

---

---

**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, 2018**

OR

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

Commission file number: 000-55158

**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 N. 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: Common Stock, \$0.001 par value

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

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

Large accelerated filer  Accelerated filer

Non-accelerated filer  Smaller reporting company

Emerging growth company

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

Indicate by check mark whether the registrant 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 30, 2018, was approximately \$53,814,000.

The number of shares outstanding of the registrant's common stock, as of March 29, 2019, was approximately 31,620,646 shares.

**Documents Incorporated by Reference**

Portions of the registrant's definitive proxy statement for its 2019 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.

---

---

## INDEX

	<b>Page</b>
<b>Part I.</b>	
Item 1. <a href="#">Business.</a>	2
Item 1A. <a href="#">Risk Factors.</a>	9
Item 1B. <a href="#">Unresolved Staff Comments.</a>	35
Item 2. <a href="#">Properties.</a>	35
Item 3. <a href="#">Legal Proceedings.</a>	36
Item 4. <a href="#">Mine Safety Disclosures.</a>	36
<b>Part II.</b>	37
Item 5. <a href="#">Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.</a>	37
Item 6. <a href="#">Selected Financial Data.</a>	37
Item 7. <a href="#">Management’s Discussion and Analysis of Financial Condition and Results of Operations.</a>	37
Item 7A. <a href="#">Quantitative and Qualitative Disclosures About Market Risk.</a>	42
Item 8. <a href="#">Financial Statements.</a>	42
Item 9. <a href="#">Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.</a>	42
Item 9A. <a href="#">Controls and Procedures.</a>	43
Item 9B. <a href="#">Other Information.</a>	44
<b>Part III.</b>	45
Item 10. <a href="#">Directors, Executive Officers and Corporate Governance.</a>	45
Item 11. <a href="#">Executive Compensation.</a>	45
Item 12. <a href="#">Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.</a>	45
Item 13. <a href="#">Certain Relationships and Related Transactions, and Director Independence.</a>	45
Item 14. <a href="#">Principal Accounting Fees and Services.</a>	45
<b>Part IV.</b>	45
Item 15. <a href="#">Exhibits, Financial Statement Schedules.</a>	45
Item 16. <a href="#">Form 10-K Summary</a>	45
<a href="#">SIGNATURES</a>	46

## 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 influenza, Hepatitis C virus (“HCV”), 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 replication function of various 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 and norovirus infections by discovering and developing drug candidates targeting the viral replication complex. 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 approach requires an extensive knowledge of viruses and drug targets to carry out. 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 three important viruses: HCV, influenza, 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) Fast onset of action and/or shortened therapeutic time;
- (2) Good safety and tolerability profile;
- (3) Effective against all viral subtypes that cause disease;
- (4) High barrier to viral resistance; 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.

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.

Norovirus spreads readily among the affected and is 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.

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.

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, spontaneously 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.

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, 2018 and to date in 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 Epclusa, an approved HCV drug. Patients are treated with CC-31244 and Epclusa for two weeks and then Epclusa 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 ongoing at the Institute of Human Virology, University of Maryland School of Medicine and final study results are expected in the second quarter of 2019.

In addition, in October 2018, the Company signed a Clinical Trial Agreement for an investigator-initiated study with the Humanity & Health Research Centre in Hong Kong, China. Under the Clinical Trial Agreement, the Phase 2a study of CC-31244 for the treatment of HCV, which is expected to commence during the first half of 2019, will be sponsored and conducted by the Humanity & Health Research Centre in Hong Kong under the guidance of Dr. George Lau, MBBS (HKU), M.D. (HKU), FRCP (Edin, Lond), FHKAM (Med), FHKCP, FAASLD, Chairman of Humanity and Health Medical Centre, Hong Kong. The Company has agreed to provide CC-31244 to be used in the Phase 2a study.

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

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 profiles. We are currently conducting additional preclinical IND enabling studies and plan to initiate a Phase 1 study during 2020.

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.

#### Norovirus Infections

We continue to identify and develop non-nucleoside polymerase inhibitors using the Company’s proprietary structure-based drug design technology platform.

#### ***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 is presently conducting 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 progressing clinically while 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 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 US as Baloxavir Marboxil (trade name Xofluza®) on October 24, 2018. See “Item 1 – Business – Research and Development Update – Influenza” for more information.

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, 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 crystals, and have identified promising NNIs. We are implementing the platform and approaches that have proven successful in our other antiviral programs.

### ***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 consisted of patents and pending applications in the areas primarily related to the treatment of HCV, Influenza A, and Influenza B.

In our NS5B NNI program, our patent portfolio consists of three related families, including two granted U.S. patents and two pending U.S. patent applications. Counterpart applications in one family are filed in various countries and regions around the world.

In our influenza A program, our patent portfolio consists of two related families, including three pending U.S. provisional applications and pending applications in Patent Cooperation Treaty countries and Taiwan. In our influenza A/B program two pending U.S. provisional applications have been filed.

In our NS3 program for HepC, we have one issued U.S. patent, an allowed European application, and three pending foreign applications in Canada, China, and Japan.

### ***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.

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.

#### 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.

## National Institute of Health

Cocrystal has two Public Health Biological Materials License Agreements with the National Institute of Health. The original license agreements were dated August 31, 2010 and amended on November 6, 2013. The materials licensed are being used in Norovirus assays to screen potential antiviral agents in our library.

### ***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 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 April 1, 2019, we employed 10 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, 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](http://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 the 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 in a Phase 2a clinical trial. Because of the need to complete clinical trials, establish safety and efficacy and obtaining 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 \$187 million from inception through December 31, 2018 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 \$187 million from inception through December 31, 2018, 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.

**Our ability to continue as a going concern is in doubt.**

We anticipate that we will continue to lose money for the foreseeable future. Based on cash on hand as of March 29, 2019 of approximately \$8,700,000, the Company may not have the capital to finance its operations, including any unforeseen expenses such as higher than anticipated legal costs and uninsured catastrophe, for the next 12 months. The Company has incurred net losses and negative operating cash flows since inception. For the year ended December 31, 2018, the Company recorded a net loss of approximately \$49,048,000 and used approximately \$8,290,000 of cash in operating activities. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and allow it to continue as a going concern. These conditions raise substantial doubt about the Company's ability to continue as a going concern. If we are unable to continue as a going concern, our stockholders will likely lose all of their investment in the Company.

**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, 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 in an investigator-sponsored 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.

**SEC regulations limit the amount of funds we may raise during any 12-month period pursuant to our shelf registration Statement on Form S-3.**

Under General Instruction I.B.6 to Form S-3 (the “Baby Shelf Rule”), the amount of funds we can raise through primary public offerings of securities in any 12-month period using our registration statement on Form S-3 is limited to one-third of the aggregate market value of the voting and non-voting common equity held by non-affiliates of the Company. As of March 29, 2019, our public float was approximately \$45 million, based on 16,406,468 shares of outstanding common stock held by non-affiliates and a price of \$2.73 per share, which was the last reported sale price of our common stock on The Nasdaq Capital Market on March 29, 2019. We therefore are limited by the Baby Shelf Rule as of the filing of this Annual Report on Form 10-K, until such time as our public float exceeds \$75 million. If we are required to file a new registration statement on another form, we may incur additional costs and be subject to delays due to review by the SEC Staff. Further, if there is another government shutdown affecting the SEC, any delays could adversely affect our ability to raise capital in a registered public offering.

#### **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 subject to a variety of risks.**

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the 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;
- 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 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 without our knowledge may be developing competitive products, we may later learn that competitive products are superior which may cause to terminate our research efforts of one or more product candidates.**

We face potential completion 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 in 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 do research using animals. Governmental authorities could, for public health or other purposes, limit the use of human or animal research or prohibit the use of our technology. In addition, animal rights activists could protest or make threats against our facilities, which may cause property damage and delay our research. Ethical and other concerns about our methods, such as our use of human subjects in clinical trials or 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. Once the patent life has expired for a product, we may be open to competition from generic medications. Further, if we encounter delays in regulatory approvals, the time during which we could market a product candidate under patent protection could be reduced.

Besides the protection afforded by patents, 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 to release clinical study reports summarizing clinical trial data. However, with only one company having disclosed information as part of the pilot program to date, the FDA in response to concerns expressed by the academic community may consider making release of clinical study reports mandatory and may consider making additional information publicly available on a routine basis, including information we may consider to be trade secrets or other proprietary information.

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 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 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. 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. 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 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, all of the current Democratic Presidential candidates are 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 proposed measures could reduce the ultimate demand for our products, once 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, and our President, Dr. Sam Lee. 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 April 1, 2019, we have 10 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 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.

**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.

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

**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.

**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 incurred impairment charges of approximately \$131,061,000 from our IPR&D prior to and as of December 31, 2017; refer to “Item 7 – Management’s Discussion and Analysis – Critical Accounting Policies and Estimates – Business Combinations and Intangible Assets.” As of December 31, 2018, we incurred an additional \$53,905,000 in non-cash impairment charges which was a full write-off of the remaining IPR&D and we no longer have an IPR&D asset.

We may in the future be required to record 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.

At December 31, 2018 and 2017, the Company had goodwill of \$65,195,000 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 at December 31, 2018; therefore, management did not consider goodwill to be impaired.

**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 28, 2019, our directors, executive officers and principal stockholders (those beneficially owning in excess of 5%), and their respective affiliates, beneficially own approximately 48% 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.

**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.**

We expect that significant additional capital will be needed to continue our planned operations. To the extent we 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 2,467,000 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. See “Item 3 – Legal Proceedings” for more information. Similar allegations are also asserted in a lawsuit filed with the U.S. District Court for the District of Minnesota by a former Biozone Pharmaceuticals, Inc. lawyer, and currently on appeal with the U.S. Court of Appeals for the Eighth Circuit. 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.

**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. If we fail to meet these continued listing requirements, 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.

**Because our common stock is not actively traded, purchasers of our stock may incur difficulty in selling their shares at or above the price they paid for them, or at all.**

Our average daily trading volume on The Nasdaq Capital Market has been approximately 35,400 shares of common stock for the 60 trading days prior to March 28, 2019. An active market for our common stock may never develop, or if it does, it may not be sustained. Accordingly, investors may experience difficulty in selling their shares of common stock at or above the price they paid for them, or at all.

**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, 2019, we had approximately 31,620,646 million shares of common stock outstanding, approximately 15 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 32% of our common stock as of March 29, 2019, resigned as our Board Chairman effective February 1, 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.

**We continue to have material weaknesses in our internal control over financial reporting. If we are unable to remediate these, or if we experience additional material weaknesses in the future or otherwise fail to maintain effective internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and could negatively impact our ability to raise capital.**

Our management has concluded that, as of December 31, 2018, our internal control over financial reporting was not effective. Management has identified two material weaknesses in our internal control over financial reporting related to the following:

- (i) management's failure to maintain an effective financial reporting process to ensure there were timely and documented reviews over completeness and accuracy of information included in the financial statements; and
- (ii) management's failure to design and maintain controls over management's review of technical accounting matters and account reconciliations.

See "Part II – Item 9A – Controls and Procedures" for more information. Although we have developed and are implementing a plan to remediate these material weaknesses, and expect to focus on remediating these material weaknesses in 2019, we may not be able to remediate all or any of them in the near future. Furthermore, additional material weaknesses in our internal control over financial reporting may be identified in the future. Material weaknesses identified by management could result in a material misstatement in our annual or interim financial statements that would not be prevented or detected. If we are unable to remediate the identified material weaknesses or implement required new or improved controls, our ability to record, process and report financial information accurately, and to prepare financial statements within the time periods specified by the rules and forms of the SEC could be adversely affected. The occurrence of or failure to remediate the material weaknesses may adversely affect investor confidence in us and could negatively impact our ability to raise capital.

Recently the SEC sued four public companies alleging in part that they had violated Section 13(b) of the Exchange Act resulting from their failure to remediate material weaknesses in their internal control over financial reporting over an extensive period of time. Three of these companies had remediated their material weaknesses at the time the lawsuits were filed. Since we acquired Cocrystal Discovery, Inc., our principal subsidiary, in January 2014, we have identified and disclosed material weaknesses in internal control over financial reporting beginning with the year ended December 31, 2014 and have since made significant progress in remediating them. As of December 31, 2018, we had two material weaknesses, both of which had previously been identified as of December 31, 2017 and have not been remediated. See “Part II – Item 9a Controls and Procedures” for more information. If the SEC Staff investigates us and following that investigation a lawsuit is filed alleging that we had not remediated our material weaknesses for a number of consecutive annual reporting periods, we will face the following risks:

- It will divert our management’s attention from our core business of drug development;
- We will incur substantial legal fees in connection with both the investigation and the lawsuit if it is filed;
- If we are sued, we may be required to pay a civil monetary penalty in addition to other remedies the SEC or a court may impose;
- Any public disclosure may cause investors to sell our stock which may result in a material decline in our stock price that will cause investors to lose money; and
- Our existing stockholders will experience more dilution as we are required to raise capital at a lower price per share.

**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.

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 has filed a notice of appeal with the United States Court of Appeals for the Eighth Circuit on October 11, 2018.

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 March 28, 2019, there were approximately 425 holders of record of our common stock.

The last reported sales price of our Common stock on Nasdaq on March 28, 2019 was \$2.72 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, 2018, 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 \$17 million gross proceeds over the past 12 months; \$4 million from upfront payment from Merck and \$13 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 signed Clinical Trial Agreement for investigator-initiated Phase 2a study in Hong Kong of CC-31244 in a novel combination therapy for ultra-short treatment of HepC.

- We received FDA clearance to initiate Phase 2a clinical study evaluating CC-31244 for the treatment HepC virus.
- We presented preclinical characterization data of CC-42344 at the 6<sup>th</sup> ISIRV-AVG Conference demonstrating excellent antiviral activity against influenza A strains and favorable pharmacokinetic and safety profile.
- We successfully completed up-listing on the Nasdaq Capital Market.

### ***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. Accordingly, we had no revenue for the years ended December 31, 2018 or 2017. For the year ended December 31, 2018, we had a net loss of \$49,048,000 compared to a net loss of \$613,000 for 2017. This net loss for the year was due to losses from ongoing operations, offset by income tax benefits. The 2018 loss was significantly higher due to an impairment charge of \$53,905,000 on our IPR&D asset offset by a \$13,582,000 deferred tax benefit associated with the impairment charge incurred. Our operating loss for the year ended December 31, 2018 was \$62,924,000 compared to an operating loss of \$8,262,000 in 2017. The operating loss for 2018 included the impairment charge of \$53,905,000 on our IPR&D asset noted above. Other income was \$294,000 for the year ended December 31, 2018, which is primarily due to a \$306,000 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, 2018, 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. This other income or expense is non-cash. We believe investors should focus on our operating loss rather than net income or loss for the periods presented.

### ***Research and Development Expense***

Research and development expenses consist primarily of compensation-related costs for our 8 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. Also included in research and development expense for the year ended December 31, 2018 is an impairment charge related to our in-process research and development (IPR&D) intangible asset in the amount of \$53,905,000, which were acquired through our November 2014 merger with RFS Pharma. We decided to move forward our HCV program solely with CC-31244 compound and abandoned the compounds associated with the IPR&D intangible asset, which were licensed to RFS Pharma by Emory.

Total research and development expenses were \$58,572,000 for the year ended December 31, 2018, compared with \$5,822,000 for the year ended December 31, 2017. This increase of \$52,750,000 is primarily the result of recognizing an impairment loss on IPR&D of \$53,905,000 in 2018. Excluding the impact of the IPR&D impairment charge, research and development expenses were \$4,667,000, and therefore decreased \$1,155,000, for the year ended December 31, 2018. This year over year decrease in research and development expenditures was primarily due to decreased employee compensation costs after closing our Tucker, Georgia lab facility in the fourth quarter of 2017. We expect research and development expenses to decrease in 2019 with the completion of the Phase 2a study in the United States.

Additionally, the planned Hong Kong study research costs will be paid by the investigator and there is limited research remaining from our 2018 United States Phase 2a trial.

### ***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 \$4,352,000 for the year ended December 31, 2018, compared with \$2,440,000 for the year ended December 31, 2017. This increase of \$1,912,000 was primarily due to an \$896,000 insurance reimbursement received by the Company in 2017 for legal costs and a \$132,000 non-cash reversal of stock compensation expense related to unvested options for executives that are no longer with the Company which decreased expenses during the year ended December 31, 2017. The Company also had increases in expenses during the year ended December 31, 2018 including approximately \$141,000 in accounting fees related to SEC filings and \$556,000 in legal costs associated with both litigation and collaboration matters, as well as listing the Company on Nasdaq Capital Market.

In the ordinary course of business, the Company entered into non-cancelable related party leases for its facilities and convertible debt (see Note 15 – Transactions with Related Parties in the following Consolidated Financial Statements).

#### ***Interest Income/Expense***

Interest income (expense) was (\$58,000) for the year ended December 31, 2018, compared to (\$7,000) for the year ended December 31, 2017. The interest expense in 2017 and 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 \$294,000 for the year ended December 31, 2018 compared with \$769,000 for the year ended December 31, 2017. Other income, net for the year ended December 31, 2018 and 2017 primarily consisted of gains of \$306,000 and \$907,000, 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, 2018, we recorded an income tax benefit of 13,582,000 resulting from reduction of our deferred tax liability primarily stemming from the impairment loss recorded for the Company's in-process research and development. For the year ended December 31, 2017, we recorded an income tax benefit of \$6,880,000 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, 2018, net cash used in operating activities was \$8,290,000, compared to net cash used in operating activities of \$6,903,000 for 2017. The increase in cash used in operating activities in 2018 as compared to 2017 was attributable to increased spending in research and development activities for the HCV Phase 2a clinical trials. In 2018, net cash provided by investing activities netted to \$1,372,000, which consisted of receipts related to our mortgage note offset by capital expenditures for lab equipment, software, and computers for the relocated Miami office. For 2017, our net cash used in investing activities consisted of \$40,000 in capital expenditures primarily for lab equipment for our R&D facilities. For the year ended December 31, 2018, net cash provided by financing activities was \$8,893,000, compared to net cash provided by financing activities of \$4,080,000 for 2017. Net cash generated by financing activities in 2018 and 2017 was the result of issuing convertible notes payable, exercises of stock options, and additional issuances of common stock, including our 2018 follow-on offering.

On March 20, 2019, the Company by written notice suspended at-the-market sales of its common stock pursuant to the previously disclosed Equity Distribution Agreement, dated July 19, 2018 (the "Distribution Agreement") by and among the Company, Ladenburg Thalmann & Co. Inc. ("Ladenburg"), Barrington Research Associates, Inc. ("Barrington"), and Alliance Global Partners ("AGP"). Previously, on December 14, 2018, the Company received notice from Ladenburg regarding the termination of its engagement as a sales agent under the Distribution Agreement. On March 20, 2019, the Company terminated Barrington's engagement 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.

Based on cash on hand as of March 29, 2019 of approximately \$8,700,000, the Company may not have the capital to finance its operations including any unforeseen expenses such as higher than anticipated legal costs and uninsured catastrophe to the Company operations for the next 12 months.

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, 2018, the Company recorded a net loss of approximately \$49,048,000 and used approximately \$8,290,000 of cash in operating activities. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and allow it to continue as a going concern. The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until it becomes profitable.

The Company's historical operating results indicate substantial doubt exists related to the Company's ability to continue as a going concern. We can give no assurances that any additional capital that we are able to obtain, if any, will be sufficient to meet our needs, or that any such financing will be obtainable on acceptable terms. If we are unable to obtain adequate capital, we could be forced to cease operations or substantially curtail our commercial activities. These conditions raise substantial doubt as to our ability to continue as a going concern. The accompanying financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should we be unable to continue as a going concern.

#### ***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 release of Phase 2a HCV study results, the commencement of our Phase 2a HCV study in Hong Kong, 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, 2018, 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. Future impairment tests of goodwill will also require substantial judgment and estimates. We completed our annual goodwill impairment tests as of November 30, 2018 and 2017, and determined that there was no impairment of goodwill in any period.

#### Income Taxes

In 2017, our deferred tax liability declined by \$6,880,000 due to the impact of recent changes in the tax laws which, among other things, lowered the corporate tax rate to 21%. The remeasurement of our deferred tax liability generated an income tax benefit of \$6,880,000. In addition to lowering the corporate tax rate for years beginning January 1, 2018, the new tax laws allow for net operating loss carryforwards (“NOL”) to be carried forward indefinitely for losses incurred beginning in 2018, subject to a limitation on the amount that can be used to offset income generated in a given year. Given the change in tax laws, we considered whether the reversal of taxable temporary differences related to the indefinite lived intangible assets may be used as a source of future taxable income in assessing the realizability of deferred tax assets that upon reversal would give rise to NOLs that do not expire, which resulted in an additional tax benefit of approximately \$6,880,000 in 2017.

In 2018, there was no additional impact to our income taxes due to the tax law changes which were measured in 2017 and noted above. The primary driver of 2018 tax benefits recognized was due to the write off of indefinite lived IPR&D intangible assets. We recorded an income tax benefit of \$13,582,000 and eliminated the deferred tax liability in our consolidated balance sheet as of December 31, 2018. Further, the federal net operating loss generated in 2018 of \$8,829,000 will carry forward indefinitely and be available to offset up to 80% of future taxable income. We continue to recognize a full valuation allowance against our net federal and state deferred tax assets at December 31, 2018 as the Company has generated cumulative losses since inception. To the extent the Company starts generating pre-tax book income and/or has other circumstances that would result in the utilization of our net deferred tax assets, our determination regarding the valuation allowance may also change.

#### **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

Our management, with the participation of our interim Chief Executive Officer and 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, 2018. 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 SEC. 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 upon that evaluation, management concluded that our disclosure controls and procedures were not effective as of December 31, 2018 as a result of the material weaknesses in our internal control over financial reporting described below in the "Management's Annual Report on Internal Controls over Financial Reporting."

### Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. 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. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management is also required to assess and report on the effectiveness of our internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 ("Section 404"). Our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2018, 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").

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

During the year ended December 31, 2017, management identified certain material weaknesses related to (i) ineffective preparation and review of manual account reconciliations and (ii) an ineffective financial reporting process with respect to preparation of financial statements in accordance with U.S. GAAP. During the fourth quarter of 2018, management concluded that the previously identified material weaknesses were not remediated as of December 31, 2018, primarily due to the timing of the turnover in our accounting team and the effect of such timing on the transition of responsibilities related to the execution of control activities during the fourth quarter of 2018.

During our assessment of the effectiveness of internal control over financial reporting as of December 31, 2018, our management concluded that our Company has the following material weaknesses in internal control over financial reporting as of December 31, 2018:

#### *Risk Assessment and Control Activities - Management's Review and Supervision of the Financial Reporting Process*

We did not maintain an effective financial reporting process to prepare and present our financial statements in accordance with accounting principles generally accepted in the United States of America. Specifically, the process lacked detailed reviews over the completeness and accuracy of information included in the financial statements. This control deficiency resulted in the reasonable possibility that a material misstatement in the consolidated financial statements would not be prevented or detected on a timely basis.

### ***Control Activities – Management’s Review over Technical Accounting Matters and Account Reconciliations***

Our design and maintenance of controls in the period end financial reporting process over management’s analysis and review of technical accounting matters and account reconciliations (including goodwill, capital leases, warrants, stock options and convertible debt), were ineffective. This material weakness could result in a material misstatement to the Company’s annual or interim financial statements that would not be prevented or detected.

As a result of the material weaknesses noted above, we completed additional procedures prior to filing this Annual Report on Form 10-K for the year ended December 31, 2018. Based on these procedures, management believes that our consolidated financial statements included in this Annual Report on Form 10-K have been prepared in accordance with generally accepted accounting principles. Our chief executive officer and principal financial officer have certified that, based on each such officer’s knowledge, the financial statements, and other financial information included in this Annual Report on Form 10-K, fairly present in all material respects our financial condition, results of operations, and cash flows as of, and for, the periods presented in this Annual Report on Form 10-K.

Our independent registered public accounting firm also attested to, and reported on, the Company’s Internal Control over Financial Reporting, which report expressed an adverse opinion on the effectiveness of our internal controls over financial reporting as of December 31, 2018.

### **Changes in Internal Control over Financial Reporting**

Unless otherwise noted above, there were no changes in internal control over financial reporting that occurred during the year ended December 31, 2018, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Management concluded that certain previously identified material weaknesses, described above, were not remediated as of December 31, 2018, primarily due to the timing of the turnover in our management team and the effect of such timing on the transition of responsibilities related to the execution of control activities.

### **Remedial Actions to Address Material Weaknesses**

With input and oversight from the Audit Committee, management is actively implementing a remediation plan to ensure that control deficiencies contributing to the material weaknesses were remediated such that these controls will operate effectively. We are taking, and expect to continue to take the following remediation actions:

- (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.

We believe that these actions, and the improvements we expect to achieve as a result, will effectively remediate the material weaknesses identified in 2018. However, the material weaknesses in our internal control over financial reporting will not be considered remediated until the remediated controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. We expect that the remediation of these material weaknesses will be completed in 2019.

### **Item 9B. Other Information**

On December 14, 2018, Ladenburg notified the Company regarding termination of its engagement as a sales agent under the Distribution Agreement. See “Part II – Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources” for more information.

COCRYSTAL PHARMA, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	<u>Page</u>
<a href="#">Report of Independent Registered Public Accounting Firm</a>	F-2
<a href="#">Report of Independent Registered Public Accounting Firm on Internal Control over Financial Reporting</a>	F-3
<a href="#">Consolidated Balance Sheets</a>	F-4
<a href="#">Consolidated Statements of Operations</a>	F-5
<a href="#">Consolidated Statements of Stockholders' Equity</a>	F-6
<a href="#">Consolidated Statements of Cash Flows</a>	F-7
<a href="#">Notes to Consolidated Financial Statements</a>	F-8

## 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, 2018 and 2017, 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, 2018 and 2017, 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.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the Company’s internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) and our report dated April 1, 2019 expressed an adverse opinion thereon.

### Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations, negative cash flows from operations and has an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the 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/ BDO USA, LLP

---

We have served as the Company’s auditor since 2013.  
Miami, Florida  
April 1, 2019

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

### Opinion on Internal Control over Financial Reporting

We have audited Cocrystal Pharma, Inc.'s (the "Company's") internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). In our opinion, the Company did not maintain, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

We do not express an opinion or any other form of assurance on management's statements referring to any corrective actions taken by the Company after the date of management's assessment.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of the Company as of December 31, 2018 and 2017, 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") and our report dated April 1, 2019 expressed an unqualified opinion thereon.

### Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying "Item 9A – Management's Report on Internal Control over Financial Reporting". Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit of internal control over financial reporting in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. Material weaknesses regarding management's failure to maintain an effective financial reporting process to ensure there were timely and documented reviews over completeness and accuracy of information included in the financial statements, and management's failure to design and maintain controls over management's review of technical accounting matters and account reconciliations, have been identified and described in management's assessment. These material weaknesses were considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2018 financial statements, and this report does not affect our report dated April 1, 2019 on those financial statements.

### Definition and Limitations of Internal Control over Financial Reporting

A company's 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ BDO USA, LLP

---

Miami, Florida

April 1, 2019

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

	December 31, 2018	December 31, 2017
<b>Assets</b>		
Current assets:		
Cash	\$ 2,723	\$ 748
Restricted cash	29	29
Prepaid expenses and other current assets	191	105
Mortgage note receivable	-	1,294
<b>Total current assets</b>	<b>2,943</b>	<b>2,176</b>
Property and equipment, net	384	119
Deposits	40	31
In-process research and development	-	53,905
Goodwill	65,195	65,195
<b>Total assets</b>	<b>\$ 68,562</b>	<b>\$ 121,426</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,077	\$ 837
Deferred rent	3	31
Current maturities of capital lease obligations	214	-
Derivative liabilities	263	569
<b>Total current liabilities</b>	<b>1,557</b>	<b>1,437</b>
Long-term liabilities		
Capital lease obligations	117	-
Convertible notes payable	-	1,007
Deferred tax liability	-	13,582
<b>Total long-term liabilities</b>	<b>117</b>	<b>14,589</b>
<b>Total liabilities</b>	<b>\$ 1,674</b>	<b>\$ 16,026</b>
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Common stock, \$.001 par value; 100,000 and 800,000 shares authorized December 31, 2018 and December 31, 2017, respectively; 29,938 and 24,275 shares issued and outstanding as of December 31, 2018 and December 31, 2017, respectively (Note 7)	30	24
Additional paid-in capital	253,949	243,419
Accumulated deficit	(187,091)	(138,043)
<b>Total stockholders' equity</b>	<b>66,888</b>	<b>105,400</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 68,562</b>	<b>\$ 121,426</b>

See accompanying notes to consolidated financial statements.

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

	2018	2017
Operating expenses:		
Research and development (includes \$53,905 IPR&D impairment in 2018)	\$ 58,572	\$ 5,822
General and administrative	4,352	2,440
Total operating expenses	62,924	8,262
Loss from operations	(62,924)	(8,262)
Other (expense) income:		
Interest expense, net	(58)	(7)
Other expense	-	(31)
Gain on settlement of mortgage note receivable	106	-
Loss on disposal of property and equipment, net	(60)	(100)
Change in fair value of derivative liabilities	306	907
Total other income, net	294	769
Loss before income taxes	(62,630)	(7,493)
Income tax benefit	13,582	6,880
Net loss	\$ (49,048)	\$ (613)
Net loss per common share, basic and diluted	\$ (1.75)	\$ (0.03)
Weighted average number of common shares outstanding, basic and diluted	28,009	24,126

See accompanying notes to consolidated financial statements.

**COCRYSTAL PHARMA, INC.**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
(in thousands)

	<b>Common Stock</b>		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance as of December 31, 2016	23,801	\$ 24	\$ 239,725	\$ (137,430)	\$ 102,319
Exercise of common stock options	57	-	80	-	80
Stock-based compensation	-	-	614	-	614
Sale of common stock, net of transaction costs	417	-	3,000	-	3,000
Net loss	-	-	-	(613)	(613)
Balance as of December 31, 2017	24,275	\$ 24	\$ 243,419	\$ (138,043)	\$ 105,400
Exercise of common stock options	143	-	228	-	228
Stock-based compensation	-	-	562	-	562
Sale of common stock, net of transaction costs	4,435	5	7,679	-	7,684
Conversion of debt instruments	1,085	1	2,061	-	2,062
Net loss	-	-	-	(49,048)	(49,048)
Balance as of December 31, 2018	29,938	\$ 30	\$ 253,949	\$ (187,091)	\$ 66,888

See accompanying notes to consolidated financial statements.

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

	2018	2017
<b>Operating activities:</b>		
Net loss	\$ (49,048)	\$ (613)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	50	101
Stock-based compensation	562	614
Interest expense, net	58	-
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, net	60	100
Change in fair value of derivative liabilities	(306)	(907)
Deferred income tax benefit	(13,582)	(6,880)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(86)	433
Deposits	(9)	-
Accounts payable and accrued expenses	240	281
Deferred rent	(28)	(32)
Net cash used in operating activities	(8,290)	(6,903)
<b>Investing activities:</b>		
Purchases of property and equipment	(28)	(40)
Proceeds from settlement mortgage note receivable	1,400	-
Net cash provided by (used in) investing activities	1,372	(40)
<b>Financing activities:</b>		
Payments of capital lease obligations	(19)	-
Proceeds from exercise of stock options	228	80
Proceeds from sale of common stock, net of transaction costs	7,684	3,000
Proceeds from issuance of convertible notes	1,000	1,000
Net cash provided by financing activities	8,893	4,080
Net increase (decrease) in cash and restricted cash	1,975	(2,863)
Cash and restricted cash at beginning of period	777	3,640
Cash and restricted cash at end of period	\$ 2,752	\$ 777
<b>SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:</b>		
Purchases of property and equipment under capital leases	\$ 347	\$ -
Issuance of commons stock upon exchange of convertible notes payable, including accrued interest	\$ 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’s historical operating results indicate substantial doubt exists related to the Company’s ability to continue as a going concern. 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 \$62,924,000 and \$8,262,000 in the years ended December 31, 2018 and 2017, 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. As of December 31, 2018, we have not sold any shares of common stock under the Distribution Agreement. On December 14, 2018, Ladenburg terminated its engagement as a sales agent 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.

Subsequent to year-end, on January 31, 2019, the Company received an upfront non-refundable payment of \$4,000,000 and anticipates future payments for employees and research expense reimbursements over the term of our collaboration with Merck Sharp & Dohme Corp. ("Merck"), effective January 2, 2019 (refer to Note 11, Licenses and Collaborations).

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, 2018 and 2017, our primary operating account held approximately \$2,723,000 and \$748,000, respectively, and our collateral account balance was \$29,000 at a different institution. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risks thereof.

### ***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, 2018 and 2017.

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, 2018	December 31, 2017
Cash	\$ 2,723	\$ 748
Restricted cash	29	29
Total cash and restricted cash shown in the statements of cash flows	<u>\$ 2,752</u>	<u>\$ 777</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

Lease agreements entered into by the Company are evaluated to determine whether they are capital leases or operating leases. The Company considers a capital lease if it meets one of the following criteria: a.) Transfer of ownership. The lease transfers ownership of the property to the lessee by the end of the lease term. This criterion is met in situations in which the lease agreement provides for the transfer of title at or shortly after the end of the lease term in exchange for the payment of a nominal fee, for example, the minimum required by statutory regulation to transfer title. b.) Bargain purchase option. The lease contains a bargain purchase option. c.) Lease term. The lease term is equal to 75 percent or more of the estimated economic life of the leased property. d.) Minimum lease payments. The present value at the beginning of the lease term of the minimum lease payments, excluding that portion of the payments representing executory costs such as insurance, maintenance, and taxes to be paid by the lessor, including any profit thereon, equals or exceeds 90 percent of the excess of the fair value of the leased property to the lessor at lease inception over any related investment tax credit retained by the lessor and expected to be realized by the lessor.

In 2018, the Company entered into two new lease agreements for lab equipment which meet the criteria for capital leases due to transfer of ownership at lease-end for a nominal fee. Additionally, the Company had two operating leases for office facilities at year-end (see Note 14 – Commitments and Contingencies).

## 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 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.

The following tables presents a summary of fair values of assets and liabilities that are re-measured at fair value at each balance sheet date presented as of December 31, 2018 and 2017, and their placement within the fair value hierarchy as discussed above (in thousands):

Description	December 31, 2018	Quoted	Significant	Unobservable
		Prices in	Other	Inputs
		Active	Observable	(Level 3)
		Markets	Inputs	
		(Level 1)	(Level 2)	
<b>Assets:</b>				
Cash and restricted cash	\$ 2,752	\$ 2,752	\$ -	\$ -
Total assets	\$ 2,752	\$ 2,752	\$ -	\$ -
<b>Liabilities:</b>				
Warrants potentially settleable in cash (Note 10)	\$ 263	\$ -	\$ -	\$ 263
Total liabilities	\$ 263	\$ -	\$ -	\$ 263

Description	December 31, 2017	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
<b>Assets:</b>				
Cash and restricted cash	\$ 777	\$ 777	\$ -	\$ -
<b>Total assets</b>	<b>\$ 777</b>	<b>\$ 777</b>	<b>\$ -</b>	<b>\$ -</b>
<b>Liabilities:</b>				
Warrants potentially settleable in cash (Note 10)	\$ 569	\$ -	\$ -	\$ 569
<b>Total liabilities</b>	<b>\$ 569</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ 569</b>

The Company has not transferred any financial instruments into or out of Level 3 classification during the years ended December 31, 2018 and 2017. 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)	
	2018	2017
Balance, January 1,	\$ 569	\$ 1,476
Change in fair value of warrants potentially settleable in cash (Note 10)	(306)	(907)
<b>Balance at December 31,</b>	<b>\$ 263</b>	<b>\$ 569</b>

#### ***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.

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.

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 recently 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 and 2017, \$0 and \$53,905,000 was included as in process research and development on the Company's consolidated balance sheets, respectively.

At December 31, 2018 and 2017, the Company had goodwill of \$65,195,000 and determined the fair value of its reporting unit, under both the Company's Nasdaq market capitalization and an income approach analysis; both methods exceeded the carrying value as of December 31, 2018; therefore, management did not consider goodwill to be impaired.

#### ***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***

As discussed in Note 4, the Company's mortgage note receivable was collected in full during 2018.

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.

#### ***Research and Development Expenses***

All research and development costs are expensed as incurred.

### ***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 ("ASUs") that have been adopted by the Company as of December 31, 2018:

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230)*, which addresses the classification of eight specific cash flow issues with the objective of reducing the existing diversity in practice. The required adoption of ASU 2016-15 in the first quarter of 2018 did not have a significant impact on our consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* (“ASU 2016-18”). The guidance requires that an explanation is included in the cash flow statement of the change in the total of (1) cash, (2) cash equivalents, and (3) restricted cash or restricted cash equivalents. The ASU also clarifies that transfers between cash, cash equivalents and restricted cash or restricted cash equivalents should not be reported as cash flow activities and requires the nature of the restrictions on cash, cash equivalents, and restricted cash or restricted cash equivalents to be disclosed. We early adopted ASU 2016-18 at December 31, 2017 and disclosure revisions have been made for the years presented in the notes to consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*, to eliminate the second step of the goodwill impairment test. ASU No. 2017-04 requires an entity to measure a goodwill impairment loss as the amount by which the carrying value of a reporting unit exceeds its fair value. Additionally, an entity should include the income tax effects from any tax-deductible goodwill on the carrying value of the reporting unit when measuring a goodwill impairment loss, if applicable. We early adopted the provisions of ASU 2017-04 prospectively in the fourth quarter of 2018. The adoption of ASU 2017-04 did not have a material impact on the Company’s consolidated financial statements and related disclosures.

In June 2018, the FASB issued ASU 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. ASU 2018-07 will be effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year, with early adoption permitted, provided the entity has also adopted ASC Topic 606, *Revenue from Contracts with Customers*. The Company early adopted ASU 2018-07 in the fourth quarter of 2018, and there was no impact to stock compensation expense recorded in on our consolidated statements of operations for the years ended 2018 and 2017. Refer to Note 9 – Share Based Awards for explanation of the Company’s measurement of fair value for incentive awards issued. As required per the adoption criteria of ASU 2018-07, the Company has concurrently adopted ASC Topic 606, which had no impact on our consolidated financial statements and related footnote disclosures.

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. ASU 2018-18 is effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years and early adoption is permitted. This ASU is to be applied retrospectively to the date of initial application of Topic 606. The Company has early adopted ASU 2018-18, effective in the fourth quarter of 2018 with no impact on our consolidated financial statements and related footnote disclosures.

The following are new FASB Accounting Standards Updates that have not been adopted by the Company as of December 31, 2018, and contain detail regarding the effective dates:

In February 2016, the FASB issued ASU No. 2016-02, *Leases*, which was subsequently amended by ASU No. 2018-01, ASU No. 2018-10 and ASU No. 2018-11 (collectively, “ASC 842”). Under this standard, which applies to both lessors and lessees, lessees will be required to recognize all leases (except for short-term leases) as a lease liability, which is a lessee’s obligation to make lease payments arising from a lease measured on a discounted basis, and as a right-of-use asset, which is an asset that represents the lessee’s right to use, or control the use of, a specified asset for the lease term. Leases will be classified as either financing or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2018. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the consolidated financial statements, with certain practical expedients available. The Company will adopt ASC 842 effective January 1, 2019 using the modified retrospective transition approach and intends to elect the package of practical expedients provided for under ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, has completed its review of all lease contracts that were in place as of December 31, 2018, and is finalizing the calculations of the right-of-use assets and related disclosures. Based upon the preliminary assessment of the Company’s leases, adoption of ASC 842 is not expected to have a material impact on the Company’s consolidated statements of operations, its consolidated statements of cash flows or its opening equity as of January 1, 2019, the effective date. The Company estimates that adoption of the new standard will result in a gross-up on its consolidated balance sheets of approximately \$830,000 relating to operating leases held for office space and laboratory facilities. Additionally, the Company will reclassify the carrying value of the capital leases on laboratory equipment of approximately \$341,000, which was reported as part of property and equipment and capital lease obligations in the consolidated balance sheet as of December 31, 2018, to right of use asset and finance lease liability, in accordance with ASC 842. Our conclusions are preliminary and subject to change as we finalize our analysis. Changes in our lease population or changes in incremental borrowing rates may alter these estimates. We will expand our consolidated financial statements disclosure upon adoption of the new standard.

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, (in thousands):

	2018	2017
Lab equipment	\$ 1,292	\$ 1,168
Computer and office equipment	75	309
Total property and equipment	1,367	1,477
Less accumulated depreciation	(983)	(1,358)
Property and equipment, net	\$ 384	\$ 119

Depreciation expense was \$50,000 and \$101,000 for the years ended December 31, 2018 and 2017, 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, 2018.

#### 5. Goodwill and In-Process Research and Development

A reconciliation of the beginning and ending goodwill for the years ended December 31, 2018 and 2017 is as follows (in thousands):

	2018	2017
Balance, January 1,	\$ 65,195	\$ 65,195
Impairment charges	-	-
Balance at December 31,	<u>\$ 65,195</u>	<u>\$ 65,195</u>

At December 31, 2018 and 2017, the Company had goodwill of \$65,195,000 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; therefore, management did not consider goodwill to be impaired.

A reconciliation of the beginning and ending in-process research and development intangible assets for the years ended December 31, 2018 and 2017 is as follows (in thousands):

	2018	2017
Balance, January 1,	\$ 53,905	\$ 53,905
Impairment charges	(53,905)	-
Balance at December 31,	<u>\$ -</u>	<u>\$ 53,905</u>

#### 6. Accounts Payable and Accrued Expenses

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

	2018	2017
Accounts payable	\$ 616	\$ 494
Accrued compensation	78	144
Accrued other expenses	383	199
Total accounts payable and accrued expenses	<u>\$ 1,077</u>	<u>\$ 837</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, 2018, the Company has authorized 100,000,000 shares of common stock, \$0.001 par value per share. The Company had 29,938,363 and 24,274,494 shares issued and outstanding as of December 31, 2018 and 2017, respectively.

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

On April 20, 2017, the Company closed on proceeds of \$3,000,000 in a private placement offering of 416,667 shares of the Company's common stock at a purchase price of \$7.20 per share to three investors, which included our former Chairman Dr. Raymond F. Schinazi and OPKO Health, Inc., of which the Company's director, Dr. Phillip Frost, is Chairman and Chief Executive Officer.

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 for gross proceeds and net proceeds (inclusive of the additional proceeds from the underwriter exercised from the overallotment options) of approximately \$8,428,000 and \$7,684,000, respectively. The Company sold 4,210,527 shares of common stock to the underwriter at approximately \$1.767 per share, which the underwriter sold to the public 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 May 14, 2018, the underwriter exercised the option to purchase an additional 225,000 shares of common stock at \$1.90 per share for additional gross proceeds and net proceeds of approximately \$428,000 and \$418,000, respectively, solely to cover overallotments. As of December 31, 2018, the underwriter has no further option to purchase additional shares.

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. See Note 8 – Convertible Notes Payable.

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.

## **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.

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 gross proceeds and net proceeds of \$8,428,000 and \$7,680,000, respectively. Although the total gross 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 for approximates \$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, 2018, 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, 2018, 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, 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	2.78	-
Cancelled	142	(142)	3.92	-
Balance at December 31, 2018	<u>873</u>	<u>1,351</u>	<u>\$ 5.73</u>	<u>\$ 788</u>

The Company did not grant any options during the year ended December 31, 2017. 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:

<b>Assumptions:</b>	
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, 2018 and 2017, equity-based compensation expense recorded was \$562,000 and \$614,000, respectively.

As of December 31, 2018, there was \$1,933,000 of total unrecognized compensation expense related to non-vested stock options that is expected to be recognized over a weighted average period of 1.9 years. For options granted and outstanding, there were 1,351,096 options outstanding which were fully vested or expected to vest, with an aggregate intrinsic value of \$788,000, a weighted average exercise price of \$5.73, and weighted average remaining contractual term of 7.5 years at December 31, 2018. For vested and exercisable options, outstanding shares totaled 411,511, with an aggregate intrinsic value of \$29,000. These options had a weighted-average exercise price of \$11.32 per share and a weighted-average remaining contractual term of 2.5 years at December 31, 2018.

The aggregate intrinsic value of outstanding and exercisable options at December 31, 2018 was calculated based on the closing price of the Company's common stock as reported on the Nasdaq Capital Market on December 31, 2018 of approximately \$3.60 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>2018</u>	<u>2017</u>
Stock options issued and outstanding	1,351	711
Shares authorized for future option grants	873	1,656
Convertible notes	-	124
Warrants outstanding	<u>243</u>	<u>209</u>
Total	<u>2,467</u>	<u>2,700</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, 2018 and 2017 (in thousands):

	<u>Warrants Accounted for as: Equity</u>		<u>Warrants Accounted for as: Liabilities</u>		<u>Total</u>
	<u>May 2018 Warrants</u>	<u>April 2013 Warrants</u>	<u>October 2013 Warrants</u>	<u>January 2014 Warrants</u>	
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>
Expiration date	October 27, 2022	April 25, 2018	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, 2018, 159,164 warrants are accounted for as liabilities and 84,211 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, 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 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, 2017:

	October 2013 Warrants	January 2014 Warrants
Strike price	\$ 15.00	\$ 15.00
Expected dividend yield	0.00%	0.00%
Expected term (years)	5.8	6.0
Cumulative volatility	86.70%	87.70%
Risk-free rate	2.30%	2.31%

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

### Emory University

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"). Pursuant to the License Agreement, Emory agreed to add to the Licensed Patents and Licensed Technology Emory's rights to any patent, patent application, invention, or technology application that was based on technology disclosed within three (3) years of March 7, 2013. The License Agreement included payments due to Emory ranging from \$40,000 to \$500,000 based on successful achievement of certain drug development milestones. Additionally, Cocrystal undertook to make royalty payments at 3.5% of net sales due to Emory with a minimum in year one of \$25,000 and increase to \$400,000 in year five upon product commercialization.

The License Agreement covered patents and patent applications for hepatitis C virus (“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 Non-Nucleoside Polymerase Inhibitor, in Phase 2a clinical trial. The Company had the right to terminate the License Agreement at its sole discretion upon a 90 days’ prior written notice and upon payment of all amounts due Emory under the License Agreement through the date of termination. No amounts are due under the License Agreement.

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. Cocrystal 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.

National Institute of Health

Cocrystal has two Public Health Biological Materials License Agreements with the National Institute of Health. The original License Agreements were dated August 31, 2010 and amended on November 6, 2013. The materials licensed are being used in Norovirus assays to screen potential antiviral agents in our library.

Duke University and Emory University

In February 2016, the Company entered into an agreement with Duke University and Emory University to license various patents and know-how to use CRISPR/Cas9 technologies for developing a possible cure for hepatitis B virus (HBV) and human papilloma virus (HPV). On September 25, 2017 (“Termination Date”), the Company mutually terminated the agreement with Duke University and Emory University, there are no further rights or obligations under this license agreement after the termination date.

**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):

	2018	2017
Numerator:		
Net loss attributable to common stockholders	\$ (49,048)	\$ (613)
Denominator:		
Weighted average number of shares outstanding used to compute net loss per share:		
Basic and diluted	28,009	24,126
Net loss per share, basic and diluted	\$ (1.75)	\$ (0.03)

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):

	2018	2017
Options to purchase common stock	1,351	711
Convertible notes	-	124
Warrants to purchase common stock	243	209
Total	1,594	1,044

### 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. At December 31, 2018, there are no unrecognized tax benefits nor any significant accruals for interest related to unrecognized tax benefits or tax penalties.

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, 2018 and 2017 is as follows (in thousands):

	2018	2017
Current:		
Federal	\$ -	\$ -
State	-	-
Total current income tax expense	-	-
Deferred:		
Federal	(10,347)	(6,880)
State	(3,235)	-
Total deferred income tax benefit	(13,582)	(6,880)
Total income tax benefit	\$ (13,582)	\$ (6,880)

Significant components of the Company's deferred income taxes at December 31, 2018 and 2017 are shown below (in thousands):

	2018	2017
<b>Deferred tax assets:</b>		
Net operating loss carryforwards (i)(ii)	\$ 16,849	\$ 15,003
Compensation	819	961
Research and development tax credits (iii)	2,023	1,789
Property and equipment	4	8
Other	84	373
<b>Total deferred tax assets, gross</b>	<b>19,779</b>	<b>18,134</b>
<b>Deferred tax liabilities:</b>		
Acquired in-process research and development	-	(13,875)
<b>Total deferred taxes, net</b>	<b>19,779</b>	<b>4,259</b>
Valuation allowance	(19,779)	(17,841)
<b>Deferred tax liability, net</b>	<b>\$ -</b>	<b>\$ (13,582)</b>

Balances of deferred tax assets as of December 31, 2018 and 2017, include the following, respectively:

- (i) California net operating loss carryforwards of \$1,190,000 and \$1,115,000,
- (ii) Georgia net operating loss carry forwards of \$543,000 and \$941,000,
- (iii) California research and development tax credits of \$203,000 and \$203,000.

The impairment of certain indefinite lived intangibles generated an income tax benefit of \$13,582,000 for the year ended December 31, 2018. After December 31, 2018, the Company does not expect any additional tax expense or tax benefit related to the fully impaired indefinite lived intangibles.

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.

Certain amounts included in the Company's gross deferred tax assets as of December 31, 2018, and specifically detailed under (i) – (iii) in the table above, are recoverable only if the Company generates taxable income in states that it no longer maintains operations, Georgia and California. Due to the Company's present stage of development, the proximity of those states to Florida and Washington where offices are currently located, and the ongoing, existing and potential strategic business relationships within those states considered significant to the Company and its related parties, the Company does not believe recoverability of the Georgia or California deferred tax assets recognized to be more remote than its other federal and state deferred tax assets, nor require additional reserves, at this time. As such, those, and all of the Company's deferred tax assets, have been reported at gross amounts within Note 13 hereto, and are subject to a full valuation allowance.

At December 31, 2018, the Company has federal and state net operating losses, or NOL, carryforwards of approximately \$70,468,000 and \$30,907,000, respectively. The federal NOL carryforwards begin to expire in 2026, and the state NOL carryforwards begin to expire in 2028. The federal loss generated in 2018 of \$8,829,000 will carry forward indefinitely and be available to offset up to 80% of future taxable income each year.

At December 31, 2018, the Company had federal and state capital loss carryforwards of approximately \$1,071,000 that expire in 2023.

At December 31, 2018, the Company also had federal and California research and development tax credit carryforwards of approximately \$1,820,000 and \$257,000, respectively. The federal research and development tax credit carryforwards begin to expire in 2028, and the California research and development tax credit carryforwards do not expire and can be carried forward indefinitely until utilized. The Company has not completed a formal research and development (“R&D”) tax credit study for any of the years the credits were generated. The IRC 41 credit may be subject to change if audited by the IRS. Any changes to the credit would also result in a change in the valuation allowance against the federal and state deferred tax asset associated with R&D tax credits.

The above NOL carryforwards and the research tax credit carryforwards may be subject to an annual limitation under 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.

In 2017, the Company adopted ASU 2016-09, *Compensation - Stock Compensation*. The Company has excess tax benefits for which a benefit could not previously be recognized of approximately \$13,000. The balance of the unrecognized excess tax benefits has been reversed with the impact recorded to retained earnings including any change to the valuation allowance as a result of the adoption in 2017. Due to the full valuation allowance on the U.S. deferred tax assets, there is no impact to the financial statements as a result of this adoption.

A reconciliation of the federal statutory income tax rate to the Company’s effective income tax rate for the years ended December 31, 2018 and 2017 is as follows:

	<u>2018</u>	<u>2017</u>
Statutory federal income tax rate	21.0%	34.0%
Change in fair value of warrant liability	0.1%	4.1%
State income taxes, net of federal benefit	0.5%	(7.5)%
Tax credits	0.3%	3.2%
Change in valuation allowance	(3.1)%	81.2%
Permanent differences	0.1%	1.2%
State rate adjustment	2.9%	-
Tax Cuts and Jobs Act	-	(22.6)%
Equity compensation adjustment	(0.1)%	(1.8)%
Effective income tax rate	21.7%	91.8%

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.

The Company measures deferred tax assets and liabilities using enacted tax rates that will apply in the years in which the temporary differences are expected to be recovered or paid. Accordingly, as of December 31, 2017, the Company's deferred tax assets and liabilities were remeasured to reflect the provisions of the 2017 Tax Act and reduction in the U.S. corporate income tax rate from the highest graduated tax of 35 percent to a 21 percent flat tax. The initial remeasurement of deferred tax liabilities that were related to indefinite-lived intangibles generated an income tax benefit of \$6,587,000, as well as an additional \$293,000 tax benefit as a result of projected NOLs expected to be generated in 2018 and beyond that have an indefinite life under the 2017 Tax Act, for a total tax benefit of \$6,880,000 reflected in the 2017 consolidated statement of operations. In addition, as of December 31, 2017, the initial remeasurement of the deferred tax assets and liabilities that are not associated with indefinite-lived intangibles generated an income tax expense of approximately \$8,282,000, which reduced the Company's gross deferred tax assets, but was entirely offset by the Company's full valuation allowance. The Company completed its evaluation of the potential impacts of the 2017 Tax Act on its 2018 consolidated financial statements and concluded to have no further impact as of December 31, 2018.

#### 14. Commitments and Contingencies

##### *Commitments*

In the ordinary course of business, the Company enters into non-cancelable leases for its facilities, including related party leases (see Note 15 – Transactions with Related Parties), and to purchase equipment. As per Note 2, leases are accounted for as operating leases or capital leases, in accordance with ASC 840, *Leases*.

##### Operating Leases

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 Company recently signed an amendment to the Bothell, Washington lease agreement by extending the lease term for a period of sixty months from, February 2019 through January 2024. Future minimum operating lease payments, by year and in aggregate, are as follows:

Year ending December 31,	(in thousands)
2019	\$ 198
2020	217
2021	207
2022	178
2023 and thereafter	198
Total minimum operating lease payments	<u>\$ 998</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 2018 and 2017, approximately \$71,000 and \$69,000 of CAM charges for the Bothell, Washington lease were included in operating expenses in the consolidated statements of operations, respectively.

The minimum lease payments above include the amounts that would be paid if the Company maintains its Bothell lease for the five-year term, starting February 2019. The Company has the right to terminate this lease after three years on January 31, 2022, by giving prior notice at least nine months before the early termination date and by paying a termination fee equal to the sum of unamortized leasing commissions and reimbursement for tenant improvements provided by the landlord amortized at 8% over the extended term.

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 (see Note 15 – Transactions with Related Parties). The lease term is three years with an optional three-year extension. On an annualized basis, rent expense is approximately \$49,000. The minimum lease payments above do not include taxes and fees, which are expected to be approximately \$9,000, annually.

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 (see Note 15 – Transactions with Related Parties). The Company closed its office in Tucker, Georgia, and the last lease payment was made in October 2018.

Rent expense, excluding capital leases and CAM charges, for 2018 and 2017 totaled \$187,000 and \$293,000, respectively.

#### Capital 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 capital lease payments, by year and in aggregate, are as follows:

Year ending December 31,	(in thousands)	
2019	\$	232
2020		106
2021		15
Total minimum capital lease payments	\$	353

The leased lab equipment is included under property and equipment and depreciable over five years. Total assets and accumulated depreciation recognized, net, under capital leases was \$347,000 and \$6,000 for the year ended December 31, 2018, respectively. The Company had no leases considered to be capital leases as of December 31, 2017.

At December 31, 2018, the aggregate outstanding balance of the capital lease obligations is \$331,000 and the Company expects to pay future interest charges of \$22,000 over the remaining capital lease terms. In 2018, the Company paid \$16,000 and \$3,000 in principal and interest related to capital leases, respectively.

#### 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 Heath, 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.

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.

#### **15. Transactions with Related Parties**

Beginning November 2014 to October 2018, the Company leased its Tucker, Georgia facility from a limited liability company owned by one of Cocrystal's former directors and principal shareholder, Dr. Raymond Schinazi. As of October 2018, the Company cancelled the leasing arrangement and closed its office in Tucker, Georgia. Total rent and other expenses paid in connection with this lease was \$77,000 and \$242,000 for the years ended December 31, 2018 and 2017, respectively.

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 \$58,000. The Company paid a lease deposit of \$4,000 and total rent and other expenses paid in connection with this lease was \$19,000 for the year ended December 31, 2018.

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, 2018 and 2017, approximately \$0 and \$504,000 included in convertible notes payable were amounts due to related parties.

#### **16. Subsequent Events**

##### Merck Collaboration

On January 2, 2019, we 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 solely responsible for worldwide commercialization of any products derived from the collaboration. We received an upfront payment of \$4,000,000 and are eligible to receive milestone payments related to designated development, regulatory and sales milestones with the potential to receive up to \$156,000,000, as well as royalties on product sales. The Collaboration Agreement contains certain termination provisions that can be invoked by either party.

##### Private Placement

On March 13, 2019, the Company closed a private placement of 1,602,283 shares of its common stock and received gross proceeds of \$4,182,000, before deducting offering expenses and commissions, and net proceeds were approximately \$3,674,000.

##### At-the-Market Sales

On 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.

**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, 2018.

**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	<a href="#">Certificate of Incorporation, as amended</a>	10-Q	8/9/18	3.1	
3.2	<a href="#">Bylaws</a>	8-K	12/1/14	3.4	
10.1	<a href="#">Sam Lee Employment Agreement*</a>	8-K	1/8/14	10.2	
10.2	<a href="#">Amendment to Sam Lee Employment Agreement*</a>	10-K	3/31/15	10.6	
10.3	<a href="#">2015 Equity Incentive Plan*</a>	DEF 14A	6/1/15	Annex A	
10.4	<a href="#">Gary Wilcox Advisory Agreement*</a>	10-K/A	4/29/16	10.16	
10.5	<a href="#">James Martin Consulting Agreement*</a>	8-K	2/24/17	10.1	
10.6	<a href="#">Form of Securities Purchase Agreement dated April 20, 2017</a>	8-K	4/24/17	10.1	
10.7	<a href="#">Chief Financial Officer Offer Letter dated May 26, 2017 - James Martin*</a>	8-K	6/1/17	10.1	
10.8	<a href="#">Form of Securities Purchase Agreement dated November 24, 2017</a>	8-K	12/1/17	10.1	
10.9	<a href="#">Form of Convertible Note dated November 24, 2017</a>	8-K	12/1/17	10.2	
10.10	<a href="#">Form of Underwriter's Warrant</a>	8-K	5/2/18	4.1	
10.11	<a href="#">Equity Distribution Agreement, dated July 19, 2018**</a>	8-K	7/20/18	1.1	
10.12	<a href="#">Exclusive License and Research Collaboration Agreement between the Company and Merck Sharp &amp; Dohme Corp., dated January 2, 2019***</a>				Filed
21.1	<a href="#">Subsidiaries</a>				Filed
23.1	<a href="#">Auditors' Consent for Form S-3 and S-8</a>				Filed
31.1	<a href="#">Certification of Principal Executive Officer (302)</a>				Filed
31.2	<a href="#">Certification of Principal Financial Officer (302)</a>				Filed
32.1	<a href="#">Certification of Principal Executive and Principal Financial Officer (906)****</a>				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 requested 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.**

April 1, 2019

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)	April 1, 2019
<u>/s/ Phillip Frost</u> Phillip Frost	Director	April 1, 2019
<u>/s/ Jane Hsiao</u> Jane Hsiao	Director	April 1, 2019
<u>/s/ Steven Rubin</u> Steven Rubin	Director	April 1, 2019
<u>/s/ Todd Brady</u> Todd Brady	Director	April 1, 2019
<u>/s/ James Martin</u> James Martin	Chief Financial Officer (Principal Accounting Officer)	April 1, 2019



**EXCLUSIVE LICENSE AND RESEARCH COLLABORATION AGREEMENT**

**by and between**

**COCRYSTAL PHARMA, INC.**

**and**

**MERCK SHARP & DOHME CORP.**

---

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

## EXCLUSIVE LICENSE AND RESEARCH COLLABORATION AGREEMENT

This Agreement (this “**Agreement**”) is effective as of January 2, 2019 (the “**Effective Date**”), and is entered into by and between Cocrystal Pharma, Inc., a corporation organized and existing under the laws of Delaware (“**Cocrystal**”) and Merck Sharp & Dohme Corp., a corporation organized and existing under the laws of New Jersey (“**Merck**”).

### RECITALS:

**WHEREAS**, Cocrystal has discovered certain Compounds (as hereinafter defined), developed Cocrystal Know-How (as hereinafter defined) and has rights to Cocrystal Patent Rights (as hereinafter defined);

**WHEREAS**, Merck and Cocrystal desire to enter into a research collaboration to discover and develop additional Compounds upon the terms and conditions set forth herein;

**WHEREAS**, Merck desires to obtain a license under the Cocrystal Patent Rights and Cocrystal Know-How upon the terms and conditions set forth herein, and Cocrystal desires to grant such a license;

**NOW, THEREFORE**, in consideration of the foregoing premises and the mutual covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, Cocrystal and Merck hereby agree as follows:

### ARTICLE 1 DEFINITIONS.

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below.

- 1.1 “**AAALAC**” shall mean the Association for Assessment and Accreditation of Laboratory Animal Care International.
- 1.2 “**Act**” shall mean, as applicable, the *United States Federal Food, Drug and Cosmetic Act*, 21 U.S.C. §§ 301 et seq., and/or the *Public Health Service Act*, 42 U.S.C. §§ 262 et seq., as amended from time to time.
- 1.3 “**Affiliate**” shall mean (i) any corporation or business entity of which, now or hereafter, fifty percent (50%) or more of the securities or other ownership interests representing the equity, the voting stock or general partnership interest are owned, controlled or held, directly or indirectly, by Merck or Cocrystal; or (ii) any corporation or business entity which, now or hereafter, directly or indirectly, owns, controls or holds fifty percent (50%) (or the maximum ownership interest permitted by law) or more of the securities or other ownership interests representing the equity, the voting stock or, if applicable, the general partnership interest, of Merck or Cocrystal; or (iii) any corporation or business entity of which, now or hereafter, fifty percent (50%) or more of the securities or other ownership interests representing the equity, the voting stock or general partnership interest are owned, controlled or held, directly or indirectly, by a corporation or business entity described in (i) or (ii).
- 1.4 “**Agreement**” shall have the meaning given such term in the preamble to this document.

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

- 1.5 **Business Day**” means any day other than a Saturday, Sunday, or a day on which commercial banks located in the country where the applicable obligations are to be performed are authorized or required by law to be closed.
- 1.6 **“Calendar Quarter”** shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.
- 1.7 **“Calendar Year”** shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31.
- 1.8 **“Clinical Trial”** shall mean a Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial, and/or Post-approval Clinical Trial.
- 1.9 **“Cocrystal Know-How”** shall mean all information and materials created by Cocrystal [\*], including but not limited to discoveries, improvements, processes, methods, protocols, formulas, data, Inventions (including without limitation any Compound conceived and/or reduced to practice by Cocrystal and as set forth on Schedule 8.4.2), know-how and trade secrets, patentable or otherwise[\*], and which are: (i) Controlled by Cocrystal or its Affiliates, (ii) not generally known, and (iii) necessary or useful to Merck to make, have made, use, import, offer to sell and sell, and otherwise develop, manufacture, market and commercialize Compound and Product in the Field and in the Territory; excluding, however, any (1) Merck Know-How, Cocrystal Patent Rights and Collaboration Information and Inventions, [\*], and (3) any other compounds, materials, adjuvants and delivery devices Controlled by Cocrystal or its Affiliates that are neither necessary nor useful to Merck to make, have made, use, import, offer to sell and sell, and otherwise develop, manufacture, market and commercialize Compound and Product in the Field and in the Territory.
- 1.10 **“Cocrystal Patent Rights”** shall mean Patent Rights that during the Term (as hereinafter defined) are Controlled by Cocrystal or any of its Affiliates, including, but not limited to, the patent application listed on Schedule 1.10, which claim or cover (i) any Compound conceived and/or reduced to practice by Cocrystal [\*], or (ii) a method of use or process of manufacture thereof conceived and/or reduced to practice by Cocrystal [\*], but excluding, however, all Collaboration Patent Rights.
- 1.11 **“Collaboration Information and Inventions”** shall mean all discoveries, improvements, processes, methods, protocols, formulas, data (including all data, results and other information generated by results of X-ray crystallography techniques used in the Research Program), Inventions (including Compounds or improvements thereto conceived and/or reduced to practice by Cocrystal and/or Merck [\*]), know-how and trade secrets, patentable or otherwise[\*], and (i) resulting from the Research Program; (ii) discovered, developed or invented (x) solely by employee(s) of Cocrystal and/or its Affiliates, and/or a Third Party acting on behalf of Cocrystal and/or its Affiliates, (y) solely by employee(s) of Merck and/or its Affiliates, or (z) jointly by the Parties and/or their respective Affiliates and/or a Third Party acting on a Party’s behalf; and (iii) discovered, developed or invented during the period commencing [\*] and ending [\*].
- 1.12 **“Collaboration Patent Rights”** shall mean Patent Rights that claim or cover Collaboration Information and Inventions. [\*]

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

- 1.13 **“Combination Product”** shall mean a Product that includes one or more pharmaceutically active ingredients other than Compound in combination with Compound. All references to Product in this Agreement shall be deemed to include Combination Product.
- 1.14 **“Commercially Reasonable Efforts”** shall mean [\*].
- 1.15 **“Compound”** shall mean any molecule that (i) inhibits the Target [\*] and was discovered, conceived and/or reduced to practice [\*] and (ii) any derivatives or modifications thereof, [\*].
- 1.16 **“Control”, “Controls” or “Controlled by”** shall mean with respect to any item of or right under Cocrystal Patent Rights or Cocrystal Know-How or Merck Know-How, or other intellectual property assets or rights, as applicable, the possession of (whether by ownership or license, other than pursuant to this Agreement) or the ability of a Party to grant access to, or a license or sublicense of, such items or right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Party would be required hereunder to grant the other Party such access or license or sublicense.
- 1.17 **“EMA”** shall mean the European Medicines Agency and any successor Regulatory Authority having substantially the same function.
- 1.18 **“EU Major Countries”** shall mean the countries of Germany, France, Great Britain, Spain and Italy.
- 1.19 **“FDA”** shall mean the United States Food and Drug Administration and any successor Regulatory Authority having substantially the same function.
- 1.20 **“Field”** shall mean all therapeutic (including, without limitation prophylactic) and/or diagnostic uses.
- 1.21 **“First Commercial Sale”** shall mean, with respect to a Product and country, the first sale for end use or consumption of such Product in the country after Marketing Authorization in such country.
- 1.22 **“FTE”** shall mean [\*] hours of a full-time scientist’s work time over [\*] consecutive calendar months (including normal vacations, sick days and holidays).
- 1.23 **“FTE Rate”** shall mean an amount equal to [\*] for one (1) full FTE, which represents the fully burdened annual rate for each such FTE and includes related salary, benefits, administration, facilities costs and overhead.
- 1.24 **“GLP” or “Good Laboratory Practice”** shall mean the applicable then-current standards for laboratory activities for pharmaceuticals or biologicals, as set forth in the Act and any regulations or guidance documents promulgated thereunder, as amended from time to time, together with any similar standards of good laboratory practice as are required by any Regulatory Authority in the Territory.
- 1.25 **“IND”** shall mean an Investigational New Drug application, Clinical Study Application, Clinical Trial Exemption, or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

- 1.26 **“IND Enabling Toxicology Study”** shall mean an animal study under conditions meeting Good Laboratory Practices that is intended to support the filing of an IND for the Product.
- 1.27 **“Indication”** shall mean a separate and distinct disease or medical condition in humans which a Product that is in Clinical Trials is intended to treat, prevent and/or diagnose and/or for which a Product has received Marketing Authorization.
- 1.28 **“Information”** shall mean any and all information and data, including without limitation all Merck Know-How, all Cocrystal Know-How, and all other scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial and commercial information or data, whether communicated in writing or orally or by any other method, which is provided by one Party to the other Party in connection with this Agreement.
- 1.29 **“Initiates”, “Initiated” or “Initiation”** shall mean, (i) with respect to an IND Enabling Toxicology Study, the administration of the first dose to the first animal in such IND Enabling Toxicology Study; or (ii) with respect to a Clinical Trial, the administration of the first dose to the first subject in such Clinical Trial.
- 1.30 **“Invention”** shall mean any process, method, composition of matter, article of manufacture, discovery or finding that is conceived and/or reduced to practice.
- 1.31 **“Liability”** shall mean any and all claims and suits asserted by Third Parties, including all losses, liabilities, damages, costs, fees and expenses, including reasonable attorneys’ fees and expenses of litigation incurred in connection therewith.
- 1.32 **“Major Countries”** shall mean the countries of the United States, United Kingdom, Germany, France, Spain, Italy, [\*].
- 1.33 **“Marketing Authorization”** shall mean all approvals from the relevant Regulatory Authority necessary to market and sell a Product in a country [\*].
- 1.34 **“Merck Know-How”** shall mean all information and materials, including but not limited to discoveries, improvements, processes, methods, protocols, formulas, data, Inventions, know-how and trade secrets, patentable or otherwise, which [\*] (i) are Controlled by Merck or its Affiliates, (ii) are not generally known and (iii) are [\*] necessary to Cocrystal in the performance of its obligations under the Research Program excluding, however, any Collaboration Information and Inventions.
- 1.35 **“NDA”** shall mean a New Drug Application, Biologics License Application, Marketing Authorization Application, filing pursuant to Section 510(k) of the Act, or similar application or submission for Marketing Authorization of a Product filed with a Regulatory Authority to obtain marketing approval for a biological, pharmaceutical or diagnostic product in that country or in that group of countries.
- 1.36 **“Net Sales”** shall mean the gross invoice price[\*] of Product sold by Merck or its Related Parties to the first Third Party after deducting, if not previously deducted, from the amount invoiced or received: [\*]

With respect to sales of Combination Products, Net Sales shall be calculated on the basis of the gross invoice price of Product(s) containing the same strength of Compound sold without other active ingredients. In the event that Product is sold only as a Combination Product, Net Sales shall be calculated on the basis of the gross invoice price of the Combination Product [\*]. In the event that Product is sold only as a Combination Product and either Party reasonably believes that the calculation set forth in this Paragraph does not fairly reflect the value of Compound relative to the other active ingredients in the Combination Product, the Parties shall [\*].

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

- 1.37 **“Party”** shall mean Merck or Cocrystal, individually, and **“Parties”** shall mean Merck and Cocrystal, collectively.
- 1.38 **“Patent Rights”** shall mean any and all patents and patent applications in the Territory (which for the purpose of this Agreement shall be deemed to include certificates of invention and applications for certificates of invention), including divisionals, continuations, continuations-in-part, reissues, renewals, substitutions, registrations, re-examinations, revalidations, extensions, supplementary protection certificates, pediatric exclusivity periods and the like of any such patents and patent applications, and international (i.e., WIPO), regional (e.g., EPO, EA), and foreign national equivalents of the foregoing.
- 1.39 **“Person”** means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, governmental authority or agency, or any other entity not specifically listed herein.
- 1.40 **“Phase I Clinical Trial”** shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(a).
- 1.41 **“Phase II Clinical Trial”** shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(b).
- 1.42 **“Phase III Clinical Trial”** shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(c).
- 1.43 **“PMDA”** shall mean the Pharmaceuticals and Medical Devices Agency in Japan and any successor Regulatory Authority having substantially the same function.
- 1.44 **“Product(s)”** shall mean any pharmaceutical or biological preparation in final form containing Compound (i) for sale by prescription, over-the-counter or any other method or (ii) for administration to human patients in a Clinical Trial, for any and all uses in the Field, including without limitation any Combination Product. For clarity, different formulations or dosage strengths of a given Product with the same Compound shall be considered the same Product for purposes of this Agreement.
- 1.45 **“Regulatory Authority”** shall mean any applicable government regulatory authority involved in granting approvals for the manufacturing, marketing, reimbursement and/or pricing of a Product in the Territory, including, in the United States, the FDA and any successor governmental authority having substantially the same function.
- 1.46 **“Related Party”** shall mean each of Merck, its Affiliates, and their respective sublicensees (which term does not include distributors), as applicable.

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

- 1.47 **“Research Program”** shall mean the research activities undertaken by the Parties as set forth in Article 2 and Schedule 2.1.
- 1.48 **“Research Program Term”** shall mean the duration of the Research Program and **“Extended Research Program Term”** shall mean any period of the Research Program as it may be extended by mutual agreement of the Parties, as described more fully in Section 2.11.
- 1.49 **“Target”** shall mean influenza [\*].
- 1.50 **“Territory”** shall mean all of the countries in the world, and their territories and possessions.
- 1.51 **“Third Party”** shall mean an entity other than Merck and its Related Parties, and Cocrystal and its Affiliates.
- 1.52 **“Valid Patent Claim”** shall mean (i) a claim of an issued, unexpired and in-force patent included within the Cocrystal Patent Rights or Collaboration Patent Rights that claims Compound [\*], which has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction (which decision is not appealable or has not been appealed within the time allowed for appeal), and which claim has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination, supplemental examination or disclaimer or otherwise or (ii) a claim in a pending patent application included in such Patent Rights (i.e. Cocrystal Patent Rights or Collaboration Patent Rights that claims Compound [\*]) that has been pending for no longer than [\*] that continues to be prosecuted in good faith. For purposes of determining whether a Product infringes or is covered by a Valid Claim, the claims of a patent application shall be presumed to have been issued as a patent.
- 1.53 **“Violation”** shall mean that either Cocrystal, or any of its officers or directors has been: (a) convicted of any of the felonies identified among the exclusion authorities listed on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) website, including 42 U.S.C. 1320a-7(a) (<https://oig.hhs.gov/exclusions/index.asp>); and/or (b) identified in the OIG List of Excluded Individuals/Entities (LEIE) database ([https://oig.hhs.gov/exclusions/exclusions\\_list.asp](https://oig.hhs.gov/exclusions/exclusions_list.asp)) or the U.S. General Services Administration’s list of Parties Excluded from Federal Programs (<https://www.sam.gov/portal/public/SAM/>) (each of (a) and (b), singly and collectively, the **“Exclusions Lists”**).

## ARTICLE 2 RESEARCH PROGRAM

- 2.1 **General.** Cocrystal and Merck shall engage in the Research Program upon the terms and conditions set forth in this Agreement. The activities to be undertaken in the course of the Research Program are set forth in Schedule 2.1 which may be amended from time to time upon mutual written agreement by authorized representative(s) of the Parties (the **“Research Plan”**).
- 2.2 **Conduct of Research.** Subject to Section 2.3, Cocrystal and Merck each shall proceed diligently with the work set out in the Research Program by using their respective reasonable good faith efforts to allocate sufficient time, effort, equipment and facilities to the Research Program and to use personnel with sufficient skills and experience as are required to accomplish the Research Program in accordance with the terms of this Agreement and Schedule 2.1.

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

Merck shall be entitled to utilize the services of its Affiliates and Third Parties to perform its Research Program activities, provided that such Third Parties are subject to confidentiality obligations consistent with the requirements of Section 4.1. Cocrystal shall be entitled to utilize the service of Third Parties to perform its Research Program activities only upon Merck's prior written consent or as specifically set forth in Schedule 2.1. Notwithstanding the foregoing, each Party shall remain at all times fully liable for its respective responsibilities under the Research Program.

**2.3 Merck Funding of Cocrystal FTEs.** During the Research Program Term and in accordance with the Research Plan, Merck will provide Cocrystal with research funding pursuant to Section 5.2 for [\*]. Notwithstanding the foregoing, Merck shall not be required to fund any FTEs for the Research Program pursuant to Section 5.2 from and after the end of the Research Program Term.

**2.4 Use of Research Funding.** Cocrystal shall apply the research funding it receives from Merck under this Agreement solely to carry out its Research Program activities in accordance with Schedule 2.1 and the terms and conditions of this Agreement.

**2.5** [\*].

**2.6 Joint Research Committee.** The Parties hereby establish a committee to facilitate the Research Program as follows:

**2.6.1 Composition of the Joint Research Committee.** The Research Program shall be conducted under the direction of a joint research committee (the "Committee") comprised of three (3) representatives of Merck (who shall be employees of Merck or its Affiliate, as applicable) and three (3) representatives of Cocrystal (who shall be employees of Cocrystal or its Affiliate, as applicable). A list of initial representatives of Merck and Cocrystal are attached hereto as Schedule 2.6.1. Each Party may change its representatives to the Committee from time to time in its sole discretion, effective upon notice to the other Party of such change. These representatives shall have appropriate technical credentials, experience and knowledge, and ongoing familiarity with the Research Program. Additional representative(s) or consultant(s) may from time to time, by mutual consent of the Parties, be invited to attend Committee meetings, subject to such representative's or consultant's written agreement to comply with the requirements of Section 4.1. The Committee shall be chaired by a representative of Merck. Decisions of the Committee shall be made unanimously by the representatives. In the event that the Committee cannot or does not, after reasonable good faith efforts, reach agreement on an issue within [\*] after such matter has been referred to the Committee, then the matter shall be [\*].

**2.6.2 Scope of Committee Oversight.** The Committee shall be responsible for overseeing the Research Program, including to (i) review and amend the Research Plan from time to time, (ii) review and coordinate the Parties' activities under the Research Program, (iii) confer regarding the status of the Research Program and the progress under the Research Program and to make determinations and decisions in connection with the activities under the Research Program (including issues of priority), (iv) review relevant data under the Research Program, (v) consider and advise on any technical issues that arise under the Research Program, and (vi) determine such other matters as allocated to the Committee hereunder. The Committee shall not have the authority to: (w) modify or amend the terms and conditions of this Agreement; (x) waive either Party's compliance with the terms and conditions of this Agreement; (y) determine any issue in a manner that would conflict with the express terms and conditions of this Agreement or (z) amend the Research Plan in a manner that would increase the financial or other resource (*i.e.*, FTEs) obligations imposed on Cocrystal or Merck beyond the scope of those required under the then current planned activities, and if such amendment would increase such financial or other resource (*i.e.*, FTEs) obligations, then such amendment must be mutually agreed to by the Parties in writing (including mutual agreement on the number of additional FTEs of Cocrystal needed to perform such work and to be funded by Merck in accordance with Section 5.1); provided that, for the avoidance of doubt if the work proposed in the amendment to the Research Program activities could be performed by the FTEs then currently being funded by Merck and such work would not impose additional financial obligations on Cocrystal beyond the then current Research Program activities, Cocrystal shall perform such work at no additional charge and the Research Program activities shall automatically be deemed to be amended to include such work as proposed by the Committee.

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

**2.6.3 Meetings.** During the Research Program Term, the Committee shall meet in accordance with a schedule established by mutual written agreement of the Parties, but no less frequently than once per Calendar Quarter, with the location for such meetings alternating between Cocrystal and Merck facilities (or such other location may be determined by the Committee). Alternatively, the Committee may meet by means of teleconference, videoconference or other similar communications equipment. The Committee shall confer regarding the status of the Research Program, review relevant data, consider and advise on any technical issues that arise, consider issues of priority, and review and advise on any budgetary and economic matters relating to the Research Program which may be referred to the Committee. For each meeting, the Committee shall designate one member to take minutes on the meeting, and such minutes shall be approved by each of Cocrystal and Merck within ten (10) Business Days of such meeting. Each Party shall bear its own expenses related to the attendance of such meetings by its representatives. At the end of the Research Program Term, the Committee shall have a final meeting to review the results of the Research Program and then shall be disbanded.

**2.6.4 Disbandment of Committee.** Upon completion (or earlier termination) of the Research Program, the Committee shall be disbanded and shall have no further authority with respect to the activities hereunder.

**2.7 Alliance Managers.**

**2.7.1 Appointment.** Each Party shall have the right to appoint an employee who shall oversee interactions between the Parties for all matters related to this Agreement (each an “**Alliance Manager**”). Such persons shall endeavor to ensure clear and responsive communication between the Parties and the effective exchange of information, and may serve as a single point of contact for any matters arising under this Agreement. The Alliance Managers shall have the right to attend all Committee meetings as non-voting participants and may bring to the attention of the Committee any matters or issues either of them reasonably believes should be discussed, and shall have such other responsibilities as the Parties may mutually agree in writing. Each Party may designate different Alliance Managers by notice in writing to the other Party.

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

**2.7.2 Responsibilities of the Alliance Managers.** The Alliance Managers, if appointed, shall have the responsibility of creating and maintaining a constructive work environment between the Parties. Without limiting the generality of the foregoing, each Alliance Manager shall:

- (a) identify and bring disputes and issues that may result in disputes (including without limitation any asserted occurrence of a material breach by a Party) to the attention of the Committee in a timely manner, and function as the point of first referral in all matters of conflict resolution;
- (b) provide a single point of communication for seeking consensus both internally within the Parties' respective organizations and between the Parties;
- (c) plan and coordinate cooperative efforts, internal communications and external communications between the Parties with respect to this Agreement; and
- (d) take responsibility for ensuring that meetings and the production of meeting agendas and minutes occur as set forth in this Agreement, and that relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.

**2.8 Exchange of Information.** Upon execution of this Agreement, and on an ongoing basis during the Research Program Term, each Party shall disclose to the other Party in writing or in an electronic format Cocrystal Know-How or Merck Know-How, as the case may be, that is reasonably necessary for a Party to perform its responsibilities under the Research Program and not previously disclosed.

**2.9 Records and Reports.**

**2.9.1 Records.** Each Party shall maintain records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall fully and properly reflect all work done and results achieved in the performance of the Research Program by the Party.

**2.9.2 Copies and Inspection of Records.** Merck shall have the right, during normal business hours and upon reasonable notice, to inspect and copy all such records of Cocrystal referred to in Section 2.9.1. Merck shall maintain such records and the information disclosed therein in confidence in accordance with Section 4.1. Merck shall have the right to arrange for its employee(s) and/or consultant(s) involved in the activities contemplated hereunder to visit the offices and laboratories of Cocrystal and any of its Third Party contractors as permitted under Section 2.2 during normal business hours and upon reasonable notice, and to discuss the Research Program work and its results in detail with the technical personnel and consultant(s) of Cocrystal; provided that such consultants and Third Party contractors agree in written agreement to comply with the requirements of Section 4.1. Upon request, Cocrystal shall provide copies of the records described in Section 2.9.1.

**2.9.3 [\*]Reports.** Within [\*] following the end of [\*], Cocrystal shall provide to Merck a written progress report in English which shall describe the work performed to date on the Research Program, evaluate the work performed in relation to the goals of the Research Program and provide such other information as may be required by the Research Program or reasonably requested by Merck relating to the progress of the goals or performance of the Research Program. For clarity, all such reports shall be considered the confidential Information of both Parties for purposes of Article 4.

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

**2.10 Collaboration Information and Inventions.** The entire right, title and interest in:

**2.10.1** Cocrystal Know-How shall be owned solely by Cocrystal;

**2.10.2** Merck Know-How shall be owned solely by Merck; and

**2.10.3** Collaboration Information and Inventions and Collaboration Patent Rights shall be owned jointly by Cocrystal and Merck. Each Party hereby assigns to the other Party an undivided interest in the Collaboration Information and Inventions that its employees or Third Party contractors or consultants (in the case of Cocrystal, approved by Merck or identified in Schedule 2.1), or employees or Third Party contractors or consultants (in the case of Cocrystal, approved by Merck or identified in Schedule 2.1) of its Affiliates, solely discovered, developed or invented and any Collaboration Patent Rights thereon.

Each Party shall promptly disclose to the other Party in writing the development, making, conception or reduction to practice of Collaboration Information and Inventions and all Compounds. Inventorship of Patent Rights shall be determined in accordance with United States patent laws (regardless of where the applicable activities occurred). Subject to the licenses granted to the other Party under this Agreement and the other terms and conditions of this Agreement, each Party shall have the non-exclusive right to exploit its interest in Collaboration Information and Inventions and Collaboration Patent Rights, and to grant licenses under its interest in Collaboration Information and Inventions and Collaboration Patent Rights, as it deems appropriate, without the consent of, and without accounting to, the other Party; provided, however, that for clarity, the foregoing joint ownership rights shall not be construed as granting, conveying or creating any license or other rights to the other Party's intellectual property, unless otherwise expressly set forth in this Agreement; and further provided that, in the event that any Collaboration Patent Rights claim or cover a Compound or the manufacturing process therefor, Cocrystal shall not grant any license under its interest in such Collaboration Patent Rights to any Third Party without Merck's prior written consent.

**2.11 Research Program Term.** Except as otherwise provided herein, the term of the Research Program shall commence on the Effective Date and continue for a period of [\*]. The Parties may extend the term of the Research Program for [\*] by mutual written agreement of the authorized representative of the Parties reached at least [\*] prior to the end of such [\*], and shall, in such case, amend Schedule 2.1 as applicable.

**2.12 Materials.** In the course of the Research Program Term, Merck and Cocrystal may provide the other Party with certain materials ("Materials") solely for the purpose of enabling such Party to perform its activities under the Research Program in accordance with the terms of this Agreement. Cocrystal shall not use any Materials provided by Merck in humans, nor shall any of the Materials, or any derivatives, analogs, modifications or components thereof be transferred, delivered or disclosed to any Third Party without the prior written approval of Merck. Upon expiration or termination of the Research Program Term, any unused Materials and any derivatives, analogs, modifications or components thereof shall be, at Merck's option, either returned to Merck or destroyed in accordance with instructions by Merck; however, upon early termination of this Agreement, any unused Materials and any derivatives, analogs, modifications or components thereof shall be, at the providing Party's option, either returned to the providing Party or destroyed in accordance with instructions by the providing Party.

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

**2.13 Exclusive Efforts.** During the Research Program Term and for a period of [\*] following the expiration or termination of the Research Program Term, [\*], Cocrystal (i) shall work exclusively (even as to Cocrystal itself) with Merck in any research and discovery efforts related to the Target, either alone or through a Third Party; provided, however, that Cocrystal shall not be obligated to perform any such work with or for the benefit of Merck during [\*] unless [\*] and (ii) shall not, and shall ensure that its Affiliates and its licensees and sublicensees who have any use or other rights in or to Cocrystal Know-How or Cocrystal Patent Rights do not, directly or indirectly, conduct, exploit, or fund any activity that involves the research and discovery efforts related to the Target, either alone or with a Third Party, regardless of whether the collaborative work with Merck under the Research Plan is ongoing or has concluded. It is the desire and intent of the Parties that the restrictive covenants contained in this Section 2.13 (Exclusive Efforts) be enforced to the fullest extent permissible under applicable laws, rules, regulations, and public policies applied in each jurisdiction in which enforcement is sought. Merck and Cocrystal believe that the restrictive covenants in this Section 2.13 are valid and enforceable. However, if any restrictive covenant should for any reason become or be declared by a competent court or competition authority to be invalid or unenforceable in any jurisdiction, such restrictive covenant shall be deemed to have been amended to the extent necessary in order that such provision be valid and enforceable, and such amendment shall apply only with respect to the operation of such provision of this Section 2.13 in the particular jurisdiction in which such declaration is made.

**2.14 Compliance with Law and Ethical Business Practices.**

- 2.14.1** The Parties shall conduct the Research Program in accordance with all applicable laws, rules and regulations including, without limitation, all current governmental regulatory requirements concerning Good Laboratory Practices. A Party shall notify the other Party in writing of any deviations from applicable regulatory or legal requirements. Each Party hereby certifies that it has not in the past [\*], and it will not, employ or otherwise use in any capacity the services of any person or entity debarred under Section 21 USC 335a in performing any services hereunder. A Party shall notify the other Party in writing immediately if any such debarment occurs or comes to its attention and shall promptly remove any person or entity so disbarred from performing any activities under the Research Program or function or capacity related to the Research Program. [\*]
- 2.14.2** Each Party acknowledges that Merck's corporate policy requires that Merck's business must be conducted within the letter and spirit of the law. By signing this Agreement, each Party agrees to conduct the services contemplated herein in a manner which is consistent with both law and good business ethics.
- 2.14.3** Specifically, Cocrystal warrants that none of its current employees, agents, officers or other members of its management are officials, officers, agents, representatives of any government or international public organization. Cocrystal shall not make any payment, either directly or indirectly, of money or other assets, including but not limited to the compensation Cocrystal derives from this Agreement (hereinafter collectively referred as a "**Payment**"), to government or political party officials, officials of international public organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing (hereinafter collectively referred as "**Officials**") where such Payment would constitute violation of any law, and for clarity, shall comply at all times with the federal *Physician Self-Referral Law*, 42 U.S.C. 1395nn, and the regulations promulgated thereunder, similar state physician self-referral laws and regulations, the federal Medicare/Medicaid Anti-kickback Law and regulations promulgated thereunder and similar state Anti-kickback laws and regulations. In addition, regardless of legality, Cocrystal shall make no Payment either directly or indirectly to Officials if such Payment is for the purpose of influencing decisions or actions with respect to the subject matter of this Agreement or any other aspect of Merck's business.

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

- 2.14.4** Each Party certifies to the other Party that as of the date of this Agreement that it has screened itself, and its officers, directors and employees against the Exclusions Lists and that it has informed the other Party whether it, or any of its officers or directors has been in Violation. After the execution of this Agreement, each Party shall notify the other Party in writing immediately if any such Violation occurs or comes to its attention.
- 2.14.5** Cocrystal's failure to abide by the provisions of this Section 2.14 shall be deemed a material breach of this Agreement. Merck may in such case and with immediate effect terminate this Agreement at its sole discretion upon written notice to Cocrystal and without prejudice to any other remedies that may be available to Merck.
- 2.14.6** Each Party shall indemnify and hold the other Party and any of its Affiliates harmless from and against any and all Liabilities (including all costs and reasonable attorneys' fees associated with defending against such claims) that may arise by reason of its acts or omissions or its agents or other Third Parties acting on its behalf which would constitute a violation of this Section 2.14. The procedure for such indemnification shall be the same as set forth in Section 6.4, which shall apply *mutatis mutandis*.
- 2.15 Animal Research.** If animals are used in research hereunder, Cocrystal will comply with the *Animal Welfare Act* or any other applicable local, state, national and international laws and regulations relating to the care and use of laboratory animals. Merck encourages Cocrystal to use the highest standards, such as those set forth in the Guide for the Care and Use of Laboratory Animals (NRC, 1996), for the humane handling, care and treatment of such research animals. Cocrystal hereby certifies that it has and shall maintain current and valid accreditation from AAALAC during the Term. Any animals which are used in the course of the Research Program, or products derived from those animals, such as eggs or milk, will not be used for food purposes, nor will these animals be used for commercial breeding purposes.

### ARTICLE 3 LICENSE; EXCHANGE OF INFORMATION; DEVELOPMENT AND COMMERCIALIZATION.

#### 3.1 License Grant.

- 3.1.1** Subject to the terms of this Agreement, Cocrystal hereby grants to Merck an exclusive license (even as to Cocrystal) in the Territory under Cocrystal Patent Rights and Cocrystal's interest in Collaboration Patent Rights, with the right to grant and authorize sublicenses, to make, have made, use, import, offer to sell and sell Compound and Product for any and all uses in the Field.
- 3.1.2** Subject to the terms of this Agreement, Cocrystal hereby grants to Merck an exclusive license (even as to Cocrystal) in the Territory under Cocrystal Know-How and Cocrystal's interest in Collaboration Information and Inventions, with the right to grant and authorize sublicenses, (i) to make, have made, use, import, offer to sell and sell Compound and Product for any and all uses in the Field and (ii) to otherwise carry out activities contemplated under this Agreement.
- 3.1.3** Notwithstanding the scope of the exclusive licenses granted to Merck under Sections 3.1.1 and 3.1.2, Cocrystal shall retain the rights during the Research Program Term within the Field necessary solely in connection with performing Cocrystal's obligations under the Research Program in accordance with this Agreement to (i) make and use in the Territory, Compound, Product and any Invention claimed in or covered by Cocrystal Patent Rights or Collaboration Patent Rights and (ii) use Cocrystal Know-How.

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

- 3.1.4** Subject to the terms of this Agreement, Merck hereby grants to Cocrystal a non-exclusive license (which shall not be sublicensable unless approved by Merck in writing) during the Research Program Term in the Territory under Merck Know-How to make and use Compound and to carry out Cocrystal's activities pursuant to the Research Program.
- 3.2 Non-Exclusive License Grant.** In the event that the making, having made, use, import, offer for sale and/or sale by Merck or its Related Parties of Compound or Product in the Field would infringe during the Term an issued letters patent in a country that Cocrystal (or its Affiliate who did not become an Affiliate as a result of a Change of Control (as defined below)) Controls that claims a composition of matter for the Compound in the country and which patents are not covered by the grant in Section 3.1, Cocrystal hereby grants to Merck, to the extent Cocrystal is legally able to do so, a non-exclusive, sublicensable, royalty-free license (except royalties or other compensation due a Third Party licensor which Merck shall pay, provided that such payments shall be considered a payment made pursuant to a Third Party License under Section 5.4.5 and eligible for offset as provided therein) under such issued letters patent for Merck and its Related Parties to make, have made, use, import, offer to sell and sell Compound and Product in the country in the Field.
- 3.3 No Implied Licenses.** Except as specifically set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, in any Information disclosed to it under this Agreement or under any patents or patent applications owned or controlled by the other Party or its Affiliates.
- 3.4 No Grant of Inconsistent Rights by Cocrystal.** During the Term, Cocrystal (and its Affiliates) shall not assign, transfer, convey or otherwise grant to any Person or otherwise encumber (including through lien, charge, security interest, mortgage, encumbrance or otherwise) (i) any rights to any Cocrystal Know-How or Cocrystal Patent Rights in any manner that is inconsistent with or would interfere with the grant of the rights or licenses to Merck hereunder; (ii) any rights to any Compounds or Products; or (iii) any rights to Cocrystal's interest in Collaboration Patent Rights; provided, however, that Cocrystal shall grant to Merck the rights to the Compounds and Products as set forth herein. Without limiting the foregoing, during the Term, (x) Cocrystal (and its Affiliates) shall not use (and shall not grant to any Third Party the right to use) any Compounds or Products for any purposes (including the development, manufacturing or commercialization thereof), except for Cocrystal's performance of the activities to be performed by Cocrystal under this Agreement and (y) Cocrystal (and its Affiliates) shall not provide or otherwise transfer to any Third Parties any Cocrystal Know-How or Collaboration Information and Inventions for use, except as provided on Schedule 3.4 or for transfers approved by Merck in writing.
- 3.5 Sublicenses.** Merck shall have the right to sublicense (through multiple tiers of sublicenses) any or all of the licenses granted to Merck hereunder. Merck shall be responsible for ensuring that the performance by any of its sublicensees hereunder that are exercising rights under a sublicense hereunder is in accordance with the applicable terms of this Agreement, and the grant of any such sublicense shall not relieve Merck of its obligations under this Agreement (except to the extent they are performed by any such sublicensee(s) in accordance with this Agreement). [\*]

Cocrystal shall not have the right to sublicense the license granted to Cocrystal Section 3.1.4, except as approved by Merck in writing.

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

- 3.6 Development and Commercialization; Reports.** Merck shall be solely responsible for development and commercialization of the Product in the Field in the Territory. Merck shall use Commercially Reasonable Efforts, at its own expense, to develop and commercialize Products. In pursuing such development and commercialization, Merck shall comply with all applicable federal, state and local laws and regulations, including, without limitation, all laws and regulations, domestic and foreign, applicable to the development, production, distribution, sale, commercialization and use of any Product, including, without limitation, in connection with labeling, packaging, instructions as to use, quality control, registration, export controls (including ITAR) and anti-bribery. Each year after the expiration of the Research Program Term and until First Commercial Sale, within [\*], Merck shall provide Cocrystal with [\*] update on the development and regulatory progress for each Product and the related Compound.
- 3.7 Excused Performance.** In addition to the provisions of Article 6, the obligations of Merck with respect to any Product under Section 3.6 are expressly conditioned upon the continuing absence of any adverse condition or event relating to the safety or efficacy of the Product, and the obligation of Merck to develop or market any such Product shall be delayed or suspended so long as in Merck's opinion any such condition or event exists. Upon such condition or event, Merck shall provide written notice thereof as soon as practicable to Cocrystal, keep Cocrystal informed of the steps being taken to remedy it and use Commercially Reasonable Efforts to avoid and to promptly remedy the delay or suspension.
- 3.8 Regulatory Matters.** In the event that Merck determines that any regulatory filings for any Compounds or Products are required for any activities hereunder (including any activities under the Research Program), including INDs, NDAs and other Marketing Authorizations (as applicable), then as between the Parties, Merck (or its Affiliate or Related Party) shall have the sole right, in its discretion, to obtain such regulatory filings (in its (or its Affiliate's or its Related Party's) name) and as between the Parties, Merck (or its Affiliate or its Related Party) shall be the owner of all such regulatory filings. As between the Parties, Merck (or its Affiliate or Related Party) shall have the sole right to communicate and otherwise interact with Regulatory Authorities with respect to the Compounds and/or Products (including during the Research Program Term). For clarity, Cocrystal shall have no right to, and shall not, make any regulatory filings related to any Compounds or Products or otherwise interact with any Regulatory Authorities with respect to the Compounds or Products.

#### ARTICLE 4 CONFIDENTIALITY AND PUBLICATION.

- 4.1 Nondisclosure Obligation.** All Information disclosed by one Party to the other Party hereunder shall be maintained in confidence by the receiving Party and shall not be disclosed to any Third Party or used for any purpose except as set forth herein without the prior written consent of the disclosing Party, except to the extent that such Information:
- 4.1.1** is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by the receiving Party's business records;
  - 4.1.2** is in the public domain by use and/or publication before its receipt from the disclosing Party, or thereafter enters the public domain through no fault of the receiving Party;

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

- 4.1.3 is subsequently disclosed to the receiving Party by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the disclosing Party;
- 4.1.4 is developed by the receiving Party independently of Information received from the disclosing Party, as documented by the receiving Party's business records;
- 4.1.5 is disclosed to governmental or other regulatory agencies in order to obtain patents or to gain or maintain approval to conduct clinical trials or to market Product, but such disclosure may be only to the extent reasonably necessary to obtain patents or authorizations;
- 4.1.6 is deemed necessary by Merck to be disclosed to Related Parties, agent(s), consultant(s), and/or other Third Parties for any and all purposes Merck and its Affiliates deem necessary or advisable in the ordinary course of business in accordance with this Agreement on the condition that such Third Parties agree to be bound by confidentiality and non-use obligations that substantially are no less stringent than those confidentiality and non-use provisions contained in this Agreement; provided, however, that the term of confidentiality for such Third Parties shall be no less than [\*]; or
- 4.1.7 is deemed necessary by counsel to the receiving Party to be disclosed to such Party's attorneys, independent accountants or financial advisors for the sole purpose of enabling such attorneys, independent accountants or financial advisors to provide advice to the receiving Party, on the condition that such attorneys, independent accountants and financial advisors agree to be bound by the confidentiality and non-use obligations contained in this Agreement; provided, however, that the term of confidentiality for such attorneys, independent accountants and financial advisors shall be no less than [\*].

Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the receiving Party.

If a Party is required by judicial or administrative process (including a request for discovery received in an arbitration or litigation proceeding) to disclose Information that is subject to the non-disclosure provisions of this Section 4.1 or Section 4.2, such Party shall promptly inform the other Party of the disclosure that is being sought in order to provide the other Party an opportunity to challenge or limit the disclosure obligations. Information that is disclosed by judicial or administrative process shall remain otherwise subject to the confidentiality and non-use provisions of this Section 4.1 and Section 4.2, and the Party disclosing Information pursuant to law or court order shall take all steps reasonably necessary, including without limitation obtaining an order of confidentiality, to ensure the continued confidential treatment of such Information.

- 4.2 **Cocrystal Know-How.** Each Party agrees to keep all Cocrystal Know-How and Collaboration Information and Inventions confidential in accordance with Section 4.1, provided, however, that, after expiration or termination of this Agreement, Cocrystal shall not be obligated to keep Cocrystal Know-How confidential and each Party may disclose Collaboration Information and Inventions to Affiliates and Third Parties on a confidential basis.

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

- 4.3 Publication.** Merck and Cocrystal each acknowledge the other Party's interest in publishing the results of the Research Program in order to obtain recognition within the scientific community and to advance the state of scientific knowledge. Each Party also recognizes the mutual interest in obtaining valid patent protection and in protecting business interests and trade secret information. Consequently, except for disclosures permitted pursuant to Section 4.1, either Party wishing to make a publication with respect to the research under the Research Program, whether before or up to [\*] after the end of the Research Program Term, shall deliver to the other Party a copy of the proposed written publication or an outline of an oral disclosure at least [\*] prior to submission for publication or presentation. The reviewing Party shall have the right (a) to propose modifications to the publication or presentation for patent reasons, trade secret reasons or business reasons or (b) to request a reasonable delay in publication or presentation in order to protect patentable information. If the reviewing Party requests a delay, the publishing Party shall delay submission or presentation for a period of not to exceed [\*] as necessary to enable patent applications protecting each Party's rights in such information to be filed in accordance with Article 7. If the reviewing Party requests modifications to the publication or presentation, the publishing Party shall edit such publication to prevent disclosure of trade secret or proprietary business information prior to submission of the publication or presentation. In addition to the foregoing, (i) during the Research Program Term, any publication or presentation shall require the express approval of the Committee and (ii) [\*] any publication or presentation shall require the written approval of Merck, provided, however, that Merck shall keep Cocrystal informed of the status of its review and approval of any proposed publication or presentation.
- 4.4 Publicity/Use of Names.** No disclosure of the existence, or the terms, of this Agreement may be made by either Party, and no Party shall use the name, trademark, trade name or logo of the other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required to comply with applicable law (including securities law, and filings required by the U.S. Securities and Exchange Commission); provided, that such disclosing Party shall give the other Party reasonable advance written notice of such required disclosure, to the extent permitted by law, and provide such other Party with at least [\*] to review such disclosure and propose reasonable modifications (including redactions); provided further that the disclosing Party shall be required to edit such disclosure as requested by such other Party to prevent disclosure of trade secret or proprietary business information except to the extent the U.S. Securities and Exchange Commission does not allow redaction of such information. Notwithstanding the foregoing, promptly following the Effective Date, Cocrystal may issue the press release attached hereto as Schedule 4.4.

#### ARTICLE 5 PAYMENTS; ROYALTIES AND REPORTS

- 5.1 Upfront Payment.** In consideration for the licenses and other rights granted to Merck herein under the Cocrystal Patent Rights and Cocrystal Know-How, upon the terms and conditions contained herein, Merck shall pay to Cocrystal an amount equal to Four Million United States Dollars (\$4,000,000), payable within thirty (30) days of the Effective Date.
- 5.2 Research Program Funding.** The funding for Cocrystal FTEs during the Research Program Term for which Merck is responsible under Section 2.3 shall be due and payable [\*] as further provided in this Section 5.2.
- 5.2.1 Quarterly FTE Payments.** During the Research Program Term, Merck shall pay Cocrystal the FTE Rate for [\*]. Such payments by Merck will be payable to Cocrystal within [\*] after Merck's receipt of [\*] invoice from Cocrystal, in an amount equal to [\*].
- 5.2.2** [\*]

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

5.2.3 [\*]

5.2.4 **Reimbursement of Certain Expenses.** Merck shall reimburse Cocrysal for out-of-pocket costs incurred by Cocrysal in performing the Research Plan to the extent such out-of-pocket costs are expressly set forth in the budget attached hereto as Schedule 5.2.4 (the “**Expense Budget**”) and to the extent Cocrysal provides appropriate documentation (including original receipts); provided, however, that in no event shall Cocrysal be entitled to receive payment for (and Cocrysal shall be solely responsible for) any and all out-of-pocket costs that are in excess of [\*] of the total out-of-pocket costs set forth in the budget for the Research Program. Cocrysal shall issue invoices to Merck for such out-of-pockets costs [\*] with no mark-up on cost. All such invoices shall be issued in U.S. dollars. Merck shall pay the undisputed amount of such invoices within [\*] after receipt thereof.

5.3 **Milestone Payments.** Subject to the terms and conditions of this Agreement, Merck shall pay to Cocrysal the following milestone payments, for which Merck (or its Related Party(ies)) achieves the following milestone events hereunder during the Term:

5.3.1 Initiation of [\*]: [\*];

5.3.2 Initiation of [\*]: [\*];

5.3.3 Initiation of [\*]: [\*];

5.3.4 Initiation of [\*]: [\*];

5.3.5 Marketing Authorization from [\*]: [\*];

5.3.6 Marketing Authorization from [\*]: [\*];

5.3.7 Marketing Authorization from [\*]: [\*];

5.3.8 [\*] in Net Sales of a Product worldwide by Merck and its Related Parties in a given Calendar Year: [\*]; and

5.3.9 [\*] in Net Sales of a Product worldwide by Merck and its Related Parties in a given Calendar Year: [\*].

Merck shall notify Cocrysal in writing within [\*] following the achievement of each milestone [\*]. With respect to the achievement of a milestone [\*], Merck shall make the appropriate milestone payment within [\*]. With respect to the achievement of a milestone [\*], Merck shall make the appropriate milestone payment within [\*]. The milestone payments shall be payable only upon the initial achievement of such milestone by any Product and no amounts shall be due hereunder for subsequent or repeated achievement of such milestone by such Product or any other Product.

5.4 **Royalties.**

5.4.1 **Royalties Payable By Merck.** Subject to the terms and conditions of this Agreement, Merck shall pay Cocrysal royalties, calculated on a Product-by-Product basis, as set forth in this Section 5.4.

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

- (a) Patent Royalties. Merck shall pay Cocrystal royalties in an amount equal to the following percentage of Net Sales of Products by Merck and its Related Parties where sale of Product would infringe a Valid Patent Claim in the country of sale (“**Patent Net Sales**”):
- (1) [\*] of worldwide Patent Net Sales in each Calendar Year up to and including [\*];
  - (2) [\*] of worldwide Patent Net Sales in each Calendar Year for the portion of Patent Net Sales exceeding [\*] up to and including [\*];
  - (3) [\*] of worldwide Patent Net Sales in each Calendar Year for the portion of Patent Net Sales exceeding [\*] up to and including [\*];
  - (4) [\*] of worldwide Patent Net Sales in each Calendar Year for the portion of Patent Net Sales exceeding [\*] up to and including [\*]; and
  - (5) [\*] of worldwide Patent Net Sales in each Calendar Year for the portion of Patent Net Sales exceeding [\*].
- (b) Know-How Royalty. Merck shall pay Cocrystal royalties in an amount equal to the following percentage of Net Sales of Products by Merck or its Related Parties where sale of Product would not infringe a Valid Patent Claim in the country of sale (“**Know-How Net Sales**”) for a period of [\*] after First Commercial Sale of such Product in such country:
- (1) [\*] of worldwide Know-How Net Sales in each Calendar Year up to and including [\*];
  - (2) [\*] of worldwide Know-How Net Sales in each Calendar Year for the portion of Know-How Net Sales exceeding [\*] up to and including [\*];
  - (3) [\*] of worldwide Know-How Net Sales in each Calendar Year for the portion of Know-How Net Sales exceeding [\*] up to and including [\*];
  - (4) [\*] of worldwide Know-How Net Sales in each Calendar Year for the portion of Know-How Net Sales exceeding [\*] up to and including [\*]; and
  - (5) [\*] of worldwide Know-How Net Sales in each Calendar Year for the portion of Know-How Net Sales exceeding [\*].
- (c) Royalty tiers in Section 5.4.1(a) shall be calculated based on worldwide Patent Net Sales of each Product, and royalty tiers in Section 5.4.1(b) shall be calculated based on worldwide Know-How Net Sales of each Product, provided that the determination of whether the royalty shall be calculated under Section 5.4.1(a) or 5.4.1(b) shall be determined on a country-by-country basis. Royalties on each Product at the rates set forth above shall continue on a country-by-country basis until the expiration of the later of: (i) the last-to-expire Valid Patent Claim claiming the Compound in such country; or (ii) for a period of [\*] after First Commercial Sale of such Product in such country.

- (d) All royalties are subject to the following conditions:
  - (i) that only one royalty shall be due with respect to the same unit of Product;
  - (ii) that no royalties shall be due upon the sale or other transfer among Merck or its Related Parties, but in such cases the royalty shall be due and calculated upon Merck's or its Related Party's Net Sales to the first independent Third Party;
  - (iii) no royalties shall accrue on the sale or other disposition of Product by Merck or its Related Parties for use in a Clinical Trial; and
  - (iv) no royalties shall accrue on the disposition of Product in reasonable quantities by Merck or its Related Parties as samples (promotion or otherwise) or as donations (for example, to non-profit institutions or government agencies for a non-commercial purpose).

**5.4.2 Change in Sales Practices.** The Parties acknowledge that during the Term, Merck's sales practices for the marketing and distribution of Product may change to the extent to which the calculation of the payment for royalties on Net Sales may become impractical or even impossible. In such event the Parties agree to meet and reasonably discuss in good faith new ways of compensating Cocrystal to the extent currently contemplated under Section 5.4.1.

**5.4.3 Royalties for Bulk Compound.** In those cases in which Merck sells bulk Compound rather than Product in packaged form to an independent Third Party, the royalty obligations of this Section 5.4 shall be applicable to the bulk Compound sales.

**5.4.4 Compulsory Licenses.** If a compulsory license is granted to a Third Party with respect to Compound or Product in any country in the Territory with a royalty rate lower than the royalty rate provided by Section 5.4.1, then the royalty rate to be paid by Merck on Net Sales in that country under Section 5.4.1 shall be reduced to the rate paid by the compulsory licensee.

**5.4.5 Third Party Licenses.** In the event that Merck obtains a license under, or other rights to, Patent Rights from any Third Party(ies) that would be necessary or advisable to avoid infringement of such Patent Rights in a country in order to make, have made, use, import, offer to sell and/or sell Product(s) (or Compound(s) contained in such Product(s)) (hereinafter "**Third Party Licenses**"), [\*] of any and all payments (including royalties and any payments for obtaining such right or license) actually paid under such Third Party Licenses by Merck or its Related Parties in connection with the manufacture, use, sale or import, as applicable, of Product(s) (or Compound(s) contained in such Product(s)) for a Calendar Quarter in the country for the Product shall be creditable against the royalty payments due Cocrystal by Merck with respect to the sale of such Product in the country in such Calendar Quarter. Notwithstanding the foregoing, in no event shall the royalties owed by Merck to Cocrystal for such Calendar Quarter with respect to sale of the Product in the country be [\*] pursuant to this Section 5.4.5 (provided, however, that to the extent Merck is not able to [\*] of the amounts paid by Merck or its Related Parties under any Third Party License as a result of the foregoing restriction, then Merck shall be entitled to carry forward such right of off-set to future royalty payments due Cocrystal by Merck with respect to the sale of such Product in the country in future Calendar Quarters with respect to such excess amount, provided that the royalty that is otherwise due Cocrystal with respect to sale of the Product in the country is not reduced by more than [\*] pursuant to this Section 5.4.5). At the request of Merck, Cocrystal shall provide assistance to Merck (or its Related Parties) in obtaining any such Third Party Licenses or otherwise taking action with respect Patent Rights of any Third Party(ies) that may be necessary in order to make, have made, use, import, offer to sell and/or sell Product(s) (or Compound(s) contained in such Product(s)).

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

**5.5 Reports; Payment of Royalty.** During the Term following the First Commercial Sale of a Product, Merck shall furnish to Cocrysal a [\*] written report for the Calendar Quarter showing, on a country-by-country and Product-by-Product basis, the Net Sales (including the gross invoice price exclusive of applicable taxes, aggregate deductions, and the number of units of Product sold) of all Products subject to royalty payments sold by Merck and Related Parties in the Territory during the reporting period and the royalties payable under this Agreement (including the applicable royalty rate and any adjustment pursuant to Section 5.4.5, if applicable). Reports shall be due on [\*]. Royalties shown to have accrued by each royalty report shall be due and payable on the date such royalty report is due. Merck shall keep complete and accurate records in sufficient detail to enable the royalties payable hereunder to be determined.

**5.6 Audits.**

**5.6.1** Upon the written request of Cocrysal and not more than [\*], Merck shall permit an independent certified public accounting firm of nationally recognized standing selected by Cocrysal and reasonably acceptable to Merck, at Cocrysal's expense, to have access during normal business hours to such of the records of Merck, its Affiliates and any of its Related Parties who have Net Sales in Major Countries as may be reasonably necessary to verify the accuracy of the royalty reports hereunder for any Calendar Year ending not more than [\*] prior to the date of such request. The accounting firm shall disclose to Cocrysal only whether the royalty reports are correct or incorrect and the amount of any discrepancy. No other information shall be provided to Cocrysal.

**5.6.2** If such accounting firm correctly identifies a discrepancy made during such period, the appropriate Party shall pay the other Party the amount of the discrepancy within [\*] of the date Cocrysal delivers to Merck such accounting firm's written report so correctly concluding, or as otherwise agreed upon by the Parties. The fees charged by such accounting firm shall be paid by Cocrysal; provided, however, that if such audit uncovers an underpayment of royalties by Merck that exceeds the greater of [\*] and [\*] of the total royalties owed, then the fees of such accounting firm shall be paid by Merck.

**5.6.3** Merck shall include in each sublicense granted by it pursuant to this Agreement a provision requiring the sublicensee to make reports to Merck, to keep and maintain records of sales made pursuant to such sublicense and to grant access to such records by Cocrysal's independent accountant to the same extent required of Merck under this Agreement.

**5.6.4** Upon the expiration of [\*] following the end of any Calendar Year, the calculation of royalties payable with respect to such Calendar Year shall be binding and conclusive upon Cocrysal unless subject to a current audit, and Merck and its Related Parties shall be released from any liability or accountability with respect to royalties for such Calendar Year.

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

**5.6.5** Cocystal shall treat all financial information subject to review under this Section 5.6 or under any sublicense agreement in accordance with the confidentiality and non-use provisions of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with Merck and/or its Related Parties obligating it to retain all such information in confidence pursuant to such confidentiality agreement.

**5.7 Payment Exchange Rate.** All payments to be made by Merck to Cocystal under this Agreement shall be made in United States dollars and may be paid by bank wire transfer in immediately available funds to such bank account in the United States as may be designated in writing by Cocystal from time to time. In the case of sales outside the United States, the rate of exchange to be used in computing the monthly amount of currency equivalent in United States dollars due Cocystal shall be made at the monthly rate of exchange utilized by Merck in its worldwide accounting system.

**5.8 Tax Matters.** Cocystal shall be liable for all taxes based on, measured by, or calculated with respect to, income or profits of Cocystal (“Income Taxes”) imposed upon any payments made by Merck to Cocystal under this Article 5 (“Agreement Payments”). If applicable laws, rules or regulations require the withholding of Income Taxes, Merck shall make such withholding payments as are required to be made from the Agreement Payment, shall subtract the amount thereof from the Agreement Payments and shall pay over such amount withheld and deducted to the proper governmental authorities. Merck shall submit to Cocystal appropriate proof of payment of the withheld Income Taxes as well as the official receipts within a reasonable period of time following payment thereof. Merck shall provide Cocystal reasonable assistance in order to allow Cocystal to reduce or mitigate any such Income Tax withholding to the extent permitted under applicable laws, including to obtain the benefit of any present or future treaty against double taxation which may apply to the Agreement Payments. [\*]

## ARTICLE 6 REPRESENTATIONS AND WARRANTIES

**6.1 Representations and Warranties of Each Party.** Each Party represents and warrants to the other Party that as of the Effective Date:

**6.1.1** such Party is duly organized and validly existing under the laws of the state or jurisdiction of its organization and has full corporate right, power and authority to enter into this Agreement and to perform its obligations hereunder;

**6.1.2** the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly authorized by the necessary corporate actions of such Party. This Agreement has been duly executed by such Party. This Agreement and any other documents contemplated hereby constitute valid and legally binding obligations of such Party enforceable against it in accordance with their respective terms, except to the extent that enforcement of the rights and remedies created thereby is subject to bankruptcy, insolvency, reorganization, moratorium and other similar laws of general application affecting the rights and remedies of creditors; and

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

6.1.3 the execution, delivery and performance by such Party of this Agreement and any other agreements and instruments contemplated hereunder will not (i) in any respect violate any statute, regulation, judgment, order, decree or other restriction of any governmental authority to which such Party is subject, (ii) violate any provision of the corporate charter, by-laws or other organizational documents of such Party, or (iii) constitute a material violation or breach by such Party of any provision of any material contract, agreement or instrument to which such Party is a party or to which such Party may be subject although not a party.

**6.2 Cocystal Representations and Warranties.** Cocystal represents and warrants to Merck that as of the Effective Date:

6.2.1 all Patent Rights within the Cocystal Patent Rights are in full force and effect, and, to the best of Cocystal's knowledge, the Cocystal Patent Rights and Cocystal Know-How are not invalid or unenforceable, in whole or in part;

6.2.2 it has the full right, power and authority to enter into this Agreement, to perform the activities hereunder, including the Research Program, and to grant the licenses granted hereunder (including under Article 3);

6.2.3 except for the transfer of Cocystal Know-How to [\*] for the performance of services as set forth in Schedule 3.4, it (and its Affiliates) has not prior to the Effective Date (i) assigned, transferred, conveyed or otherwise encumbered its right, title and interest in Cocystal Patent Rights or Cocystal Know-How, or (ii) otherwise granted any rights to any Third Parties that would conflict with the rights granted to Merck hereunder;

6.2.4 [\*] it is the sole and exclusive owner of the Cocystal Patent Rights and Cocystal Know-How, all of which are free and clear of any liens, charges and encumbrances, and no other person, corporate or other private entity, or governmental entity or subdivision thereof, has any claim of ownership whatsoever with respect to the Cocystal Patent Rights and Cocystal Know-How;

6.2.5 neither it nor any of its Affiliates has received any written notification from a Third Party that the research, development, manufacture, use, sale or import of Compounds or Products infringes or misappropriates the Patent Rights or know-how owned or controlled by such Third Party, and Cocystal has no knowledge that a Third Party has any basis for any such claim;

6.2.6 [\*] the exercise of the license granted to Merck under the Cocystal Patent Rights and Cocystal Know-How, including without limitation the development, manufacture, use, sale and import of Compounds and Products do not interfere with or infringe any intellectual property rights owned or possessed by any Third Party;

6.2.7 there are no claims, judgments or settlements against or owed by Cocystal (or any of its Affiliates) and no pending or threatened claims or litigation relating to the Cocystal Patent Rights and Cocystal Know-How;

6.2.8 Cocystal has disclosed to Merck all reasonably relevant information regarding (i) the Compounds and/or Products and/or (ii) the Cocystal Patent Rights and Cocystal Know-How licensed under this Agreement, including (a) any licenses and material agreements related to the Cocystal Patent Rights, Cocystal Know-How, Compounds and/or Products and (b) and safety or efficacy information related to the Compounds and/or Products;

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

- 6.2.9 Cocrysal has disclosed to Merck the existence of any patent opinions related to the Cocrysal Patent Rights and Cocrysal Know-How licensed under this Agreement;
- 6.2.10 Cocrysal has complied with all existing country-specific laws and regulations involving inventor remuneration associated with the Cocrysal Patent Rights;
- 6.2.11 Schedule 1.10 sets forth a true, correct and complete list of Cocrysal Patent Rights existing as of the Effective Date. The Cocrysal Patent Rights and Cocrysal Know-How constitute all intellectual property owned or otherwise Controlled (through license or otherwise) by Cocrysal (or any of its Affiliates) that relate to the Compounds and/or Products or the development, manufacture, commercialization and/or use thereof;
- 6.2.12 neither Cocrysal nor any of its Affiliates has obtained, or filed for, any INDs, NDAs or Marketing Authorizations for any Compounds or Products, and, to the best of Cocrysal's knowledge, no other Person has obtained, or filed for, any INDs, NDAs or Marketing Authorizations for any Compounds or Products;
- 6.2.13 Cocrysal (and its Affiliates) has not employed or otherwise used in any capacity in the past [\*], and will not employ or otherwise use in any capacity, the services of any Person debarred under United States law, including under Section 21 USC 335a or any foreign equivalent thereof, with respect to the Compounds or Products or otherwise in performing any portion of the Research Program.
- 6.2.14 all research and development (including non-clinical studies) related to the Compounds prior to the Effective Date has been conducted in accordance with all Applicable Laws;
- 6.2.15 except for the transfer of Cocrysal Know-How to [\*] for the performance of services as set forth in Schedule 3.4, there are no agreements (including any licenses), written or oral, granting any licenses or other rights to (or from) Cocrysal (or any of its Affiliates) relating to the Compounds or Products or the Cocrysal Know-How or Cocrysal Patent Rights;
- 6.2.16 all information and data provided by or on behalf of Cocrysal to Merck on or before the Effective Date in contemplation of this Agreement was and is true and accurate and complete in all material respects, and Cocrysal has not intentionally disclosed, failed to disclose, or cause to be disclosed, any information or data that would reasonably be expected to cause the information and data that has been disclosed to be misleading in any material respect; and
- 6.2.17 it has or expects to have the resources and capabilities to do the work contemplated by the Research Plan.

### 6.3 Indemnification.

- 6.3.1 **By Cocrysal.** Cocrysal shall indemnify and defend Merck, its Affiliates and its and such Affiliates' respective directors, officers, employees and agents from and against any Liabilities arising out of or relating to Cocrysal's breach of any of its representations, warranties, covenants and obligations in this Agreement except to the extent arising out of or relating to Merck's breach of any of its representations, warranties, covenants and obligations in this Agreement.

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

**6.3.2 By Merck.** Merck shall indemnify and defend Cocrystal, its Affiliates and its and such Affiliates' respective directors, officers, employees and agents from and against any Liabilities arising out of or relating to Merck's exercise of its licenses hereunder, including the research, development, manufacture, use, sale or other disposition of Compounds and Products by Merck or its Affiliates or Related Parties, or Merck's breach of any of its representations, warranties, covenants and obligations in this Agreement, except to the extent arising out of or relating to Cocrystal's breach of any of its representations, warranties, covenants and obligations in this Agreement.

**6.4 Indemnification Procedure.**

**6.4.1** Any Party that may be indemnified pursuant to Sections 6.3 (the "**Indemnified Party**") shall give prompt written notification to the Party from whom indemnification is sought (the "**Indemnifying Party**") of the assertion by a Third Party of any Liabilities for which indemnification may be sought (it being understood and agreed, however, that the failure by the Indemnified Party to give such notification shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually prejudiced as a result of such failure to give such notification).

**6.4.2** Within [\*], the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such Liabilities [\*] and will consult with the Indemnified Party with respect to a possible conflict of interest of such counsel retained by the Indemnifying Party. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense at the expense of the Indemnifying Party.

**6.4.3** The Party not controlling such defense may participate therein at its own expense. If the Parties cannot agree as to the application of Section 6.3 or 6.4 to any claim, pending resolution of the dispute pursuant to Section 9.7, the Parties may conduct separate defenses of such claims, with each Party retaining the right to claim indemnification from the other Party in accordance with Section 6.3 or 6.4 upon resolution of the underlying claim.

**6.4.4** The Party controlling such defense shall keep the other Party advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider in good faith recommendations made by the other Party with respect thereto. Such other Party shall provide such cooperation as may be reasonably requested by the Party controlling such defense in connection with or in furtherance of such defense.

**6.4.5** The Indemnified Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld or delayed. The Indemnifying Party shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all Liability with respect thereto or that imposes any Liability or obligation on the Indemnified Party without the prior written consent of the Indemnified Party, which shall not be unreasonably withheld or delayed.

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

## ARTICLE 7 PATENT PROVISIONS.

### 7.1 Filing, Prosecution and Maintenance of Patents.

#### 7.1.1 Cocrystal Patent Rights.

(a) Merck agrees, at its expense, to file patent applications claiming Cocrystal Know-How and Cocrystal Patent Rights, and to prosecute and maintain in the Territory, after appropriate consultation with Cocrystal, the Cocrystal Patent Rights licensed to Merck under this Agreement. Merck shall give Cocrystal an opportunity to review the text of any patent application before filing, shall consult with Cocrystal with respect thereto, and shall supply Cocrystal with a copy of the application when filed and as filed, together with notice of its filing date and serial number. Merck shall keep Cocrystal promptly advised of the status of Cocrystal Patent Rights and, upon Cocrystal's request, shall provide advance copies of any papers related to the prosecution and maintenance of Cocrystal Patent Rights. Merck shall promptly give notice to Cocrystal of the grant, lapse, revocation, surrender, invalidation or abandonment of any Cocrystal Patent Rights licensed to Merck for which Merck is responsible for the filing, prosecution and maintenance.

(b) Merck shall give notice to Cocrystal and the Committee of any desire to not file patent applications claiming Cocrystal Patent Rights or Cocrystal Know-How or to cease prosecution and/or maintenance of Cocrystal Patent Rights on a country by country basis in the Territory. [\*]

In addition to the foregoing, in the event Merck does not continue the prosecution or maintenance of the applicable Cocrystal Patent Rights, and such Cocrystal Patent Rights have been published by a patent office, Merck shall permit Cocrystal to continue the prosecution or maintenance of the applicable patent application or patent at its own expense and Merck shall execute documents in a timely manner as may be reasonably necessary to allow Cocrystal to continue such prosecution or maintenance.

7.1.2 **Collaboration Patent Rights.** Merck shall have the first right to file, prosecute, and maintain patents and patent applications claiming Collaboration Information and Inventions. Merck shall keep Cocrystal promptly advised of the status of any actual and prospective patent filings and upon Cocrystal's request, shall provide advance copies of any papers related to the filing of Collaboration Information and Inventions and the prosecution and maintenance of Collaboration Patent Rights. Merck shall give notice to Cocrystal of any desire to cease prosecution and/or maintenance of Collaboration Patent Rights on a country-by-country basis in the Territory [\*].

7.1.3 **Patent Term Extension.** The Parties shall cooperate fully with each other to provide necessary information and assistance, as the other Party may reasonably request, in obtaining patent term extension or supplemental protection certificates or their equivalents in any country in the Territory where applicable to Cocrystal Patent Rights and Collaboration Patent Rights. In the event that elections with respect to obtaining such patent term extension are to be made, Merck shall have the right to make the election and Cocrystal agrees to abide by such election.

7.1.4 **Other Cooperation.** The Parties agree to cooperate fully and provide any information and assistance that either may reasonably request for the filing, prosecution and maintenance of Cocrystal Patent Rights and Collaboration Patent Rights. The Parties further agree to take reasonable actions to maximize the protections available under the safe harbor provisions of 35 U.S.C. 102(c) for U.S. patents and patent applications.

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

**7.1.5 Filing, Prosecution and Maintenance Expenses.** With respect to all filing, prosecution and maintenance activities under this Section 7.1, the filing and/or prosecuting Party shall be responsible for payment of all costs and expenses related to such activities.

**7.1.6 Inventor Remuneration.** Cocrystal shall comply with all applicable country-specific inventor remuneration laws and regulations associated with Cocrystal Patent Rights and Collaboration Patent Rights when inventor remuneration obligations are triggered by an employee or contractor of Cocrystal or its Affiliates, or a Third Party acting on behalf of Cocrystal or its Affiliates. Merck shall comply with all applicable country-specific inventor remuneration laws and regulations associated with Cocrystal Patent Rights and Collaboration Patent Rights when inventor remuneration obligations are triggered by an employee or contractor of Merck or its Affiliates, or a Third Party acting on behalf of Merck or its Affiliates. For clarity, any applicable country-specific inventor remuneration paid by Merck or its Related Parties is not considered a payment subject to 5.4.5.

**7.2 Interference, Derivation, Opposition, Reexamination, Reissue, Supplemental Examination, *Inter Partes* Review and Post-Grant Review Proceedings.**

**7.2.1 Third Party Initiated Proceedings.** Each Party shall, within [\*] of learning of such event, inform the other Party of any request for, or filing or declaration of, any interference, derivation proceeding, opposition, reexamination requested by a Third Party, *inter partes* review, post-grant review or similar contested administrative proceeding involving a Third Party relating to Cocrystal Patent Rights or Collaboration Patent Rights. Merck and Cocrystal shall thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. Merck shall have the first right to control such proceedings with respect to Cocrystal Patent Rights and Collaboration Patent Rights, and Cocrystal shall have the right to review and approve any submission to be made in connection with such proceeding, which approval will not be unreasonably withheld or delayed, and shall be provided copies of all documents filed in connection with such proceedings. In the event that Merck chooses not to control such proceeding under this Section 7.2.1, and upon Merck's written consent with respect to Collaboration Patent Rights, which consent shall not be unreasonably withheld or delayed, Cocrystal shall have the right to control such proceeding.

**7.2.2 Party Initiated Proceedings.** Merck shall have the first right, at its expense, to initiate a reexamination, supplemental examination, reissue or similar administrative proceeding relating to Cocrystal Patent Rights or Collaboration Patent Rights. Notwithstanding the foregoing, Merck shall not initiate any such proceeding without the prior written consent of Cocrystal, which consent shall not be unreasonably withheld or delayed. Cocrystal shall have the right to review and approve any submission to be made in connection with such proceeding, which approval shall not be unreasonably withheld or delayed, and shall be provided copies of all documents filed in connection with such proceedings. If there is disagreement regarding whether a reexamination, supplemental examination, reissue or similar administrative proceeding relating to Cocrystal Patent Rights or Collaboration Patent Rights should be initiated, such disagreement shall be referred to the senior intellectual property officers of the Parties. In the event that these two executives do not, after reasonable good faith efforts, reach agreement, the resolution and/or course of conduct shall be determined by Merck, in good faith, with respect to Collaborative Patent Rights. In the event that Merck chooses not to initiate a proceeding under this Section 7.2.2, and upon Merck's written consent with respect to Collaboration Patent Rights, which consent shall not be unreasonably withheld or delayed, Cocrystal shall have the right to initiate such proceedings. The initiating Party shall have the first right to control such proceedings.

**7.2.3 Cooperation.** In connection with any administrative proceeding under Section 7.2.1 or 7.2.2, Merck and Cocrysal shall cooperate fully and provide each other with any information or assistance that either may reasonably request. The Parties shall keep each other informed of developments in any such action or proceeding, including the status of any settlement negotiations and the terms of any offer related thereto. For any proceeding, the controlling Party shall obtain the prior approval from the other Party of any settlement offer or settlement agreement, which approval shall not be unreasonably withheld or delayed.

**7.2.4 Expenses.** The Party controlling any administrative proceeding pursuant to Section 7.2.1 and 7.2.2 shall bear all expenses related thereto, with the exception that each Party shall have the right to be represented by counsel of its own choice at its own expense.

### **7.3 Enforcement and Defense.**

**7.3.1** The Parties shall give notice to each other of either (i) any infringement of Cocrysal Patent Rights or Collaboration Patent Rights, or (ii) any misappropriation or misuse of Cocrysal Know-How or Collaboration Information and Inventions, that may come to its attention. Merck and Cocrysal shall thereafter consult and cooperate fully to determine a course of action, including but not limited to the commencement of legal action by either or both Merck and Cocrysal, to terminate any infringement of Cocrysal Patent Rights or Collaboration Patent Rights or any misappropriation or misuse of Cocrysal Know-How or Collaboration Information and Inventions. Merck, upon notice to Cocrysal, shall have the first right to initiate and prosecute legal action at its expense and in the name of Merck and/or Cocrysal, or to control the defense of any declaratory judgment action relating to Cocrysal Patent Rights, Cocrysal Know-How, Collaboration Patent Rights or Collaboration Information and Inventions. Each Party shall have the right to be represented by counsel of its own choice at its own expense.

**7.3.2** Merck shall promptly inform Cocrysal if it elects not to exercise its first right under Section 7.3.1 to initiate and prosecute legal action, and Cocrysal shall thereafter have the right, at its expense, to either initiate and prosecute such action or to control the defense of such declaratory judgment action in the name of Cocrysal and, if necessary, Merck. Each Party shall have the right to be represented by counsel of its own choice at its own expense.

**7.3.3** For any action to terminate any infringement of Cocrysal Patent Rights or Collaboration Patent Rights or any misappropriation or misuse of Cocrysal Know-How or Collaboration Information and Inventions, in the event that a Party is unable to initiate or prosecute such action solely in its own name, the other Party will join such action voluntarily and will execute and cause its Affiliates to execute all documents necessary for the Party to initiate litigation to prosecute and maintain such action under this Section 7.3. In connection with any action or potential action, Merck and Cocrysal will cooperate fully and will provide each other with any information or assistance that either may reasonably request, including cooperating with regard to any pre-litigation review of the Cocrysal Patent Rights and Collaboration Patent Rights. Each Party shall keep the other informed of developments in any action or proceeding and provide the other Party, upon request, with copies of documents filed in connection therewith. For any proceeding, the controlling Party shall obtain the approval from the other Party of any settlement offer or settlement agreement, which approval shall not be unreasonably withheld or delayed.

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

- 7.3.4 Any recovery obtained by either or both Merck and Cocrystal in connection with or as a result of any action contemplated by this Section 7.3, whether by settlement or otherwise, shall be shared in order as follows:
- (a) the Party which initiated and prosecuted the action shall recoup all of its costs and expenses incurred in connection with the action;
  - (b) the other Party shall then, to the extent possible, recover its costs and expenses incurred in connection with the action; and
  - (c) the amount of any recovery remaining shall then be allocated between the Parties on a pro-rata basis taking into consideration the relative economic losses suffered by each Party.
- 7.3.5 Each Party shall inform the other Party of any certification regarding any Cocrystal Patent Rights or Collaboration Patent Rights it has received pursuant to either 21 U.S.C. §§355(b)(2)(A)(iv) or (j)(2)(A)(vii)(IV), or its successor provisions or any similar provisions in a country in the Territory other than the United States, and shall provide a copy of such certification within [\*] of receipt. Merck has the first right to initiate and prosecute any legal action as a result of such certification; provided, however, that Merck shall inform Cocrystal of such decision to initiate such action within [\*] of receipt of the certification, after which time Cocrystal shall have the right to initiate and prosecute such action. Regardless of which Party has the right to initiate and prosecute such action, both Parties shall, as soon as practicable after receiving notice of such certification, convene and consult with each other regarding the appropriate course of conduct for such action. The non-initiating Party shall have the right to be kept fully informed and participate in decisions regarding the appropriate course of conduct for such action, and the right to join and participate in such action. Cocrystal's and Merck's rights and obligations with respect to the prosecution of any legal action as a result of such certification and any recovery obtained as a result of such legal action shall be as defined in Sections 7.3.3 and 7.3.4.

## ARTICLE 8 TERM AND TERMINATION

- 8.1 **Term and Expiration.** This Agreement shall be effective as of the Effective Date and unless terminated earlier pursuant to Sections 8.2 or 8.3, this Agreement shall continue in full force and effect on a Product-by-Product and country-by-country basis until expiration of all Merck royalty obligations hereunder with respect to such Product in such country. Upon expiration of this Agreement as to each Product and country, Merck's licenses pursuant to Section 3.1 and 3.2 shall become fully paid-up, perpetual [\*] licenses. The period from the Effective Date until the date of expiration or earlier termination of this Agreement in its entirety, or as the case may be, until the date of the expiration or earlier termination of this Agreement in part with respect to a given Product on a country-by-country basis, shall be referred to herein as the "Term".

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

**8.2 Termination by Merck.** Notwithstanding anything contained herein to the contrary, prior to the First Commercial Sale of the first Product hereunder, Merck shall have the right to terminate this Agreement at any time in its sole discretion by giving [\*] advance written notice to Cocrystal. For the avoidance of doubt, termination by Merck under this Section 8.2 can be effected only through a written notice specifically referring to this Section 8.2. No later than [\*] after the effective date of such termination, each Party shall return or cause to be returned to the other Party all Information received from the other Party and all copies thereof; provided, however, that each Party may keep one copy of Information received from the other Party in its confidential files for record purposes, and Merck and its Affiliates may retain Information reasonably necessary to practice under its continued license to use Cocrystal Know-How specified below. In the event of termination under this Section 8.2: (i) each Party shall pay all amounts then due and owing as of the termination date; and (ii) except for the surviving provisions set forth in Section 8.5, the rights and obligations of the Parties hereunder shall terminate as of the date of such termination; provided, further, that Merck and its Affiliates shall have a fully paid-up [\*] license to use Cocrystal Know-How for research purposes only, and that both Parties shall be entitled to exploit their interest under Collaboration Information and Inventions and Collaboration Patent Rights, subject to Section 8.4, for any and all purposes without having to consult with, account to or seek consent from the other Party.

[\*]

**8.3 Termination for Cause.**

**8.3.1 Cause for Termination.** This Agreement may be terminated at any time during the Term:

- (a) upon written notice by either Party if the other Party is in breach of its material obligations hereunder by causes and reasons within its control and has not cured such breach within [\*] after notice requesting cure of the breach; provided, however, in the event of a good faith dispute with respect to the existence of a material breach, the [\*] cure period shall be tolled until such time as the dispute is resolved pursuant to Section 9.7; or
- (b) by either Party (the “**Terminating Party**”) upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party (the “**Bankruptcy Party**”); provided, however, that in the case of any involuntary bankruptcy or receivership proceeding such right to terminate shall only become effective if the Bankruptcy Party consents to such involuntary proceeding is not dismissed within [\*] after the filing thereof.

**8.3.2 Effect of Termination for Cause on License.**

- (a) If either Party terminates this Agreement pursuant to Section 8.3.1, then [\*] and each Party shall, within [\*] after the effective date of such termination, return or cause to be destroyed all Information of the other Party in tangible form and all Compound substances or compositions delivered or provided by the other Party, as well as any other material provided by the other Party in any medium; provided, however, that each Party may retain one copy of Information received from the other Party in its confidential files for record purposes, and Merck and its Affiliates may retain Information reasonably necessary to practice under its continued licenses to use Cocrystal Know-How and Merck and its Affiliates shall have a fully paid-up [\*] license to use Cocrystal Know-How for research purposes only. For the avoidance of doubt, each Party may retain Collaboration Information and Inventions since each Party has an undivided interest therein, and both Parties shall be entitled to exploit their interest under Collaboration Information and Inventions and Collaboration Patent Rights, subject to Section 8.4, for any and all purposes without having to consult with, account to or seek consent from the other Party.

[\*]

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

- (b) Upon termination of this Agreement by Merck pursuant to Section 8.2, or by Cocrystal pursuant to Section 8.3.1(a), Merck and its Affiliates, sublicensees and distributors shall be entitled, during the [\*] period immediately following the effective date of termination, to finish any work-in-progress and to sell any Product or Compound remaining in inventory, in accordance with the terms of this Agreement.
- (c) If this Agreement is terminated by the Terminating Party pursuant to Section 8.3.1(b) due to the rejection of this Agreement by or on behalf of the Bankruptcy Party under Section 365 of the United States Bankruptcy Code (the “Code”), all licenses and rights to licenses granted under or pursuant to this Agreement by the Bankruptcy Party to the Terminating Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Code, licenses of rights to “intellectual property” as defined under Section 101(35A) of the Code. The Parties agree that the Terminating Party, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Code, and that upon commencement of a bankruptcy proceeding by or against the Bankruptcy Party under the Code, the Terminating Party shall be entitled to a complete duplicate of or complete access to (as the Terminating Party deems appropriate), any such intellectual property and all embodiments of such intellectual property. Such intellectual property and all embodiments thereof shall be promptly delivered to the Terminating Party (i) upon any such commencement of a bankruptcy proceeding upon written request therefore by the Terminating Party, unless the Bankruptcy Party elects to continue to perform all of its obligations under this Agreement or (ii) if not delivered under (i) above, upon the rejection of this Agreement by or on behalf of the Bankruptcy Party upon written request therefore by the Terminating Party. The foregoing provisions of this Section 8.3.2(c) are without prejudice to any rights the Terminating Party may have arising under the Code or other applicable law.
- (d) [\*]

**8.4**    [\*]

**8.5**    **Effect of Expiration or Termination; Survival.** Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Any expiration or termination of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to expiration or termination, including without limitation the obligation to pay royalties for Product(s) or Compound sold prior to such expiration or termination. The provisions of Article 4 shall survive the expiration or termination of this Agreement and shall continue in effect for [\*]. In addition, the provisions of Article 1, Article 7 (with respect to Collaboration Patent Rights), Article 8 and Article 9 shall survive any expiration or termination of this Agreement and the provisions of Article 6 shall survive until the expiration of the applicable statute of limitations.

## ARTICLE 9 MISCELLANEOUS

- 9.1 Force Majeure.** Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, potentially including, but not limited to, embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any governmental authority or the other Party. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, keep the other Party informed of the steps being taken to remedy the circumstances and promptly undertake all reasonable and diligent efforts necessary to cure such force majeure circumstances.
- 9.2 Assignment/Change of Control.** Except as provided in this Section 9.2, this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the consent of the other Party. Merck may, without Cocrystal's consent, assign this Agreement and its rights and obligations hereunder in whole or in part to a Merck Affiliate or in connection with a Change of Control (as defined below). Cocrystal may, without Merck's consent, assign this Agreement and its rights and obligations hereunder in connection with a Change of Control; provided, however, that Cocrystal must notify Merck at least [\*] prior to completion of any such Change of Control. Without limiting the foregoing, in the event that there is a Company Change of Control that is a Competing Pharma Change of Control, then Cocrystal shall provide written notice to Merck at least [\*] prior to the completion of such Change of Control and [\*]. Any permitted assignee shall assume all obligations of its assignor under this Agreement. All Patent Rights, know-how or other intellectual property rights licensed to Merck hereunder prior to any Change of Control (or otherwise coming under the Control of Cocrystal (or any of its Affiliates that were Affiliates prior to such Change of Control) following such Change of Control) shall, in all cases, continue to be licensed to Merck hereunder in accordance with this Agreement. Any attempted assignment not in accordance with this Section 9.2 shall be void. If a proposed assignment would have an adverse impact upon the tax treatment of payments due under this Agreement to the other Party, the assigning Party shall undertake such steps as are necessary to remedy such adverse impact. Notwithstanding anything in this Agreement to the contrary, the Patent Rights, know-how or other intellectual property owned or otherwise Controlled, as of the effective date of the Change of Control of Cocrystal or its Affiliates and thereafter, by (i) any counterparty (a Third Party) to a Change of Control (the "**Acquirer**") of Cocrystal or its Affiliates (the "**Acquired Party**") or (ii) any of Acquirer's Affiliates that are not Affiliates of the Acquired Party, in each case immediately prior to the closing of such Change of Control, shall not become subject to the license grants and other requirements of this Agreement. For purposes of this Section 9.2, a "**Change of Control**" of a Party shall be deemed to occur if such Party is involved in a merger, reorganization or consolidation, or if there is a sale of all or substantially all of such Party's assets or business relating to this Agreement or if a person or group other than the current controlling person or group shall effectively acquire control of the management and policies of such Party. For purposes of this Section 9.2, a "**Competing Pharma Change of Control**" shall mean [\*].
- 9.3 Use of Affiliates.** Merck shall have the right to exercise its rights and perform its obligations under this Agreement either itself or through any of its Affiliates.

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

**9.4 Severability.** If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use reasonable efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

**9.5 Notices.** All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to Cocrystal, to: Cocrystal Pharma, Inc.  
19805 N. Creek Parkway  
Bothell, WA 98011  
[\*]

and: Cocrystal Pharma, Inc.  
4400 Biscayne Blvd  
Suite 101  
Miami, FL 33137  
[\*]

if to Merck, to: Merck Sharp & Dohme Corp.  
One Merck Drive  
Whitehouse Station, NJ 08889-0100  
[\*]

and: Merck Sharp & Dohme Corp.  
2000 Galloping Hill Road  
[\*]  
Kenilworth, NJ 07033-1310  
[\*]

or to such other address(es) as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered if personally delivered or sent by facsimile on a business day (or if delivered or sent on a non-business day, then on the next business day); (b) on the business day after dispatch if sent by nationally-recognized overnight courier; or (c) on the fifth (5th) business day following the date of mailing, if sent by mail. The Parties hereby agree that, to the extent permitted by law, any notice provided in accordance with this Section 9.5 shall constitute due service of process with respect to any legal proceeding between the Parties arising hereunder and that compliance with the Hague Convention for the Service of Process, if otherwise applicable, shall not be required.

**9.6 Applicable Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of New York without reference to any rules of conflict of laws or renvoi.

**9.7 Dispute Resolution.**

**9.7.1** The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement or the breach thereof (a “**Dispute**”). Any Party shall give the other Party written notice of any Dispute not resolved in the normal course of business and referring to this Section 9.7.1. Within [\*] from the date of delivery of such notice, the receiving Party shall submit to the other Party a written response. The notice and response shall include (a) a statement of that Party’s position and a summary of arguments supporting that position, and (b) the name and title of the executive who will represent that Party and of any other person who will accompany the executive. Within [\*] from the date of delivery of the initial notice, the executives of both Parties shall meet at a mutually acceptable time and place, and thereafter as often as they reasonably deem necessary, to attempt to resolve the Dispute. [\*] All negotiations pursuant to this Section 9.7 are confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence.

**9.7.2** If the Parties do not fully settle following the procedure in Section 9.7.1, and a Party wishes to pursue the matter, each dispute, controversy or claim arising from or related to this Agreement or the breach thereof that is not an Excluded Claim (as defined below) shall be brought in the federal court located in New York, New York, if federal jurisdiction is available, or, alternatively, in the state courts located in New York, New York. Each of the Parties hereby submits to the exclusive jurisdiction of such courts for the purpose of any such litigation; provided, that a final judgment in any such litigation shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law. **Each Party irrevocably and unconditionally agrees not to assert (a) any objection which it may ever have to the laying of venue of any such litigation in such courts, (b) any claim that any such litigation brought in any such court has been brought in an inconvenient forum, and (c) any claim that such court does not have jurisdiction with respect to such litigation. EACH PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT TO A TRIAL BY JURY AND AGREES THAT ANY OF THEM MAY FILE A COPY OF THIS PARAGRAPH WITH ANY COURT AS WRITTEN EVIDENCE OF THE KNOWING, VOLUNTARY AND BARGAINED-FOR AGREEMENT AMONG THE PARTIES IRREVOCABLY TO WAIVE ITS RIGHT TO TRIAL BY JURY IN ANY LITIGATION.**

**9.7.3** As used in this Section 9.7, the term “**Excluded Claim**” shall mean a dispute, controversy or claim that concerns (a) a decision by the Committee or Merck within the proper scope of the Committee’s authority pursuant to Section 2.6, or an issue concerning the integrity of data submitted to a regulatory agency, neither of which shall be justiciable in any forum; (b) the validity or infringement of a patent, trademark or copyright; or (c) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory. Any action concerning Excluded Claims identified in clauses (b) and (c) of this Paragraph may be brought in any court having jurisdiction.

**9.8 Limitation of Liability.** Notwithstanding anything to the contrary contained herein, neither Party shall be liable to the other Party under any theory for any special, incidental, indirect, consequential or other similar damages, or any punitive damages, whether arising directly or indirectly out of the transactions contemplated by this Agreement. To be clear, neither Party shall be entitled to recover for any lost profit or lost sale damages of any kind, whether those claimed damages are direct or indirect.

**9.9 Entire Agreement; Amendments.** This Agreement, together with the Schedules and Exhibits hereto, contains the entire understanding of the Parties with respect to the subject matter hereof. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, with respect to the subject matter hereof are superseded by the terms of this Agreement. The Schedules and Exhibits to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representative(s) of both Parties hereto.

Notwithstanding anything to the contrary in the foregoing, that certain Mutual Confidential Disclosure Agreement between the Parties dated as of July 11, 2018, shall remain in full force and effect with respect to the subject matter thereof and information disclosed thereunder.

**9.10 Headings.** The captions to the several Articles, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.

**9.11 Independent Contractors.** It is expressly agreed that Cocrystal and Merck shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Cocrystal nor Merck shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

**9.12 Waiver.** The waiver by either Party hereto of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach by or failure of such other Party whether of a similar nature or otherwise.

**9.13 Waiver of Rule of Construction.** Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

**9.14 Certain Conventions.** Any reference in this Agreement to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit shall be deemed to be a reference to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit, of or to, as the case may be, this Agreement, unless otherwise indicated. Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. Unless the context of this Agreement otherwise requires, (a) words of any gender include each other gender, (b) words such as “herein”, “hereof”, and “hereunder” refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (c) words using the singular shall include the plural, and vice versa, and (d) the term “including” (or “includes”) will be deemed to mean “including without limitation” (or “includes without limitations”).

**9.15 Business Day Requirements.** In the event that any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a business day (excluding notices required under Section 2.14), then such notice or other action or omission shall be deemed to be required to be taken on the next occurring business day.

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

- 9.16 Further Assurances.** Each Party agrees to duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including, without limitation, the filing of such additional assignments (including assignments for recordation in patent offices), agreements, documents and instruments, that may be necessary or as the other Party hereto may at any time and from time to time reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes of, or to better assure and confirm unto such other Party its rights and remedies under, this Agreement.
- 9.17 Counterparts.** This Agreement may be signed in any number of counterparts (including by facsimile or electronic transmission), each of which shall be deemed an original, but all of which shall constitute one and the same instrument. After facsimile or electronic transmission, the Parties agree to execute and exchange documents with original signatures.

*[Remainder of this Page Intentionally Left Blank]*

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

**MERCK SHARP & DOHME CORP.**

**COCRYSTAL PHARMA, INC.**

BY: /s/Benjamin B. Thorner  
Benjamin B. Thorner

BY: /s/ Gary L. Wilcox  
Gary L. Wilcox

TITLE: *Senior Vice President &  
Head Business Development & Licensing*

TITLE: *Chief Executive Officer*



[Signature Page to Exclusive License and Collaboration Agreement]

---

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

**SCHEDULE 1.10 PATENT RIGHTS**

[\*]

---

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

**SCHEDULE 2.1 RESEARCH PROGRAM**

[\*]

---

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

**SCHEDULE 2.6.1 REPRESENTATIVES OF THE JRC**

**Merck Representatives**

[\*]

**Cocrystal Representatives**

[\*]

---

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

**SCHEDULE 3.4 TRANSFER EXCEPTIONS**

[\*]

---

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

#### SCHEDULE 4.4 PRESS RELEASE

### Cocrystal Pharma Announces Exclusive Worldwide License and Collaboration Agreement with Merck

**BOTHELL, WA**, January \_\_, 2019 – Cocrystal Pharma, Inc. (NASDAQ: COCP), (“Cocrystal” or the “Company”), a clinical stage biotechnology company discovering and developing novel antiviral therapeutics that target the replication machinery of influenza viruses, hepatitis C viruses and noroviruses, announced today that it has entered into an exclusive license and collaboration agreement with Merck to discover and develop certain proprietary influenza A/B antiviral agents.

Under the terms of the 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. Cocrystal will be paid an undisclosed upfront sum and is eligible to receive payments related to designated development, regulatory and sales milestones with the potential to earn up to \$156 million, as well as undisclosed royalties on product sales.

“We are thrilled to work with Merck, a preeminent research-intensive pharmaceutical company, to advance the development of certain influenza A/B antivirals. Our R&D team has been intently focused on advancing our influenza program forward and we believe the combination of Merck resources and our innovative platform will enable us to rapidly advance important new treatments for influenza, which is a significant worldwide unmet need,” commented Dr. Gary Wilcox, Vice Chairman and Chief Executive Officer of Cocrystal. “This collaboration is a significant milestone for Cocrystal that we believe further validates our approach to drug discovery with our unique structure-based technologies and Nobel Prize winning expertise to create first- and best-in-class antiviral drugs.”

“Collaborations like this are an integral part of our infectious disease R&D strategy,” said Dr. Daria Hazuda, Chief Scientific Officer Merck Exploratory Science Center and Vice President Infectious Diseases and Vaccines Discovery, Merck Research Laboratories. “New meaningful options for the treatment of influenza are badly needed. We look forward to working with Cocrystal’s experienced team.”

#### **About Cocrystal Pharma, Inc.**

Cocrystal Pharma, Inc. is a clinical stage biotechnology company discovering and developing novel antiviral therapeutics that target the replication machinery of influenza viruses, hepatitis C viruses, and noroviruses. Cocrystal employs unique structure-based technologies and Nobel Prize winning expertise to create first- and best-in-class antiviral drugs. Novel inhibitors effective against influenza strains A and B have been identified and are in the preclinical stage. Several of these have potencies approaching single digit nanomolar. The Company’s lead candidate CC-42344 for influenza strain A is effective in animal models against both the pandemic and seasonal strains of influenza A. We continue to identify and develop non-nucleoside polymerase inhibitors for Norovirus infections using the Company’s proprietary structure-based drug design technology platform. For further information about Cocrystal, please visit [www.cocrystalpharma.com](http://www.cocrystalpharma.com).

---

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

### **Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including our expectations regarding the timing for achievement of certain research and clinical development milestones related to the licensing agreement with Merck as well as royalties on any product sales. 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. Some or all of the events anticipated by these forward-looking statements may not occur. Important factors that could cause actual results to differ from those in the forward-looking statements include the availability of products manufactured by third parties, the results of planned research and, if successful, clinical trials, and receipt of regulatory approvals. Further information on our risk factors is contained in our filings with the SEC, including our Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, the Prospectus Supplement dated July 19, 2018, and our Annual Report on Form 10-K for the year ended December 31, 2017. Any forward-looking statement made by us herein speaks only as of the date on which it is made. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by law.

### **Investor and Media Contact:**

Jenene Thomas Communications, LLC  
(833) 475-8247  
[COCP@jtcir.com](mailto:COCP@jtcir.com)

---

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

**SCHEDULE 5.2.4 EXPENSE BUDGET**

[\*]

---

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

**SCHEDULE 8.4.2 COCRYSTAL COMPOUNDS**

**See attached.**

---

[\*] Designates portions of this document that have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission

[\*]

---



**Subsidiaries of Cocystal Pharma, Inc.**

<b>Name of Subsidiary</b>	<b>Jurisdiction of Incorporation</b>
RFS Pharma, LLC	Georgia
Cocystal Discovery, 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 reports dated April 1, 2019, relating to the consolidated financial statements and the effectiveness of Cocrystal Pharma, Inc.'s internal control over financial reporting, which appear in this Form 10-K. Our report on the consolidated financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern. Our report on the effectiveness of internal control over financial reporting expresses an adverse opinion on the effectiveness of the Company's internal control over financial reporting as of December 31, 2018.

*/s/ BDO USA, LLP*  
Miami, Florida  
April 1, 2019

---



## 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: April 1, 2019

*/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: April 1, 2019

*/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, 2018, 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: April 1, 2019

In connection with the report of Cocrystal Pharma, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2018, 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: April 1, 2019

---

