying collateral, less the cost to sell. As discussed in Note 4, the Company's mortgage note receivable was collected in full during 2018.

Research and Development Expenses

All research and development costs are expensed as incurred.

Revenue Recognition

The Company recognizes revenue from research and development arrangements. In accordance with Accounting Standards Codification ("ASC") Topic 606-*Revenue from Contracts with Customers* ("Topic 606"), revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which the Company expects to be entitled to receive in exchange for these goods and services.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*. This ASU provides guidance on whether certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. Accordingly, this amendment added unit of account guidance in Topic 606 when an entity is assessing whether the collaborative arrangement, or a part of the arrangement, is within the scope of Topic 606. In addition, the amendment provides certain guidance on presenting the collaborative arrangement transaction together with Topic 606. The Company adopted ASU 2018-18, effective in the fourth quarter of 2018 with no impact on our consolidated financial statements and related footnote disclosures.

On January 2, 2019, the Company entered into an Exclusive License and Research Collaboration Agreement (the "Collaboration Agreement") with Merck Sharp & Dohme Corp. ("Merck") to discover and develop certain proprietary influenza A/B antiviral agents. Under the terms of the Collaboration Agreement, Merck will fund research and development for the program, including clinical development, and will be responsible for worldwide commercialization of any products derived from the collaboration. During the year ended December 31, 2019 the Company recognized revenue of \$4,368,000 as consideration in exchange for conveyance of intellectual property rights at the signing of the agreement, \$1,838,000 for research and development activities related to its influenza A/B program and \$358,000 for program expense reimbursements.

The Company recognized revenue for the year ended December 31, 2019 and 2018 were \$6,564,000 and \$0, respectively. As of December 31, 2019, accounts receivable of \$644,000 was due from Merck.

Income Taxes

The Company accounts for income taxes under the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to be recovered or settled. Realization of deferred tax assets is dependent upon future taxable income. A valuation allowance is recognized if it is more likely than not that some portion or all of a deferred tax asset will not be realized based on the weight of available evidence, including expected future earnings. The Company recognizes an uncertain tax position in its financial statements when it concludes that a tax position is more likely than not to be sustained upon examination based solely on its technical merits. Only after a tax position passes the first step of recognition will measurement be required. Under the measurement step, the tax benefit is measured as the largest amount of benefit that is more likely than not to be realized upon effective settlement. This is determined on a cumulative probability basis. The full impact of any change in recognition or measurement is reflected in the period in which such change occurs. The Company elects to accrue any interest or penalties related to income taxes as part of its income tax expense.

Stock-Based Compensation

The Company recognizes compensation expense using a fair value-based method for costs related to stock-based payments, including stock options. The fair value of options awarded to employees is measured on the date of grant using the Black-Scholes option pricing model and is recognized as expense over the requisite service period on a straight-line basis.

Use of the Black-Scholes option pricing model requires the input of subjective assumptions including expected volatility, expected term, and a risk-free interest rate. The Company estimates volatility using a blend of its own historical stock price volatility as well as that of market comparable entities since the Company's common stock has limited trading history and limited observable volatility of its own. The expected term of the options is estimated by using the Securities and Exchange Commission Staff Bulletin No. 107's *Simplified Method for Estimate Expected Term*. The risk-free interest rate is estimated using comparable published federal funds rates.

Convertible Notes Payable

The Company accounts for convertible notes payable (when it has determined that the embedded conversion options should not be bifurcated from their host instruments) in accordance with ASC 470-20, *Debt with Conversion and Other Options*. Accordingly, the Company records, when necessary, discounts to convertible notes payable for the intrinsic value of conversion options embedded in debt instruments based upon the differences between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the note. Debt discounts under these arrangements are amortized over the term of the related debt to their earliest date of redemption. The Company determined that the embedded conversion options in its issued convertible notes payable do not meet the definition of a derivative liability.

Common Stock Purchase Warrants and Other Derivative Financial Instruments

We classify as equity any contracts that require physical settlement or net-share settlement or provide us a choice of net-cash settlement or settlement in our own shares (physical settlement or net-share settlement) provided that such contracts are indexed to our own stock as defined in ASC 815-40, *Contracts in Entity's Own Equity*. We classify as assets or liabilities any contracts that require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside our control) or give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement). We assess classification of our common stock purchase warrants and other freestanding derivatives at each reporting date to determine whether a change in classification between assets and liabilities is required.

Recent Accounting Pronouncements

The following are new FASB Accounting Standards Updates that have not been adopted by the Company as of December 31, 2019, and contain detail regarding the effective dates:

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*. This ASU eliminates, adds and modifies certain disclosure requirements for fair value measurements as part of its disclosure framework project. The standard is effective for all entities for financial statements issued for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted. The Company is currently assessing this ASU and has not yet determined the impact ASU 2018-13 may have on its consolidated financial statements.

Other recent authoritative guidance issued by the FASB (including technical corrections to the ASC), the American Institute of Certified Public Accountants, and the Securities and Exchange Commission (“SEC”) did not, or are not expected to, have a material impact on the Company’s consolidated financial statements and related disclosures.

3. Property and Equipment

Property and equipment as of December 31, consists of the following (in thousands):

| | 2019 | 2018 |
|---|----------|--------|
| Lab equipment (excluding equipment under finance leases) | \$ 1,073 | \$ 945 |
| Finance lease right-of-use lab equipment obtained in exchange for finance lease liabilities | 347 | 347 |
| Computer and office equipment | 92 | 75 |
| Total property and equipment | 1,512 | 1,367 |
| Less accumulated depreciation | (1,081) | (983) |
| Property and equipment, net | \$ 431 | \$ 384 |

Depreciation expense was \$98,000 and \$50,000 for the years ended December 31, 2019 and 2018, respectively.

4. Mortgage Note Receivable

In June 2014, the Company acquired a mortgage note from a bank for approximately \$2,626,000 which was collateralized by, among other things, the underlying real estate and related improvements. The property subject to the mortgage was owned by an entity managed by Daniel Fisher, one of the founders of Biozone, the property was also under lease to MusclePharm. The mortgage note had an original maturity date of August 1, 2032 and bore an interest rate of 7.24%.

Shortly thereafter in 2014, Daniel Fisher and his affiliate, 580 Garcia Properties LLC (the primary obligor of the note), brought multiple lawsuits against the Company involving its predecessors and subsidiaries. The lawsuits were later settled and the complaints dismissed, without the Company making any payments to either Mr. Fisher or 580 Garcia Properties LLC. At the time of the note’s acquisition, 580 Garcia Properties LLC was delinquent in its obligation to make monthly payments. In December 2015, the Company proceeded in accordance with rights of a secured real estate creditor under California law, to initiate private foreclosure proceedings. During 2017, the court enjoined the Company from proceeding with the foreclosure sale pending further developments in the litigation.

In February 2018, the Company, Daniel Fisher, and 580 Garcia Properties LLC resolved all outstanding claims and disputes. As part of this settlement, the Company received a payment of \$1,400,000 in exchange for the release of the mortgage note and deed of trust, resulting in a net gain of \$106,000 for disposal of the mortgage note receivable reflected in the consolidated statement of operations for the year ended December 31, 2019.

5. Goodwill and In-Process Research and Development

A reconciliation of the beginning and ending goodwill for the years ended December 31, 2019 and 2018 is as follows (in thousands):

| | 2019 | 2018 |
|-------------------------|------------------|------------------|
| Balance, January 1, | \$ 65,195 | \$ 65,195 |
| Impairment charges | 46,103 | - |
| Balance at December 31, | <u>\$ 19,092</u> | <u>\$ 65,195</u> |

At December 31, 2018, the Company had goodwill of 65,195,000. On November 30, 2019 the Company performed its annual impairment test and determined the fair value of its reporting unit, measured by the Company's Nasdaq market capitalization and an income approach analysis, exceeded the carrying value by \$46,103; therefore, management considered goodwill to be impaired.

A reconciliation of the beginning and ending in-process research and development intangible assets for the years ended December 31, 2019 and 2018 is as follows (in thousands):

| | 2019 | 2018 |
|-------------------------|-------------|-------------|
| Balance, January 1, | \$ - | \$ 53,905 |
| Impairment charges | - | (53,905) |
| Balance at December 31, | <u>\$ -</u> | <u>\$ -</u> |

6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following as of December 31, (in thousands):

| | 2019 | 2018 |
|---|-----------------|-----------------|
| Accounts payable | \$ 1,511 | \$ 616 |
| Accrued compensation | 83 | 78 |
| Accrued other expenses | 405 | 386 |
| Total accounts payable and accrued expenses | <u>\$ 1,999</u> | <u>\$ 1,080</u> |

Accounts payable and accrued other expenses contain unpaid general and administrative expenses and costs related to research and development that have been billed and estimated unbilled, respectively, as of year-end.

7. Common Stock

As of December 31, 2019, the Company has authorized 100,000,000 shares of common stock, \$0.001 par value per share. The Company had 35,150,000 and 29,938,363 shares issued and outstanding as of December 31, 2019 and 2018, respectively.

The holders of common stock are entitled to one vote for each share of common stock held.

On January 18, 2018, the Board of Directors of the Company filed an amendment (the "Amendment") with the Delaware Secretary of State to effect a one-for-thirty reverse split of the Company's common stock. The Amendment took effect on January 24, 2018. No fractional shares were issued or distributed as a result of the Amendment. There was no change in the par value of our common stock.

In May 2018, the Company closed a public offering of 4,435,000 shares of its common stock for net proceeds after transaction costs of approximately \$7,684,000 at \$1.90 per share, and issued the underwriter a warrant to purchase 84,211 shares of common stock at \$2.09 per share over a four-year period beginning October 27, 2018.

On August 6, 2018, the Company held its 2018 Annual Meeting of Shareholders and voted to reduce the number of shares of common stock, \$0.001 par value per share, authorized from 800,000,000 to 100,000,000 shares.

In January, March and November 2019, the Company closed a series of placements of its common stock resulting in the sale of 5,211,695 shares of its common stock for net proceeds after transaction costs of approximately \$6,638,422

In July 2018, the Company entered into an Equity Distribution Agreement (the “Distribution Agreement”) with Ladenburg Thalmann & Co. Inc. (“Ladenburg”), Barrington Research Associates, Inc. (“Barrington”), and Alliance Global Partners (“AGP” and together the “Sales Agents”), pursuant to which, and at the Company’s sole discretion, may issue and sell over time, and from time to time, to or through the Sales Agents, up to \$10,000,000 worth of shares of the Company’s common stock. On December 14, 2018, Ladenburg terminated its engagement as a sales agent under the Distribution Agreement. As of December 31, 2018, we had not sold any shares of common stock under the Distribution Agreement. In March 20, 2019, the Company by written notice suspended at-the-market sales of its common stock pursuant to the Distribution Agreement, dated July 19, 2018 by and among the Company, Ladenburg, Barrington, and AGP. The Company also terminated the engagement of Barrington as a sales agent under the Distribution Agreement effective March 21, 2019. The Distribution Agreement remains in place with respect to AGP, subject to the suspension of sales discussed above until further notice is provided by the Company to AGP. In January 2019, we sold 80,000 shares of common stock under the Distribution Agreement and received net proceeds of approximately \$344,000 which amount was included in the proceeds discussed above.

8. Convertible Notes Payable

On November 24, 2017 and January 31, 2018, the Company entered into securities purchase agreements with two investors, including the Company’s former Chairman of the Board, pursuant to which the company sold an aggregate principal of \$1,000,000, and OPKO Health Inc., a related party, (collectively, the “Purchasers”), pursuant to which the Company sold an additional \$1,000,000, of its 8% convertible notes (collectively, “Convertible Notes”) due on November 24, 2019 and January 31, 2020, respectively. On May 21, 2018, the Company issued a total of 1,085,105 shares of common stock upon conversion of all outstanding 8% convertible notes.

The Convertible Notes, with accrued interest, were convertible into common stock for \$8.10 per share at the option of the Purchasers. In the event the Company completed a financing in which the Company received at least \$10,000,000 in gross proceeds and issued common stock or common stock equivalents to the investor (a “Financing”) or there is a change of control of the Company (or sale of substantially all of the Company’s assets), the outstanding principal amount of the Convertible Notes would automatically convert. Upon the closing of a Financing, the conversion price of the Convertible Notes shall be the lesser of (i) \$8.10 per share or (ii) the price per share of the securities sold in the Financing.

The Company evaluated the embedded conversion features within the Convertible Notes under ASC 815-15 and ASC 815-40 to determine if they required bifurcation as a derivative instrument. The Company determined the embedded conversion features do not meet the definition of a derivative liability, and therefore, do not require bifurcation from the host instrument. In addition, the down-round provision under which the conversion price could be affected by future equity offerings, qualified for a scope exception from derivative accounting with the Company’s early adoption of ASU 2017-11, *Simplifying Accounting for Certain Financial Instruments with Characteristics of Liabilities and Equity*, during the year ended December 31, 2017. Since the embedded conversion features were not considered derivatives, the convertible notes were accounted for in accordance with ASC 470-20, *Debt with Conversion and Other Options*.

In May 2018, the Company completed a financing and issued a total of 4,435,527 shares of common stock at \$1.90 per share, for net proceeds \$7,680,000. Although the financing amount did not contractually effectuate the conversion feature of the Convertible Notes’ securities purchase agreements, the Company allowed Purchasers to convert the Convertible Notes to common stock at the \$1.90 per share price of the May 2018 financing. All outstanding 8% convertible notes were converted to shares of common stock in May 2018 at the aggregate amount of the principal and accrued interest of approximately \$2,062,000 as of the date of conversion, for a total of 1,085,105 common shares issued. The conversion was approved by disinterested members of the Company’s Board of Directors.

9. Stock Based Awards

Equity Incentive Plans

The Company adopted an equity incentive plan in 2007 (the “2007 Plan”) under which 1,786,635 shares of common stock have been reserved for issuance to employees and nonemployee directors and consultants of the Company. Recipients of incentive stock options granted under the 2007 Plan shall be eligible to purchase shares of the Company’s common stock at an exercise price equal to no less than the fair market value of such stock on the date of grant. The maximum term of options granted under the 2007 Plan is ten years. The options generally vest 25% after one year, with the remaining balance vesting monthly over the following three years. As of December 31, 2019, 189,894 options remain available for future grant under this plan.

The Company adopted a second equity incentive plan in 2015 (the “2015 Plan”) under which 1,666,667 shares of common stock have been reserved for issuance to employees, and nonemployee directors and consultants of the Company. Recipients of incentive stock options granted under the 2015 Plan shall be eligible to purchase shares of the Company’s common stock at an exercise price equal to no less than the estimated fair market value of such stock on the date of grant. The maximum term of options granted under the 2015 Plan is ten years. The options generally vest 25% after one year, with the remaining balance vesting monthly over the following three years. As of December 31, 2019, 683,333 options remain available for future grant under the 2015 Plan.

The following table summarizes stock option transactions for the 2007 Plan and 2015 Plan, collectively, for the year ended December 31, 2019 and 2018 (in thousands, except per amounts):

| | Number of Shares Available for Grant | Total Options Outstanding | Weighted Average Exercise Price | Aggregate Intrinsic Value |
|------------------------------|---|---------------------------------|--|---------------------------------|
| Balance at December 31, 2017 | 1,656 | 711 | 8.39 | 1,640 |
| Exercised | - | (143) | 1.69 | - |
| Granted | (925) | 925 | 1.78 | - |
| Cancelled | 142 | (142) | 3.92 | - |
| Balance at December 31, 2018 | 873 | 1,351 | \$ 5.73 | \$ 788 |
| Exercised | - | - | - | - |
| Authorized | 2,295 | - | - | - |
| Cancelled | 420 | (420) | 7.04 | - |
| Balance at December 31, 2019 | 3,588 | 931 | \$ 4.14 | \$ - |

The Company did not grant any stock options during the year ended December 31, 2019. The 925,000 options granted during the year ended December 31, 2018 had a grant date fair value of approximately \$1,949,000. The Black-Scholes option pricing model includes the following weighted average assumptions for grants made during the year ended December 31, 2018:

| Assumptions: | |
|--|---------|
| Weighted average per share grant date fair value | \$ 2.11 |
| Risk-free interest rate | 2.99% |
| Expected dividend yield | 0.00% |
| Expected volatility | 90.00% |
| Expected terms (in years) | 6.1 |

The Company accounts for share-based awards to employees and nonemployees directors and consultants in accordance with the provisions of ASC 718, *Compensation—Stock Compensation*, and under the recently issued guidance following FASB’s pronouncement, ASU 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. Under ASC 718, and applicable updates adopted, share-based awards are valued at fair value on the date of grant and that fair value is recognized over the requisite service, or vesting, period. The Company values its equity awards using the Black-Scholes option pricing model, and accounts for forfeitures when they occur. For the years ended December 31, 2019 and 2018, equity-based compensation expense recorded was \$351,000 and \$562,000, respectively.

As of December 31, 2019, there was \$1,179,000 of total unrecognized compensation expense related to non-vested stock options that is expected to be recognized over a weighted average period of 1.5 years. For options granted and outstanding, there were 930,708 options outstanding which were fully vested or expected to vest, with an aggregate intrinsic value of \$0.00, a weighted average exercise price of \$4.14, and weighted average remaining contractual term of 8 years at December 31, 2019. For vested and exercisable options, outstanding shares totaled 370,395, with an aggregate intrinsic value of \$0.00. These options had a weighted-average exercise price of \$6.20 per share and a weighted-average remaining contractual term of 7 years at December 31, 2019.

The aggregate intrinsic value of outstanding and exercisable options at December 31, 2019 was calculated based on the closing price of the Company's common stock as reported on the Nasdaq Capital Market on December 31, 2019 of approximately \$0.50 per share less the exercise price of the options. The aggregate intrinsic value is calculated based on the positive difference between the closing fair market value of the Company's common stock and the exercise price of the underlying options.

Common Stock Reserved for Future Issuance

The following table presents information concerning common stock available for future issuance as of December 31, (in thousands):

| | <u>2019</u> | <u>2018</u> |
|--|--------------|--------------|
| Stock options issued and outstanding | 931 | 1,351 |
| Shares authorized for future option grants | 3,588 | 873 |
| Convertible notes | - | - |
| Warrants outstanding | <u>243</u> | <u>243</u> |
| Total | <u>4,762</u> | <u>2,467</u> |

10. Warrants

The following is a summary of activity in the number of warrants outstanding to purchase the Company's common stock for the years ended December 31, 2019 and 2018 (in thousands):

| | Warrants Accounted for as: | | Warrants Accounted for as: | | Total |
|--------------------------------|-----------------------------------|------------------------|-----------------------------------|--------------------------|--------------|
| | Equity | | Liabilities | | |
| | May 2018 Warrants | April 2013 Warrants | October 2013 Warrants | January 2014 Warrants | |
| Outstanding, December 31, 2017 | - | 50 | 26 | 133 | 209 |
| Exercised | - | - | - | - | - |
| Granted | 84 | - | - | - | 84 |
| Expired | - | (50) | - | - | (50) |
| Outstanding, December 31, 2018 | <u>84</u> | <u>-</u> | <u>26</u> | <u>133</u> | <u>243</u> |
| Exercised | - | - | - | - | - |
| Granted | - | - | - | - | - |
| Expired | - | - | - | - | - |
| Outstanding, December 31, 2019 | <u>84</u> | <u>-</u> | <u>26</u> | <u>133</u> | <u>243</u> |
| Expiration date | October 27, 2022 | | October 24, 2023 | January 16, 2024 | |

Warrants consist of equity-classified warrants and warrants with the potential to be settled in cash, which are liability-classified warrants. As of December 31, 2019 and 2018, 159,000 warrants are accounted for as liabilities and 84,000 warrants are accounted for as equity.

Warrants Classified as Equity

Equity-classified warrants consist of stand-alone warrants with rights to buy shares of the Company at a pre-designated price on or before the date of expiration, irrespective of the market price. These purchase warrants are not attached to any debt or equity instruments, thus considered freestanding, and there are no circumstances under ASC 815 that require the warrants to be classified as liabilities or as derivatives. Thus, our May 2018 warrants will be classified as equity, and their value will be carried in the additional paid-in capital account in the stockholders' equity section of the balance sheet.

These warrants were granted to the underwriters and investment brokers for services provided related to the Company's May 2018 equity financing, and collectively grant the right to buy 84,211 shares of our stock at \$2.09 per share for up to four years until expiration from the commencement date of October 27, 2018.

Warrants Classified as Liabilities

Liability-classified warrants consist of warrants issued by Biozone in connection with equity financings in October 2013 and January 2014, which were assumed by the Company in connection with its merger with Biozone in January 2014. Warrants accounted for as liabilities have the potential to be settled in cash or are not indexed to the Company's own stock.

The estimated fair value of outstanding warrants accounted for as liabilities is determined at each balance sheet date. Any decrease or increase in the estimated fair value of the warrant liability since the most recent balance sheet date is recorded in the consolidated statement of operations as changes in fair value of derivative liabilities. The fair value of the warrants classified as liabilities is estimated using the Black-Scholes option-pricing model with the following inputs as of December 31, 2019:

| | October 2013 Warrants | January 2014 Warrants |
|-------------------------|--------------------------|--------------------------|
| Strike price | \$ 15.00 | \$ 15.00 |
| Expected dividend yield | 0.00% | 0.00% |
| Expected term (years) | 3.8 | 4.0 |
| Cumulative volatility | 89.59% | 90.58% |
| Risk-free rate | 1.67% | 1.68% |

The fair value of the warrants classified as liabilities is estimated using the Black-Scholes option-pricing model with the following inputs as of December 31, 2018:

| | October 2013 Warrants | January 2014 Warrants |
|-------------------------|--------------------------|--------------------------|
| Strike price | \$ 15.00 | \$ 15.00 |
| Expected dividend yield | 0.00% | 0.00% |
| Expected term (years) | 4.8 | 5.0 |
| Cumulative volatility | 89.64% | 89.76% |
| Risk-free rate | 2.59% | 2.60% |

The Company estimates volatility using a blend of its own historical stock price volatility as well as that of market comparable entities since the Company's common stock has limited trading history and limited observable volatility of its own. The expected life assumption is based on the remaining contractual terms of the warrants. The risk-free rate is based on the zero coupon rates in effect at the balance sheet date. The dividend yield used in the pricing model is zero, because the Company has no present intention to pay cash dividends.

11. Licenses and Collaborations

Merck Sharp & Dohme Corp.

On January 2, 2019, the Company entered into an Exclusive License and Research Collaboration Agreement (the “Collaboration Agreement”) with Merck Sharp & Dohme Corp. (“Merck”) to discover and develop certain proprietary influenza A/B antiviral agents. Under the terms of the Collaboration Agreement, Merck will fund research and development for the program, including clinical development, and will be responsible for worldwide commercialization of any products derived from the collaboration. Cocrysal received an upfront payment of \$4 million and is eligible to receive payments related to designated development, regulatory and sales milestones with the potential to earn up to \$156,000,000, as well as royalties on product sales. Merck can terminate the Collaboration Agreement at any time prior to the first commercial sale of the first product developed under the Collaboration Agreement, in its sole discretion, without cause. The Company continues working with Merck under this Collaboration Agreement.

During the year ended December 31, 2019 the Company recognized revenue of \$4,368,000 as consideration in exchange for conveyance of intellectual property rights at the signing of the agreement, \$1,838,000 for research and development activities related to its influenza A/B program and \$358,000 for program expense reimbursements.

The company recognized revenue for the year ended December 31, 2019 and 2018 were \$6,564,000 and \$0, respectively. As of December 31, 2019, accounts receivable of \$644,000 was due from Merck.

Kansas State University Research Foundation

On February 18, 2020, Cocrysal Pharma, Inc. (the “Company”) entered into a License Agreement (the “Agreement”) with Kansas State University Research Foundation (the “Foundation”) effective February 12, 2020.

Pursuant to the terms of the Agreement, the Foundation granted the Company an exclusive for human use a royalty bearing license to practice under certain patent rights, including a patent and a patent application covering antiviral compounds against coronaviruses and norovirus, and related know-how, to make and sell therapeutic, diagnostic and prophylactic products.

The Company agreed to pay the Foundation a one-time non-refundable license initiation fee in the amount of \$80,000 and an annual license maintenance fee in the amount of \$20,000 per year, and agreed to reimburse the Foundation for third party expenses associated with the filing, prosecution and maintenance of the patent rights in question. The Company also agreed to make certain future milestone payments up to \$3.1 million, dependent upon the progress of clinical trials, regulatory approvals, and initiation of commercial sales in the United States and certain countries outside the United States.

The Agreement will remain in effect until the expiration of the patent rights covered by the Agreement, unless earlier terminated pursuant to customary terms.

12. Net Loss per Share

The Company accounts for and discloses net loss per common share in accordance with FASB ASC Topic 260, *Earnings Per Share*. Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding. Diluted net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares that would have been outstanding during the period assuming the issuance of common stock for all potential dilutive common shares outstanding. Potential common shares consist of shares issuable upon the exercise of stock options and warrants and the conversion of convertible notes payable.

The following table sets forth the computation of basic and diluted net loss per share (in thousands, except per share amounts):

| | 2019 | 2018 |
|---|-------------|-------------|
| Numerator: | | |
| Net loss attributable to common stockholders | \$ (48,169) | \$ (49,048) |
| Denominator: | | |
| Weighted average number of shares outstanding used to compute net loss per share: | | |
| Basic and diluted | 31,859 | 28,009 |
| Net loss per share, basic and diluted | \$ (1.51) | \$ (1.75) |

The following table sets forth the number of potential common shares excluded from the calculations of net loss per diluted share because their inclusion would be anti-dilutive (in thousands):

| | 2019 | 2018 |
|-----------------------------------|--------------|--------------|
| Options to purchase common stock | 930 | 1,351 |
| Convertible notes | - | - |
| Warrants to purchase common stock | 243 | 243 |
| Total | <u>1,173</u> | <u>1,594</u> |

13. Income Taxes

In accordance with the authoritative guidance for income taxes under ASC 740, a deferred tax asset or liability is determined based on the difference between the financial statement and the tax basis of assets and liabilities as measured by the enacted tax rates, which will be in effect when these differences reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized.

The Company recognizes the impact of a tax position in the consolidated financial statements only if that position is more likely than not of being sustained upon examination by taxing authorities, based on the technical merits of the position. The Company's practice is to recognize interest and/or penalties related to income tax matters as income tax expense.

The Company is subject to taxation and files income tax returns in the United States and various state jurisdictions. All tax years from inception to date are subject to examination by the U.S. and state tax authorities due to the carry-forward of unutilized net operating losses and research and development credits. Currently, no years are under examination.

A reconciliation of income tax expense (benefit) for the years ended December 31, 2019 and 2018 is as follows (in thousands):

| | 2019 | 2018 |
|-----------------------------------|-------------|--------------------|
| Current: | | |
| Federal | \$ - | \$ - |
| State | - | - |
| Total current income tax expense | <u>-</u> | <u>-</u> |
| Deferred: | | |
| Federal | - | (10,347) |
| State | - | (3,235) |
| Total deferred income tax benefit | <u>-</u> | <u>(13,582)</u> |
| Total income tax benefit | <u>\$ -</u> | <u>\$ (13,582)</u> |

Significant components of the Company's deferred income taxes at December 31, 2019 and 2018 are shown below (in thousands):

| | 2019 | 2018 |
|--|---------------|---------------|
| Deferred tax assets: | | |
| Net operating loss carryforwards (i)(ii) | \$ 15,406 | \$ 16,849 |
| Compensation | 762 | 819 |
| Research and development tax credits (iii) | 1,996 | 2,023 |
| Property and equipment | (9) | 4 |
| Other | 121 | 84 |
| Total deferred tax assets, gross | 18,425 | 19,779 |
| Deferred tax liabilities: | | |
| Acquired in-process research and development | - | - |
| Total deferred taxes, net | 18,425 | 19,779 |
| Valuation allowance | (18,425) | (19,779) |
| Deferred tax liability, net | \$ - | \$ - |

Balances of deferred tax assets as of December 31, 2019 and 2018, include the following, respectively:

- (i) California net operating loss carryforwards of \$0 and \$1,190,000,
- (ii) Georgia net operating loss carry forwards of \$0 and \$543,000,
- (iii) California research and development tax credits of \$0 and \$203,000.
- (iv) Florida net operating loss carryforwards of \$35,000 and \$28,000.

The Company has established a valuation allowance against net deferred tax assets due to the uncertainty that such assets will be realized. The Company periodically evaluates the recoverability of the deferred tax assets. At such time as it is determined that it is more likely than not that deferred tax assets will be realizable, the valuation allowance will be reduced.

At December 31, 2019, the Company has federal and state net operating losses, or NOL, carryforwards of approximately \$72,100,000 and \$1,000,000, respectively. The federal and Florida loss generated after 2017 of \$10,500,000 and \$1,000,000, respectively, will carryforward indefinitely and be available to offset up to 80% of future taxable income each year. The federal NOL carryforwards begin to expire in 2026.

At December 31, 2019, the Company had federal and state capital loss carryforwards of approximately \$2,000,000 that expire in 2028.

At December 31, 2019, the Company had federal and state capital loss carryforwards of approximately \$1,070,000 that expire in 2023.

The above NOL carryforward and the 3 research tax credit carryforward may be subject to an annual limitation under the Section 382 and 383 of the Internal Revenue Code of 1986, and similar state provisions if the Company experienced one or more ownership changes, which would limit the amount of NOL and tax credit carryforwards that can be utilized to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382 and 383, results from transactions increasing ownership of certain stockholders or public groups in the stock of the corporation by more than 50 percentage points over a three-year period. The Company has not completed an IRC Section 382/383 analysis. If a change in ownership were to have occurred, NOL and tax credits carryforwards could be eliminated or restricted. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance.

A reconciliation of the federal statutory income tax rate to the Company's effective income tax rate is as follows:

| | 2019 | 2018 |
|-----------------------------------|-------------|--------------|
| Statutory federal income tax rate | 21.0% | 21.0% |
| Goodwill impairment | (20.1)% | 0.0% |
| Change in valuation allowance | 3.1% | (3.1)% |
| Other tax, credit and adjustments | (4.0)% | (3.8)% |
| Effective income tax rate | 0.0% | 21.7% |

In December 2017, the Tax Cuts and Jobs Act (the “2017 Tax Act”) was enacted. The 2017 Tax Act includes a number of changes to existing U.S. tax laws that impact the Company, most notably a reduction of the U.S. corporate income tax rate from 35 percent to 21 percent for tax years beginning after December 31, 2017. The 2017 Tax Act also provides for the acceleration of depreciation for certain assets placed in service after September 27, 2017, as well as prospective changes beginning in 2018, including additional limitations on executive compensation, on the deductibility of interest, and on capitalization of research and development expenditures.

In December 2017, the SEC issued Staff Accounting Bulletin No. 118 (“SAB 118”), which provides guidance on accounting for the income tax effects of the 2017 Tax Act. SAB 118 provides a measurement period that should not extend beyond one year from the 2017 Tax Act enactment date for companies to complete the accounting relating to the 2017 Tax Act under Accounting Standards Codification Topic 740, *Income Taxes* (“ASC 740”). In accordance with SAB 118, an entity must reflect the income tax effects of those aspects of the 2017 Tax Act for which the accounting under ASC 740 is complete. To the extent that an entity’s accounting for 2017 Tax Act related income tax effects is incomplete, but the entity is able to determine a reasonable estimate, it must record a provisional estimate in its financial statements.

14. Lease Commitment

The Company leases office space in Miami, Florida and laboratory space in Bothell, Washington under operating leases that expire on August 31, 2021 and January 31, 2024, respectively. The lease for our Miami office is with a related party (see below).

Operating lease right-of-use (“ROU”) assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. ROU assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Generally, the implicit rate of interest in arrangements is not readily determinable and the Company utilizes its incremental borrowing rate in determining the present value of lease payments. The Company’s incremental borrowing rate is a hypothetical rate based on its understanding of what its credit rating would be. The operating lease ROU asset includes any lease payments made and excludes lease incentives.

Prior to January 1, 2019, the Company accounted for leases under ASC 840, Accounting for Leases. Effective January 1, 2019, the Company adopted the guidance of ASC 842, Leases (“ASC 842”), which requires an entity to recognize a right-of-use asset and a lease liability for certain leases. The Company adopted ASC 842 using a modified retrospective approach. As a result, the comparative financial information has not been updated and the required disclosures prior to the date of adoption have not been updated and continue to be reported under the accounting standards in effect for those periods. The adoption of ASC 842 on January 1, 2019, resulted in the recognition of operating lease right-of-use assets of \$833,000 and corresponding lease liabilities of approximately the same amount. There was no cumulative-effect adjustment to accumulated deficit. As of December 31, 2019, the unamortized right of use asset was \$677,000 and total lease liabilities were \$700,000, of which \$177,000 was current.

The components of rent expense and supplemental cash flow information related to leases for the period are as follows (in thousands):

| | Year Ended December 31, 2019 | |
|---|---------------------------------|-----|
| Lease Cost | | |
| Operating lease cost (included in operating expenses in the Company’s consolidated statement of operations) | \$ | 214 |
| Other Information | | |
| Cash paid for amounts included in the measurement of lease liabilities | \$ | 211 |
| Weighted average remaining lease term – operating leases (in years) | | 3.8 |
| Average discount rate – operating leases | | 8% |

The supplemental balance sheet information related to leases for the period is as follows (in thousands):

| | At December 31, 2019 |
|--|-----------------------|
| Operating leases | |
| Long-term right-of-use assets of which \$40 relates to related party, net of amortization of \$156 | \$ 677 |
| Short-term operating lease liabilities, of which \$59 relates to related party | 177 |
| Long-term operating lease liabilities, of which \$40 relates to related party | 523 |
| Total operating lease liabilities | <u>\$ 700</u> |
| Year ending December 31, | (in thousands) |
| 2019 | \$ - |
| 2020 | 226 |
| 2021 | 213 |
| 2022 | 178 |
| 2023 and thereafter | 198 |
| Total minimum operating lease payments | \$ 815 |
| Less: present value discount | (115) |
| Total operating lease liabilities | <u>700</u> |

The minimum lease payments above do not include common area maintenance (CAM) charges, which are contractual obligations under the Company's Bothell, Washington lease, but are not fixed and can fluctuate from year to year. CAM charges for the Bothell, Washington facility are calculated and billed based on total common expenses for the building incurred by the lessor and apportioned to tenants based on square footage. In 2019 and 2018, approximately \$80,000 and \$71,000 of CAM charges for the Bothell, Washington lease were included in operating expenses in the consolidated statements of operations, respectively.

On September 1, 2018, the Company entered into a lease agreement with a limited liability company controlled by Dr. Phillip Frost, a director and a principal shareholder of the Company for the lease of its Miami office (see Note 16 – Transactions with Related Parties). The lease term is three years with an optional three-year extension. Monthly lease payments under this lease total \$254,000 through September 2021. The minimum lease payments above do not include taxes and fees, which are expected to be approximately \$9,000 annually. As of December 31, 2019, the remaining right of use asset relating to this lease was \$677,000 and the remaining lease obligation was \$700,000.

Rent expense, excluding capital leases and CAM charges, for 2019 and 2018 totaled \$226,000 and \$187,000, respectively.

Finance Leases

In November 2018, the Company entered into two lease agreements to acquire equipment with 18 monthly payments of \$18,000 payable through May 27, 2020 and 36 monthly payments of \$1,000 payable through November 21, 2021. The lease agreements have an effective interest rate of 8.01%.

Future minimum finance lease payments, by year and in aggregate, are as follows:

| Year ending December 31, | (in thousands) |
|--------------------------------------|----------------|
| 2019 | \$ - |
| 2020 | 103 |
| 2021 | 14 |
| Total minimum capital lease payments | <u>\$ 121</u> |

The leased lab equipment is included under property and equipment and depreciable over five years. Total assets and accumulated depreciation recognized, net, under finance leases was \$347,000 and \$75,000 as of December 31, 2019, respectively. Total assets and accumulated depreciation recognized, net, under finance leases was \$347,000 and \$6,000 as of December 31, 2018

15. Commitments and Contingencies

Contingencies

From time to time, the Company is a party to, or otherwise involved in, legal proceedings arising in the normal course of business. As of the date of this report, except as described below, the Company is not aware of any proceedings, threatened or pending, against it which, if determined adversely, would have a material effect on its business, results of operations, cash flows or financial position.

On September 20, 2018, Anthony Pepe, individually and on behalf of a class, filed with the United States District Court for the District of New Jersey a complaint against the Company, certain current and former executive officers and directors of the Company and the other defendants named therein for violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. The class consists of the persons and entities who purchased the Company's common stock during the period from September 23, 2013 through September 7, 2018. Pepe also alleges violation of other sections of the Exchange Act by the defendants named in the complaint other than the Company. Pepe seeks damages, pre-judgment and post-judgment interest, reasonable attorneys' fees, expert fees and other costs.

On January 16, 2019, Ms. Susan Church, a stockholder of the Company, filed with the United States District Court for the Western District of Washington a derivative suit against certain current and former executive officers and directors of the Company alleging breach of fiduciary duties, unjust enrichment, waste of corporate assets, and violations of the rules governing proxy solicitation. Church seeks, among other things, money damages, disgorgement of profits from alleged wrongful conduct, including cash bonuses, pre-judgment and post-judgment interest, reasonable attorneys' fees, expert fees and other costs.

On September 7, 2018, the SEC filed with the United States District Court for the Southern District of New York a complaint against Dr. Philip Frost, a director and principal stockholder of the Company, a trust Dr. Frost controls and OPKO Health, Inc., a stockholder of the Company, of which Dr. Frost is the Chief Executive Officer, as well as other defendants named therein. On January 10, 2019, the District Court entered final judgments against these defendants on their consent without admitting or denying the allegations set forth in the complaint. Dr. Frost was permanently enjoined from violating a certain anti-fraud provision of the Securities Act of 1933, future violations of Section 13(d) of the Exchange Act and Rule 13d-1(a) thereunder, and participating in penny stock offerings subject to certain exceptions.

In November 2017, Lee Pederson, a former Biozone lawyer, filed a lawsuit in Minnesota against co-defendants the Company, Dr. Phillip Frost, OPKO Health, Inc. and Brian Keller for various allegations. On September 13, 2018, the United States District Court granted the Company and its co-defendants' motion to dismiss Pederson's amended complaint. Subsequent to September 30, 2018, Pederson has filed a notice of appeal with the United States Court of Appeals for the Eighth Circuit on October 11, 2018. The Court of Appeals recently affirmed the lower court.

While the Company intends to defend itself vigorously from the claims in the aforementioned disputes, it is unable to predict the outcome of these legal proceedings. Any potential loss as a result of these legal proceedings cannot be reasonably estimated. As a result, the Company has not recorded a loss contingency for any of the aforementioned claims.

16. Transactions with Related Parties

In September 2018, the Company leased administrative offices from a limited liability company owned by one of the Company's directors and principal shareholder, Dr. Phillip Frost. The lease term is three years with an optional three-year extension. On an annualized basis, rent expense, including taxes and fees, for this location would be approximately \$62,000. The Company paid a lease deposit of \$4,000 and total rent and other expenses paid in connection with this lease was \$57,000 and \$19,000 for the years ended December 31, 2019 and 2018, respectively.

The offices and laboratory space in Tucker, Georgia were leased from a limited liability company owned by one of Cocrystal's former directors, Dr. Raymond Schinazi and previously leased on a month to month basis. The Company closed its office in Tucker, Georgia, and the last lease payment was made in October 2018. Payments during the year ended December 31, 2018 under this lease were \$77,000.

As further explained in Note 8 – Convertible Notes Payable, on November 24, 2017, the Company entered into a securities purchase agreement with a company significantly owned by the Company's former Chairman of the Board, Dr. Schinazi, pursuant to which the Company sold a principal amount of \$500,000 of 8% convertible notes due November 24, 2019. On January 31, 2018, the Company entered into a securities purchase agreement with OPKO Health, Inc. (the "Purchaser"), a Company affiliated with Dr. Frost, pursuant to which the Company borrowed \$1,000,000 from the Purchaser in exchange for issuing the Purchaser an 8% convertible note due January 31, 2020.

All 8% convertible notes, including accrued interest, were converted to common stock shares in May 2018 at \$1.90 per share. Dr. Schinazi's affiliated Company received 273,367 shares for its 8% convertible notes balance of approximately \$519,000, and OPKO Health, Inc., affiliated with Dr. Frost, received 538,544 shares for its 8% convertible notes balance of approximately \$1,023,000 upon conversion. In the consolidated balance sheets, as of December 31, 2019 there were no amounts due in convertible notes payable to related parties.

17. Subsequent Events

Kansas State University Research Foundation

On February 18, 2020, Cocrystal Pharma, Inc. (the "Company") entered into a License Agreement (the "Agreement") with Kansas State University Research Foundation (the "Foundation") effective February 12, 2020.

Pursuant to the terms of the Agreement, the Foundation granted the Company an exclusive for human use a royalty bearing license to practice under certain patent rights, including a patent and a patent application covering antiviral compounds against coronaviruses and norovirus, and related know-how, to make and sell therapeutic, diagnostic and prophylactic products.

The Company agreed to pay the Foundation a one-time non-refundable license initiation fee in the amount of \$80,000 and an annual license maintenance fee in the amount of \$20,000 per year, and agreed to reimburse the Foundation for third party expenses associated with the filing, prosecution and maintenance of the patent rights in question. The Company also agreed to make certain future milestone payments up to \$3.1 million, dependent upon the progress of clinical trials, regulatory approvals, and initiation of commercial sales in the United States and certain countries outside the United States.

The Agreement will remain in effect until the expiration of the patent rights covered by the Agreement, unless earlier terminated pursuant to customary terms.

Common Stock Sales

On January 29, 2020, the Company entered into a securities purchase agreement with certain institutional investors, pursuant to which the Company agreed to sell and issue, in a registered direct offering, 3,492,063 of the Company's shares of common stock, par value \$0.001 at a purchase price per share of \$0.63 for aggregate gross proceeds to the Company of approximately \$2.2 million, before deducting fees payable to the placement agent and other estimated offering expenses payable by the Company. The Company closed the offering on January 31, 2020.

On February 27, 2020, the Company entered into a securities purchase agreement with certain institutional investors, pursuant to which the Company agreed to sell and issue, in a registered direct offering, 8,461,540 of the Company's shares of common stock, par value \$0.001 at a purchase price per share of \$1.30 for aggregate gross proceeds to the Company of approximately \$11.0 million, before deducting fees payable to the placement agent and other estimated offering expenses payable by the Company. The Company closed the offering on February 28, 2020.

On March 9, 2020, the Company entered into a securities purchase agreement with certain institutional investors, pursuant to which the Company agreed to sell and issue, in a registered direct offering, 5,037,038 of the Company's shares of common stock, par value \$0.001 at a purchase price per share of \$1.35 for aggregate gross proceeds to the Company of approximately \$6.8 million, before deducting fees payable to the placement agent and other estimated offering expenses payable by the Company. The Company closed the offering on March 10, 2020.

PART III

The information required in Items 10 (Directors, Executive Officers and Corporate Governance), Item 11 (Executive Compensation), Item 12 (Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters), Item 13 (Certain Relationships and Related Transactions, and Director Independence), and Item 14 (Principal Accounting Fees and Services) is incorporated by reference to the Company's definitive proxy statement for the 2019 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of December 31, 2019.

PART IV

Item 15. Exhibits, Financial Statement Schedules

EXHIBIT INDEX

| Exhibit No. | Exhibit Description | Incorporated by Reference | | | Filed or Furnished Herewith |
|-------------|--|---------------------------|----------|---------|-----------------------------|
| | | Form | Date | Number | |
| 3.1 | Certificate of Incorporation, as amended | 10-Q | 8/9/18 | 3.1 | |
| 3.2 | Bylaws | 8-K | 12/1/14 | 3.4 | |
| 4.1 | Description of Capital Stock | | | | Filed |
| 10.1 | Sam Lee Employment Agreement* | 8-K | 1/8/14 | 10.2 | |
| 10.2 | Amendment to Sam Lee Employment Agreement* | 10-K | 3/31/15 | 10.6 | |
| 10.3 | 2015 Equity Incentive Plan* | DEF | 6/1/15 | Annex A | |
| 10.4 | Gary Wilcox Advisory Agreement* | 10-K/A | 4/29/16 | 10.16 | |
| 10.5 | James Martin Consulting Agreement* | 8-K | 2/24/17 | 10.1 | |
| 10.6 | Chief Financial Officer Offer Letter dated May 26, 2017 - James Martin* | 8-K | 6/1/17 | 10.1 | |
| 10.7 | Form of Convertible Note dated November 24, 2017 | 8-K | 12/1/17 | 10.2 | |
| 10.8 | Form of Underwriter's Warrant | 8-K | 5/2/18 | 4.1 | |
| 10.9 | Equity Distribution Agreement, dated July 19, 2018** | 8-K | 7/20/18 | 1.1 | |
| 10.9(a) | Amendment No. 1 to the Equity Distribution Agreement | 8-K | 3/26/19 | 10.1 | |
| 10.9(b) | Amended and Restated Equity Distribution Agreement, dated October 30, 2019** | 8-K | 10/30/19 | 1.1 | |
| 10.9(c) | Amendment No. 1 to the Amended and Restated Equity Distribution Agreement | 8-K | 1/29/20 | 1.1 | |
| 10.10 | Exclusive License and Research Collaboration Agreement between the Company and Merck Sharp & Dohme Corp., dated January 2, 2019*** | 10-K | 4/1/19 | 10.12 | |
| 10.11 | Securities Purchase Agreement, dated March 11, 2019 | 8-K | 3/11/19 | 10.1 | |
| 10.12 | Underwriting Agreement, dated October 30, 2019** | 8-K | 10/31/19 | 1.1 | |
| 10.13 | Placement Agency Agreement, dated January 29, 2020 | 8-K | 1/31/20 | 1.1 | |
| 10.14 | Form of Securities Purchase Agreement** | 8-K | 1/31/20 | 10.1 | |
| 10.15 | Engagement Letter, dated February 26, 2020 | 8-K | 3/4/20 | 10.2 | |
| 10.16 | Form of Securities Purchase Agreement, dated February 27, 2020** | 8-K | 3/4/20 | 10.1 | |
| 10.17 | Form of Securities Purchase Agreement, dated March 9, 2020** | 8-K | 3/13/20 | 10.1 | |
| 21.1 | Subsidiaries | | | | Filed |
| 23.1 | Auditors' Consent for Form S-3 and S-8 | | | | Filed |
| 31.1 | Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | | | | Filed |
| 31.2 | Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | | | | Filed |
| 32.1 | Certification of Principal Executive and Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**** | | | | Furnished |
| 101.INS | XBRL Instance Document | | | | Filed |
| 101.SCH | XBRL Taxonomy Extension Schema Document | | | | Filed |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document | | | | Filed |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document | | | | Filed |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document | | | | Filed |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document | | | | Filed |

* Represents management contracts or compensatory plan or arrangement.

** Exhibits have been omitted. The Company undertakes to furnish the omitted exhibits to the Commission upon request.

*** Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been submitted separately to the SEC.

**** This exhibit is being furnished rather than filed and shall not be deemed incorporated by reference into any filing, in accordance with Item 601 of Regulation S-K.

Copies of this report (including the financial statements) and any of the exhibits referred to above will be furnished at no cost to our shareholders who make a written request to our Corporate Secretary at Cocrystal Pharma, Inc., 19805 N. Creek Parkway Bothell, WA 98011.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of 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, thereunto duly authorized.

COCRYSTAL PHARMA, INC.

March 27, 2020

By: /s/ Gary Wilcox
Gary Wilcox
Chief Executive Officer
(Principal Executive Officer)

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

| <u>SIGNATURE</u> | <u>TITLE</u> | <u>DATE</u> |
|---|--|----------------|
| <u>/s/ Gary Wilcox</u> Gary Wilcox | Chief Executive Officer and Chairman (Principal Executive Officer) | March 27, 2020 |
| <u>/s/ Phillip Frost</u> Phillip Frost | Director | March 27, 2020 |
| <u>/s/ Jane Hsiao</u> Jane Hsiao | Director | March 27, 2020 |
| <u>/s/ Steven Rubin</u> Steven Rubin | Director | March 27, 2020 |
| <u>/s/ Anthony Japour</u> Anthony Japour | Director | March 27, 2020 |
| <u>/s/ James Martin</u> James Martin | Chief Financial Officer (Principal Accounting Officer) | March 27, 2020 |

DESCRIPTION OF CAPITAL STOCK

The following is a summary of our capital stock and provisions of our amended and restated articles of incorporation and amended and restated by-laws. For more detailed information, please refer to our certificate of incorporation and by-laws, which are filed, or incorporated by reference, as exhibits to the Annual Report on Form 10-K for the year ended December 31, 2019.

Authorized Capital Stock

We are authorized to issue 100,000,000 shares of common stock, par value \$0.001 per share, and 5,000,000 shares of preferred stock, par value \$0.001 per share. As of March 30, 2020, there were 52,140,699 shares of common stock outstanding.

Common Stock

The holders of common stock are entitled to one vote per share on all matters submitted to a vote of shareholders, including the election of directors. There is no cumulative voting in the election of directors. The holders of common stock are entitled to any dividends that may be declared by the Board of Directors out of funds legally available for payment of dividends subject to the prior rights of holders of preferred stock and any contractual restrictions we have against the payment of dividends on common stock. We have not paid dividends on our common stock since inception and do not plan to pay dividends on our common stock in the foreseeable future. In the event of our liquidation or dissolution, holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preferences of any outstanding shares of preferred stock. Holders of common stock have no preemptive rights and have no right to convert their common stock into any other securities.

Preferred Stock

We are authorized to issue 5,000,000 shares of \$0.001 par value “blank check” preferred stock with designations, rights and preferences as may be determined from time to time by our Board of Directors. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change in control of the Company without further action by shareholders and could adversely affect the rights and powers, including voting rights, of the holders of common stock. In certain circumstances, the issuance of preferred stock could depress the market price of the common stock.

Certain Anti-Takeover Provisions of Our Certificate of Incorporation, Bylaws and Delaware Law

The following is a summary of certain provisions of our Certificate of Incorporation, Bylaws and the Delaware General Corporation Law (“DGCL”) that may have the effect of delaying, deterring or preventing hostile takeovers or changes in control or management of the Company. Such provisions could deprive our shareholders of opportunities to realize a premium on their stock. At the same time, these provisions may have the effect of inducing any persons seeking to acquire or control us to negotiate terms acceptable to our Board.

Effects of authorized but unissued common stock and blank check preferred stock. One of the effects of the existence of authorized but unissued common stock and undesignated preferred stock may be to enable our to make more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, and thereby to protect the continuity of management. If, in the due exercise of its fiduciary obligations, our Board were to determine that a takeover proposal was not in our best interest, such shares could be issued by our Board without shareholder approval in one or more transactions that might prevent or render more difficult or costly the completion of the takeover transaction by diluting the voting or other rights of the proposed acquirer or insurgent shareholder group, by putting a substantial voting block in institutional or other hands that might undertake to support the position of the incumbent Board, by effecting an acquisition that might complicate or preclude the takeover, or otherwise.

In addition, our Certificate of Incorporation grants our Board broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance also may adversely affect the rights and powers, including voting rights, of those holders and may have the effect of delaying, deterring or preventing a change in control of us.

No Cumulative Voting. Our Certificate of Incorporation does not provide for cumulative voting in the election of directors which would allow holders of less than a majority of the stock to elect some directors.

Vacancies. Our Bylaws provide that vacancies on the Board may be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum.

Special Meeting of Shareholders. A special meeting of shareholders may be called by the Board or the holders of not less than 20 percent of all the shares entitled to vote at the meeting.

Amendments to Bylaws. Our Bylaws permit our Board and our shareholders to repeal or amend our Bylaws, and to adopt new Bylaws, in accordance with the DGCL.

Anti-takeover Effects of Delaware Law

We are subject to the “business combination” provisions of Section 203 of the DGCL. In general, such provisions prohibit a publicly-held Delaware corporation from engaging in various “business combination” transactions such as a merger with any interested shareholder which includes, a shareholder owning 15% of a corporation’s outstanding voting securities, for a period of three years after the date in which the person became an interested shareholder, unless:

- The transaction is approved by the corporation’s Board prior to the date the shareholder became an interested shareholder;
- Upon closing of the transaction which resulted in the shareholder becoming an interested shareholder, the shareholder owned at least 85% of the shares of stock entitled to vote generally in the election of directors of the corporation outstanding excluding those shares owned by persons who are both directors and officers and specified types of employee stock plans; or
- On or after such date, the business combination is approved by the Board and at least 66 2/3% of outstanding voting stock not owned by the interested shareholder.

A Delaware corporation may opt out of Section 203 with either an express provision in its original Certificate of Incorporation or an amendment to its Certificate of Incorporation or Bylaws approved by its shareholders. We have not opted out of this Statute. This Statute could prohibit, discourage or delay mergers or other takeover attempts to acquire us.

Transfer Agent and Registrar

Equity Stock Transfer serves as the registrar and transfer agent for our common stock.

Subsidiaries of Cocrystal Pharma, Inc.

| <u>Name of Subsidiary</u> | <u>Jurisdiction of Incorporation</u> |
|----------------------------------|---|
| Cocrystal Discovery, Inc. | Delaware |
| Cocrystal Merger Sub, Inc. | Delaware |

Consent of Independent Registered Public Accounting Firm

Cocrystal Pharma, Inc.
Bothell, Washington

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-220632) and Form S-8 (No. 333-193161 and No. 333-224869) of Cocrystal Pharma, Inc. of our report dated March 27, 2020, relating to the consolidated financial statements, which appear in this Form 10-K.

/s/ Weinberg & Company
Los Angeles, California
March 27, 2020

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Gary Wilcox, certify that:

1. I have reviewed this annual report on Form 10-K of Cocrystal Pharma, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 27, 2020

/s/ Gary Wilcox

Gary Wilcox

Chief Executive Officer

(Principal Executive Officer)

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, James Martin, certify that:

1. I have reviewed this annual report on Form 10-K of Cocrystal Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 27, 2020

/s/ James Martin

James Martin
Chief Financial Officer
(Principal Financial Officer)

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the report of Cocrystal Pharma, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof, I, Gary Wilcox, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and
2. The information contained in the report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Gary Wilcox

Gary Wilcox
Chief Executive Officer
(Principal Executive Officer)
Dated: March 27, 2020

In connection with the report of Cocrystal Pharma, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof, I, James Martin, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and
2. The information contained in the report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ James Martin

James Martin
Chief Financial Officer
(Principal Financial Officer)
Dated: March 27, 2020
