

**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, 2017**

OR

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

For the transition period from: \_\_\_\_\_ to \_\_\_\_\_

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.)*

**1860 Montreal Road, Tucker GA**

*(Address of Principal Executive Office)*

**30084**

*(Zip Code)*

Registrant's telephone number, including area code: **(678)-892-8800**

Securities registered pursuant to Section 12(b) of the Act: Common Stock, \$0.01 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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, 2017, was approximately \$66 million.

The number of shares outstanding of the registrant's common stock, as of March 16, 2018, was approximately 24.4 million shares.

**Documents Incorporated by Reference**

Portions of the registrant's definitive proxy statement for its 2018 Annual Meeting of Stockholders are incorporated by reference in Items 10, 11, 12, 13, and 14 of Part III of this Annual Report on Form 10-K.

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## INDEX

	<u>Page</u>
<b><u>Part I.</u></b>	
Item 1. <a href="#"><u>Business.</u></a>	2
Item 1A. <a href="#"><u>Risk Factors.</u></a>	9
Item 1B. <a href="#"><u>Unresolved Staff Comments.</u></a>	32
Item 2. <a href="#"><u>Properties.</u></a>	32
Item 3. <a href="#"><u>Legal Proceedings.</u></a>	32
Item 4. <a href="#"><u>Mine Safety Disclosures.</u></a>	32
<b><u>Part II.</u></b>	33
Item 5. <a href="#"><u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.</u></a>	33
Item 6. <a href="#"><u>Selected Financial Data.</u></a>	35
Item 7. <a href="#"><u>Management’s Discussion and Analysis of Financial Condition and Results of Operations.</u></a>	36
Item 7A. <a href="#"><u>Quantitative and Qualitative Disclosures About Market Risk.</u></a>	43
Item 8. <a href="#"><u>Financial Statements and Supplementary Data.</u></a>	44
Item 9. <a href="#"><u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.</u></a>	44
Item 9A. <a href="#"><u>Controls and Procedures.</u></a>	44
Item 9B. <a href="#"><u>Other Information.</u></a>	46
<b><u>Part III.</u></b>	47
Item 10. <a href="#"><u>Directors, Executive Officers and Corporate Governance.</u></a>	47
Item 11. <a href="#"><u>Executive Compensation.</u></a>	47
Item 12. <a href="#"><u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.</u></a>	47
Item 13. <a href="#"><u>Certain Relationships and Related Transactions, and Director Independence.</u></a>	47
Item 14. <a href="#"><u>Principal Accounting Fees and Services.</u></a>	47
<b><u>Part IV.</u></b>	47
Item 15. <a href="#"><u>Exhibits, Financial Statement Schedules.</u></a>	47
Item 16. <a href="#"><u>Form 10-K Summary</u></a>	47
<b><u>SIGNATURES</u></b>	48

## PART I

### Forward-Looking Statements

*Except for the historical information contained herein or incorporated by reference, this Annual Report and the information incorporated by reference contains forward-looking statements that involve risks and uncertainties. These statements include projections about our accounting and finances, plans and objectives for the future, future operating and economic performance and other statements regarding future performance. These statements are not guarantees of future performance or events. Our actual results may differ materially from those discussed here. Factors that could cause or contribute to differences in our actual results include those discussed in the following section and included in the Item 1A the Risk Factors.*

### Item 1. Business.

#### Overview

Our primary business is to develop novel medicines for use in the treatment of human viral diseases. Cocrysal Pharma, Inc. (“the 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. On January 2, 2014, Biozone Pharmaceuticals, Inc. sold substantially all of its assets to MusclePharm Corporation (“MusclePharm”), and, on the same day, merged with Cocrysal 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 Cocrysal 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”).

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

#### Cocrysal Technology

We are developing antiviral therapeutics that inhibit the essential replication function of various viruses. Our first goal is to decrease the length of Hepatitis C (HCV) clinical treatment by advancing drug candidates targeting HCV RNA-dependent RNA polymerase enzyme, HCV helicase, and the HCV NS5A protein. Additional goals include treating human and avian (bird) influenza virus and norovirus by discovering and developing drug candidates targeting the RNA-dependent RNA polymerases. The polymerase inhibitors include both nucleosides (Nucs) and non-nucleosides (NNIs). To discover and design these inhibitors, we use a proprietary platform comprising computation, nucleoside and medicinal chemistry, X-ray crystallography, and our extensive know-how. We determine the structures of cocrysal 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 cocrysal 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. While this approach is easy to describe, it is much more difficult to carry out. In particular, an extensive knowledge of viruses and drug targets is required. In addition, knowledge and experience in the fields of structural biology, enzymology, and nucleoside chemistry is required.

We developed our proprietary structure-based drug design and antiviral nucleoside chemistry under the guidance of Dr. Roger Kornberg, our Chief Scientist and recipient of the Nobel Prize in Chemistry in 2006, and Dr. Raymond Schinazi, our Chairman and a world leader in the area of nucleoside chemistry and the cofounder of several biotechnology companies focusing on antiviral drug discovery and development, including Triangle Pharmaceuticals, Idenix Pharmaceuticals, and Pharmasset, Inc. 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 nucleosides, non-nucleoside inhibitors, metal-binding inhibitors, and 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: hepatitis C, 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.

Fast onset of action and / or shortened therapeutic time: In order to improve patient care and penetrate the HCV marketplace, drugs are needed with faster onset of viral load lowering resulting in shorter therapeutic 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 and a viral replication protein, 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 hepatitis C (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 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. Any 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, and in pill-form.

## Research and Development update

### 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 hepatitis C. 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), Viekira Pak (ombitasvir/paritaprevir/ritonavir, dasabuvir), Eplclusa (sofosbuvir/velpatasvir), Zepatier (elbasvir/grazoprevir) and Mavyret (glecaprevir/pibrentasvir).

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. Although injection drug use is the major route of HCV transmission in some regions, the provision of effective harm reduction services has been inadequate. Globally, 5% of health-care-related injections remained unsafe. As a result, an estimated 1.75 million new HCV infections occurred worldwide in 2015.

We have four classes of HCV DAAs targeting three different HCV replication proteins - NS5B polymerase (NNI and Nuc), NS5A, and NS3 helicase. These DAAs could be developed as part of an all-oral, pan-genotypic combination regimen with significant upside. Our focus is on developing what is now called ultrashort treatment regimens from 2 to 6 weeks in length. Such a combination treatment with different classes of DAAs has the potential to change the paradigm of treatment for HCV with its efficacy, higher barrier to viral resistance, improved compliance, and shorter duration of treatment. These strategies could allow us to expand and broaden our portfolio in the HCV antiviral therapeutic area globally and could lead to a high and fast cure rate, to improve compliance, and to simplified treatment duration. To our knowledge no competing company has yet developed a short HCV treatment of 4 weeks or less successfully with a high (>95%) sustained virologic response (SVR) at week 12.

CC-31244, HCV NNI, is a potential best in class pan-genotypic inhibitor of NS5B polymerase for the treatment of hepatitis C infection. The Company completed a Phase 1a study in Canada in September 2016, with favorable safety results in a randomized, double-blinded, Phase 1a study in healthy volunteers and HCV-infected subjects. The Company is presently conducting a Phase 1b study in HCV genotype 1 subjects. Cocrystal Pharma presented the interim results from the 1b 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 fast acting, shortened duration all-oral HCV combination therapy. The Company has three additional preclinical candidates: a pan-genotypic nucleoside inhibitor, an NS5A inhibitor, and an NS3 helicase inhibitor.

The Company is progressing clinically while seeking a partner for further clinical development of CC-31244 and the preclinical candidates.

#### 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 (CDC) estimates that influenza is linked to 49,000 deaths and 200,000 hospitalizations each year in the United States. The worldwide market for antiviral drugs to treat influenza was \$3.8 billion in 2012 and is expected to grow to \$6 billion by 2018 (bccResearch).

Influenza viruses are significant human respiratory pathogens that cause both seasonal, endemic infections and periodic, unpredictable pandemics. The worst pandemic on record, in 1918, killed approximately 50 million people worldwide. Human infections caused by H5N1 highly pathogenic avian influenza viruses have raised concern about the emergence of another pandemic. The histopathology of fatal influenza virus pneumonias has been documented over the past 120 years. Strikingly, the spectrum of pathologic changes described in the 1918 influenza pandemic is not significantly different from the histopathology observed in other less lethal pandemics or even in deaths occurring during seasonal influenza outbreaks.

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).

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 profiles. We plan to initiate IND-enabling studies this year. Antiviral product candidates that are competitors for the Company's influenza program 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.

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 21 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. Few companies, including Chimerix, are developing antiviral treatments for this disease. However, 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. It owns one of the earliest patents on nucleosides that could treat norovirus infections. Similar to the hepatitis C virus 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.

As of December 31, 2017, our patent portfolio consisted of patents and pending applications in the areas primarily related to the treatment of HCV, HIV, and Norovirus.

With respect to treatment of HCV, our portfolio is divided into three groups, related to our NS5B, NS5A and NS3 programs. The NS5B program includes both nucleoside (Nuc) and non-nucleoside (NNI) compounds. In our NS5B Nuc program, we have two patents, one U.S. non-provisional application, three international applications filed under the Patent Cooperation Treaty (PCT) at the World Intellectual Property Organization (WIPO), and nineteen foreign counterpart applications, over seven patent families. The counterpart foreign applications were filed in a number of countries and regions depending on the particular patent family, including Brazil, Canada, China, Europe, India, Japan, Korea, Mexico and Russia.

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 NS5A program, we have two issued U.S. patents, two pending U.S. application, twenty-four foreign counterpart applications pending in Australia, Brazil, Canada, China, Columbia, Europe, India, Indonesia, Israel, Japan, Korea, Mexico, Malaysia, New Zealand, the Philippines, Russia, Singapore, South Africa, Thailand, the Ukraine, and Vietnam.

In our influenza program, our patent portfolio consists of two related families, including two pending US patent applications.

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

In our Norovirus program, our patent portfolio consists of one issued U.S. patent and three pending foreign counterpart applications. Claims directed to the treatment of norovirus were also pending in another patent family, which also focused on the treatment of HCV.

We have one issued patent focused on HIV, and many of the patent applications related to NS5B nucleosides also disclose treating HIV. Management is considering the best approach to proceed with this asset.

## **Collaborations**

Emory University: The Company has an exclusive license from Emory University for use of certain inventions and technology related to inhibitors of HCV that were jointly developed by Emory and the Company employees. The License Agreement was dated March 7, 2013. As part of the 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 is based on technology disclosed within three (3) years of March 7, 2013. The agreement includes payments due to Emory ranging from \$40,000 to \$500,000 based on successful achievement of certain drug development milestones. Additionally, the Company may have 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 Company's Chairman and largest shareholder, Dr. Raymond Schinazi, is an inventor, and also a faculty member at Emory University.

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

Genoscience, BioLineRx and CTTQ: On February 1, 2012, Discovery, now a subsidiary of the Company, in collaboration with Genoscience entered into a worldwide license agreement with BioLineRx (NASDAQ: BLRX; TASE: BLRX), a biopharmaceutical development company, to develop and commercialize BL-8030, an orally available treatment for hepatitis C. The agreement included upfront royalties and milestones payable to both companies. BL-8030 was co-developed through a joint collaboration between Discovery and Genoscience. Advanced preclinical studies were conducted in collaboration with CTTQ for China and Hong Kong markets. This collaboration was terminated in February 2016.

University of Pittsburgh and Emory University: Discovery assigned its patent rights to the patent titled “3’-Azido Purinenucleotide Prodrugs for Treatment Of Viral Infections” to University of Pittsburgh on November 21, 2014. This patent is jointly owned by Discovery, the University of Pittsburgh and Emory University. Dr. Raymond Schinazi, is an inventor, and also a faculty member at Emory University.

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 there are no further rights or obligations under this license agreement after the Termination Date.

## **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 dominates the market for HCV with an estimated market share greater than 70%. Its products are widely considered effective.

In February 2017, Merck & Co. announced it would write off \$2.9 billion (pretax) relating to a prior acquisition for a hepatitis C drug still in clinical trials. Meanwhile Gilead announced lower forecasted sales from its three hepatitis drugs. Many of these and other 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.

In August 2017, AbbVie, Inc. announced that the U.S. Food and Drug Administration approved Mavyret (glecaprevir/pibrentasvir), a once-daily, ribavirin-free treatment for adults with chronic hepatitis C virus infection across all major genotypes (GT1-6). Mavyret is an 8-week, pan-genotypic treatment for patients without cirrhosis and who are new to treatment.

## **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.

## **Research and Development Expenses**

### **Manufacturing**

We do not own or operate, and have no plans to establish, any manufacturing facilities. Our chemistry laboratory can produce research scale (milligram-gram) quantities of our lead drug candidates. As such, our progress is often dependent on successful project execution by third party vendors.

## Employees

As of March 16, 2018, we employ 10 full-time employees. Of these full-time employees, 8 are engaged in research and development activities.

## Legacy Business

### **Our Legacy Business**

Prior to the merger with Discovery on January 2, 2014, while operating as Biozone Pharmaceuticals, Inc., we were primarily engaged in the business of developing and manufacturing over-the-counter drug products (OTC) and cosmetic and beauty products for third parties. In addition, we marketed two lines of proprietary skin care products. All of these assets were sold to MusclePharm as part of the January 2, 2014 Asset Purchase Agreement in exchange for 1,200,000 shares of MusclePharm common stock which had a market value as of January 2, 2014 of \$9,840,000. In addition, MusclePharm licensed back to us the patents we sold it for six months in exchange for our paying it a 5% royalty on gross sales.

While operating as Biozone Pharmaceuticals, Inc., we also owned a 45% interest in BetaZone Laboratories, LLC (“BetaZone”), which was engaged in the sale and license of pharmaceutical and cosmetic products in Latin America. We received no material royalties from BetaZone, which had licensed our proprietary technology. This technology was also sold to MusclePharm.

We were incorporated as a Nevada corporation on December 4, 2006 under the name International Surf Resorts Inc. We changed our name to Biozone Pharmaceuticals, Inc. on March 1, 2011 and we acquired Biozone Labs and our other subsidiaries on June 30, 2011. On January 30, 2014, we re-incorporated in Delaware. We acquired our current corporate structure and business operations following our merger with RFS Pharma, LLC effective November 25, 2014.

### **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 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 not ever generate revenue and may continue to incur significant losses for the foreseeable future.**

We are primarily a pre-clinical and early stage clinical, biopharmaceutical discovery and development company. Since inception, our operations have been 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. In 2016, we initiated our first clinical trial in Canada, a Phase 1 study for a HCV product. In August 2017 we announced positive data from the completion of the HCV Phase 1 study. In 2018, we plan to initiate a Phase 2a study for HCV in the United States. Because of the need to complete clinical trials, establish safety and efficacy and obtaining regulatory approval, we do not anticipate generating revenue for at least five years and will continue to sustain large losses.

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. 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.

**Because we have lost \$138 million from inception through December 31, 2017 and expect to continue losing money for an unforeseen number of years, we cannot assure you we will ever generate revenue, achieve income from operations or have positive cash flow.**

As an early stage drug development company, our focus is on developing product candidates, obtaining regulatory approval and commercializing pharmaceutical products. As a result, we have lost \$138 million from inception through December 31, 2017, expect losses to continue, and have never generated material revenue or 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 revenue, income from operations or have positive cash flow.

**Our ability to continue as going concern is in doubt absent obtaining adequate new financing.**

In 2017, we incurred a net loss of approximately \$0.6 million and operating loss of \$7.5 million and used approximately \$6.9 million in net cash in operations. We anticipate that we will continue to lose money for the foreseeable future. Based on cash on hand as of March 16, 2018 of approximately \$1.9 million, the Company does not have the capital to finance operations for the next 12 months. This raises substantial doubt about our ability to be a going concern. Our auditors issued an audit opinion for the year ended December 31, 2017 which contained what is referred to as a “going concern” opinion. Our continued existence is dependent upon obtaining adequate new financing. Because of our continuing losses, we may have to continue to reduce our expenditures, without new financing. Working capital limitations may impinge on our day-to-day operations, including causing us to reduce our research and development or planned clinical trials.

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 more recently, convertible notes. 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.

**Because we have yet to generate any revenue 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 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 in the near future, 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;
- 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.

**If we do not raise additional debt or equity capital, we may not be able to remain operational.**

Presently we have cash to last through June 2018. Accordingly, we must raise approximately \$8 to \$10 million to support our planned operations over the next 12 months. The Company is presently exploring various financing options, including but not limited to a private placement.

There can be no assurances that we will raise the necessary capital or, if we do, it will be on terms that are favorable to our stockholders. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is very expensive. We expect our research and development expenses to substantially increase as we advance our product candidates toward clinical programs. In order to conduct these trials, we will need to raise additional capital to support our operations and such funding 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 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 at all.

**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 identify and implement successfully 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 product is expensive, often 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 testing is expensive, difficult to design and implement, can take many years to complete and is 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”), 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 are observed in any clinical trials of our product candidates, including those our partners may develop under our 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.

**Even if we complete the necessary preclinical studies and clinical trials, we cannot predict whether or when we will obtain regulatory approval to commercialize a product candidate and we cannot, therefore, predict the timing of any revenue from a product.**



Neither we nor any partners we may have can commercialize a product until the appropriate regulatory authorities, such as the FDA or its foreign equivalent, have reviewed and approved the product candidate. The regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or foreign regulatory authority recommends restrictions on approval or recommends non-approval.

**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 including Canada, 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 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 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.

**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 the success of 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 due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, 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.

**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 practice 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 trial, 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.

**If we are not successful in completing preclinical or clinical testing or are unable to demonstrate safety and efficacy of our product candidates to the satisfaction of the regulatory authorities, we may suffer impairment on our IPR&D assets.**

In-process research and development (IPR&D) represents a series of awarded patents, filed patent applications and an in-process research program acquired in the acquisition of RFS Pharma that are integral to the development of the Company's planned future products. In-process research and development represent an indefinite-lived intangible asset. Any series of preclinical and clinical outcomes that reduce the probability for technical and regulatory success, may trigger interim impairment testing. If our IPR&D becomes impaired, write down on the carrying amount of these assets may result, which could depress our stock price. During 2015, we lowered our forecasts of future cash flows, which caused a reduction in our IPR&D, resulting in an impairment charge of \$38.7 million. In 2016, we lowered our forecasts of future cash flow again. This reduction caused us to write-down our IPR&D by \$92.4 million.

## **RISKS RELATED TO OUR RELIANCE ON THIRD PARTIES**

**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.**

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;
- 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, or we may not be able to do so on terms acceptable to us, in which case it may be necessary for us to limit the size or scope of one or more of our programs or increase 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 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 be delayed in completing, the necessary clinical trials and preclinical studies to enable us or our partners to select viable product candidates for IND submissions and will not be able to, or may be delayed in our efforts to, successfully develop and commercialize such product candidates.

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

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; 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 expect 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 expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials. While we will have agreements governing their activities, we and 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 all legal, regulatory and scientific standards. 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 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. We cannot offer any assurances about which patents will issue or whether any issued patents will be found invalid and unenforceable or will be threatened 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. However 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, we cannot provide any assurances that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. The FDA, as part of its Transparency Initiative, is considering whether to make additional information publicly available on a routine basis, including information we may consider to be trade secrets or other proprietary information. In 2017 a FDA Transparency Initiative research team made recommendations that the FDA make disclosure of clinical and statistical reviews of products, and the availability of data sets and analysis through clinical data repositories. The FDA has the legal authority to implement recommendations however it is not clear how the FDA's disclosure policies may change, if at all.

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 claims of intellectual property infringement may prevent or delay our development and commercialization efforts.**

Our commercial success depends in part on our avoiding infringement of 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 ("U.S. PTO"), 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 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 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 employee resources 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 a patent of ours or our licensors 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 substantial costs and distract 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 for which a clinical trial is underway in Canada, 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;

- 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 coverage and adequate reimbursement are not available for our product candidates, it could make it difficult for us to sell products profitably.**

Market acceptance and sales of any product candidates we develop will depend on coverage and reimbursement policies and may be affected by future healthcare reform measures. 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. We cannot be sure that coverage and adequate reimbursement will be available for any product candidates. Also, inadequate reimbursement amounts may reduce the demand for, or the price of, our future products. If reimbursement is not available, or is available only at limited levels, we may not be able to successfully commercialize product candidates we develop. Presently, we cannot predict whether any healthcare or health insurance legislation will affect our products or proposed products, although it is a key issue for President Trump. If reimbursement is not available, or is available at limited levels, we may not be able to successfully commercialize product candidates we develop.

We cannot be certain if and when we will obtain formulary approval to allow us to sell any products we may develop and commercialize into our target markets. Obtaining formulary approval from hospitals and from payors can be an expensive and time-consuming process. Failure to obtain timely formulary approval will limit our commercial success.

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. These legislative and/or regulatory changes may negatively impact the reimbursement for drug products, following approval. The availability of generic treatments may also substantially 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 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. If we fail to successfully secure and maintain reimbursement coverage for our future products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed.

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.**

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, Dr. Raymond Schinazi, our interim Chief Executive Officer, Dr. Gary Wilcox, and our President, Dr. Sam Lee. We do not carry “key-man” life insurance on the lives of our Chairman, who is not an employee, or any of our employees or advisors. Furthermore, our future success will also depend in part on the continued service of our key scientific and management personnel and our ability to identify, hire, and retain additional personnel. We may not be able to attract and retain personnel on acceptable terms, as there is significant competition among numerous pharmaceutical companies for individuals with similar skill sets. Because of this competition, our compensation costs may increase significantly. If we lose key employees, our business may suffer.

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

As of March 14, 2018, 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 will depend, in part, on our ability to manage any 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.

We do not have any product liability insurance coverage. We anticipate obtaining such insurance prior to the commencement of any clinical trials but any such insurance coverage we obtain may not reimburse us for all expenses or losses we may suffer. 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 could delay us in developing our future products.**

We have locations in Washington and Georgia. We are vulnerable to natural disasters such as earthquakes and tornados as well as other events that could disrupt our operations. 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 business operations.

**If our information technology systems are hacked, a third party may misappropriate our trade secrets which could harm our business and future results of operations.**

We keep some of our intellectual property, including trade secrets and results of our clinical and preclinical research on a central server, and our employees email such information to each other and to third parties outside of our offices. In addition, since we do not encrypt all of this information, there is a risk that hackers could misappropriate our intellectual property. Any such misappropriation could harm our business and future results of operations.

#### **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 industry 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 industry or both, 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.

**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 16, 2018, our directors, executive officers and principal stockholders (those beneficially owning in excess of 5%), and their respective affiliates, beneficially own approximately 68% 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 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 1.7 million shares of common stock are available for future grant.

**If we are subject to securities class action litigation, we may sustain material costs.**

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could cause substantial costs and a diversion of management's attention and resources, which could harm our business.

**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 thinly traded, purchasers of our stock may incur difficulty in selling their shares at or above the price they paid for them.**

Although our common Stock recently was listed on Nasdaq, it has not been actively traded. We cannot assure you that an active market for our common stock will develop, or if it does, it will be sustained. Accordingly, investors may experience difficulty in selling their shares of common stock.

**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.

**Because many of our outstanding shares are freely tradable, sales of these shares could cause the market price of our common stock to drop significantly, even if our business is performing well.**

As of March 16, 2018, we had approximately 24.4 million shares of common stock outstanding, approximately 9.6 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 non-affiliate of the Company, 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.



The remainder of our shares of common stock outstanding are held by affiliates of the Company. An affiliate may sell after six months (subject to contractual restrictions as described above) 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 our common stock could cause the market price of our common stock to drop 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 material weaknesses, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of 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.**

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. Although we have developed and are implementing a plan to remediate these material weaknesses and believe, based on our evaluation to date, that these material weaknesses will be remediated during 2018, we cannot assure you that this will occur within the contemplated timeframe. Moreover, we cannot assure you that we will not identify additional material weaknesses in our internal control over financial reporting in the future. If we are unable to remediate the material weaknesses, 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 Securities and Exchange Commission 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.

As described under "Item 9A. Controls and Procedures," we have identified control deficiencies which constitute material weaknesses in our internal control over financial reporting related to the following:

**I. Risk Assessment Control Activities - Financial Reporting Process**

We did not maintain an effective financial reporting process to prepare financial statements in accordance with U.S. GAAP. Specifically, the process lacked timely and documented financial statement reviews of information included in the financial statements and procedures to ensure all required disclosures were made in the financial statements.

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.

**II. Control Activities - Preparation and Review of Manual Account Reconciliations**

Our design and maintenance of controls in the period-end financial reporting process, specifically the execution of controls over the preparation, analysis and review of account reconciliations, were ineffective. These control deficiencies resulted in adjustments to 2017 consolidated financial statements related to stock-based compensation and the fair value of warrant liabilities.

This control environment material weakness could result in a material misstatement to the Company's annual or interim financial statements that would not be prevented or detected.

The material weaknesses identified by management could result in a material misstatement to our annual or interim financial statements that would not be prevented or detected. Management has concluded that our internal control over financial reporting was not effective as of December 31, 2017 due to the material weaknesses identified. We reviewed the results of management's assessment with the Audit Committee of the Company's Board of Directors.

#### **Item 1B. Unresolved Staff Comments**

Not Applicable

#### **Item 2. Properties**

We have operating facilities in Bothell, WA and Tucker, GA.

In January 2015, the Company renewed its lease for approximately 9,400 square feet of office and laboratory space in Bothell, Washington. The lease expires on February 1, 2019 and provides for annual rent of approximately \$168,500.

As part of the merger (that occurred on November 25, 2014) with RFS Pharma, the Company assumed the lease for RFS Pharma facilities located in Tucker, Georgia. This lease was amended on January 1, 2014 and expired on December 31, 2016 for approximately 6,148 square feet of office and laboratory space. The Company executed a short-term lease extension for six months, through June 30, 2017 and then again through December 31, 2017. The Company leases the Tucker, Georgia facility from a limited liability company owned by the Company's Chairman of the Board and principal shareholder, Dr. Raymond Schinazi. In January 2018 we reduced the lease area to approximately 1,200 square feet and continued on a pro-rated month to month term while we prepare a new lease. The annual expense for this space is estimated to be \$44,000.

We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available if needed for future work.

#### **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.

In 2014, Daniel Fisher and his affiliate, 580 Garcia Properties LLC, brought multiple lawsuits against the Company involving its predecessors and subsidiaries. The lawsuits have been settled and the complaints initiating them dismissed, without the Company making any payments to either Mr. Fisher or 580 Garcia Properties LLC. The Company held a promissory note secured by a deed of trust under which 580 Garcia Properties LLC is the primary obligor. As of the time of the acquisition by the Company of the promissory note, 580 Garcia Properties LLC, was delinquent in its obligation to make certain monthly payments thereunder. Consequently, in December 2015, the Company issued notice of default letters to 580 Garcia Properties LLC, Daniel Fisher, and Sharon Fisher for said delinquencies, and proceeded in accordance with rights of a secured real estate creditor under California law, to initiate private foreclosure proceedings respecting the property, to foreclose under the promissory note secured by the deed of trust. A foreclosure sale was set in accordance with California law for January 27, 2017. Prior to the date of this foreclosure sale, Mr. Fisher filed a motion where he sought among other things an order of the court enjoining the foreclosure sale, alleging wrongdoing by the Company and Biozone Pharmaceuticals, Inc. and others that Mr. Fisher claimed the Company has direct responsibility over.

Because the Company intended to foreclose on the property and foreclosure was probable, the Company recognized an impairment on the mortgage note receivable of \$1,176,000 in 2016 to adjust the carrying value of the note to its fair value. The fair value of the note was determined by reference to the estimated fair value of the underlying property, which was determined based on analysis of comparable properties and recent market data. Furthermore, as a result of the Company's plan to divest of this asset within the next 12 months, the asset was reclassified from long-term to current.

On or about February 8, 2018 a series of transactions concluded, involving the Company, Daniel Fisher, 580 Garcia Properties LLC, and others, by the terms of which, inter alia, the Company resolved all outstanding claims and disputes with Daniel Fisher, his spouse Sharon Fisher, and 580 Garcia Properties, LLC, and by which the Company received a payment of \$1.4 million in exchange for the release of the aforementioned note and deed of trust, under which 580 Garcia Properties, LLC owed \$1.3 million of principal and accrued interest.

#### **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

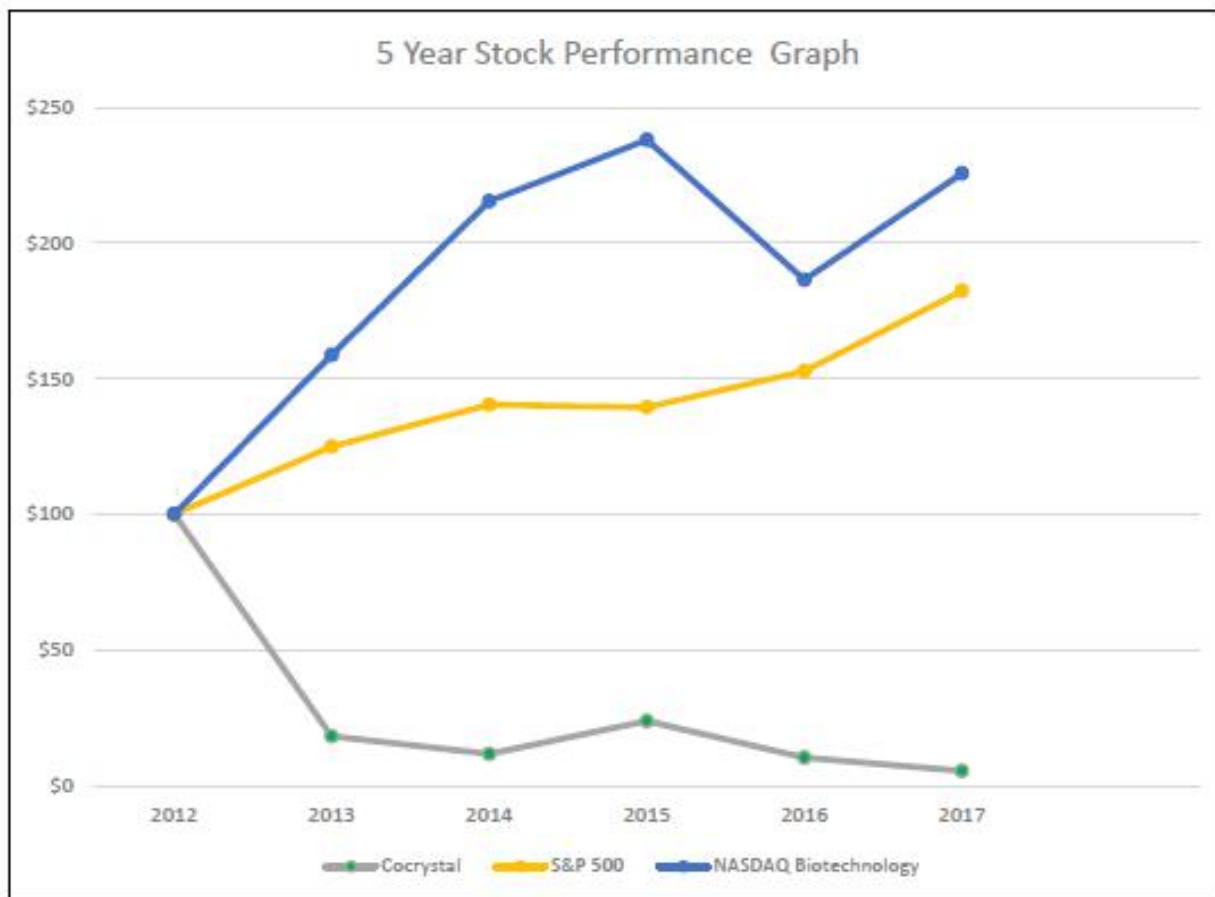
Our common stock has been quoted on the OTCQB under the symbol "COCP" since April 15, 2014. Beginning March 12, 2018, our common stock moved to the NASDAQ market under the same symbol "COCP". The following table sets forth the high and low prices as reported on the OTCQB for the prior two fiscal years. The quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions. The prices have been adjusted to reflect a 1-for-30 reverse stock split which was effective January 24, 2018. As of March 10, 2018, there were approximately 235 holders of record of our common stock.

	<u>High</u>	<u>Low</u>
<b>Year ended December 31, 2017</b>		
January 1, 2017 through March 31, 2017	\$ 12.30	\$ 5.73
April 1, 2017 through June 30, 2017	\$ 9.60	\$ 4.80
July 1, 2017 through September 30, 2017	\$ 9.00	\$ 5.10
October 1, 2017 through December 31, 2017	\$ 8.70	\$ 5.04
<b>Year ended December 31, 2016</b>		
January 1, 2016 through March 31, 2016	\$ 27.60	\$ 13.80
April 1, 2016 through June 30, 2016	\$ 25.80	\$ 12.60
July 1, 2016 through September 30, 2016	\$ 17.10	\$ 9.60
October 1, 2016 through December 31, 2016	\$ 15.60	\$ 11.10

The last reported sales price of our Common stock on NASDAQ on March 15, 2018 was \$4.89 per share.

#### Stock Performance Graph

The following graph compares the five-year cumulative total return of our Common Stock with the S&P 500 Index and the NASDAQ Biotechnology Index. The graph assumes \$100 invested on December 31, 2012 in our Common Stock and in each of the foregoing indices. The stock price performance reflected in the graph below is not necessarily indicative of future price performance. The stock price performance before 2014 was that of Biozone Pharmaceuticals, Inc., prior to the merger on January 2, 2014 that formed the Company.



Period	The Company	S&P 500	NASDAQ Biotechnology
2012	\$ 100	\$ 100	\$ 100
2013	18	125	159
2014	12	140	215
2015	24	139	238
2016	10	153	186
2017	5	182	226

#### 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.

## Securities Authorized for Issuance under Equity Compensation Plans

### Equity Compensation Plan Information

The following chart reflects the number of awards granted under equity compensation plans approved and not approved by shareholders and the weighted average exercise price for such plans as of December 31, 2017.

<b>Name of Plan (Share values in 000's)</b>	<b>Number of shares of common stock to be issued upon exercise of outstanding options (1) (a)</b>	<b>Weighted Average Exercise Price of Outstanding Options (b) (\$)</b>	<b>Number of shares remaining available for issuance under equity compensations plans (excluding the shares reflected in column a)</b>
Equity compensation plans not approved by security holders	-	-	-
Equity compensation plans approved by security holders (2)	<u>711</u>	<u>8.39</u>	<u>1,656</u>
<b>Total</b>	<b><u>711</u></b>	<b><u>8.39</u></b>	<b><u>1,656</u></b>

(1) Consists of stock options.

(2) This represents securities issued under the 2007 Equity Incentive Plan (the "Prior Plan") and 2015 Equity Incentive Plan.

In 2014, in connection with the Discovery merger, the Company adopted and assumed the Prior Plan. On April 13, 2015, the Board adopted the 2015 Equity Incentive Plan (the "2015 Plan"). The 2015 Plan provides for the grant of incentive stock options, qualified stock options, restricted stock awards, restricted stock units, stock appreciation rights, and performance shares or units and cash awards. Awards may be granted under the 2015 Plan to our employees, directors and independent contractors.

### Recent Sales of Unregistered Securities

All recent sales of unregistered securities have been previously reported.

### Item 6. Selected Financial Data

The following selected historical consolidated statement of operations data for the years ended December 31, 2017, 2016, 2015, 2014 and 2013 and the consolidated balance sheet data as of December 31, 2017, 2016, 2015, 2014 and 2013, below are derived from our audited consolidated financial statements and related notes thereto. This data should be read in conjunction with our "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes thereto.

For the years ended December 31,

<u>(In thousands, except per share information)</u>	2017	2016	2015	2014	2013
<b>Statement of operations data:</b>					
Grant Revenues	\$ -	\$ -	\$ 78	\$ 9	\$ -
<b>Costs and expenses:</b>					
Research and development (a)	5,822	101,679	47,261	4,071	18
General and administrative	2,440	4,140	6,765	1,737	3,283
Total costs and expenses	8,262	105,819	54,026	5,808	3,301
Operating loss	(8,262)	(105,819)	(53,948)	(5,799)	(3,301)
Other income (expense), net	769	1,551	(11,422)	5,648	(20,457)
Income tax benefit	6,880	29,394	15,248	52	-
Net loss	(613)	(74,874)	(50,122)	(99)	(23,758)
Net loss attributable to common shareholders	\$ (613)	\$ (74,874)	\$ (50,122)	\$ (99)	\$ (23,758)
<b>Loss per share, basic:</b>					
Net loss per share	\$ (0.03)	\$ (3.18)	\$ (2.40)	\$ (0.30)	\$ (9.90)
<b>Loss per share, diluted:</b>					
Net loss per share	\$ (0.03)	\$ (3.30)	\$ (2.40)	\$ (0.30)	\$ (9.90)
<b>Weighted average number of common shares</b>					
outstanding (basic) (b):	24,126	23,518	21,011	10,893	2,417
Weighted average number of common shares					
outstanding (diluted) (b):	24,126	23,533	21,011	10,925	2,417
<b>Balance sheet data:</b>					
Total assets	\$ 121,426	\$ 124,883	\$ 224,230	\$ 259,283	\$ 6,456
Long-term liabilities	\$ 14,620	\$ 20,525	\$ 49,936	\$ 65,257	\$ -
Total stockholders' equity (deficit)	\$ 105,400	\$ 102,319	\$ 167,594	\$ 6,651	\$ (6,026)

(a) Includes \$92,396 and \$38,665 impairment on IPR&D in 2016 and 2015, respectively.

(b) Includes retroactive application of 1 for 30 reverse stock split of the Company's Common Stock effectuated on January 24, 2018.

## 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

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

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.

## Results of Operations

### For the Years Ended December 31, 2017 and December 31, 2016

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, 2017 or 2016. For the year ended December 31, 2017, we had a net loss of \$613,000 compared to a net loss of \$74,874,000 for 2016. This net loss for the year was due to losses from ongoing operations, offset by income tax benefits. The 2016 losses were primarily due to an impairment loss of \$92,396,000 on our IPR&D, \$13,400,000 from ongoing operations, \$1,177,000 impairment on our mortgage note, offset by a \$29,394,000 deferred tax benefit associated with the impairment charge incurred on our IPR&D asset. Our operating loss for the year ended December 31, 2017 was \$8,262,000, compared to an operating loss of \$105,819,000 in 2016. The operating loss for 2016 included the impairment charge of \$92,369,000 on our IPR&D asset noted above. Other income was \$769,000 for the year ended December 31, 2017, which is primarily due to a \$907,000 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, 2017, 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 expense consists 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, 2016 is an impairment charge related to our in-process research and development (IPR&D) intangible asset in the amount of \$92,369,000.

Total research and development expenses were \$5,822,000 for the year ended December 31, 2017, compared with \$101,679,000 for the year ended December 31, 2016. This decrease of \$95,857,000 is primarily the result of recognizing an impairment loss on IPR&D of \$92,396,000 in 2016. Excluding the impact of the IPR&D impairment charge, research and development expenses decreased \$3,461,000 from \$9,283,000 for the year ended December 31, 2016. We continue to expect research and development expenses to increase in 2018 as a result of HCV Phase 2 programs and preparation for Influenza Phase 1 start up.

### 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 \$2,440,000 for the year ended December 31, 2017, compared with \$4,140,000 for the year ended December 31, 2016. This decrease of \$1,700,000 was primarily due to an insurance reimbursement of prior legal costs, a non-cash reversal of stock compensation expense related to unvested options for the former General Counsel and Interim CFO that left the Company during 2017, a decrease in compensation costs due to staffing turnover, and a general decrease in legal costs.

### Interest Income/Expense

Interest income (expense) was (\$7,000) for the year ended December 31, 2017, compared to \$126,000 for the year ended December 31, 2016. The interest expense in 2017 is a result of the convertible promissory notes we entered into in November 2017. The 2016 income amounts primarily represent interest earned on the mortgage note we acquired in June 2015. As further explained in Note 4 to the consolidated financial statements, we have sold this note in February 2018.

## **Other Income/Expense**

Other Income, net, was \$769,000 for the year ended December 31, 2017 compared with \$1,551,000 for the year ended December 31, 2016. Other Income, net for the year ended December 31, 2017 primarily consisted of a gain recognized from a decrease in the fair value of our derivative liabilities as our stock price decreased. Other Income for the year ended December 31, 2016 also included a gain of \$2,603,000 due to a decrease in the fair value of our derivative liabilities, offset by an impairment loss of \$1,177,000 related to our mortgage note receivable.

## **Income Taxes**

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%. For the year ended December 31, 2016, we recorded an income tax benefit of \$29,394,000 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 Years Ended December 31, 2016 and December 31, 2015**

### **Research and Development Expense**

Research and development expense consists primarily of compensation-related costs for our 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.

Total research and development expenses were \$101,679,000 for the year ended December 31, 2016, compared with \$ 47,261,000 for the year ended December 31, 2015. This increase of \$54,418,000 is primarily the result of recognizing an impairment loss on IPR&D of \$92,396,000 in 2016 as compared to an impairment loss of \$38,665,000 in 2015. Excluding the impact of the IPR&D impairment charges in each period, research and development expenses were \$9,283,000 for the year ended December 31, 2016, which is an increase of \$687,000 from \$8,596,000 for the year ended December 31, 2015.

### **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 \$4,140,000 for the year ended December 31, 2016, compared with \$6,765,000 for the year ended December 31, 2015. This decrease of \$2,625,000 is primarily the result of lower stock option expense due to the resignation of the CEO and CMO during the year. Because we had assumed a zero forfeiture rate related to these options, expense associated with these options that had been recorded in previous periods was reversed during 2016, since none of these options had vested prior to forfeiture.

### **Interest Income/Expense**

Interest income was \$126,000 for the year ended December 31, 2016, compared to \$180,000 for the year ended December 31, 2015. These amounts primarily represent interest earned on the mortgage note we acquired in June 2015.

### **Other Income/Expense**

Other Income, net, was \$1,551,000 for the year ended December 31, 2016 compared with Other Expense, net of \$11,422,000 for the year ended December 31, 2015.

Other Income, net for the year ended December 31, 2016 primarily consists of a gain recognized from a decrease in the fair value of our derivative liabilities as our stock price decreased offset by an impairment loss of \$1,177,000 related to our mortgage note receivable. Other Expense for the year ended December 31, 2015 is primarily due to a loss of \$9,916,000 associated with an increase in the fair value of our derivative liabilities as our stock price increased.



In the year ended December 31, 2015, we also recorded other expense of \$1,686,000 related to a loss of shares that were previously held in escrow related to our sale of certain assets to MusclePharm. These shares were to be held in escrow but instead were released by the escrow agent to MusclePharm, which resulted in us recording a loss upon release of these shares.

### **Income Taxes**

For the year ended December 31, 2016, we recorded an income tax benefit of \$29,394,000 resulting from reduction of our deferred tax liability primarily stemming from the impairment loss recorded for the Company's in-process research and development asset. For the year ended December 31, 2015, we recorded an income tax benefit of \$15,248,000, also primarily stemming from the impairment loss recorded for the Company's in-process research and development tax asset.

### **Liquidity and Capital Resources**

For the year ended December 31, 2017, net cash used in operating activities was \$6,903,000, compared to net cash used in operating activities of \$14,655,000 for 2016. The decrease in cash used in operating activities from 2017 to 2016 was attributable to reduced spending in research and development activities following the completion of the HCV Phase 1 clinical trials. In 2017, net cash used in investing activities consisted of \$40,000 in capital expenditures for lab equipment. For 2016, our net cash provided by investing activities netted to \$3,000, which consisted of receipts related to our mortgage note offset by capital expenditures primarily for lab equipment for our R&D facilities. For the year ended December 31, 2017, net cash provided by financing activities was \$4,080,000, compared to net cash provided by financing activities of \$9,016,000 for 2016. Net cash generated by financing activities in 2017 was the result of issuing convertible notes payable and additional issuances of common stock. During 2016, net cash from financing activities was generated solely from the issuance of common stock.

For the year ended December 31, 2016, net cash used in operating activities was \$14,655,000, compared to net cash used in operating activities of \$10,317,000 for 2015. The increase in cash used in operating activities in 2016 as compared to 2015 was attributable to our increase in research and development activities, including Phase I testing of our lead non-nucleoside inhibitor. In 2016, net cash provided by investing activities of \$3,000 consisted of receipts related to our mortgage note offset by capital expenditures primarily for lab equipment for our R&D facilities, as compared to cash used by investing activities of \$262,000 in 2015 when our capital expenditures exceeded amounts received for our mortgage note. For the year ended December 31, 2016, net cash provided by financing activities was \$9,016,000, compared to cash provided by financing activities of \$15,885,000 for 2015. In both years, net cash generated by financing activities was primarily generated from the issuance of common stock.

As further explained in Note 6 to the consolidated financial statements, on November 24, 2017, the Company entered into a Securities Purchase Agreement with two accredited investors, including the Company's Chairman of the Board, pursuant to which the Company sold an aggregate principal amount of \$1,000,000 of its 8% convertible notes due November 24, 2019.

As further explained in Note 15 to the consolidated financial statements, on January 31, 2018, the Company entered into a Securities Purchase Agreement with OPKO Health, Inc. (the "Purchaser"), 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.

As of March 16, 2018, we have approximately \$1.9 million cash on hand. Presently we have cash to last through June 2018. Accordingly, we must raise approximately \$8 to \$10 million to support our planned operations over the next 12 months. The Company is presently exploring various financing options, including but not limited a sale of common stock. We have a history of operating losses as we have focused our efforts on raising capital and research and development activities.

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, 2017, the Company recorded a net loss of approximately \$613,000 and used approximately \$6.9 million 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.

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.

Over the next 12 months ending December 31, 2018, we estimate negative cash flow from operations. Management intends to fund future operations through additional private or public equity and convertible note offerings and may seek additional capital through arrangements with strategic partners or from other sources.

#### **Cautionary Note Regarding Forward Looking Statements**

This report includes forward-looking statements including statements regarding our future business development, regulatory compliance, 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 are contained in the "Risk Factors" in Item 1A of this 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 the 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, 2017, 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 \$185.0 million 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 \$38.7 million 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 forecasts of future cash flows, which caused a reduction in value of our hepatitis C assets. This resulted in an impairment charge recorded to our IPR&D asset in the amount of \$92.4 million in 2016.

During 2017, our impairment test concluded no impairment of our IPR&D asset was required. However, as we continue work on this program, we may be required to record additional impairment charges in the future depending on the outcome of our research activities and changes in the market for our hepatitis C assets.

We also recorded \$65.2 million 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, 2017, 2016, and 2015, and determined that there was no impairment of goodwill in any period.

#### *Income Taxes*

As noted above, we initially recorded a deferred tax liability of \$65.2 million related to the RFS Pharma acquisition. In 2015, we recognized an impairment loss on our in-process research and development asset, resulting in a reduction of our deferred tax liability of approximately \$15.3 million. In 2016, we recognized another impairment loss on our in-process research and development of \$92.4 million, which reduced our deferred tax liability to approximately \$20.5 million. For 2017, our deferred tax liability declined by \$6.8 million 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 \$6.6 million. In addition to lowering the corporate tax rate for years beginning January 1, 2018, the new tax laws allow for net operating loss carryforwards 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. Prior to 2017, we have not considered the deferred tax liability as a source of future income in our determination of the need for a valuation allowance against our deferred tax assets due to the fact that this deferred tax liability relates to our indefinite-lived IPR&D asset, and the timing of reversal of this deferred tax liability cannot currently be determined due to uncertainty regarding the ultimate outcome of our research activities associated with the intellectual property acquired in the RFS Pharma transaction. 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 than upon reversal would give rise to NOLs that do not expire, which resulted in an additional tax benefit of approximately \$293,000 in 2017. In 2018, we will likely record a tax benefit to reflect the indefinite carryforward period for future net operating losses that would allow such net operating losses to be used to offset any income recorded upon reversal of the deferred tax liability; however, we are still evaluating the impact on our future financial statements. To the extent our estimates regarding the outcome of those activities changes in future periods, our determination regarding the valuation allowance may also change.

#### *Contractual Obligations*

The following table summarizes our significant contractual obligations at December 31, 2017 (in thousands):

	<b>Total</b>	<b>Less than 1 year</b>	<b>1 to 3 years</b>
Operating lease obligations	\$ 182	\$ 168	\$ 14
Total	<u>\$ 182</u>	<u>\$ 168</u>	<u>\$ 14</u>

The minimum lease payments above do not include common area maintenance (CAM) charges, which are contractual obligations under some of the Company's operating leases, but are not fixed and can fluctuate from year to year.

## Licenses and Collaborations

In addition to the above contractual commitments, we also have potential future payments due under various licenses and collaborations as follows:

Emory University: The Company has an exclusive license from Emory University for use of certain inventions and technology related to inhibitors of hepatitis C virus that were jointly developed by Emory and Company employees. The License Agreement is dated March 7, 2013 wherein Emory agrees to add to the Licensed Patents and Licensed Technology Emory's rights to any patent, patent application, invention, or technology application that is based on technology disclosed within three (3) years of March 7, 2013. The agreement includes payments due to Emory ranging from \$40,000 to \$500,000 based on successful achievement of certain drug development milestones. Additionally, the Company may have 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.

## **Recent Accounting Pronouncements**

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases* (Topic 842). ASU 2016-02 impacts any entity that enters into a lease with some specified scope exceptions. This new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the statement of operations. The guidance updates and supersedes Topic 840, *Leases*. For public entities, ASU 2016-02 is effective for fiscal years, and interim periods with those years, beginning after December 15, 2018, and early adoption is permitted. A modified retrospective transition approach is required for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company has not implemented this guidance as of December 31, 2017. However, based upon on the Company's current operating lease arrangements, the Company does not expect the adoption of this standard to have a material impact on its financial statements.

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. ASU 2016-15 will be effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, with early adoption permitted. We have not yet adopted this guidance and are currently evaluating the impact of this new guidance on our Consolidated Financial Statements.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles - Goodwill and Other (Topic 350)*, which simplifies how an entity is required to test for goodwill impairment. ASU 2017-04 will be effective for annual or interim goodwill impairment tests in fiscal years beginning after December 15, 2019, with early adoption permitted after January 1, 2017. We have not yet adopted this guidance and are currently evaluating the impact of this new guidance on our Consolidated Financial Statements.

## **Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. However, as our investments are in highly liquid money market funds, we do not believe we are subject to any material market risk exposure. As of December 31, 2017, we did not have any material derivative financial instruments held as assets. The fair value of our cash and cash equivalents was \$0.7 million as of December 31, 2017.

We do not currently have any hard to value investment securities or securities for which a market is not readily available or active.

We are not subject to significant credit risk as this risk does not have the potential to materially impact the value of our assets and liabilities.

## **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 Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of December 31, 2017. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms of the Securities and Exchange Commission. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based upon that evaluation, management concluded that our disclosure controls and procedures were not effective as of December 31, 2017 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 Securities 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, 2017, 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, 2016, management identified certain material weaknesses related to (i) an effective control environment; (ii) inadequate segregation of duties in our accounting and financial reporting processes; (iii) inadequate supervision and review of complex accounting areas; (iv) inadequate processes to authorize, identify, and report related party transactions; and (v) an ineffective financial reporting process with respect to preparation of financial statements in accordance with U.S. GAAP. To remediate the material weaknesses, during 2017, we designed and implemented a comprehensive remediation plan to remediate the material weaknesses and generally strengthen our internal control over financial reporting. During the fourth quarter of 2017, we successfully completed the testing necessary to conclude that certain material weakness identified in 2016 had been remediated. However, management concluded that some of the previously identified material weaknesses were not remediated as of December 31, 2017, primarily due to the additional time needed to incorporate all controls and processes as it relates to our internal control over financial reporting.

During our assessment of the effectiveness of internal control over financial reporting as of December 31, 2017, our management concluded that our Company has the following material weaknesses in internal control over financial reporting as of December 31, 2017:

***Risk Assessment and Control Activities - Financial Reporting Process***

We did not maintain an effective financial reporting process to prepare financial statements in accordance with U.S. GAAP. Specifically, the process lacked timely and documented financial statement reviews of information included in the financial statements and procedures to ensure all required disclosures were made in the financial statements.

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.

***Control Activities - Preparation and Review of Manual Account Reconciliations***

Our design and maintenance of controls in the period-end financial reporting process, specifically the execution of controls over the preparation, analysis and review of account reconciliations, were ineffective. These control deficiencies resulted in adjustments to the 2017 consolidated financial statements related to stock-based compensation and the fair value of warrant liabilities.

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.

The effectiveness of our internal control over financial reporting as of December 31, 2017 has been audited by BDO USA, LLP, an independent registered public accounting firm, as stated in their report, as set forth at the beginning of Part II, Item 8 of this Annual Report on Form 10-K.

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

As previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2016, we concluded there were material weaknesses in the design and operating effectiveness of our internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act, as of December 31, 2016. With the oversight of senior management and our audit committee, we took additional measures to remediate the underlying causes of the material weaknesses. During the year ended December 31, 2017, we worked with a third-party consultant to assist our management team in addressing the underlying cause of the material weaknesses primarily through the documentation of improved processes and documented procedures which were designed and implemented by our management team. Management concluded that certain previously identified material weaknesses, described above, were not remediated as of December 31, 2017, 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.

However, certain internal control improvements were implemented during the fourth quarter of 2017 that remediated certain of our previously identified material weaknesses. The following changes that occurred during the fourth quarter of the year ended December 31, 2017 have materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

### **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 weakness are remediated such that these controls will operate effectively. Our efforts have focused on strengthening our finance organization and designing a suite of controls with respect to our stock-based compensation related processes and financial close processes, as well as implementing procedures to determine that related party transactions are appropriately authorized, identified, and disclosed in our financial statements. Consistent with the remediation plan as reported in Item 9A of our Annual Report on Form 10-K for the year ended December 31, 2016, during 2017 we are taking, and expect 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.

As discussed above, during 2017, our Board of Directors appointed a new Chief Financial Officer to assist in designing the implementation and execution of controls to prevent and detect control deficiencies. In order to consider this material weakness to be fully remediated, we believe that additional time is needed to incorporate all controls and processes as it relates to our internal control over financial reporting.

We believe that these actions, and the improvements we expect to achieve as a result, will effectively remediate the material weaknesses identified in 2017. 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 2018.

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

Not applicable.



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.  
Tucker, Georgia

### Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Cocrystal Pharma, Inc. (the “Company”) as of December 31, 2017 and 2016, the related consolidated statements of operations, stockholders’ equity, and cash flows for each of the three years in the period ended December 31, 2017, 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, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, 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, 2017, 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 March 21, 2018 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 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.

Seattle, Washington

March 21, 2018

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders  
Cocrystal Pharma, Inc.  
Tucker, Georgia

### 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, 2017, 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, 2017, based on the COSO criteria.

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, 2017 and 2016, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2017, and the related notes (collectively referred to as "the financial statements") and our report dated March 21, 2018 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. A material weakness regarding management's failure to design and maintain controls over preparation and review of account reconciliations, including manual calculations of stock-based compensation and warrant liabilities, as well as a material weakness over preparation and review of a comprehensive financial statement disclosure checklist to ensure completeness and accuracy of all financial statement disclosures, 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 2017 financial statements, and this report does not affect our report dated March 21, 2018 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

Seattle, Washington

March 21, 2018

**COCRYSTAL PHARMA, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
(in thousands)

	December 31, 2017	December 31, 2016
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 748	\$ 3,605
Restricted cash	29	35
Accounts receivable	1	21
Prepaid and other current assets	104	517
Mortgage note receivable	1,294	1,294
Total current assets	2,176	5,472
Property and equipment, net	119	280
Deposits	31	31
In process research and development	53,905	53,905
Goodwill	65,195	65,195
Total assets	\$ 121,426	\$ 124,883
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 837	\$ 563
Derivative liabilities	569	1,476
Total current liabilities	1,406	2,039
Long-term liabilities		
Deferred rent	31	63
Convertible notes payable	1,007	-
Deferred tax liability	13,582	20,462
Total long-term liabilities	14,620	20,525
Total liabilities	\$ 16,026	\$ 22,564
<b>Commitments and contingencies</b>		
<b>Stockholders' equity:</b>		
Common stock, \$.001 par value; 800,000 shares authorized; 24,275 and 23,801 shares issued and outstanding as of December 31, 2017 and December 31, 2016, respectively	24	24
Additional paid-in capital	243,419	239,725
Accumulated deficit	(138,043)	(137,430)
Total stockholders' equity	105,400	102,319
Total liabilities and stockholders' equity	\$ 121,426	\$ 124,883

See accompanying notes to consolidated financial statements.

**COCRYSTAL PHARMA, INC.**

**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands)

	<u>2017</u>	<u>2016</u>	<u>2015</u>
Grant revenues	\$ -	\$ -	\$ 78
Operating expenses			
Research and development	5,822	101,679	47,261
General and administrative	2,440	4,140	6,765
Total operating expenses	<u>8,262</u>	<u>105,819</u>	<u>54,026</u>
Loss from operations	(8,262)	(105,819)	(53,948)
Interest income (expense), net	(7)	126	180
Other expense	(131)	(1)	-
Loss on return of escrowed shares	-	-	(1,686)
Impairment loss on mortgage note receivable	-	(1,177)	-
Change in fair value of derivative liabilities	907	2,603	(9,916)
Total other income (expense), net	<u>769</u>	<u>1,551</u>	<u>(11,422)</u>
Loss before income taxes	(7,493)	(104,268)	(65,370)
Income tax benefit	<u>6,880</u>	<u>29,394</u>	<u>15,248</u>
Net loss	<u>\$ (613)</u>	<u>\$ (74,874)</u>	<u>\$ (50,122)</u>
Net loss per common share:			
Net loss per share, basic	\$ (0.03)	\$ (3.18)	\$ (2.40)
Net loss per share, diluted	\$ (0.03)	\$ (3.30)	\$ (2.40)
Weighted average common shares outstanding, basic	24,126	23,518	21,011
Weighted average common shares outstanding, diluted	24,126	23,533	21,011

See accompanying notes to consolidated financial statements.

**COCRYSTAL PHARMA, INC.**

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

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance as of December 31, 2014	33	\$ 178,218	33	\$ 1	4,083	\$ 4	\$ 18,845	236	\$ (12,434)	\$ 6,651
Conversion of series A convertible stock	(33)	(178,218)	(33)	(1)	18,194	18	178,200	-	-	178,218
Stock-based compensation	-	-	-	-	-	-	2,934	-	-	2,934
Exercise of common stock options	-	-	-	-	6	-	23	-	-	23
Unrealized gain on marketable securities, net of tax	-	-	-	-	-	-	-	\$ (236)	-	(236)
Sale of common stock	-	-	-	-	575	1	15,861	-	-	15,862
Exercise of warrants	-	-	-	-	288	-	14,264	-	-	14,264
Net loss	-	-	-	-	-	-	-	-	(50,122)	(50,122)
Balance as of December 31, 2015	-	\$ -	-	\$ -	23,146	\$ 23	\$ 230,127	\$ -	\$ (62,556)	\$ 167,594
Exercise of common stock options	-	-	-	-	1	-	3	-	-	3
Stock-based compensation	-	-	-	-	-	-	548	-	-	548
Sale of common stock	-	-	-	-	653	1	9,012	-	-	9,013
Exercise of warrants	-	-	-	-	1	-	35	-	-	35
Net loss	-	-	-	-	-	-	-	-	(74,874)	(74,874)
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	-	-	-	-	417	-	3,000	-	-	3,000
Net loss	-	-	-	-	-	-	-	-	(613)	(613)
Balance as of December 31, 2017	-	\$ -	-	\$ -	24,275	\$ 24	\$ 243,419	\$ -	\$ (138,043)	\$ 105,400

See accompanying notes to consolidated financial statements.

**COCRYSTAL PHARMA, INC.**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)

	<u>2017</u>	<u>2016</u>	<u>2015</u>
<b>Operating activities:</b>			
Net loss	\$ (613)	\$ (74,874)	\$ (50,122)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	101	201	192
Stock-based compensation	614	548	2,934
Change in fair value of derivative liabilities	(907)	(2,603)	9,916
Deferred income tax	(6,880)	(29,413)	(15,267)
Loss on return of escrowed shares	-	-	1,686
Impairment on mortgage note receivable	-	1,177	-
Impairment on IPR&D	-	92,396	38,665
Loss on disposal of equipment	100	-	-
Changes in operating assets and liabilities:			
Accounts receivable	20	11	-
Prepaid expenses and other current assets	413	(76)	(212)
Accounts payable and accrued expenses	281	(2,022)	1,891
Deferred rent	(32)	2	-
Net cash used in operating activities	<u>(6,903)</u>	<u>(14,655)</u>	<u>(10,317)</u>
<b>Investing activities</b>			
Purchase of property and equipment	(40)	(51)	(339)
Interest earned on mortgage note receivable	-	33	-
Principal payments received on mortgage note receivable	-	21	77
Net cash provided by (used in) investing activities	<u>(40)</u>	<u>3</u>	<u>(262)</u>
<b>Financing activities</b>			
Proceeds from exercise of stock options	80	3	23
Proceeds from issuance of convertible notes payable	1,000	-	-
Proceeds from issuance of common stock	3,000	9,013	15,862
Net cash provided by financing activities	<u>4,080</u>	<u>9,016</u>	<u>15,885</u>
Net (decrease) increase in cash, cash equivalents, and restricted cash	(2,863)	(5,636)	5,306
Cash, cash equivalents, and restricted cash at beginning of period	3,640	9,276	3,970
Cash, cash equivalents, and restricted cash at end of period	<u>\$ 777</u>	<u>\$ 3,640</u>	<u>\$ 9,276</u>
<b>SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:</b>			
Cashless exercise of warrants	\$ -	\$ 35	\$ 14,265

See accompanying notes to consolidated financial statements.

## COCRYSTAL PHARMA, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Organization and Basis of Presentation

Cocrystal Pharma, Inc. (the “Company”) is a biopharmaceutical company focused on developing antiviral therapeutics for human diseases.

On January 2, 2014, Biozone Pharmaceuticals, Inc. merged with Cocrystal Discovery, Inc. (“Discovery”) with Discovery becoming a wholly-owned subsidiary of the Company. The Company was previously incorporated in Nevada under the name Biozone Pharmaceuticals, Inc. (“Biozone”). On March 18, 2014, the Company reincorporated in Delaware under the name Cocrystal Pharma, Inc. (“we”, the “Company”, or “Cocrystal”).

Our primary business is to develop novel medicines for use in the treatment of human viral diseases. Cocrystal has been developing novel technologies and approaches to create 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 Merger was treated as a reverse merger and recapitalization effected by a share exchange for financial accounting and reporting purposes since substantially all of Biozone’s operations were disposed of immediately prior to the consummation of the Merger. Discovery was treated as the accounting acquirer as its shareholders controlled the Company after the Merger, even though Biozone was the legal acquirer. As a result, the assets and liabilities and the historical operations that are reflected in these financial statements are those of Discovery as if Cocrystal had always been the reporting company and, on the Merger date, changed its name and reorganized its capital stock. Since Biozone had no operations upon the Merger taking place, the transaction was treated as a recapitalization for accounting purposes and no goodwill or other intangible assets were recorded by the Company as a result of the Merger. Historical common stock amounts and additional paid-in capital were retroactively adjusted.

Effective November 25, 2014, Cocrystal, Cocrystal Holdings, Inc., a Delaware corporation and wholly-owned subsidiary of Cocrystal, Cocrystal Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of the Company (the “Cocrystal Merger Sub”), RFS Merger Sub, LLC, a Delaware limited liability company and wholly-owned subsidiary of the Company (the “RFS Merger Sub”) and RFS Pharma, LLC, a Georgia limited liability company (“RFS Pharma”), entered into and closed an Agreement and Plan of Merger (the “RFS Merger Agreement”).

The consideration paid by the Company was approximately \$184.8 million, consisting of the issuance of shares of Series A Preferred stock, which subsequently converted to common stock with an estimated fair value of approximately \$178.2 million and the issuance of 551,418 options to purchase the Company’s common stock as replacements of awards previously issued to employees of RFS Pharma with an estimated fair value of approximately \$6.6 million.

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 (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 outstanding convertible notes, its options and warrants they have been proportionately adjusted to reflect the Reverse Stock Split, and, pursuant to their terms, a proportionate adjustment was made to the per share exercise price and number of shares issuable under all of the Company’s outstanding stock options, convertible notes and warrants to Common Stock, and the number of shares reserved for issuance pursuant to the Company’s equity compensation plans have been reduced proportionately.

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



### ***Basis of Presentation***

The financial statements are prepared in accordance with accounting principles generally accepted in the United States (“GAAP”).

### ***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.

### ***Liquidity***

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 \$8.3 million, \$105.8 million, and \$53.9 million in the years ended December 31, 2017, 2016 and 2015, respectively. The Company does not believe that its cash and cash equivalents of \$0.7 million as of December 31, 2017 are sufficient to fund its operations for the next twelve months. 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 can give no assurances that any additional capital that it is able to obtain, 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 commercial activities. The Company believes these conditions raise substantial doubt as to the Company’s ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should the Company be unable to continue as a going concern.

In order to continue as a going concern, the Company will need, among other things, additional capital resources. Management plans to obtain such resources for the Company include obtaining capital from the sale of its equity and convertible note securities during 2018. However, management cannot provide any assurance that the Company will be successful in accomplishing any of its plans.

## **2. Summary of Significant Accounting Policies**

### ***Segments***

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

### ***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

### ***Concentrations of Credit Risk***

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risk on its cash.

### ***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, regulatory approvals, competition from current treatments and therapies and larger companies, protection of proprietary technology, 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, Cash Equivalents, 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. Cash and cash equivalents include cash in a readily available checking account.

	December 31, 2017	December 31, 2016
Cash and cash equivalents	\$ 748	\$ 3,605
Restricted cash	29	35
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	<u>\$ 777</u>	<u>\$ 3,640</u>

Restricted cash represents amounts pledged as collateral for financing arrangements with Silicon Valley Bank. These financing arrangements are currently limited to the issuance of business credit cards. The restriction will end upon the conclusion of financing arrangement.

***Property and Equipment***

Property and equipment, which consists of lab equipment, computer equipment, and office equipment, are stated at cost and depreciated over the estimated useful lives of the assets (three to five years) using the straight-line method.

***Goodwill and In-Process Research and Development***

Goodwill and an intangible asset for in-process research and development were recorded in connection with the acquisition of RFS Pharma in November 2014. In-process research and development represent a series of awarded patents, filed patent applications and an in-process research program acquired in the acquisition of RFS Pharma that are integral to the development of the Company’s planned future products. In-process research and development represent an indefinite-lived intangible asset. As a result, both goodwill and in-process research and development are not amortized but are tested for impairment annually at the reporting unit level on November 30 or more frequently if events and circumstances indicate impairment may have occurred. Factors the Company considers important that could trigger an interim review for impairment include, but are not limited to, the following:

- Significant changes in the manner of its use of acquired assets or the strategy for its overall business;
- Significant negative industry or economic trends;
- Significant decline in the Company’s stock price for a sustained period;
- Significant decline in market capitalization relative to net book value;
- Limited funding that could further delay development efforts;
- Safety or efficacy issues that surface during development efforts; and
- Clinical outcomes for drug candidates do not lead to regulatory approval.

Goodwill and in-process research and development are evaluated for impairment first by a qualitative assessment to determine the likelihood of impairment. If it is determined that impairment is more likely than not, the Company will then proceed to the two step impairment test. For goodwill, the first step is to compare the fair value of the reporting unit to the carrying amount of the reporting unit and for in-process research and development to compare the fair value of the in-process research and development asset to its carrying amount (the "First Step"). If the carrying amount exceeds the fair value, a second step must be followed to calculate impairment (the "Second Step"). Otherwise, if the fair value exceeds the carrying amount, the goodwill or indefinite-lived research and development asset is not considered to be impaired as of the measurement date. In its review of the carrying value of the goodwill for its single reporting unit and its in-process research and development, the Company determines fair values of its goodwill using the market approach, and its in-process research and development asset using the income approach. For the years ended December 31, 2017, 2016, and 2015, the Company determined that a quantitative assessment of impairment of goodwill and in-process research and development was necessary and performed its annual impairment tests as of November 30 of each year.

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 Pharma's product candidates. The fair values of intangible assets were calculated primarily using a discounted cash flow analysis of future revenues to be generated from the eventual sale of potential products to be developed under the programs by geographic region, expected development costs and exit values under a number of different scenarios. Company management estimated the probabilities of occurrence of each scenario and prepared forecast balance sheets and income statements for the combined company. The rates utilized to discount net cash flows to their present values were based on a discount rate of 18.6%. Other assumptions used to develop our estimated cash flows include prices charged by competitors for similar products, the expected price of our product candidates if and when they begin generating revenues, the probabilities of our product candidates obtaining regulatory approvals through various phases of development, and the market size of potential candidates for the products we are developing.

Upon completion of the impairment evaluation, we have determined that in-process research and development assets related to our Hepatitis C programs were impaired in 2015 and 2016. During the fourth quarter of 2015, we determined the carrying value of our Hepatitis C in-process research and development was impaired by \$38.7 million. During the fourth quarter of 2016, we determined the carrying value of our Hepatitis C in-process research and development was impaired by an additional \$92.4 million. For 2017, we determined there was no impairment based on our impairment test performed as of November 30, 2017. These impairments recorded in 2016 and 2015 were the result of increased competition within the marketplace that put downward pressure on revenue projections and partially the result of further data defining the scientific and commercial potential of Company HCV compounds during those years. We have included these impairment charges in Research and Development expenses in our Consolidated Statements of Operations.

#### ***Long-Lived Assets***

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

#### ***Mortgage Note Receivable***

The Company records its mortgage note receivable at the amount advanced to the borrower, which includes the stated principal amount and certain loan origination and commitment fees that are recognized over the term of the mortgage note. Interest income is accrued as earned over the term of the mortgage note. The Company evaluates the collectability of both interest and principal of the note to determine whether it is impaired. The note is considered to be 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.

### ***Grant Revenue and Accounts Receivable***

Research and development grants are recorded as revenue when there is reasonable assurance that the Company has complied with all conditions necessary to achieve the grants, collectability is reasonably assured, and as the expenditures are incurred. Accounts receivable represents amounts due under research and development grants that have not yet been received.

### ***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***

In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-02, *Leases* (Topic 842). ASU 2016-02 impacts any entity that enters into a lease with some specified scope exceptions. This new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the statement of operations. The guidance updates and supersedes Topic 840, *Leases*. For public entities, ASU 2016-02 is effective for fiscal years, and interim periods with those years, beginning after December 15, 2018, and early adoption is permitted. A modified retrospective transition approach is required for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company has not implemented this guidance as of December 31, 2017. However, based upon on the Company’s current operating lease arrangements, the Company does not expect the adoption of this standard to have a material impact on its financial statements.

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. ASU 2016-15 will be effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, with early adoption permitted. We have not yet adopted this guidance and are currently evaluating the impact of this new guidance on our Consolidated Financial Statements.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles - Goodwill and Other (Topic 350)*, which simplifies how an entity is required to test for goodwill impairment. ASU 2017-04 will be effective for annual or interim goodwill impairment tests in fiscal years beginning after December 15, 2019, with early adoption permitted after January 1, 2017. We have not yet adopted this guidance and are currently evaluating the impact of this new guidance on our Consolidated Financial Statements.

### **3. Property and Equipment**

Property and equipment as of December 31 (in thousands):

	<u>2017</u>	<u>2016</u>
Lab equipment	\$ 1,168	\$ 1,241
Computer and office equipment	309	393
Total equipment	<u>1,477</u>	<u>1,634</u>
Less accumulated depreciation	<u>(1,358)</u>	<u>(1,354)</u>
Property and equipment, net	<u>\$ 119</u>	<u>\$ 280</u>

Depreciation expense was \$101,000, \$201,000 and \$192,000 for the years ended December 31, 2017, 2016 and 2015, respectively.

### **4. Mortgage Note Receivable**

In June 2014, the Company acquired a mortgage note from a bank for \$2,626,290 which is collateralized by, among other things, the underlying real estate and related improvements. The property subject to the mortgage is owned by Daniel Fisher, one of the founders of Biozone, and is currently under lease to MusclePharm. The mortgage note has a maturity date of August 1, 2032 and bears an interest rate of 7.24%.

In 2014, Daniel Fisher and his affiliate, 580 Garcia Properties LLC, brought multiple lawsuits against the Company involving its predecessors and subsidiaries. The lawsuits have been settled and the complaints initiating them dismissed, without the Company making any payments to either Mr. Fisher or 580 Garcia Properties LLC. In addition, the mortgage note discussed above is a promissory note secured by a deed of trust under which 580 Garcia Properties LLC is the primary obligor. As of the time of the acquisition by the Company of the promissory note, 580 Garcia Properties LLC, was delinquent in its obligation to make certain monthly payments thereunder. Consequently, in December 2015, the Company issued notice of default letters to 580 Garcia Properties LLC, Daniel Fisher, and Sharon Fisher for said delinquencies, and proceeded in accordance with rights of a secured real estate creditor under California law, to initiate private foreclosure proceedings respecting the property, to foreclose under the promissory note secured by the deed of trust. A foreclosure sale was set in accordance with California law for January 27, 2017. Prior to the date of this foreclosure sale, Mr. Fisher filed a motion where he sought among other things an order of the court enjoining the foreclosure sale, alleging wrongdoing by the Company and Biozone Pharmaceuticals, Inc. and others that Mr. Fisher claims the Company has direct responsibility over. The court in the Fisher/Biozone Lawsuit heard oral argument on Mr. Fisher's motion on March 2, 2017. On March 23, 2017, the court ordered further briefing by March 30, 2017 on the issue of whether to enjoin the foreclosure sale. Since the filing of Mr. Fisher's motion the Company has voluntarily postponed the announced foreclosure sale several times.

Because the Company intended to foreclose on the property and foreclosure was deemed to be probable, the Company recognized an impairment on the mortgage note receivable of \$1,176,000 in 2016 to adjust the carrying value of the note to its fair value. The fair value of the note was determined by reference to the estimated fair value of the underlying property, which was determined based on analysis of comparable properties and recent market data. Furthermore, as a result of the Company's plan to divest of this asset within the next twelve months, the asset was reclassified from long-term to current in 2016.

In February 2018 a series of transactions concluded, involving the Company, Daniel Fisher, 580 Garcia Properties LLC, and others, by the terms of which, inter alia, the Company resolved all outstanding claims and disputes with Daniel Fisher, his spouse Sharon Fisher, and 580 Garcia Properties, LLC, and by which the Company received a payment of \$1.4 million in exchange for the release of the aforementioned note and deed of trust.

## **5. Common Stock**

As of December 31, 2017, the Company had 800,000,000 shares of authorized common stock, \$0.001 par value per share, and had 24,274,494 shares issued and outstanding.

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

On March 15, 2016, the Company accepted subscription agreements representing investor commitments totaling \$5,004,370 in a private placement offering to investors who participated in the March 2015 private placement on a pro-rata basis to their participation in the March 2015 private placement of 327,083 shares of the Company's common stock at a purchase price of \$15.30 per share. The purchasers included 7 members of the Company's board of directors including Dr. Raymond F. Schinazi and Dr. Phil Frost.

On September 1, 2016, the Company closed on proceeds of \$4,008,201 in a private placement offering of 325,870 shares of the Company's common stock at a purchase price of \$12.30 per share. The purchasers included three members of the Company's board of directors, including Chairman Dr. Raymond F. Schinazi, Interim Chief Executive Officer Dr. Gary Wilcox, and Dr. David Block. In addition, OPKO Health, Inc., of which the Company's director Dr. Phillip Frost is Chairman and Chief Executive Officer, invested in the Offering.

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 accredited investors, which included Chairman Dr. Raymond F. Schinazi and OPKO Health, Inc., of which the Company's director Dr. Phillip Frost is Chairman and Chief Executive Officer.

## 6. Convertible Notes

On November 24, 2017, the Company entered into a Securities Purchase Agreement with two accredited investors, including the Company's Chairman of the Board, pursuant to which the Company sold an aggregate principal amount of \$1,000,000 of its 8% convertible notes ("Notes") due November 24, 2019. At the option of the Purchaser, the Note is convertible at \$8.10 per share. In the event the Company completes a financing in which the Company receives at least \$10,000,000 in gross proceeds and issues 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 Note shall automatically convert. Upon the closing of a Financing, the conversion price of the Note shall be the lesser of (i) \$8.10 per share and (ii) the price per share of the securities sold in the Financing.

The Company evaluated the embedded conversion features within the above 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 accordance with ASC 470-20, *Debt with Conversion and Other Options*.

## 7. Stock Based Awards

### *Equity Incentive Plans*

The Company adopted an equity incentive plan (the "2007 Plan") in 2007 under which 1,786,635 shares of common stock have been reserved for issuance to employees, nonemployee directors and consultants of the Company. Recipients of incentive stock options 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 balance vesting monthly over the remaining three years. As of December 31, 2017, 54,615 shares remain available for future grant under this plan.

The Company adopted a second equity incentive plan (the "2015 Plan") in 2015 under which 1,666,667 shares of common stock have been reserved for issuance to employees, directors and consultants of the Company. Recipients of incentive stock options 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 balance vesting monthly over the remaining three years. As of December 31, 2017, 1,601,667 shares of common stock remain available for future grant under the 2015 Plan.

The following table summarizes stock option transactions for the 2007 and 2015 Plans for the year ended December 31, 2017 (amounts in thousands, except per share amounts):

	<b>Number of shares available for grant</b>	<b>Total options outstanding</b>	<b>Weighted Average Exercise Price</b>	<b>Aggregate Intrinsic Value</b>
Balance at December 31, 2016	1,612	812	\$ 9.00	\$ 5,457
Exercised	-	(57)	1.41	-
Granted	-	-	-	-
Cancelled	44	(44)	28.87	-
Balance at December 31, 2017	<u>1,656</u>	<u>711</u>	<u>\$ 8.39</u>	<u>\$ 1,640</u>

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. The Company did not grant any options during the years ended December 31, 2017 or 2016. The Black-Scholes option pricing model includes the following weighted average assumptions for grants made during the year ended December 31, 2015:

	<u>2015</u>
<b>Assumptions:</b>	
Risk-free interest rate	1.66 - 2.08%
Expected dividend yield	0%
Expected volatility	78 - 108%
Expected terms (in years)	5.00 - 6.50

As of January 1, 2017, the Company adopted the forfeiture rate methodology change in accordance with ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting (Topic 718)*, to account for forfeitures as they occur, rather than estimate expected forfeitures over the course of a vesting period. Prior to the adoption of ASU 2016-09, the Company was required to estimate forfeitures at the time of grant and revised those estimates in subsequent periods if actual forfeitures differed from those estimates. No adjustment was necessary to accumulated deficit as a result of the adoption since the Company has assumed a zero forfeiture rate in the valuation of awarded stock options. The Company recorded employee stock-based compensation expense of \$614,000, \$548,000 and \$2,934,000 for the years ended December 31, 2017, 2016 and 2015, respectively.

As of December 31, 2017, there was \$546,000 of total unrecognized compensation expense related to non-vested employee stock options that is expected to be recognized over a weighted average period of 1.1 years. For options granted and outstanding, there were 711,000 options outstanding which were fully vested or expected to vest, with an aggregate intrinsic value of \$1,640,000 and a weighted average remaining contractual term of 4.1 years at December 31, 2017. For vested and exercisable options, outstanding shares totaled 682,000, with an aggregate intrinsic value of \$1,640,000. These options had a weighted-average exercise price of \$7.24 per share and a weighted-average remaining contractual term of 3.6 years at December 31, 2017.

The aggregate intrinsic value of outstanding and exercisable options at December 31, 2017 was calculated based on the closing price of the Company's common stock as reported on the Over-the-Counter Bulletin Board and the OTCQx markets on December 31, 2017 of approximately \$6.00 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 present information concerning common stock available for future issuance (in thousands):

	<u>December 31,</u>	
	<u>2017</u>	<u>2016</u>
Stock options issued and outstanding	711	812
Authorized for future option grants	1,656	1,612
Convertible notes	124	-
Warrants outstanding	209	209
Total	<u>2,700</u>	<u>2,633</u>



## 8. 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, 2017, 2016 and 2015 (in thousands):

	Warrants accounted for as:			Warrants accounted for as:					Total
	Equity			Liabilities					
	January 2012 warrants	March 2013 warrants	April 2013 warrants	February 2012 warrants	August 2013 warrants	October 2013 warrants	October 2013 Series A warrants	January 2015 warrants	
Outstanding, January 1, 2015	22	15	62	33	333	7	234	183	889
Warrants exercised	-	-	(12)	-	(333)	(7)	(208)	(50)	(610)
Outstanding, December 31, 2015	22	15	50	33	-	-	26	133	279
Warrants expired	(22)	(15)	-	(30)	-	-	-	-	(67)
Warrants exercised	-	-	-	(3)	-	-	-	-	(3)
Outstanding, December 31, 2016	-	-	50	-	-	-	26	133	209
Warrants expired	-	-	-	-	-	-	-	-	-
Warrants exercised	-	-	-	-	-	-	-	-	-
Outstanding, December 31, 2017	-	-	50	-	-	-	26	133	209
Expiration date	January 11, 2016	March 1, 2016	April 25, 2018	February 28, 2016	August 26, 2023	October 18, 2018	October 24, 2023	January 16, 2024	

Warrants consist of warrants with the potential to be settled in cash, which are liability-classified warrants, and equity-classified warrants.

### *Warrants classified as liabilities*

Liability-classified warrants consist of warrants issued by Biozone in connection with equity financings in February 2012, August 2013, October 2013 and January 2014, which were assumed by the Company in connection with its merger with Biozone in January 2014. As of December 31, 2017, 159,000 warrants are accounted for as liabilities and 50,000 warrants are accounted for as equity. 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, 2017:

	October 2013 warrants	January 2015 warrants
Strike price	\$ 15.00	\$ 15.00
Expected term (years)	5.8	6.0
Cumulative volatility %	86.7%	87.7%
Risk-free rate %	2.30%	2.31%

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, 2016:

	October 2013 warrants	January 2015 warrants
Strike price	\$ 15.00	\$ 15.00
Expected term (years)	6.8	7.0
Cumulative volatility %	99.7%	100%
Risk-free rate %	2.24%	2.25%

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.

## 9. Licenses and Collaborations

**Emory University:** Cocrystal Pharma has an exclusive license from Emory University for use of certain inventions and technology related to inhibitors of hepatitis C virus that were jointly developed by Emory and Cocrystal Pharma employees. The License Agreement is dated March 7, 2013 wherein Emory agrees to add to the Licensed Patents and Licensed Technology Emory's rights to any patent, patent application, invention, or technology application that is based on technology disclosed within three (3) years of March 7, 2013. The agreement includes payments due to Emory ranging from \$40,000 to \$500,000 based on successful achievement of certain drug development milestones. Additionally, Cocrystal may have 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. One of Cocrystal's Directors, Dr. Raymond Schinazi, is also a faculty member at Emory University.

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

**University of Pittsburgh and Emory University:** Cocrystal Pharma assigned its patent rights to the patent titled "3'-AZIDO PURINENUCLEOTIDE PRODRUGS FOR TREATMENT OF VIRAL INFECTIONS" to University of Pittsburgh on November 21, 2015. This patent is jointly owned by Cocrystal Pharma, the University of Pittsburgh and Emory University. One of Cocrystal's Directors, Dr. Raymond Schinazi, is also a faculty member at Emory University.

**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 there are no further rights or obligations under this license agreement after the Termination Date.

## 10. Fair Value Measurement

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 categorized its cash equivalents as Level 1 fair value measurements. The warrants are valued using the Black-Scholes option-pricing model as discussed in Note 8 above.

The following table presents a summary of fair values of assets and liabilities that are remeasured at fair value at each balance sheet date as of December 31, 2017 and 2016, and their placement within the fair value hierarchy as discussed above (in thousands):

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, cash equivalents, and restricted cash	\$ 777	\$ 777	\$ -	\$ -
<b>Liabilities:</b>				
Warrants potentially settleable in cash	\$ 569	\$ -	\$ -	\$ 569

Description	December 31, 2016	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
<b>Assets:</b>				
Cash, cash equivalents, and restricted cash	\$ 3,640	\$ 3,640	\$ -	\$ -
<b>Liabilities:</b>				
Warrants potentially settleable in cash	\$ 1,476	\$ -	\$ -	\$ 1,476

The Company has not transferred any financial instruments into or out of Level 3 classification during the years ended December 31, 2017, 2016, or 2015. A reconciliation of the beginning and ending Level 3 liabilities for the years ended December 31, 2017, 2016 and 2015, is as follows (in thousands):

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)		
	2017	2016	2015
Balance, January 1,	\$ 1,476	\$ 4,115	\$ 8,464
Value of warrants converted in cashless exercise	-	(36)	(14,265)
Change in fair value of warrants for the year ended	(907)	(2,603)	9,916
Balance at December 31,	<u>\$ 569</u>	<u>\$ 1,476</u>	<u>\$ 4,115</u>

## 11. 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 (amounts in thousands, except per share amounts):

	For the year ended:		
	2017	2016	2015
Numerator:			
Net loss attributable to common shareholders	\$ (613)	\$ (74,874)	\$ (50,122)
Adjustment for change in fair value of derivative liability	-	(2,603)	-
Net loss attributable to common shareholders, as adjusted	<u>\$ (613)</u>	<u>\$ (77,477)</u>	<u>\$ (50,122)</u>
Denominator:			
Weighted average shares outstanding used to compute net loss per share:			
Basic	24,126	23,518	21,011
Adjustment for dilutive effects of warrants	-	16	-
Diluted	<u>24,126</u>	<u>23,534</u>	<u>21,011</u>
Net loss per share			
Basic	\$ (0.03)	\$ (3.18)	\$ (2.40)
Diluted	\$ (0.03)	\$ (3.30)	\$ (2.40)

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):

	For the year ended December 31,		
	2017	2016	2015
Options to purchase common stock	711	812	1,436
Convertible notes	124	-	-
Warrants to purchase common stock	209	-	276
Total	<u>1,044</u>	<u>812</u>	<u>1,712</u>

## 12. 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 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 in income tax expense.

The Company is subject to taxation in the U.S. and various state jurisdictions. Currently no years are under examination. All tax years 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.

A reconciliation of income tax expense (benefit) for the years ended December 31, 2017, 2016, and 2015 is as follows:

	<b>Year Ended December 31,</b>		
	<b>2017</b>	<b>2016</b>	<b>2015</b>
<b>Current:</b>			
Federal	\$ -	\$ -	\$ -
State	-	19	19
<b>Total current income tax expense</b>	<b>-</b>	<b>19</b>	<b>19</b>
<b>Deferred:</b>			
Federal	(6,880)	(32,421)	(12,001)
State	-	3,008	(3,266)
<b>Total deferred income tax benefit</b>	<b>(6,880)</b>	<b>(29,413)</b>	<b>(15,267)</b>
<b>Total income tax benefit</b>	<b>\$ (6,880)</b>	<b>\$ (29,394)</b>	<b>\$ (15,248)</b>

Significant components of the Company's deferred income taxes at December 31, 2017 and 2016 are shown below (in thousands):

	<b>December 31,</b>	
	<b>2017</b>	<b>2016</b>
<b>Deferred Tax Assets:</b>		
Net operating loss carryforwards	\$ 15,003	\$ 20,633
Compensation	961	1,323
Research and development tax credits	1,789	1,390
Property and equipment	8	22
Other	373	545
<b>Total gross deferred tax assets</b>	<b>18,134</b>	<b>23,912</b>
<b>Deferred Tax Liabilities</b>		
Acquired in-process research and development	(13,875)	(20,462)
<b>Total Deferred Tax Liabilities</b>	<b>(13,875)</b>	<b>(20,462)</b>
<b>Net deferred tax assets</b>	<b>4,259</b>	<b>3,450</b>
Valuation allowance	(17,841)	(23,912)
<b>Net Deferred Tax Liability</b>	<b>\$ (13,582)</b>	<b>\$ (20,462)</b>

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

At December 31, 2017, the Company had federal and California net operating losses, or NOL, carryforwards of approximately \$61.7 million and \$35.8 million, respectively. The federal NOL carryforwards begin to expire in 2026, and the California NOL carryforwards begin to expire in 2028. At December 31, 2017, the Company also had federal and California research tax credit carryforwards of approximately \$1.6 million and \$0.3 million, respectively. The federal research tax credit carryforwards begin to expire in 2028, and the California research tax credit carryforwards do not expire and can be carried forward indefinitely until utilized.

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 credit 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.

The Company adopted ASU 2016-09 in 2017. 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. 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 is as follows:

	<b>Year Ended December 31,</b>		
	<b>2017</b>	<b>2016</b>	<b>2015</b>
Statutory federal income tax rate	34.0%	34.0%	34%
Change in fair value of warrant liability	4.1%	0.9%	(5.2)%
State income taxes, net of federal benefit	(7.5)%	4.8%	0.1%
Tax credits	3.2%	0.4%	0.3%
Change in valuation allowance	81.2%	(7.3)%	(12.5)%
Permanent differences	1.2%	-	(0.8)%
State rate adjustment	-	(5.3)%	3.3%
Tax Cuts and Jobs Act	(22.6)%	-	-
Equity compensation adjustment	(1.8)%	-	-
Return to provision	-	0.9%	(0.1)%
Other	-	-	4.5%
Effective Rate	91.8%	28.3%	23.6%

In December 2017, the Tax Cuts and Jobs Act (the "2017 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, limitations on the deductibility of interest and capitalization of research and development expenditures.

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, the Company's deferred tax assets and liabilities were remeasured to reflect the reduction in the U.S. corporate income tax rate from the highest graduated tax 35 percent to a 21 percent flat tax. The remeasurement of deferred tax liabilities that are indefinite lived intangibles, generated an income tax benefit of \$6.6 million, while the remeasurement of the deferred tax assets and liabilities that are not associated with indefinite lived intangibles generated an income tax expense of \$8.3 million. The income tax expense of \$8.3 million was entirely offset by the Company's valuation allowance.

The Company files income tax returns in the United States and various state jurisdictions. Due to the Company's incurred losses, the Company is essentially subject to income tax examination by tax authorities from inception to date. The Company's policy is to recognize interest expense and penalties related to income tax matters as tax expense. At December 31, 2017, there were no significant accruals for interest related to unrecognized tax benefits or tax penalties.

### 13. Commitments and Contingencies

#### Commitments

The Company leases office and laboratory space in Bothell, Washington under an operating lease that expires in January 2019, respectively. Future minimum lease payments, by year and in aggregate, are as follows:

Year ending December 31	(in thousands)	
2018	\$	168
2019		14
<b>Total Minimum Lease Payments</b>	<b>\$</b>	<b>182</b>

The minimum lease payments above do not include common area maintenance (CAM) charges, which are contractual obligations under some of the Company's operating leases, but are not fixed and can fluctuate from year to year.

The minimum lease payments above include the amounts that would be paid if the Company maintains its Bothell lease for the five-year term. The Company has the right to terminate this lease after three years, by giving prior notice at least 180 days prior to such early termination date and by paying a termination fee equal to the sum of three months' rent plus the unamortized balance of the sum of (a) all brokerage commissions paid by the landlord of the property in connection with the lease and (b) the abated free base rent related to the five months of the lease, treating items (a) and (b) as being amortized on a level basis over the five year base term of the lease.

The offices and laboratory space in Tucker, Georgia are leased from a limited liability company owned by one of Cocystal's Directors, Dr. Raymond Schinazi and are currently on a month to month basis.

Rent expense for 2017, 2016, and 2015, totaled \$293,000, \$345,000 and \$375,000 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.

### 14. Quarterly Results (Unaudited)

Selected quarterly financial data for 2017 and 2016 are contained in the Condensed Interim Financial Data table below.

<i>(\$ in thousands except per share amounts)</i>	4th Q	3rd Q	2nd Q	1st Q
<b>2017</b>				
Research and development	1,103	1,393	1,255	2,071
General and administrative	728	717	(55)	1,050
<b>Total costs and expenses</b>	<b>1,831</b>	<b>2,110</b>	<b>1,200</b>	<b>3,121</b>
Operating loss	(1,831)	(2,110)	(1,200)	(3,121)
Other income (expense), net	(152)	150	198	573
Income tax benefit	\$ 6,880	\$ -	\$ -	\$ -
<b>Net (loss) income</b>	<b>4,897</b>	<b>(1,960)</b>	<b>(1,002)</b>	<b>(2,548)</b>
Basic earnings (loss) per common share	\$ 0.20	\$ (0.08)	\$ (0.04)	\$ (0.11)
Earnings (loss) per common share assuming dilution	\$ 0.20	\$ (0.08)	\$ (0.04)	\$ (0.11)
<b>2016</b>				
Research and development	93,876(1)	2,093	2,368	3,342
General and administrative	510	(199)	1,836	1,992
<b>Total costs and expenses</b>	<b>94,386</b>	<b>1,894</b>	<b>4,204</b>	<b>5,334</b>
Operating loss	(94,386)	(1,894)	(4,204)	(5,334)
Other income (expense), net	(762)	13	977	1,322
Income tax benefit	\$ 29,394	\$ -	\$ -	\$ -
<b>Net loss</b>	<b>(65,754)</b>	<b>(1,881)</b>	<b>(3,227)</b>	<b>(4,012)</b>
Basic loss per common share	\$ (3.06)	\$ (0.03)	\$ (0.14)	\$ (0.17)
Loss per common share assuming dilution	\$ (3.06)	\$ (0.03)	\$ (0.14)	\$ (0.17)

(1) Includes impairment charge for the company's IPR&D asset of \$92,369,000

## 15. Subsequent Events

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-30 reverse split of the Company's class of Common Stock. The Amendment took effect on January 24, 2018. No fractional shares will be issued or distributed as a result of the Amendment. There was no change in the par value of our common stock.

On January 31, 2018, the Company, entered into a Securities Purchase Agreement (the "SPA") with OPKO Health, Inc. (the "Purchaser"), pursuant to which the Company borrowed \$1,000,000 from the Purchaser in exchange for issuing the Purchaser an 8% Convertible Note (the "Note") due January 31, 2020. At the option of the Purchaser, the Note is convertible at \$8.10 per share. In the event the Company completes a financing in which the Company receives at least \$10,000,000 in gross proceeds and issues 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 Note shall automatically convert. Upon the closing of a Financing, the conversion price of the Note shall be the lesser of (i) \$8.10 per share and (ii) the price per share of the securities sold in the Financing.

On or about February 8, 2018 a series of transactions concluded, involving the Company, Daniel Fisher, 580 Garcia Properties LLC, and others, by the terms of which, *inter alia*, the Company resolved all outstanding claims and disputes with Daniel Fisher, his spouse Sharon Fisher and 580 Garcia Properties, LLC. Pursuant to the terms of the Agreement, the Company received \$1,400,000 on February 9, 2018 from a third party in exchange for the Company transferring a mortgage promissory note (the "Mortgage Note") to the third party. After appropriate write downs of the Mortgage Note, the Company had carried the Mortgage Note as a \$1.294 million asset on its balance sheet. The approximately \$106,000 difference will be reported as a gain for the quarter ending March 31, 2018.



### 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 2018 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of December 31, 2017.

### 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</a>	8-K	12/1/14	3.2	
3.1(a)	<a href="#">Certificate of Amendment to Certificate of Incorporation</a>	8-K	12/1/14	3.3	
3.1(b)	<a href="#">Certificate of Amendment to Certificate of Incorporation</a>	8-K	3/3/15	3.1	
3.1(c)	<a href="#">Certificate of Amendment to Certificate of Incorporation</a>	8-K	1/24/18	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="#">Chief Financial Officer Offer Letter dated May 26, 2017 - James Martin*</a>	8-K	6/1/17	10.1	
10.4	<a href="#">2015 Equity Incentive Plan*</a>	DEF 14A	6/1/15	Annex A	
10.5	<a href="#">Form of Securities Purchase Agreement</a>	8-K	09/02/16	10.1	
10.6	<a href="#">Form of Securities Purchase Agreement</a>	10-K	3/15/16	10.1	
10.7	<a href="#">Form of Securities Purchase Agreement dated November 24, 2017</a>	8-K	12/1/17	10.1	
10.8	<a href="#">Form of Convertible Note dated November 24, 2017</a>	8-K	12/1/17	10.2	
10.9	<a href="#">Securities Purchase Agreement</a>	8-K	4/24/17	10.1	
10.10	<a href="#">Gary Wilcox Advisory Agreement*</a>	10-K/A	04/29/16	10.16	
21.1	<a href="#">Subsidiaries</a>	10-K	3/31/15	21.1	
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

\* Management contract or compensatory plan or arrangement.

\*\* 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 Cocystal Pharma, Inc., 1860 Montreal Road, Tucker Georgia 30084.

#### ITEM 16. FORM 10-K SUMMARY

Not applicable.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

### COCRYSTAL PHARMA, INC.

March 21, 2018

By: /s/ Gary Wilcox

Gary Wilcox  
Interim 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	Interim Chief Executive Officer and Vice Chairman (Principal Executive Officer)	March 21, 2018
<u>/s/ Raymond F. Schinazi</u> Raymond F. Schinazi	Chairman	March 21, 2018
<u>/s/ David Block</u> David Block	Director	March 21, 2018
<u>/s/ Phillip Frost</u> Phillip Frost	Director	March 21, 2018
<u>/s/ Jane Hsiao</u> Jane Hsiao	Director	March 21, 2018
<u>/s/ Steven Rubin</u> Steven Rubin	Director	March 21, 2018
<u>/s/ James Martin</u> James Martin	Chief Financial Officer (Principal Accounting Officer)	March 21, 2018



Consent of Independent Registered Public Accounting Firm

Cocrystal Pharma, Inc.  
Tucker, Georgia

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) of Cocrystal Pharma, Inc. of our reports dated March 21, 2018, 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, 2017.

*/s/ BDO USA, LLP*  
Seattle, Washington  
March 21, 2018

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**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER**

I, Gary Wilcox, certify that:

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

Date: March 21, 2018

*/s/ Gary Wilcox*

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Gary Wilcox

Interim Chief Executive Officer  
(Principal Executive Officer)

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**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 I and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 21, 2018

*/s/ James Martin*

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James Martin  
Chief Financial Officer  
(Principal Financial Officer)

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**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 annual report of Cocrystal Pharma, Inc. (the "Company") on Form 10-K for the year ended December 31, 2017, 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 annual 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 annual report fairly presents, in all material respects, the financial condition and results of operations of the Company.

*/s/ Gary Wilcox*

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Gary Wilcox  
Interim Chief Executive Officer  
(Principal Executive Officer)  
Dated: March 21, 2018

In connection with the annual report of Cocrystal Pharma, Inc. (the "Company") on Form 10-K for the year ended December 31, 2017, 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 annual 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 annual report fairly presents, in all material respects, the financial condition and results of operations of the Company.

*/s/ James Martin*

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James Martin  
Chief Financial Officer  
(Principal Financial Officer)  
Dated: March 21, 2018

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