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, 2022**

OR

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

Commission file number: 001-38418

Cocrystal Pharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**35-2528215**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
19805 North Creek Parkway Bothell, WA	**98011**
(Address of Principal Executive Office)	*(Zip Code)*

Registrant's telephone number, including area code: **(305) 425-1780**

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

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

Securities registered pursuant to Section 12(g) of the Act: None

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No □

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

Large accelerated filer	□	Accelerated filer	□
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	□		

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

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. □

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). □

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, 2022, was approximately $38.0 million.

The number of shares outstanding of the registrant's common stock, as of March 21, 2023, was approximately 8,143,332 shares.

Documents Incorporated by Reference

Portions of the registrant's definitive proxy statement for its 2022 Annual Meeting of Stockholders are incorporated by reference in Items 10, 11, 12, 13, and 14 of Part III of this Annual Report on Form 10-K.

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PART I

Item 1. Business.

Overview

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

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

Cocrystal Technology

We are developing antiviral therapeutics that inhibit the essential viral replication function of RNA viruses causing acute and chronic viral diseases. Our goals include treating influenza virus, coronavirus, and norovirus infections by discovering and developing drug candidates targeting the viral replication process. Additionally, one of our goals is to decrease the duration of HCV therapy by advancing our drug candidate targeting the HCV RNA-dependent RNA polymerase enzyme through partnerships and/or licensing activities. In the case of coronavirus antiviral therapeutics, we target replication enzymes and proteases that are required for the viral replication and transcription. To discover and design these inhibitors, we use a proprietary platform comprising computational chemistry, medicinal chemistry, X-ray crystallography and our extensive know-how. We determine the structures of cocrystals containing the inhibitors bound to the enzyme or protein to guide our structure-based drug design. We also use advanced computational methods to screen and design product candidates using proprietary cocrystal structural information. In designing the candidates, we seek to anticipate and avert potential viral mutations leading to resistance. By designing and selecting drug candidates that interrupt the viral replication process and also have specific binding characteristics, we seek to develop drugs that are not only effective against both the virus and possible mutants of the virus, but which also have reduced off-target interactions that may cause undesirable clinical side effects. The successful application of our approach requires an extensive knowledge of viruses and drug targets. In addition, knowledge and experience in the fields of structural biology, and enzymology are required. We developed our proprietary structure-based drug design under the guidance of Dr. Roger Kornberg, our Chief Scientist and Chairman of both our Scientific Advisory Board and Board of Directors (the "Board"), in addition to a recipient of the Nobel Prize in Chemistry in 2006. Our drug discovery process focuses on the highly conserved regions of the viral enzymes and inhibitor-enzyme interactions at the atomic level. Additionally, we have developed proprietary chemical libraries consisting of non-nucleoside inhibitors, metal-binding inhibitors, and drug-like fragments. Our drug discovery process is different from traditional, empirical, medicinal chemistry approaches that often require iterative high-throughput compound screening and lengthy hit-to-lead processes. We will 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 activity.

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

Market-Driven Product Profiles

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

(1) High barrier to viral resistance;

(2) Effective against all viral subtypes that cause disease;

(3) Fast onset of action and/or shortened therapeutic time;

(4) Good safety and tolerability profile; and

(5) Multiple routes of administration including oral, inhalation, and/or injection.

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

High barrier to drug resistance: Drug resistance is a major obstacle to developing effective antiviral therapies. Viruses can reproduce rapidly and in enormous quantities in infected human cells. During viral replication, random changes in the viral genome, called mutations, develop. If such a mutation occurs in a region of the viral genome that is targeted by a given antiviral therapy, that therapy may no longer be effective against the mutated virus. These mutated or “resistant” viruses can freely infect and multiply even in individuals who have received drug treatment. In some cases, resistant virus strains may even predominate. For example, in the 2009 swine influenza pandemic, the predominant strain was resistant to the best available therapies. In the COVID-19 pandemic mutated viruses have been identified and sequenced demonstrating that the potential for resistance to current drugs and reduced effectiveness of vaccines is already present. For example, the Omicron variant which arose as the dominant strain of COVID-19 in late 2021 until it diminished in the winter of 2022 displayed increased resistance to available vaccines and treatments, resulting in the limitation or suspension of emergency use authorizations by the FDA for certain therapeutic products.

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, and therefore, sensitive to change. A mutation in these critical components is likely to inactivate the replication protein and, in turn, render the virus incapable of replicating. Because such mutations cannot propagate, the virus cannot effectively develop resistance to the enzyme inhibitors we employ. We test the effectiveness of our compounds against potential viral mutations and select compounds with the highest barrier to resistance.

Broadly effective against major strains responsible for a viral disease: For any given viral disease, there are different strains of viruses that cause the disease. For example, there are 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 a given virus 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 required for viral replication are essentially similar (highly conserved) among all strains of a given virus. By targeting these highly conserved regions of the replication enzymes, our antiviral compounds are designed and tested to be effective against major virus strains. Replication enzymes are generally conserved not only among subtypes of a given virus but also among many different viruses, creating an opportunity for the development of broad-spectrum antiviral drugs.

Fast onset of action: As viruses can reproduce rapidly and in enormous quantities in human cells, antiviral drugs are needed with faster onset of viral load reduction resulting in shorter treatment time.

Safety and tolerability: All drugs have side effects, also referred to as adverse effects. These usually result from a drug's ability to bind to human molecules (usually proteins). When this interaction is intentional (i.e., part of the drug's mechanism of action), the adverse effects are classified as on-target effects. When this interaction is unintentional (i.e., resulting from the drug's interaction with an unintended human molecule), the effects are called off-target effects. Our inhibitors target viral replication enzymes, which are generally unique to viruses. Because the targets are viral, not human, minimal adverse effects may be the result. 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 human homologous proteins. In December 2022, we reported favorable safety and tolerability results from a Phase 1 study of our oral antiviral CC-42344 developed for the treatment of both pandemic and seasonal influenza A.

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

Research and Development Update

During the year ended December 31, 2022 the Company focused its research and development efforts primarily in three areas:

Influenza infections

We have several candidates under development for the treatment of influenza infection. CC-42344, a novel oral PB2 inhibitor, was selected as a preclinical lead for the treatment of pandemic and seasonal influenza A, and was advanced to a Phase 1 clinical trial in 2022 as described in more detail below. This candidate binds to a highly conserved PB2 site of influenza polymerase complex (PB1: PB2: PA) and exhibits a novel mechanism of action. CC-42344 showed excellent antiviral activity against influenza A strains, including avian pandemic strains and Tamiflu resistant strains, and has favorable pharmacokinetic and drug resistance profiles.

In March 2022 enrollment was initiated in a randomized, double-blind, placebo-controlled Phase 1 study of CC-42344, which was conducted in Australia. In April 2022 we announced preliminary results from the first two cohorts of the single-ascending dose portion of the study in which CC-42344 demonstrated a favorable safety and pharmacokinetic profile. In December 2022, we reported favorable safety and tolerability results from a Phase 1 study of CC-42344 for the treatment of both pandemic and seasonal influenza A.

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

In January 2021, we announced that we completed all research obligations under the Merck exclusive worldwide license and collaboration agreement, and that Merck would be solely responsible for further development of the influenza A/B antiviral compounds that were discovered using Cocrystal's unique structure-based technologies and Nobel Prize-winning expertise. Merck is continuing development of the influenza A/B antiviral compounds under the terms of our Collaboration Agreement and is legally protecting the intellectual property of the collaboration compounds.

Coronavirus infections

In October 2022 we announced the selection of a novel, broad-spectrum antiviral drug candidate CDI-988 for clinical development as an oral treatment for SARS-CoV-2, the virus that causes COVID-19. CDI-988 targets a highly conserved region in the active site of SARS-CoV-2 main (3CL) protease required for viral replication and was specifically designed and developed as an oral antiviral candidate for COVID-19 using Cocrystal's proprietary structure-based drug discovery platform technology.

In January 2022 we announced the selection of two investigational novel antiviral drug candidates, CDI-988 and CDI-873, for further development as oral treatments for coronaviruses, including SARS-CoV-2, the virus that causes COVID-19. Both compounds exhibited superior in vitro potency against SARS-CoV-2 with activity maintained against recent variants of concern. In preclinical studies, both candidates demonstrated a favorable safety profile and pharmacokinetic properties supportive of daily oral dosing. We plan to begin a randomized, double-blind, placebo-controlled Phase 1 study of CDI-988 during the first half of 2023.

In December 2020 we announced the selection of CDI-45205 for further development against coronaviruses including SARS-CoV-2, that causes COVID-19. CDI-45205 was one of the broad-spectrum protease inhibitors that were obtained from Kansas State University Research Foundation ("KSURF") under an exclusive license agreement announced in April 2020. That agreement provides Cocrystal with an exclusive, royalty-bearing license to develop and commercialize therapeutic, diagnostic and prophylactic products against coronaviruses, caliciviruses and picornaviruses based on antivirals discovered by KSURF. See "Collaborations – Kansas State University Research Foundation."

Norovirus Infections

We continue to identify and develop non-nucleoside polymerase and protease inhibitors using the Company's proprietary structure-based drug design technology platform. In addition, we now have exclusive rights to norovirus protease inhibitors for use in humans obtained in the license from KSURF (see under Collaborations below). We expect to select a preclinical lead in the first half of 2023.

Therapeutic Targets

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

Influenza is a severe respiratory illness, caused primarily by influenza A or B virus. The Centers for Disease Control and Prevention (the "CDC") estimates that influenza was linked to approximately 79,000 deaths and 960,000 hospitalizations in the United States during the 2017-2018 flu season. According to the report published by BCC Research in May 2018, the global influenza market was valued at approximately $5.6 billion in 2017 and was expected to reach nearly $6.5 billion by 2022, increasing at a compound annual growth rate (CAGR) of 3.0% from 2017 through 2022.

Currently, approved antiviral treatments for influenza are effective, but burdened with significant viral resistance. Strains of influenza virus that are resistant to the approved treatments osteltamivir phosphate (Tamiflu®) and zanamavir (Relenza®), baloxavir marboxil (Xofluza®) have appeared, and in some cases predominated. 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 selected CC-42344, a novel PB2 inhibitor, as a lead candidate and has clinically completed a Phase 1 study. In December 2022, the Company reported on the favorable safety and tolerability results of the CC-42344 Phase 1 study and plan to initiate a Phase 2a study in the first half of 2023. CC-42344 binds to a highly conserved PB2 site of the influenza polymerase (PB1: PB2: PA), and exhibits a novel mechanism of action. CC-42344 has shown excellent antiviral activity against influenza A strains, including avian pandemic strains, and Tamiflu-resistant, Xofluza-resistant strains, and has a favorable pharmacokinetic profile. In addition to Tamiflu, an approved antiviral product candidate that is a competitor for the Company's influenza programs, S-033188, being developed by Shionogi/Roche. S-033188 was approved as Xofluza in Japan on February 23, 2018, and in the US as baloxavir marboxil (trade name Xofluza®) on October 24, 2018. See "Item 1 – Business – Research and Development Update – Influenza" for more information. Xofluza-resistant strains emerged in both the US and Japan within several months of Xofluza being on the market.

Coronavirus: COVID-19 continues to be a global pandemic fueled by an emergence of new strains.

As a global pandemic with 760,360,956 COVID-19 confirmed cases globally, including 6,873,477 deaths, as of March 16, 2023, according to the data reported by the World Health Organization ("WHO"). The COVID-19 pandemic and the measures taken by the federal, state and foreign governments to stop the spread of the virus have caused a significant disruption to the U.S. and global economy.

Coronaviruses (CoV) are a large family of RNA viruses that historically have been associated with illness ranging from mild symptoms similar to the common cold to more severe respiratory disease. Infection with the novel SARS-CoV-2 has been associated with a wide range of responses, from no symptoms to more severe disease that has included pneumonia, severe acute respiratory syndrome, kidney failure, and death. The incubation period for SARS-CoV-2 is believed to be within 14 days after exposure, with most illness occurring within about 5 days after exposure. SARS-CoV-2, like other RNA viruses, is prone to mutate over time, resulting in the emergence of multiple variants. Adaptive mutations in the viral genome can alter the virus's pathogenic potential. Even a single amino acid exchange can drastically affect a virus's ability to evade the immune system and complicate the vaccine and antibody therapeutics development against the virus. Based on the recent epidemiological update by the WHO, five SARS-CoV-2 VOCs (variants of concern) have been identified since the beginning of the pandemic. Also, as demonstrated in Delta and Omicron variants, some variations allow the virus to spread more easily and make it resistant to the treatments and vaccines.

On October 22, 2020, FDA approved the antiviral drug Veklury (remdesivir) for the treatment of COVID-19 requiring hospitalization. Remdesivir is a nucleotide prodrug that inhibits viral replication and was previously evaluated in clinical trials for Ebola treatment in 2014. In addition to Veklury, the FDA has issued emergency authorization use on several antibody and antiviral therapeutics, including Paxlovid (nirmatrelvir and ritonavir) and Lagevrio (molpiravir). We continue pursuing the development of novel antiviral compounds for the treatment of coronavirus infections using our established proprietary drug discovery platform. By targeting the viral replication enzymes and protease, we believe it is possible to develop an effective treatment for all coronavirus diseases including COVID-19, Severe Acute Respiratory Syndrome (SARS), and Middle East Respiratory Syndrome (MERS) - coronaviruses.

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

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

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

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

CC-31244, an HCV NNI, is a potential best in class pan-genotypic inhibitor of NS5B polymerase for the treatment of HCV. The Company completed a Phase 1a/b study in Canada in September 2016, with favorable safety results in a randomized, double-blinded, Phase 1a/b study in healthy volunteers and HCV-infected subjects. The Company completed a Phase 2a study in HCV genotype 1 subjects in the United States. Cocrystal presented the interim results from the Phase1a/b study at the APASL in February 2017. HCV-infected subjects treated with CC-31244 had a rapid and marked decline in HCV RNA levels, and slow viral rebound after treatment. Results of this study suggest that CC-31244 could be an important component in a shortened duration all-oral HCV combination therapy. Patient enrollment has been completed in the Phase 2b and the final study report filed with the FDA. See “Item 1 – Business – Research and Development Update – Hepatitis C” for more information.

The Company has been seeking a partner for further clinical development of CC-31244 since completing Phase 2a trials.

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, childcare facilities, and cruise ships. In the United States alone, noroviruses are the most common cause of acute gastroenteritis, and are estimated to cause 19-21 million illnesses each year and contribute to 109,000 hospitalizations and 900 deaths. Noroviruses are responsible for up to 1.1 million hospitalizations and 218,000 deaths annually in children in the developing world. In immunosuppressed patients, chronic norovirus infection can lead to a debilitating illness with extended periods of nausea, vomiting and diarrhea. There is currently no effective treatment or effective vaccine for norovirus, and the ability to curtail outbreaks is limited. A few companies have been developing antiviral treatments for this disease and four candidate vaccines are in stages of clinical testing by Vaxart Pharmaceutical, Takeda Pharmaceuticals, Anhui Zhifei Longcom Biopharmaceutical (China) and National Vaccine and Serum Institute (China).

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

Intellectual Property

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

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

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

In our Influenza A program, our patent portfolio consists of several patent families, including two pending international (PCT) applications and two families of pending applications in the U.S. and various foreign countries.

In our Influenza A/B program, our patent portfolio consists of a number of patent families pending, variously, as international (PCT) applications and in Taiwan. Aspects of this program are developed in collaboration with Merck, which is legally protecting the intellectual property of the collaboration compounds.

In our norovirus and coronavirus programs, our patent portfolio consists of three pending families of U.S. provisional applications, and a portfolio of patent families licensed through KSURF.

Collaborations

Merck Collaboration

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

Under the terms of the Collaboration Agreement, Merck is funding research and development for the program at Cocrystal and Merck, including clinical development at Merck, protecting intellectual property and Merck is responsible for worldwide commercialization of any products derived from the collaboration. The Company received an upfront payment of $4,000,000 in January 2019 and is eligible to receive milestone payments related to designated development, regulatory and sales milestones with the potential to earn up to $156,000,000, as well as royalties on product sales. Other than the initial upfront payment, to date we have not received any payments under this Collaboration Agreement.

The Collaboration Agreement operates under a Research Operating Plan (ROP) which includes goals for both organizations. In January 2021, the Company announced it had completed all research obligations under the Collaboration Agreement, and that Merck is now solely responsible for further development of the influenza A/B antiviral compounds that were discovered in the collaboration using Cocrystal's unique structure-based technologies and Nobel Prize-winning expertise.

Kansas State University Research Foundation

Cocrystal entered into a License Agreement with KSURF on February 18, 2020 to further develop certain proprietary broad-spectrum antiviral compounds for the treatment of norovirus and coronavirus infections.

Pursuant to the terms of the License Agreement, KSURF granted the Company an exclusive royalty bearing license to practice under certain patent rights, under patent applications covering antivirals against coronaviruses, caliciviruses, and picornaviruses, and related know-how, including to make and sell therapeutic, diagnostic and prophylactic products.

The Company agreed to pay KSURF a one-time non-refundable license initiation fee of $80,000 under the License Agreement, and annual license maintenance fees. The Company also agreed to make certain future milestone payments of up to approximately $3.1 million, dependent upon the progress of clinical trials, regulatory approvals, and initiation of commercial sales in the United States and certain countries outside the United States.

On April 19, 2020, the Company entered into a second License Agreement with KSURF in addition to the License Agreement entered into in February 2020.

Pursuant to the terms of the second License Agreement, KSURF granted the Company an exclusive royalty bearing license to practice under certain patent rights under patent applications covering antivirals against coronaviruses, caliciviruses, and picornaviruses, and related know-how, including to make and sell therapeutic, diagnostic and prophylactic products.

The Company agreed to pay KSURF a one-time non-refundable license initiation fee and annual license maintenance fees. The Company also agreed to make certain future milestone payments of up to approximately $4.2 million, dependent upon the progress of clinical trials, regulatory approvals, and initiation of commercial sales in the United States and certain countries outside the United States.

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 face worldwide competition from larger biotechnology and pharmaceutical companies, universities and other academic or research institutions and government agencies that are developing and commercializing pharmaceutical products similar to our product candidates that target the viruses we are seeking to treat. We know of several companies that have marketed or are developing products for the treatment of influenza, coronavirus and HCV, including Roche, Gilead Sciences, Inc. ("Gilead"), Merck, Janssen Pharmaceuticals, Inc., Bristol-Myers Squibb, Toyama Chemical Co., Shionogi/Roche and Abbvie, Inc. Their products are widely considered effective. Further, in the wake of the global COVID-19 pandemic a number of third parties, including large biotechnology and pharmaceutical companies such as Pfizer Inc., Moderna, Inc., Janssen Pharmaceuticals, Inc., and academic institutions have been conducting research aimed at development of an effective treatment for, or a vaccine against, COVID-19. A number of vaccines and treatments for COVID-19 have been commercialized under the FDA's emergency use authorization. At least one treatment and four vaccines for COVID-19 have received FDA approval. Many of the companies developing products for the viral diseases that are the focus of our programs have substantially greater financial resources, including government funding, expertise and capabilities than we do and have existing products in significantly more advanced stages of development. Additionally, viral mutations can lead to new strains or variants of a virus that may be more resistant to products we develop when compared to those of competitors. See "Risk Factors" for more information on the risks we face with respect to our competition.

To date, we have not fully developed, received regulatory approval for or commercialized any of our product candidates. Our ability to compete will depend, to a great extent, on the speed in which we and our collaborators can develop safe and effective product candidates, complete clinical testing and regulatory approval processes, and coordinate with third parties to produce and distribute the resulting products in sufficient commercial quantities to create and maintain a market for such products at favorable costs and prices. If we do complete development of and obtain regulatory approval to market any product candidate, we anticipate that the competition we would face with respect to such product would be based on a combination of a number of factors including efficacy, safety, reliability, availability, price, patent position, and other factors.

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.

In addition to the U.S. requirements such as those enforced by the FDA with respect to safety and efficacy of research, testing, development and production, we also must comply with applicable laws and regulations of any foreign jurisdictions in which we operate. For example, our Phase 1 trial in Australia in 2022 for CC-42344, our lead Influenza A product candidate, caused us to be subject to the Australian government's laws and regulations pertaining to the research and development, including clinical testing on human subjects, of therapeutic product candidates. Our presence in Australia has also subjected us to more general laws applicable to operations abroad, such as the U.S. Foreign Corrupt Practices Act (the "FCPA") and comparable legislation and regulation in foreign jurisdictions. In general, the FCPA prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate to obtain or retain business abroad. The scope of the FCPA includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anti-corruption laws and/or regulations. Further, because of our reliance on one or more CROs and CMOs with respect to our research and development activities both in the U.S. and in foreign jurisdictions, we may have limited control over compliance with such requirements in certain instances.

With respect to coronavirus-related products as of the date of this Report, with the exception of Veklury (remdesivir), an antiviral drug commercialized by Gilead, no treatment has been approved by the FDA for COVID-19 symptoms. Instead, most existing treatments for COVID-19 that are or have been offered by competing companies have been made available under the FDA's emergency use authorization. The FDA has, however, reduced or removed many of these authorizations, including for treatments using monoclonal antibodies such as the REGEN-COV treatment commercialized by Regeneron Pharmaceuticals, Inc., due to waning efficacy against symptoms caused by the Omicron variant of the virus which until recently was the dominant strain. As the foregoing description demonstrates, our coronavirus programs and any product candidates that we may develop therefrom are subject to uncertainty as to the FDA's actions, which are in turn inherently unpredictable given the unpredictable nature of the virus and its mutations, as well as their effects on treatment compounds.

Human Capital

As of March 21, 2023, we employed 12 full-time employees. Of these full-time employees, nine are engaged in research and development activities. In addition, we have contracts with CROs, CMOs and consultants to provide chemistry, toxicology, preclinical, clinical, and regulatory work on our programs, including in both preclinical and clinical studies for our product candidates.

Available Information

Our corporate website is www.cocrystalpharma.com. We make available on our website under "Investors – SEC Filings" access to our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Proxy Statements on Schedule 14A and amendments to those materials filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), free of charge.

ITEM 1A. RISK FACTORS

You should carefully consider the risks described below, as well as other information contained in this report, including the consolidated financial statements and the notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events discussed below could significantly and adversely affect our business, prospects, results of operations, financial condition, and cash flow.

Summary Risk Factors

Our business is subject to numerous risks and uncertainties that you should consider before investing in our common stock. The following is a summary of the principal risk factors we face:

- We have incurred significant losses since our inception, expect to incur losses over the next several years and may never achieve or maintain profitability.
- We have no history of commercializing products.
- We will need additional funding to pursue our business objectives, including to eventually commercialize our product candidates if we complete research and development efforts and receive the required regulatory approvals for a product candidate in the future.
- We allocated a significant amount of time and resources into developing a treatment for COVID-19, and these efforts may ultimately be unfruitful.

- The regulatory approval processes of the FDA and other government authorities are lengthy, time consuming and inherently unpredictable.
- If we are unable to successfully develop, receive regulatory approval for and commercialize our product candidates, our business will be harmed.
- Even if we do commercialize one or more products, most pharmaceutical products that achieve commercialization still do not recoup their cost of capital.
- We face uncertainties with respect to the potential for new United States healthcare legislation which may lead to reduced pricing, among other things.
- The cost of our research and development programs may be higher than expected, and there is no assurance that such efforts will be successful in a timely manner or at all.
- Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials or an ability to ultimately receive approval from the FDA.
- We may not be successful in our efforts to research, develop, or in-license or acquire product candidates.
- We face intense competition, which may limit or eliminate our commercial prospects with respect to product candidates.
- We rely on third parties to research, develop and commercialize certain product candidates, and such third parties may not perform satisfactorily or act in our best interests.
- If we are unable to obtain or protect intellectual property rights related to any of our product candidates, we may not be able to compete effectively in the market.
- We may become subject to expensive intellectual property litigation to enforce our intellectual property rights or defend against claims asserted by others.
- The trading price and volume of our common stock may be volatile and could decline in which case investors could lose all or part of their investment.

Risk Factors

RISKS RELATED TO OUR BUSINESS

We have never generated revenue from product sales and all of our product candidates are currently in the preclinical and early clinical stage, and we may continue to incur significant losses for the foreseeable future and never generate revenue from product sales.

We are a preclinical and early stage clinical, biopharmaceutical discovery and development company. We completed a Phase 1 clinical trial for our Influenza A lead oral candidate CC-42344 in December 2022. We also plan to commence a COVID-19 clinical trial in 2023 for our lead oral candidate CDI-988. Because of the need to complete clinical trials, establish safety and efficacy and obtain regulatory approval, which is an expensive and time-consuming process, we do not anticipate generating revenue from product sales for at least five years and will continue to sustain considerable losses. We may develop a partnership that could generate income sooner, but there is no guarantee that will be achievable.

We had an accumulated deficit of $297,930,000 from inception through December 31, 2022 and expect to continue losing money in the future. We may never achieve income from operations or have positive cash flow from operations.

As an early-stage drug development company, our focus is on developing product candidates, obtaining regulatory approvals and commercializing pharmaceutical products. As a result, we have lost $297,930,000 from inception through December 31, 2022, expect losses to continue, and have never generated revenue from product sales. It is likely that we will need to raise additional capital in the future. There can be no assurance that we will ever generate income from operations or have positive cash flow from operations.

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

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with partners, to successfully complete the development of, obtain the regulatory approvals for and commercialize pharmaceutical product candidates. We have no pharmaceutical product candidates that have generated any commercial revenue, do not expect to generate revenues from the commercial sale of pharmaceutical products for foreseeable 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;
- entering into collaborations with large pharmaceutical or biotechnology companies, similar to our Collaboration Agreement with Merck;
- completing our research and preclinical development of pharmaceutical product candidates;
- initiating and completing clinical trials for pharmaceutical product candidates;
- seeking and obtaining regulatory marketing approvals for pharmaceutical product candidates that successfully complete clinical trials;
- establishing and maintaining supply and manufacturing relationships with third parties;
- launching and commercializing pharmaceutical product candidates for which we obtain regulatory marketing approval with a partner or, if launched independently, successfully establishing a sales force, marketing and distribution infrastructure;
- maintaining, protecting, enforcing, defending and expanding our intellectual property portfolio; and
- attracting, hiring and retaining qualified personnel.

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

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

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

We are still in the early stages of preclinical and clinical development of our product candidates and have no products approved for commercial sale or presently in clinical trials. However, our ability to conduct clinical trials in a cost-effective manner and within the desired timeframes remains subject to uncertainties arising from COVID-19 (including the pandemic's effect on third parties on which we rely), supply chain shortages, and potential difficulties in obtaining adequate participant enrollments. Further, developing pharmaceutical products, including conducting preclinical studies and clinical trials, is capital-intensive. As a rule, research and development expenses increase substantially as we advance our product candidates toward clinical programs. If we are able to advance our products through clinical trials, we may need to raise additional capital to support our operations and/or form partnerships, in addition to our existing collaborative alliances, which may give substantial rights to a partner. Such funding or partnerships may not be available to us on acceptable terms, or at all. Moreover, any future financing may be very dilutive to our existing stockholders.

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

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

- accept terms that restrict our ability to issue securities, incur indebtedness, or otherwise raise capital in the future, or restrict our ability to pay dividends or engage in acquisitions;
- 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.

RISKS RELATED TO THE DISCOVERY, DEVELOPMENT AND COMMERCIALIZATION OF PRODUCT CANDIDATES

Our COVID-19 programs are in the preclinical stage and we face significant competition from major companies who have developed vaccines or COVID-19 treatments. If we fail to gain market share because our competitors develop and successfully commercialize effective COVID-19 vaccines or therapies or if we fail to obtain or maintain FDA authorization or to otherwise account for uncertainties surrounding the virus, our business and future prospects could be materially and adversely affected.

While we plan to commence a Phase 1 clinical study of our COVID-19 lead oral candidate CDI-988 in the first half of 2023, we may be unable to produce an effective therapy in a timely manner or at all. Additionally, we are committing substantial financial and other resources to our COVID-19 program, which may negatively impact our other programs. Further, in the wake of the global COVID-19 pandemic a number of third parties, including large biotechnology and pharmaceutical companies and academic institutions have developed vaccines, at least two of which have FDA approval. Some competitors have also received FDA approval or emergency use authorization for the treatment of COVID-19. Some of these large pharmaceutical companies, including Pfizer, Moderna and Janssen Biotech, Inc., have obtained FDA approval for vaccines which have demonstrated high efficacy rates and are currently being distributed to the general population, with the permitted age of use for certain vaccines as low as six months and older. While our COVID-19 program is focused on treatment rather than prevention, widespread vaccination limits our prospects with respect to any therapeutic product candidate we develop.

Further, some of our competitors that are also developing treatments for the virus have substantially more resources, including government funding, than we do and have existing products in significantly more advanced stages of development. For example, the FDA approved remdesivir, an investigational antiviral agent developed by Gilead for the treatment of patients with COVID-19 requiring hospitalization. In addition, the FDA has issued an emergency use authorization for the investigational monoclonal antibody therapy for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients. At least one other competitor is conducting a combination Phase 2/3 clinical trials for a treatment using cannabidiol to treat COVID-19 for patients with heart issues. Another competitor is conducting Phase 2 clinical trials for the treatment of "long" COVID, also known as post-COVID syndrome, for patients who experience symptoms for more than four weeks. Even if we do obtain FDA authorization for a therapeutic product, the FDA may subsequently rescind or limit such authorization as more information about the product, including its efficacy and side effects, becomes available. Further, this virus is highly mutative and a number of variants have already arisen, and any treatment we are able to develop and commercialize will therefore remain subject to the risk that a mutation will occur that produces a strain or strains of the virus to which such treatment has a diminished effect or is ineffective. For example, the Omicron variant of the virus is more resistant to treatments that were effective against prior variants of the virus. If we do develop a treatment that is effective against a current variant, a later variant may arise that reduces or eliminates the product's efficacy before we are able to commercialize it. Further, if this occurs, one or more competitors' products may be more effective against new variants than ours, resulting in a diminished market for our products. For example, on February 11, 2022, the FDA announced its emergency use authorization for bebtelovimab, a new monoclonal antibody for the treatment of COVID-19 by non-hospitalized patients, that retains activity against the Omicron variant. If we are unable to timely advance our COVID-19 program, or if we fail to gain or maintain a market share as a result of our competitors developing and successfully commercializing vaccines and effective COVID-19 therapies more quickly than we do, our business and future prospects could be materially and adversely affected.

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

We are party to the Collaboration Agreement, dated January 4, 2019, with Merck to research, develop, and commercialize certain proprietary Influenza A/B antiviral agents. On January 19, 2021, the Company announced that it had completed all research obligations under the Collaboration Agreement with Merck, and Merck is now solely responsible for further development of the Influenza A/B antiviral compounds and will also be solely responsible for the commercialization of any products derived therefrom. See "Item 1 – Business – Collaborations – Merck Collaboration" for more information on the Collaboration Agreement. As such, the success of this collaborative alliance will depend on the efforts and activities of Merck, particularly moving forward.

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

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

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

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

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

Further, pursuant to the Collaboration Agreement Merck will only be obligated to make many of the milestone payments if our Influenza A/B product receives required regulatory approvals, is commercialized and net sales exceed the thresholds set forth in the Collaboration Agreement. Achieving milestones may be difficult and time-consuming. If some or all of these goals are not achieved, we may not receive some or all of the milestone payments under the Collaboration Agreement. As of the date of this Report, none of the milestones under the Collaboration Agreement have been reached.

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

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

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

- a partner may shift its priorities and resources away from our programs due to a change in business strategies, or a merger, acquisition, sale or downsizing of its company or business unit;

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

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

We expect to rely on third parties to conduct some or all aspects of our compound formulation, research and preclinical testing, if those third parties do not perform satisfactorily our business and future prospects would be materially and adversely affected.

We do not expect to independently conduct 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 CROs to conduct clinical trials. This reliance can materially delay our research and developments efforts, and increase the costs of undertaking them. For example, beginning in 2021, certain of our CROs began experiencing staffing shortages and other issues due to the outbreak of Omicron cases, resulting in delays and increased costs in researching our product candidates. We have also experienced material delays and cost increases in general throughout the pandemic caused by pandemic-related difficulties faced by our CROs and CMOs. See the risk factor titled "Our business has been and may continue to be affected by the COVID-19 pandemic, and the full extent of such impact remains uncertain." Further, any disputes that may arise from our arrangements with CROs or CMOs may result in additional unexpected expenses and force our management to allocate their limited time to seeking a resolution to the problem, which could materially adversely affect our operations.

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

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

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

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

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

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

We intend to establish manufacturing relationships with a limited number of suppliers to manufacture raw materials, drug substances, 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 a New Drug Application ("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.

If third party manufacturing issues arise, it could increase product and regulatory approval costs or delay commercialization.

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

Since we expect to continue to rely on third parties to conduct, supervise and monitor our clinical trials, if those third parties fail to perform in a satisfactory manner and one that meets applicable regulatory, scientific and safety requirements, it may materially harm our business.

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

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

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

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

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 on 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 never commercialized any products. The scientific discoveries that form the basis for our efforts to discover and develop drug product candidates are relatively new and unproven. The scientific evidence to support the feasibility of developing product candidates based on our approach is limited. If we do not successfully develop and commercialize drug product candidates based upon our technological approach, we may not become profitable and the value of our stock may decline.

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

If we do not succeed in our efforts to identify or discover additional 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 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. For example, the FDA indicates that approximately 70% of drugs proceed past Phase 1 studies, 33% proceed past Phase 2, and just 25%-30% proceed past Phase 3 to Phase 4 which is the final phase in the FDA review and approval process for marketing therapeutic product candidates. The process for obtaining regulatory approval to market product candidates is expensive, usually takes many years, and can vary substantially based on the type, complexity, and novelty of the product candidates involved. Our ability to generate revenue 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 have invested and intend to continue to invest a significant portion of our efforts and financial resources in the identification and preclinical development of product candidates that target viral replication enzymes. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates.

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

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

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

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

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

Events that may cause a delay or unsuccessful completion of clinical development include, among other things:

- 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;
- negative or inconclusive results of clinical trials of our product candidates;
- time and expenses 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
- The FDA or foreign regulator will remove the product from the market after obtaining marketing approval.

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

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

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

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

- 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 ("REMS") which may restrict the manner in which the product can be distributed or administered;
- 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 may decide or be forced to temporarily or permanently remove the affected product from the marketplace;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

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

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

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

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

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

- issue a warning letter asserting we are in violation of the law;
- impose a REMS or other restrictions on the manufacturing, marketing or use of the product;
- 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 and could generate negative publicity. Further, the FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates or increase the cost of compliance. The occurrence of any event or penalty described above may prevent or inhibit our ability to commercialize our products and generate revenues.

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

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

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

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

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

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

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

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 two exceptions, including recently completing a Phase 1 trial for our Influenza A product candidate in late 2022, we have not entered other compounds into human clinical trials. We plan to advance the Influenza A product to a Phase 2a trial, and to commence a Phase 1 trial for a COVID-19 product candidate, in 2023. We may be unable to progress our product candidates undergoing preclinical testing into clinical trials. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will succeed, and favorable initial results from a clinical trial do not determine outcomes in subsequent clinical trials. The indications of use for which we are pursuing development may have clinical effectiveness endpoints not previously reviewed or validated by the FDA or foreign regulatory authorities, which may complicate or delay our effort to obtain marketing approval. We cannot guarantee that our clinical trials will succeed. In fact, most compounds fail in clinical trials, even at companies far larger and more experienced than us.

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

RISKS RELATED TO OUR BUSINESS OPERATIONS AND INDUSTRY

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 potentially relevant prior art relating to our patents and patent applications has been found; such prior art can invalidate a patent or prevent issuance of a patent based on a pending patent application. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may cause such patents to be narrowed or invalidated. Even if unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims.

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

In addition to patent protection, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology not covered by patents. Each of our employees agrees to assign their inventions to us through an employee inventions agreement. In addition, as a general practice, our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology enter into confidentiality agreements. Nonetheless, our trade secrets and other confidential proprietary information may be disclosed and competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. In addition, in January 2018 the FDA as part of its Transparency Initiative, launched a voluntary pilot program calling on biopharmaceutical research companies to release clinical study reports summarizing clinical trial data. Following the completion of this pilot program in March 2020, the FDA may consider making release of clinical study reports mandatory and may consider making additional information publicly available on a routine basis in response to concerns expressed by the academic community emphasized by the COVID-19 pandemic, including information we may consider to be trade secrets or other proprietary information. If the FDA takes these measures, we may be forced to disclose propriety information about our product candidates and research, which could materially harm our business.

The laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. We may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. Further, governments may in the future alter intellectual property rights in a manner adverse to us or to our third-party collaborators, including actions taken at the international level. For example, in June 2022 member countries of the World Trade Organization ("WTO") agreed to implement a multi-jurisdictional five-year waiver of patent protection with respect to vaccines that target COVID-19 in an effort to fight the pandemic and allow for a more equal distribution of resources, particularly for developing countries, towards that goal. This resulted from ongoing discussions among WTO member countries which began in 2020 with a proposal for a more extensive waiver that would have covered patents for COVID-19 related diagnostics and therapeutics as well as vaccines, and the WTO is still under discussions to potentially extend the waiver to such products. Similarly, some have argued that the WTO should also extend the waiver to apply to other types of intellectual property such as know-how related to the development and distribution of the COVID-19 related products. However, as of March 15, 2023 no definitive action has been taken on expanding upon the WTO waiver that is currently in effect. The WTO waiver, together with similar actions that may be taken with respect to COVID-19-related products or other products in which we are or may become involved could materially diminish or eliminate our ability to protect the underlying intellectual property rights we rely on for such products, including those licensed from third parties, and as a result any potential competitive advantage would be lost. 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.

If third-party intellectual property infringement claims are asserted against us, it may prevent or delay our development and commercialization efforts and have a material adverse effect on our business and future prospects.

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

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

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

Because of the costs involved in defending patent litigation, we may in the future lack the capital to defend our intellectual property rights.

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

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

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

We depend on intellectual property licensed from third parties in one of our COVID-19 programs and termination of any of these licenses could have a material adverse effect on our business.

In one of our COVID-19 programs, we leverage the rights to preclinical leads from our two License Agreements with KSURF. See "Item 1 – Business – Research and Development Update – Coronavirus infections" for more information on these License Agreements.

We depend on the patents, know-how and other intellectual property for the development and, if approved, commercialization of our COVID-19 therapies. If these licenses are terminated, or found to be unenforceable, it could result in the loss of significant rights and could harm our ability to commercialize our future product candidates in the coronavirus program.

The License Agreements impose certain obligations on us, including obligations to use diligent efforts to meet development thresholds and payment obligations. Failure by us to comply with such obligations may result in termination of the respective License Agreement. If KSURF terminates these License Agreements, we may not be able to proceed with that particular coronavirus program or discover, develop or commercialize any other product candidates covered by these agreements.

Further, the License Agreements are complex, and contain certain provisions which may be susceptible to multiple interpretations. Accordingly, disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including those relating to:

- the scope of rights, if any, granted under the license agreement and other interpretation-related issues;
- whether and to what extent our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- whether our licensor or its licensor had the right to grant the license agreement;
- whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of the intellectual property without their authorization;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- whether we are complying with our obligations with respect to the use of the licensed technology in relation to our development and commercialization of product candidates;
- our involvement in the prosecution and enforcement of the licensed patents and our licensors' overall patent prosecution and enforcement strategy;
- the allocation of ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and by us and any future partners or collaborators; and
- the amounts of royalties, milestones or other payments due under the license agreement.

The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement.

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

We may need to obtain additional 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

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to develop and commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. We may not be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding product candidates that we may seek to acquire, in which case our business could be harmed.

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

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

The biotechnology and pharmaceutical industries are intensely competitive. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. This enables them, among other things, to make greater research and development investments and efficiently utilize their research and development costs. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may cause even more resources being concentrated in our competitors. Additionally, smaller or early-stage companies of which we may not be aware could also prove to be material competitors, particularly through collaborative arrangements with larger, more well-established companies or by competing with us for limited resources and strategic alliances with our current or prospective partners. 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.

The programs we are focusing on are in a preclinical d or early clinical 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 and retain 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. For example, the widespread distribution of COVID-19 vaccines will reduce the demand for any therapeutic product we develop to treat symptoms caused by the virus. We will not achieve our business plan if the acceptance of our products is inhibited by price competition or the reluctance of physicians to switch from existing drug products to our products, or if physicians switch to other new drug products or reserve our products for use in limited circumstances. Additionally, the biopharmaceutical industry is characterized by rapid technological and scientific change, and we may not be able to adapt to these rapid changes to the extent necessary to keep up with competitors or at all. The inability to compete with existing or subsequently introduced drug products would have a material adverse impact on our business, financial condition and prospects.

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

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

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

- demonstration of clinical safety and efficacy compared to other products;
- the relative convenience, ease of administration and acceptance by physicians, patients and healthcare payors;
- the prevalence and severity of any adverse effects or serious adverse effects;
- limitations or warnings in the label approved by FDA and/or foreign regulatory authorities for such products;
- the timing of market introduction of our products relative to competitive products and the availability of alternative treatments;
- pricing and cost-effectiveness;
- the execution and effectiveness of our or any partners' 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 we obtain regulatory approval for one product candidate, we expect sales to generate substantially all of our product revenues, and as such, the failure of such product to find market acceptance would adversely affect our results of operations.

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

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

Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process, and no uniform policy of coverage and reimbursement for products exists among third-party payors in the United States. A primary trend in the U.S. healthcare industry is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular products. Further, third-party payors are increasingly challenging prices charged for pharmaceutical products, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. There can be no assurance that coverage and reimbursement will be available for any product we commercialize. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptable. If reimbursement is not available, or is available at limited levels, we may not be able to successfully commercialize product candidates we develop.

Due to the recent change in the United States presidency, we expect increased regulation as well as uncertainty, which may adversely affect our business.

Under President Biden, we expect that the FDA, the Centers for Disease Control and other agencies which affect our business may increase their regulatory efforts. At the senior administrative level, new regulators with a regulatory zeal may tighten existing regulations and that approach may also be taken in the routine interactions between staff and our scientists and others. For example, since taking office in 2021, the Biden Administration has forwarded proposed rules and budget allocations intended to expand the FDA's purview and regulatory capabilities. These rules or other regulatory developments which may occur in the future could have an adverse impact, directly or indirectly, on our operations or on the operations of our collaborators. Increased regulation and enforcement may lead to increased costs and further delays in getting approvals, which may adversely affect our business.

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

There have been numerous legislative and regulatory proposals to change the healthcare system in the United States and in some foreign jurisdictions that could affect our ability to sell products profitably. President Biden has expressed support for implementing a new health plan that would rely on a "Medicare-like" public option for individuals who are not on Medicare and transition to a Medicare-for-All single payor system in the future. Among other things, such a system may seek to:

- lower prescription prices by permitting Medicare to negotiate prices;
- limit price increases;
- set prices for drugs which do not have competition; and
- permit consumers to buy prescriptions from other countries.

Additionally, in 2022 the Biden administration proposed legislation to implement a number of regulatory changes to make affordable healthcare available for a larger number of Americans, including by lowering the costs of prescription drugs. The proposal includes measures that would allow the government to negotiate prices of certain prescription drugs under Medicare and would redesign the Medicare Part D benefit to limit patient out-of-pocket drug costs and shift liabilities among stakeholders, including manufacturers. Following the proposal, the Inflation Reduction Act was enacted later in 2022 which provides for lower cost prescription drugs and vaccines in Medicare and other federal programs, including by establishing a $2,000 annual cap on out-of-pocket drug costs for Medicare participants beginning in 2025. In a similar vein, in October 2022, President Biden issued an executive order to address concerns about the high costs of prescription drugs in the U.S., wherein the Secretary of the Department of Health and Human Services ("HHS") was tasked with evaluating potential new health care payment and delivery models designed to lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled in the Medicare and Medicaid programs, including models that may lead to lower cost-sharing for commonly used drugs and support value-based payment that promotes high-quality care. In its responsive report, the HHS indicated that it was "full steam ahead in delivering cost savings" and identified three potential price-reducing models for further consideration, as well as other areas for further research. Like the Inflation Reduction Act, certain of the recent or newly proposed regulatory changes will be subject to Congressional approval, and we cannot predict what, if any, of these broad proposals or other legislation or regulation will pass or otherwise be implemented, particularly with a divided Congress.

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

In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. The European Union, or EU, provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for our products, if any are approved. Historically, products launched in the EU do not follow price structures of the U.S. and tend to be priced significantly lower.

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

We do not have a team with experience in 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 provide 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 efforts 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;
- the impact of any war or hostilities such as the Russian invasion of Ukraine;
- 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.

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 President and Co-Chief Executive Officer, Dr. Sam Lee and our Chief Financial Officer and Co-Chief Executive Officer, James Martin. We may be unable to locate a new Chief Executive Officer capable of running our company effectively, and any such individual will require high compensation in a competitive market for experienced and qualified personnel within our industry. We do not carry "key-man" life insurance on any of our employees or advisors. Furthermore, our future success will also depend in part on the continued service of our key scientific and management personnel and our ability to identify, hire, and retain additional personnel. We may not be able to attract and retain personnel on acceptable terms, as there is significant competition among numerous pharmaceutical companies for individuals with similar skill sets. Because of this competition, our compensation costs may increase significantly. If we lose key employees, our business may suffer.

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

As of March 21, 2023, we have 12 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 manage these growth activities. We may not be able to effectively manage the expansion of our operations, which may cause weaknesses in our infrastructure, and give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as developing additional product candidates. If our management cannot effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to manage our future growth.

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and

- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

Because we face potential product liability if 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;

- regulatory scrutiny and product recalls, withdrawals or labeling, marketing or promotional restrictions;

- the inability to commercialize our product candidates; and

- decreased demand for our product candidates, if approved for commercial sale.

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

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

Our principal offices are in Bothell, Washington where we conduct our scientific research. We also maintain a small finance and accounting office in Miami, Florida and an administrative office in Australia. In addition, our Influenza A Phase 1 clinical trial depends on one or more CROs and their facilities located in Australia for Phase 1 and the United Kingdom for Phase 2a for the furtherance of our research and development efforts as to that product. We also plan use Australian CROs for our planned COVID-19 clinical trial in 2023. We and third parties on which we rely are vulnerable to natural disasters such as earthquakes, tornados, severe storms, hurricanes, tsunamis, and fires, as well as other events that could disrupt our operations and cause delays in research and development of our product candidates. We do not carry insurance for natural disasters or similar events, and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our operations.

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

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

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

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

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

Although our workers' compensation insurance may cover us for costs and expenses, we may incur additional costs due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, and this insurance may not provide adequate coverage against other potential liabilities. We may incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may cause substantial fines, penalties or other sanctions.

If we fail to comply with Nasdaq's minimum bid price requirement in the future, it could result in delisting of our common stock, negatively affect the price of our common stock and limit investors' ability to trade in our common stock.

Our common stock is listed on The Nasdaq Capital Market ("Nasdaq"). Nasdaq rules impose certain continued listing requirements, including the minimum $1 bid price, corporate governance standards and number of public stockholders. In November 2021 we were notified by Nasdaq that we are not compliant with its closing bid price requirement because the closing bid price of our common stock was below $1.00 per share for 30 consecutive trading days. Because our common stock failed to trade at higher levels so that we could regain compliance with the Nasdaq minimum closing bid price, our Board recommended and our stockholders approved a reverse stock split subject to further Board approval. In order to regain compliance with the Nasdaq minimum bid provision, we effected a 1-for-12 reverse stock split by amending our Certificate of Incorporation on October 11, 2022.

Previously in December 2019 and again in November 2020, we failed to comply with the Nasdaq minimum bid price but were able to regain compliance without effecting a reverse stock split at those times.

Additionally, a reverse stock split typically has the effect of reducing the number of holders of shares in "round lots," meaning those holding 100 or more shares. Another requirement for being listed on Nasdaq is that the Company have a minimum of 300 round lot holders. While the bid price of our common stock was $1.91 on March 10, 2023. If we again fail to comply with Nasdaq's minimum bid price, it is possible in the future that we will again have to seek stockholder approval, which we may not obtain particularly since retail investors often oppose reverse splits or do not vote and a reverse split requires the approval of the holders of the majority of the outstanding shares of our common stock.

RISKS RELATED TO OUR COMMON STOCK

Our stock price and trading volume has historically been volatile, and any increases in these metrics may be temporary for a number of reasons, which may cause investors to lose money.

Our stock price and trading volume is volatile, and the limited periods in which there were increases to our stock price and trading volume have historically been temporary in nature. Therefore, there can be no assurance that our stock price or trading volume will increase in the future, permanently or at all. For example, in order to increase our stock price above the $1.00 Nasdaq bid price minimum requirement, we effected a 1-for-12 reverse stock split on October 22, 2022. In the months leading up to the reverse split, the closing prices for our common stock (as retroactively adjusted for the reverse split) declined from $5.03 in late August 2022 down to $2.75 on October 10, 2022, and declined further following the reverse split taking effect to below $2.00 on certain dates in December 2022 and February 2023. Our common stock may continue to be volatile and could materially fall for a number of reasons including:

- Announcements by the FDA of final approval of vaccines and treatments for COVID-19;
- Announcements relating to the spread of new variants of COVID-19;
- Announcements by competitors that they are initiating human trials of drugs to treat COVID-19;
- Events which demonstrate that the rapid spread of COVID-19 has receded;
- Our disclosure that the use of our technology and the patents we licensed do not appear promising for the treatment of this virus;

- The results of our planned COVID-19 trial and other clinical trials;
- Our announcement concerning the initiation of or delay in our planned clinical trials;
- Merck's announcements concerning our Influenza A/B product candidate; or
- The termination of any other factors which may have created the unusual volatility and spike in volume.

If the current price and volume level is reduced, investors may sustain large losses.

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

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

- price and volume fluctuations in the overall stock market from time-to-time;
- due to external factors such as geopolitical turmoil, inflation or other events, including the Russian invasion of Ukraine or other unknown hostilities, investors may sell our common stock to meet margin calls on other stocks or as the result of economic disruptions;
- volatility in the market prices and trading volumes of biotechnology stocks generally, or those in our peer group in particular;
- 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;
- Announcement of a future reverse split or our failure to obtain stockholder approval for a reverse split;
- 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;
- 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. Any litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

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

On January 10, 2019, Dr. Phillip Frost, one of our directors, was permanently enjoined from violating a certain anti-fraud provision of the Securities Act of 1933 (the "Securities Act"), future violations of Section 13(d) of the Exchange Act and Rule 13d-1(a) thereunder and participating in penny stock offerings with certain exceptions. So long as Dr. Frost is a director or until January 11, 2024, the Company will be unable to rely on certain exemptions from registration including the exemptions under Rule 506 and Regulation A promulgated under the Securities Act absent a waiver issued by the Securities and Exchange Commission (the "SEC"). We have not applied for a waiver, and even if we do, the SEC may choose not to grant us a waiver. While there is a statutory exemption for private placements under Section 4(a)(2) of the Securities Act, case law creates uncertainty on establishing an exemption outside of the Rule 506 safe harbor. The absence of the Rule 506 safe harbor could adversely affect our ability to raise necessary capital in private placements. It has not and will not affect our ability to raise capital in registered public offerings.

Because of the Russian invasion of Ukraine and other major events, the effect on the capital markets and the economy is uncertain, and we may have to deal with a recessionary economy and economic uncertainty including possible material adverse effects upon our business.

Beginning with the Russian invasion of Ukraine, certain events began to affect the global and United States economy including increased inflation, increases in the prices of commodities such as oil and gas, large Western companies ceasing to do business in Russia and uncertain capital markets with declines in leading market indexes. The duration of this war and its impact are at best uncertain and continuation may result in Internet access issues if Russia, for example, began illicit cyber activities. More recently, in March 2023 two major U.S. banks collapsed, while certain other banks began facing extreme financial difficulty and seeking immediate sources of liquidity to remain open. These developments were widely considered a product of the rising interest rates that began in 2022 as the Federal Reserve in U.S. and central banks in other jurisdictions have sought to combat inflation. In the wake of these events, the U.S. and global capital markets have demonstrated substantial volatility, as many investors consider economic outlooks to be uncertain at best. Ultimately the economy may turn into a recession with uncertain and potentially severe impacts upon public the capital markets and us. We cannot predict how this will affect our business, but the impact may be material and adverse.

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 21, 2023, our directors, executive officers and our former Board Chairman, and their respective affiliates, beneficially own approximately 12.6% of our outstanding shares of common stock. As a result, these stockholders, acting together, would have the ability to influence or control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. Dr. Raymond Schinazi, our former Board Chairman, owns approximately 7.9% of our common stock.

Dr. Schinazi and Dr. Philip Frost, a director, and certain other stockholders entered into a Stockholder Rights Agreement in November 2014. This Agreement gives each of Dr. Schinazi (together with certain other stockholders) and Dr. Frost (together with 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.

Future issuances of our common stock or rights to purchase our common stock could cause additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

During the year ended December 31, 2022 we did not conduct public or private offerings of securities. We expect that our current cash position will be sufficient to fund our operations over the next 12 months subject to the many uncertainties and risks that may rise such as those described herein, significant additional capital may be needed in the future to continue our planned operations. To the extent we have raised and continue to raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Future sales of large amounts of our common stock in the public market or a perception that such sales might occur could cause a decrease in our stock price.

As of March 21, 2023, out of approximately 8.1 million shares of common stock outstanding, approximately 6.8 million 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 our officers, directors and one 5% stockholder subject to a voting agreement, who we deem affiliates, are subject to additional restrictions as described below.

In general, Rule 144 provides that any person who is not an affiliate of the Company and has not been an affiliate for 90 days, and who has held restricted common stock for at least six months, is entitled to sell their restricted stock freely, provided that we remain subject to the Exchange Act reporting requirements and stay current in our SEC filings.

The shares of common stock outstanding which are held by affiliates of the Company are subject to additional restrictions. An affiliate may sell the greater of (i) one percent of our outstanding stock or (ii) as long as our common stock is listed on Nasdaq, the average weekly trading volume over a prior four-week period after a six-month holding period with the following restrictions:

(i) we are current in our filings;

(ii) certain manner of sale provisions; and

(iii) filing of Form 144.

Additionally, as of December 31, 2022, we had approximately 350,000 options and 13,000 warrants outstanding that, if fully exercised, would result in the issuance of 363,000 shares of common stock and approximately 484,000 shares of common stock remain available for future grants under the Cocrystal Pharma, Inc. 2015 Equity Incentive Plan.

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

External pressures and requirements which may arise related to, environmental, social and governance ("ESG") matters, and any undertakings or disclosure by us which may result, would expose us to numerous risks, including risks to our reputation and stock price.

Institutional and individual investors are increasingly using ESG screening criteria to determine whether certain equity securities such as our common stock should be included in their investment portfolios, although certain states are resisting using ESG criteria. In recent years, a growing number of investors, regulators, self-regulatory organizations and other stakeholders have expressed an interest in setting often-ambitious ESG goals and to require the provision of new and more robust disclosure and implementation of such goals, including progress toward the goals and other matters of interest to ESG stakeholders. In response, we may voluntarily elect or be required to adopt strategies, policies, or procedures related to ESG matters, in response to new rules or regulations, external pressures or otherwise. Any efforts we may undertake to accomplish and accurately report on ESG goals and objectives could present numerous material operational, reputational, financial, legal and other risks, any of which could have a material negative impact, including on our reputation and stock price. For example, any ESG objectives or policies we implement, be it in response to new laws, regulations or rules (including any that may in the future be implemented by the SEC or Nasdaq), actions taken by self-regulatory organizations, investors or other stakeholders, or otherwise, could cause us to expend significant capital and human resources and/or divert management's attention from central operational matters. Further, any failure by us to accurately disclose and effectively carry out ESG undertakings, which may include forward-looking proposals based on assumptions and subject to factors beyond our control, could expose us to reputational harm, government enforcement or private litigation, and stock price and volume volatility.

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, LLC and Cocrystal Discovery, Inc. mergers and other transactions that have occurred more than seven years ago, 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 generate taxable income, our ability to use our pre-change NOLs 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 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.

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 the stockholders who formerly held our Series A Convertible Preferred Stock, which is no longer authorized. 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.

Our amended and restated Bylaws provide for an exclusive forum in the Court of Chancery of the State of Delaware for certain disputes between us and our stockholders, and the exclusive forum in the Delaware federal courts for the resolution of any complaint asserting a cause of action under the Securities Act and the Exchange Act.

Our amended and restated Bylaws provide that unless the Company consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if such court does not have subject matter jurisdiction thereof, the U.S. District Court of Delaware) will, to the fullest extent permitted by law, be the sole and exclusive forum for: (i) any derivative action or proceeding brought on behalf of the Company (except to the extent that the Exchange Act provides otherwise), (ii) any action asserting a claim of breach of a fiduciary duty owed by any director or officer (or affiliate of any of the foregoing) of the Company to the Company or the Company's stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, the Company's Certificate of Incorporation or Bylaws, or (iv) any other action asserting a claim arising under, in connection with, and governed by the internal affairs doctrine. The amended and restated Bylaws further provide that unless the Company consents in writing to the selection of an alternative forum, the federal district courts of the United States of America located in Delaware will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act or the Exchange Act and any person or entity purchasing or otherwise acquiring or holding any interest in shares of capital stock of the Company will be deemed to have notice of and consented to these provisions.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. If a court were to find the choice of forum provision that is contained in our amended and restated Bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially adversely affect our business, results of operations, and financial condition. For example, Section 22 of the Securities Act provides that state and federal courts have concurrent jurisdiction over claims to enforce any duty or liability created by the Securities Act or the rules and regulations promulgated thereunder. Accordingly, there is uncertainty as to whether a court would enforce such a forum selection provision as written in connection with claims arising under the Securities Act. To date, the Delaware Supreme Court has upheld the exclusive jurisdiction provisions in certificates of incorporation for claims under the Securities Act, but the U.S. Court of Appeals for the Seventh Circuit held that a forum selection clause was unenforceable as to a derivative claim that was brought under the Exchange Act. Further, to date no court has ruled on the exclusive venue provision for claims under the Securities Act. Accordingly, if a stockholder files a Securities Act claim or an Exchange Act claim in a federal court and we seek to rely upon the Delaware venues, we may not be successful.

Because the choice of forum provisions in our Bylaws may have the effect of severing certain causes of action between federal and state courts, stockholders seeking to assert claims against us or any of our current or former directors, officers, other employees, agents, or stockholders, may be discouraged from bringing such claims due to a possibility of increased litigation expenses arising from litigating multiple related claims in two separate courts. Additionally, a stockholder could face uncertainty as to which jurisdiction and venue a case will ultimately be heard in, particularly given that variations in facts, circumstances and the particular provisions at issue often alter the legal analysis and judicial interpretation, which may delay, prevent or impose additional obstacles on the stockholder in such litigation. The choice of forum provisions may therefore limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for, or otherwise present obstacles and challenges in connection with, disputes with us or any of our current or former director, officer, other employee, agent, or stockholder.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

We have operating facilities in Bothell, Washington and Miami, Florida, as well as an administrative facility in Melbourne, Australia.

We lease approximately 9,400 square feet of office and laboratory space in Bothell, Washington under a lease agreement expiring in January 2024.

We also lease office space in Miami, Florida under a lease that expires in August 2024.

The Company believes that its properties are suitable for their intended purposes and have capacities adequate for current and projected needs related to the Company's programs.

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.

Liberty Insurance Underwriters Inc. filed suit against us in federal court in Delaware seeking a declaratory judgment that there was no insurance coverage for any settlement, judgment, or defense costs in the class and derivative litigation, that the monies totaling approximately $1 million it paid to the Company in connection with the SEC investigation were not covered by insurance, and for recoupment of the monies already paid. We have retained counsel to defend us which has filed an answer to the complaint denying its material allegations, as well as a counterclaim against Liberty for breach of contract, declaratory judgment, bad faith and violation of the Washington State Consumer Protection Act, alleging among other things that Liberty wrongfully denied the Company's claims for coverage of the class and derivative litigations, and seeking money damages. Liberty Insurance Underwriters Inc. filed suit against us in federal court in Delaware seeking a declaratory judgment that there was no insurance coverage for any settlement, judgment, or defense costs in the class and derivative litigation, that the monies totaling approximately $1 million it paid to the Company in connection with the SEC investigation were not covered by insurance, and for recoupment of the monies already paid. On June 7, 2022, the court filed a Stipulation and Order for Entry of Judgment in the amount of $1,359,063.72 in favor of Liberty (the "Judgment") following summary judgment granted by the court to Liberty on all but one of the matters at issue in the case. The Company filed an appeal in July 2022. Pending the outcome of the appeal, the Company paid $1.6 million into the registry of the court which stayed execution of the Judgment. The United States Court of Appeals for the Third Circuit (the "Third Circuit") held oral argument on the appeal on March 8, 2023. As of the date of this Report, the Third Circuit has not issued a ruling on the appeal.

In November 2017, Lee Pederson, a former Biozone lawyer, filed a lawsuit in the U.S. District Court in Minnesota against co-defendants the Company, Dr. Phillip Frost, OPKO Health, Inc. and Brian Keller alleging that defendants engaged in wrongful conduct related to Biozone, including causing Biozone to enter into an allegedly improper licensing agreement and engaged in alleged market manipulation ("Pederson I"). On September 13, 2018, the United States District Court granted the Company and its co-defendants' motion to dismiss Pederson's amended complaint in Pederson I for lack of personal jurisdiction in Minnesota. On October 11, 2018, Pederson filed a notice of appeal with the United States Court of Appeals for the Eighth Circuit. The plaintiff's appeal was denied and the dismissal of Pederson I affirmed in March 2020. Meanwhile, in July 2019, Lee Pederson had filed another lawsuit in the U.S. District Court in Minnesota against co-defendants the Company, Dr. Frost, and Daniel Fisher ("Pederson II"). In his complaint in Pederson II, Pederson alleges tortious interference by the Company and Dr. Frost with an alleged collaboration agreement between Mr. Pederson and Mr. Fisher. In Pederson II, Mr. Pederson seeks damages in the amount of $800,000 or such other amount as may be determined at trial. Pederson II had previously been stayed by the court, pending disposition of Pederson I. With that first lawsuit having been dismissed and appeal denied, the stay was lifted in Pederson II, and the Company and all other defendants in that case filed Motions to Dismiss the (then amended) complaint. On November 19, 2020 the Magistrate Judge recommended dismissal of Pederson II, and further recommended that Pederson be restricted from filing any other actions in the District of Minnesota against defendants on the same or similar allegations as those in Pederson II, and on January 4, 2021 the District Court Judge adopted those recommendations and ordered dismissal of Pederson II. On February 1, 2021 Pederson filed a Notice of Appeal from the order of dismissal of Pederson II in the Eighth Circuit, and on December 29, 2021 the Eighth Circuit affirmed the decision of the District Court. Thereafter, on or about January 11, 2022 Pederson sought via petition, re-hearing en banc by the Eighth Circuit. On October 3, 2022, the U.S. Supreme Court denied Pederson's petition for a writ of certiorari.

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

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

Our common stock is traded on The Nasdaq Capital Market under the symbol "COCP". As of March 21, 2023, there were approximately 434 holders of record of our common stock.

Dividend Policy

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

Unregistered sales of equity securities

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

Item 6. Selected Financial Data

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

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

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

Company Overview

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

During fiscal year ended December 31, 2022, the following key aspects of our business advanced:

<u>*Pandemic and Seasonal Influenza A*</u>

- Our novel oral PB2 inhibitor, *CC-42344,* has shown excellent antiviral activity against influenza A strains including pandemic and seasonal strains, as well as strains resistant to Tamiflu® and Xofluza®.
- We initiated enrollment in our randomized, double-controlled, dose-escalating Phase 1 study to evaluate the safety, tolerability and pharmacokinetics of orally administered *CC-42344* in healthy adults.

- In April 2022 we announced preliminary Phase 1 study data, demonstrating a favorable safety and PK profile in the first two cohorts in the single-ascending dose portion of the study.
- In July 2022 we reported PK results from the single-ascending dose of the study supporting once-daily dosing.
- In December 2022 we reported favorable safety and tolerability results from the Phase 1 study with *CC-42344* for influenza A.
- We entered into an agreement with a United Kingdom-based clinical research organization to conduct a human challenge Phase 2a study evaluating safety, viral and clinical measures of orally administered *CC-42344* in influenza A-infected subjects. Under the human challenge model, healthy adults will be infected with the influenza A virus under carefully controlled conditions, which we believe will hasten trial enrollment.
- Preparations made to apply with the United Kingdom Medicines and Healthcare Products Regulatory Agency in the first half of 2023 to conduct a human challenge Phase 2a study. Pending clearance by the agency, we expect to initiate the study in the second half of 2023.
- Preclinical development is underway with an inhaled formulation of *CC-42344* as a treatment and prophylaxis for influenza A.

Pandemic and Seasonal Influenza A/B Program

- Merck Sharp & Dohme Corp. notified the Company that they continue development activities with the compounds discovered under a collaborative Exclusive License and Research Collaboration Agreement to discover and develop certain proprietary influenza antiviral agents that are effective against both influenza A and B strains. This agreement includes milestone payments of up to $156 million plus royalties on sales of products discovered under the agreement.

Oral Protease Inhibitor CDI-988

- We selected *CDI-988* as our lead candidate for development as a potential oral treatment for SARS-CoV-2. *CDI-988*, which was designed and developed using our proprietary structure-based drug discovery platform technology, targets a highly conserved region in the active site of SARS-CoV-2 3CL (main) protease required for viral RNA replication.
- We are currently conducting good laboratory practice (GLP) toxicology studies in preparation for a Phase 1 study.
- Preparations are underway to submit an application to the Australian regulatory authority for a planned randomized, double-blind, placebo-controlled Phase 1 study. Pending regulatory clearance, we expect to initiate the study in the first half of 2023.

Intranasal/Pulmonary Protease Inhibitor CDI-45205

- An IND-enabling study is ongoing with *CDI-45205,* our novel SARS-CoV-2 3CL (main) protease inhibitor being developed as a potential treatment for COVID-19 and its variants.

Replication Inhibitors

- We are using our proprietary structure-based drug discovery platform technology to discover replication inhibitors for orally administered therapeutic and prophylactic treatments for SARS-CoV-2. Replication inhibitors hold potential to work with protease inhibitors in a combination therapy regimen.

Norovirus Program

- We are developing certain proprietary broad-spectrum, non-nucleoside polymerases for the treatment of human norovirus infections using our proprietary structure-based drug design technology platform. We also hold exclusive rights to norovirus protease inhibitors for use in humans under the KSURF license.

Results of Operations

Research and Development Expense

Research and development expenses consist primarily of compensation-related costs for our ten 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 $12,392,000 for the year ended December 31, 2022, compared with $8,794,000 for the year ended December 31, 2021. The increase of $3,598,000 was primarily due to advancing our influenza lead candidate CC-42344 through a Phase 1 trial and preparation for a Phase 2a clinical trial planned for 2023, as well as advancing our lead COVID-19 clinical oral candidate CDI-988 in preparation for a Phase 1 clinical trial planned for 2023.

General and Administrative Expense

General and administrative expenses include 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 $5,745,000 for the year ended December 31, 2022, compared with $5,427,000 for the year ended December 31, 2021. This increase of $318,000 was primarily due professional fees and litigation.

In the ordinary course of business, the Company entered into non-cancellable related party leases for its facilities (see Note 13 – Transactions with Related Parties in the following Consolidated Financial Statements).

Goodwill Impairment

During the six months ended June 30, 2022, the Company saw a significant decrease in its price of common stock resulting in an overall reduction in market capitalization and our recorded net book value exceeded our market capitalization as of June 30, 2022. Pre-impairment, the carrying value of the reporting unit exceeded the market capitalization of the Company at June 30, 2022 and concluded that goodwill was impaired in its entirety and recorded during the second quarter ended June 30, 2022 a $19,092,000 non-cash impairment. As of December 31, 2022, the Company had no remaining goodwill.

Legal Settlement

In July 2022, the Company filed a legal appeal and deposited $1,600,000 with the United State District Court for the District of Delaware as security during pending our appeal. During the second quarter ended June 30, 2022, the Company recorded a legal judgement for this amount inclusive of estimated costs.

Interest Income/Expense

Interest expense was $2,000 for the year ended December 31, 2022, compared to $4,000 for the year ended December 31, 2021. The interest expense in 2022 and 2021 is related to lease agreements.

Other Income/Expense

Other income/expense, net, was an expense of $8,000 for the year ended December 31, 2022 compared with income of $36,000 for the year ended December 31, 2021. This year-over-year change primarily consisted of recognized non-cash changes in the fair value of our derivative liabilities as our stock price fluctuated. 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 increases during a period, which occurred during the year ended December 31, 2022, 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.

Net Loss

We had a net loss of $38,837,000 for the year ended December 31, 2022, compared to a net loss of $14,185,000 for the year ended December 31, 2021. This increase of $24,652,000 was primarily due to a $19,092,000 non-cash impairment-loss of goodwill and increased research and development expenses as we continue in our efforts to advance CC-42344, CDI-988 and other product candidates.

Liquidity and Capital Resources

For the year ended December 31, 2022, net cash used in operating activities was $21,435,000, compared to net cash used in operating activities of $12,719,000 for the year ended December 31, 2021. The increase in cash used in operating activities in 2022 as compared to 2021 was attributable to the increase of operating costs related to our COVID-19 and influenza-A clinical trials.

For the year ended December 31, 2022, net cash used in investing activities netted to $74,000, which consisted of capital expenditures for lab equipment, software, and networking for our Lab located in Bothell, Washington. For the year ended December 31, 2021, our net cash used in investing activities consisted of $52,000.

For the year ended December 31, 2022, net cash used by financing activities was $27,000, compared to net cash provided by financing activities of $38,466,000 for the year ended December 31, 2021. Net cash used by financing activities in 2022 was result of finance lease payments, and 2021 net cash generated was the result of issuance common stock, net of finance lease payments.

The Company had approximately $35 million cash on hand on March 21, 2023. We expect that this cash balance will be sufficient to support the Company's working capital needs for the 12 months following the filing of this Report.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is capital-intensive. As a rule, research and development expenses increase substantially as a company advances a product candidate toward clinical programs. Historically, we have financed our operations with the proceeds from public and private equity and debt offerings, including additional investments by certain existing stockholders, and entered into strategic partnerships and collaborations for the research, development and commercialization of product candidates. We have one hepatitis C product candidate that has completed a Phase 2a clinical trial and one influenza A product candidate that has completed a Phase 1 trial and is expected to proceed to Phase 2a in 2023, as well as other influenza A/B product candidates under our Collaboration Agreement with Merck. Additionally, we expect that in the long term in case of successful development and commercialization of one or more influenza A/B antiviral agents under the Collaboration Agreement we will be eligible to receive certain milestone payments up to a total of $156 million, including payments associated with the successful product development and attainment of certain U.S. and EU regulatory approvals for the developed products and sales volume and royalties on net sales of the products. See "Item 1 – Business – Collaborations – Merck Collaboration." However, in order to conduct research and development of our other product candidates, including our potential COVID-19 therapy, we may need to raise additional capital to support our operations or form partnerships, in addition to our existing collaborative alliances. Such funding or partnerships may not be available to us on acceptable terms, or at all.

We did not raise any proceeds from the sale of common stock during the year ended December 31, 2022. Set forth below is a summary of financings which occurred since 2020.

The Company is party to the At-The-Market Offering Agreement, dated July 1, 2020 ("ATM Agreement") with H.C. Wainwright & Co., LLC ("Wainwright"), pursuant to which the Company may issue and sell over time and from time to time, to or through Wainwright, up to $10,000,000 of shares of the Company's common stock. In January 2021, the Company sold 1,030,000 shares of its common stock pursuant to the ATM Agreement for net proceeds of approximately $2.1 million. There were no sales under the ATM Agreement for the remainder of 2021 or 2022.

On May 4, 2021, the Company entered into an underwriting agreement with Wainwright pursuant to which the Company agreed to issue and sell 26,000,000 shares of the Company's common stock at a public offering price of $1.54 per share, less underwriting discounts and commissions (the "Offering"). The Company received approximately $36.4 million in net proceeds from the Offering, after deducting underwriting discounts and estimated offering expenses. The Offering closed on May 7, 2021.

Cautionary Note Regarding Forward Looking Statements

This Annual Report includes forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, including statements regarding our plans for the future development of preclinical and clinical drug candidates, our expectations regarding future characteristics of the product candidates we develop, the expected time of achieving certain value driving milestones in our programs, including, preparation, commencement and advancement of clinical studies for certain product candidates in 2023, our expectations with respect to HCV market opportunity and our plans regarding further clinical development of CC-31244, the potential future results of our collaboration with Merck pursuant to the Collaboration Agreement, including potential receipt of milestone payments and royalties, our expectations related to our collaborations with KSURF, our expectations regarding future operating results, statement regarding the suitability and adequacy of our properties and capital resources, anticipated payments under the license agreements with KSURF, and our future liquidity.

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

The results anticipated by any or all of these forward-looking statements might not occur. Important factors, uncertainties and risks that may cause actual results to differ materially from these forward-looking statements include the risks and uncertainties arising from the risks arising from the impact of COVID-19 (including long-term and pervasive effects of the virus), inflation, interest rate increases and the Ukraine war on our Company, our collaboration partners, and on the U.S., U.K. and global economy, including manufacturing and research delays arising from raw materials and labor shortages, supply chain disruptions and other business interruptions including any adverse impacts on our ability to obtain raw materials and test animals as well as similar problems with our vendors and our current and any future CROs and CMOs, the results of the studies for CC-42344 and CDI-988, the ability of our CROs to recruit volunteers for, and to proceed with, clinical studies, our reliance on Merck for further development in the influenza A/B program under the license and collaboration agreement, our and our collaboration partners' technology and software performing as expected, financial difficulties experienced by certain partners, the results of future preclinical and clinical trials, general risks arising from clinical trials, receipt of regulatory approvals, regulatory changes, development of effective treatments and/or vaccines by competitors, including as part of the programs financed by the U.S. government, potential mutations in a virus we are targeting which may result in variants that are resistant to a product candidate we develop, and the outcome of our appeal of the summary judgment. Further information on such uncertainties and risks is contained in the "Risk Factors" in Item 1A of this this Annual Report. We undertake no obligation to publicly update or revise any forward-looking statements, whether as the result of new information, future events or otherwise. For more information regarding some of the ongoing risks and uncertainties of our business, see "Item 1A – Risk Factors" and our other filings with the SEC.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. Generally Accepted Accounting Principles, or GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate these estimates and judgments, including those described below. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates. While our significant accounting policies are more fully described in the accompanying notes to the consolidated financial statements included in this Annual Report on Form 10-K for the year ended December 31, 2022, 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 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.

Goodwill

In November 2014, goodwill was recorded in connection with the acquisition of RFS Pharma.

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

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

The Company uses judgement in assessing whether assets may have become impaired between annual impairment tests. The occurrence of a change in circumstances, such as a continued decline in the market capitalization of the Company, would determine the need for impairment testing between annual impairment tests. During the six months ended June 30, 2022, the Company saw a significant decrease in its price of common stock resulting in an overall reduction in market capitalization and our recorded net book value exceeded our market capitalization as of June 30, 2022. Pre-impairment, the carrying value of the reporting unit exceeded the market capitalization of the Company at June 30, 2022 and concluded that goodwill was impaired in its entirety and recorded a $19,092,000 non-cash impairment. On December 31, 2022, the Company had no goodwill.

Recently Issued Accounting Standards

See discussion in Note 2 to the consolidated financial statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 8. Financial Statements

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

COCRYSTAL PHARMA, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Cocrystal Pharma, Inc. (the "Company") and subsidiaries as of December 31, 2022 and 2021, the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board of the United States ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate to accounts or disclosures that are material to the financial statements and (2) involved especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Goodwill Impairment Assessment

As described in Note 5 to the consolidated financial statements, the Company's consolidated net goodwill balance was $19,092 as of December 31, 2021. Management tests its goodwill for impairment on November 30 or more frequently if circumstances indicate that the carrying value of a reporting unit may exceed its fair value. If the carrying amount of the Company, as a sole reporting unit, including goodwill, exceeds its fair value, an impairment loss is recognized in an amount equal to that excess up to the amount of the recorded goodwill. During the second quarter of 2022, the Company experienced a sustained decrease in its share price, and as of June 30, 2022, the Company's market capitalization was below the carrying value of the Company's net assets. Pursuant to current accounting guidance, management concluded that this was an impairment triggering event, and performed an impairment assessment of its goodwill. Based on the results of the impairment assessment, management determined that its goodwill was impaired and recognized an impairment charge of $19,092 related to goodwill during the year ended December 31, 2022. Following the impairment, the Company had no remaining goodwill as of December 31, 2022.

We identified the evaluation of goodwill impairment as a critical audit matter because of the significant judgment by management when determining the fair value of the reporting unit. This required a high degree of auditor judgment and increased auditor effort in auditing such assumptions.

The primary procedures we performed to address this critical audit matter included: (i) obtained an understanding of management's process for determining the fair value of the reporting unit, (ii) We evaluated the allocation of the Company's estimated fair value to its reporting units and the comparison of the Company's estimated fair value to its market capitalization, and (iii) we recalculated the impairment recorded for goodwill of $19,092 based on the excess of the carrying values of goodwill over its estimated fair value as of December 31, 2022.

We have served as the Company's auditor since 2019.

/s/ Weinberg & Company
Los Angeles, California
March 29, 2023

COCRYSTAL PHARMA, INC.

CONSOLIDATED BALANCE SHEETS
(in thousands, except per share data)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash	$ 37,144	$ 58,705
Restricted cash	75	50
Tax credit receivable	716	-
Prepaid expenses and other current assets	2,243	568
Total current assets	40,178	59,323
Property and equipment, net	342	453
Deposits	46	46
Operating lease right-of-use assets, net (including $99 and $153 to related party)	274	478
Goodwill	-	19,092
Total assets	$ 40,840	$ 79,392
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 976	$ 1,297
Current maturities of finance lease liabilities	7	27
Current maturities of operating lease liabilities (including $59 and $53 to related party)	233	209
Derivative liabilities	-	12
Total current liabilities	1,216	1,545
Long-term liabilities:		
Finance lease liabilities	-	7
Operating lease liabilities (including $42 and $101 to related party)	57	291
Total long-term liabilities	57	298
Total liabilities	1,273	1,843
Commitments and contingencies		
Stockholders' equity:		
Common stock $0.001 par value; 150,000 shares authorized as of December 31, 2022 and December 31, 2021, respectively; 8,143 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	8	8
Additional paid-in capital	337,489	336,634
Accumulated deficit	(297,930)	(259,093)
Total stockholders' equity	39,567	77,549
Total liabilities and stockholders' equity	$ 40,840	$ 79,392

See accompanying notes to consolidated financial statements.

COCRYSTAL PHARMA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	December 31,	
	2022	2021
Operating expenses:		
Research and development	$ 12,392	$ 8,794
General and administrative	5,745	5,427
Legal settlement	1,600	-
Impairments	19,092	-
Total operating expenses	38,829	14,221
Loss from operations	(38,829)	(14,221)
Other (expense) income:		
Interest expense, net	(2)	(4)
Change in fair value of derivative liabilities	12	49
Foreign exchange loss	(18)	(9)
Total other income (expense), net	(8)	36
Net loss	$ (38,837)	$ (14,185)
Net loss per common share:		
Loss per share, basic and diluted	$ (4.77)	$ (0.16)
Weighted average number of common shares outstanding, basic and diluted	8,143	7,364

See accompanying notes to consolidated financial statements.

COCRYSTAL PHARMA, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance as of December 31, 2020	5,891	6	297,407	(244,908)	52,505
Stock-based compensation	-	-	724	-	724
Sale of common stock, net of transaction costs	2,252	2	38,503	-	38,505
Net loss	-	-	-	(14,185)	(14,185)
Balance as of December 31, 2021	8,143	$ 8	$ 336,634	$ (259,093)	$ 77,549
Stock-based compensation	-	-	855	-	855
Net loss	-	-	-	(38,837)	(38,837)
Balance as of December 31, 2022	8,143	$ 8	$ 337,489	$ (297,930)	$ 39,567

See accompanying notes to consolidated financial statements.

COCRYSTAL PHARMA, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	December 31,	
	2022	2021
Operating activities:		
Net loss	$ (38,837)	$ (14,185)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	185	190
Right of use assets	203	192
Loss on impairment of goodwill	19,092	-
Stock-based compensation	855	724
Change in operating lease liabilities	(209)	(195)
Change in fair value of derivative liabilities	(12)	(49)
Changes in operating assets and liabilities:		
Accounts receivable	-	556
Tax credit receivable	(716)	-
Prepaid expenses and other current assets	(1,675)	(169)
Accounts payable and accrued expenses	(321)	(217)
Net cash used in operating activities	(21,435)	(12,719)
Investing activities:		
Purchases of property and equipment	(74)	(52)
Net cash used in investing activities	(74)	(52)
Financing activities:		
Payments of finance lease obligations	(27)	(39)
Proceeds from sale of common stock, net of transaction costs	-	38,505
Net cash provided by (used in) financing activities	(27)	38,466
Net increase (decrease) in cash and restricted cash	(21,536)	25,695
Cash and restricted cash at beginning of period	58,755	33,060
Cash and restricted cash at end of period	$ 37,219	$ 58,755
SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING ACTIVITIES:		
Recognition of operating lease right-of-use assets and operating lease liabilities	$ -	$ 171

See accompanying notes to consolidated financial statements.

1. Organization and Business

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

In September 2021, the Company opened a wholly owned foreign subsidiary in Australia named Cocrystal Pharma Australia, Ltd ("Cocrystal Australia") with the objective of operating clinical trials in Australia.

On September 27, 2022, the Company filed a Certificate of Amendment to the Certificate of Incorporation (the "Amendment") with the Delaware Secretary of State to effect a reverse stock split of all outstanding shares of the Company's common stock at a ratio of one-for-12. At the Company's 2022 Annual Meeting of Stockholders, holders of a majority of the outstanding voting power approved an amendment to the Certificate of Incorporation of the Company to effect a reverse stock split of all outstanding shares of our common stock at a ratio to be determined by the Board of Directors within a range of one-for-four through one-for-12. Following such approval, The Board of Directors determined to effect the reverse stock split at the ratio of one-for-12. The Amendment became effective October 11, 2022 and the effect of the reverse stock split was reflected on the Nasdaq Stock Market.

All share and per share amounts have been retroactively restated to reflect the one-for-12 stock split as if it occurred at the beginning of the earliest period presented.

Liquidity

The Company's consolidated financial statements are prepared using generally accepted accounting principles in the United States of America applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred net losses and negative operating cash flows since inception. For the year ended December 31, 2022, the Company recorded a net loss of approximately $38,837,000 and used approximately $21,435,000 of cash in operating activities.

On December 31, 2022, the Company had cash and cash equivalents of approximately $37,219,000. We believe that our current resources will be sufficient to fund our operations beyond the next 12 months. This estimate is based, in part, upon our currently projected expenditures.

The Company's activities since inception have principally consisted of acquiring product and technology rights, raising capital, and performing research and development. Successful completion of the Company's development programs, obtaining regulatory approvals of its products and, ultimately, the attainment of profitable operations is dependent on future events, including, among other things, its ability to access potential markets, secure financing, develop a customer base, attract, retain and motivate qualified personnel, and develop strategic alliances. Through December 31, 2022, the Company has primarily funded its operations through equity offerings.

The Company will need to continue obtaining adequate capital to fund operating losses until it becomes profitable. The Company can give no assurances that the additional capital it is able to raise, if any, will be sufficient to meet its needs, or that any such financing will be obtainable on acceptable terms. Our future cash requirements, and the timing of those requirements, will depend on a number of factors, including economic conditions, the evolving impact of the COVID-19 pandemic on our business, the approval and success of our products in development, the continued progress of research and development of our product candidates, the timing and outcome of clinical trials and regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights, the status of competitive products, the availability of financing, our success in developing markets for our product candidates and legal proceedings that may arise. We have historically not generated sustained positive cash flow and if we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical trials or research and development programs. If the Company is unable to obtain adequate capital, it could be forced to cease operations or substantially curtail its drug development activities. The Company expects to continue incurring substantial operating losses and negative cash flows from operations over the next several years during its pre-clinical and clinical development phases.

Additionally, the rapid development and fluidity of the COVID-19 pandemic and new variants of the virus makes it very difficult to predict its ultimate impact on our business, results of operations and liquidity. The pandemic presents a significant uncertainty that could materially and adversely affect our results of operations, financial condition and cash flows. The combination of potential disruptions to our business resulting from COVID-19 together with and volatile credit and capital markets could adversely impact our future liquidity, which could have an adverse effect on our business and results of operations. We will continue to monitor and assess the impact COVID-19 and new variants of the virus may have on our business and financial results.

2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

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

Principles of Consolidation

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

Segments

The Company operates in one segment. In accordance with the "Segment Reporting" Topic of the ASC, the Company's chief operating decision makers have been identified as the Co-Chief Executive Officers, who review operating results to make decisions about allocating resources and assessing performance for the entire Company. Existing guidance, which is based on a management approach to segment reporting, establishes requirements to report selected segment information quarterly and to report annually entity-wide disclosures about products and services, major customers, and the countries in which the entity holds material assets and reports revenue. All material operating units qualify for aggregation under "Segment Reporting" due to their similar customer base and similarities in: economic characteristics; nature of products and services; and procurement, manufacturing and distribution processes. Since the Company operates in one segment, all financial information required by "Segment Reporting" can be found in the accompanying consolidated financial statements.

Use of Estimates

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

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash deposited in accounts held at two U.S. financial institutions, which may, at times, exceed federally insured limits of $250,000 for each institution accounts are held. At December 31, 2022 and 2021, our primary operating account held approximately $37,144,000 and $58,705,000, respectively, and our collateral account balance of $75,000 as of December 31, 2022 and other cash accounts are maintained at different institutions. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risks thereof.

Risks and Uncertainties

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

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

Cash and Restricted Cash

The Company considers all highly liquid investments with an original maturity from the date of purchase of three months or less to be cash equivalents, and the Company held no cash equivalents as of December 31, 2022 and 2021.

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

	December 31, 2022	December 31, 2021
Cash	$ 37,144	$ 58,705
Restricted cash	75	50
Total cash and restricted cash shown in the statements of cash flows	$ 37,219	$ 58,755

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

Property and Equipment

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

Fair Value Measurements

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

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

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

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

The Company categorizes its cash and restricted cash as Level 1 fair value measurements. The Company categorizes its warrants potentially settleable in cash as Level 3 fair value measurements. The warrants potentially settleable in cash are measured at fair value on a recurring basis and are being marked to fair value at each reporting date until they are completely settled or meet the requirements to be accounted for as component of stockholders' equity. The warrants are valued using the Black-Scholes option pricing model as discussed in Note 9 – Warrants.

At December 31, 2022 and 2021, the carrying amounts of financial assets and liabilities, such as cash, accounts receivable, other assets, and accounts payable and accrued expenses approximate their fair values due to their short-term nature. The carrying values of notes payable approximate their fair values due to the fact that the interest rates on these obligations are based on prevailing market interest rates.

The Company has not transferred any financial instruments into or out of Level 3 classification during the years ended December 31, 2022 and 2021. A reconciliation of the beginning and ending Level 3 liabilities for is as follows (in thousands):

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)	
	2022	2021
Balance, January 1,	$ 12	$ 61
Change in fair value of warrants potentially settleable in cash (Note 9)	(12)	(49)
Balance at December 31,	$ 0	$ 12

Goodwill

In November 2014, goodwill was recorded in connection with the acquisition of RFS Pharma.

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

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

Long-Lived Assets

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

Patent and Licensing Related Legal and Filing Costs

Due to the significant uncertainty associated with the successful development of one or more commercially viable products based on the Company's research efforts and related patent applications, all patent-related legal and filing fees and licensing-related legal fees are charged to operations as incurred. Patent and licensing-related legal and filing costs were $506,000 and $533,000 for the years ended December 31, 2022 and 2021, respectively. Patent and licensing related legal and filing costs are included in general and administrative costs in the Company's consolidated statements of operations.

Research and Development Expenses

Research and development costs consist primarily of fees paid to consultants and outside service providers, and other expenses relating to the acquisition, design, development and testing of the Company's clinical products. All research and development costs are expensed as incurred. Research and development costs are presented net of tax credits.

The Company's Australian subsidiary is entitled to receive government assistance in the form of refundable and non-refundable research and development tax credits from the federal and provincial taxation authorities, based on qualifying expenditures incurred during the fiscal year. The refundable credits are from the provincial taxation authorities and are not dependent on its ongoing tax status or tax position and accordingly are not considered part of income taxes. The Company records refundable tax credits as a reduction of research and development expenses when the Company can reasonably estimate the amounts and it is more likely than not, they will be received. During the year ended December 31, 2022, the Company recorded tax credits of $805,000 as a reduction of research and development expense, of which approximately $716,000 was recorded as tax credit receivable as of the year then ended.

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 periodically issues stock-based compensation to officers, directors, and consultants for services rendered. Such issuances vest and expire according to terms established at the issuance date.

Stock-based payments to employees, directors, and for acquiring goods and services from nonemployees, which include grants of employee stock options, are recognized in the financial statements based on their grant date fair values in accordance with ASC 718, Compensation-Stock Compensation. Stock option grants to employees, which are generally time vested, are measured at the grant date fair value and depending on the conditions associated with the vesting of the award, compensation cost is recognized on a straight-line or graded basis over the vesting period. Recognition of compensation expense for non-employees is in the same period and manner as if the Company had paid cash for the services. The fair value of stock options granted is estimated using the Black-Scholes option-pricing model, which uses certain assumptions related to risk-free interest rates, expected volatility, expected life, and future dividends. The assumptions used in the Black-Scholes option pricing model could materially affect compensation expense recorded in future periods.

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 the 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.

Net Income (Loss) per Share

The Company accounts for and discloses net income (loss) per common share in accordance with FASB ASC Topic 260, *Earnings Per Share*. Basic income (loss) per common share is computed by dividing income (loss) attributable to common stockholders by the weighted average number of common shares outstanding. Diluted net income (loss) per common share is computed by dividing net income (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.

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):

	December 31,	
	2022	2021
Outstanding options to purchase common stock	350	206
Warrants to purchase common stock	13	20
Total	363	226

Recent Accounting Pronouncements

The following are new FASB Accounting Standards Updates that have not been adopted by the Company as of December 31, 2022, and contain detail regarding the effective dates:

In June 2016, the FASB issued ASU No. 2016-13, Credit Losses - Measurement of Credit Losses on Financial Instruments ("ASC 326"). The standard significantly changes how entities will measure credit losses for most financial assets, including accounts and notes receivable. The standard will replace today's "incurred loss" approach with an "expected loss" model, under which companies will recognize allowances based on expected rather than incurred losses. Entities will apply the standard's provisions as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective. The standard is effective for interim and annual reporting periods beginning after December 15, 2019. The adoption of ASU 2016-13 is not expected to have a material impact on the Company's financial position, results of operations, and cash flows.

In August 2020, the FASB issued ASU 2020-06, Debt — Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU 2020-06"). ASU 2020-06 simplifies the accounting for convertible debt by eliminating the beneficial conversion and cash conversion accounting models. Upon adoption of ASU 2020-06, convertible debt proceeds, unless issued with a substantial premium or an embedded conversion feature that is not clearly and closely related to the host contract, will no longer be allocated between debt and equity components. This modification will reduce the issue discount and result in less non-cash interest expense in financial statements. ASU 2020-06 also updates the earnings per share calculation and requires entities to assume share settlement when the convertible debt can be settled in cash or shares. For contracts in an entity's own equity, the type of contracts primarily affected by ASU 2020-06 are freestanding and embedded features that are accounted for as derivatives under the current guidance due to a failure to meet the settlement assessment by removing the requirements to (i) consider whether the contract would be settled in registered shares, (ii) consider whether collateral is required to be posted, and (iii) assess stockholder rights. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, and only if adopted as of the beginning of such fiscal year. The Company adopted ASU 2020-06 effective January 1, 2021. The adoption of ASU 2020-06 did not have any impact on the Company's consolidated financial statement presentation or disclosures.

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

3. Foreign Currency Remeasurement

The U.S. dollar has been determined to be the functional currency for the net assets of Cocrystal Australia operations. The transactions are recorded in the local currencies and are remeasured at each reporting date using the historical rates for nonmonetary assets and liabilities and current exchange rates for monetary assets and liabilities at the balance sheet date. Exchange gains and losses from the remeasurement of monetary assets and liabilities are recognized in other income (loss). The Company recognized an income (loss) of approximately $(18,161) and $(8,631) for the years ended December 31, 2022 and 2021, respectively.

As of December 31, 2022 and 2021, the Company's cash balances consisted of the following (in thousands):

	2022	**2021**
U.S. Dollars	$ 37,177	$ 58,741
Australian Dollars – in US $	42	14
Cash Balance	$ 37,219	$ 58,755

4. Property and Equipment

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

	2022	2021
Lab equipment (excluding equipment under finance leases)	$ 1,631	$ 1,557
Finance lease right-of-use lab equipment obtained in exchange for finance lease liabilities, net	194	194
Computer and office equipment	131	131
Total property and equipment	1,956	1,882
Less accumulated depreciation	(1,614)	(1,429)
Property and equipment, net	$ 342	$ 453

Depreciation expense was $185,000 and $190,000 for the years ended December 31, 2022 and 2021, respectively.

5. Goodwill

The Company completed its annual impairment test in November 2021, and at that time determined the fair value of its reporting unit, as determined utilizing both the Company's Nasdaq market capitalization and an income approach analysis; exceeded the carrying value of the reporting unit as of December 31, 2021; therefore, management did not consider the $19,092,000 of goodwill to be impaired.

The Company uses judgement in assessing whether assets may have become impaired between annual impairment tests. The occurrence of a change in circumstances, such as a continued decline in the market capitalization of the Company, would determine the need for impairment testing between annual impairment tests. During the six months ended June 30, 2022, the Company saw a significant decrease in its price of common stock resulting in an overall reduction in market capitalization and our recorded net book value exceeded our market capitalization as of June 30, 2022. Pre-impairment, the carrying value of the reporting unit exceeded the market capitalization of the Company at June 30, 2022 and management concluded that goodwill was impaired in its entirety and recorded a $19,092,000 non-cash impairment.

As of December 31, 2022, the Company had no remaining goodwill.

6. Accounts Payable and Accrued Expenses

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

	2022	2021
Accounts payable	$ 614	$ 578
Accrued compensation	130	104
Accrued other expenses	232	615
Total accounts payable and accrued expenses	$ 976	$ 1,297

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

7. Common Stock

As of December 31, 2022, the Company has authorized 150,000,000 shares of common stock, $0.001 par value per share. The Company had approximately 8,143,000 shares issued and outstanding as of December 31, 2022 and 2021, respectively.

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

The Company was a party to the At-The-Market Offering Agreement, dated July 1, 2020 ("ATM Agreement") with H.C. Wainwright & Co., LLC ("Wainwright"), pursuant to which the Company may issue and sell over time and from time to time, to or through Wainwright, up to $10,000,000 of shares of the Company's common stock. During January 2021, the Company sold 85,834 shares of its common stock pursuant to the ATM Agreement for net proceeds of approximately $2.1 million. There were no sales under the ATM Agreement during the remainder of 2021 or 2022.

On May 4, 2021, the Company entered into an underwriting agreement with H.C. Wainwright & Co., LLC, pursuant to which the Company agreed to issue and sell 2,167,000 shares of the Company's common stock at a public offering price of $18.48 per share, less underwriting discounts and commissions (the "Offering"). The Company received approximately $36.4 million in net proceeds from the Offering, after deducting underwriting discounts and estimated offering expenses. The Offering closed on May 7, 2021.

8. Stock Based Awards

Equity Incentive Plans

The Company adopted an equity incentive plan in 2007 (the "2007 Plan"). The 2007 Plan has expired, and the Company no longer issues any awards under the 2007 Plan. As of December 31, 2022, there are 424 outstanding incentive stock options granted under the 2007 Plan that are eligible to purchase shares of the Company's common stock. The maximum term of options granted under the 2007 Plan was ten years.

The Company adopted a second equity Incentive plan in 2015 (the "2015 Plan") under which 833,333 shares of common stock have been reserved for issuance to employees, and non-employee directors and consultants of the Company. Recipients of incentive stock options granted under the 2015 Plan shall be eligible to purchase shares of the Company's common stock at an exercise price equal to no less than the estimated fair market value of such stock on the date of grant. The maximum term of options granted under the 2015 Plan is ten years. The options generally vest 25% after one year, with the remaining balance vesting monthly over the following three years. As of December 31, 2022, approximately 483,833 million options remain available for future grant under the 2015 Plan.

The following table summarizes stock option transactions for the 2007 Plan and 2015 Plan, collectively, for the years ended December 31, 2022 and 2021 (table in thousands, except per share amounts):

	Number of Shares Available for Grant	Total Options Outstanding	Weighted Average Exercise Price	Aggregate Intrinsic Value
Balance at December 31, 2020	190	148	$ 30.36	$ 29
Increase in authorized options	416	-	-	-
Granted	(87)	86	13.32	-
Expired	81	-	-	-
Cancelled	29	(29)	26.16	-
Balance at December 31, 2021	629	205	$ 23.76	$ -
Increase in authorized options	-	-	-	-
Granted	(158)	158	5.04	-
Expired	12	(12)	33.24	-
Cancelled	1	(1)	15.36	9
Balance at December 31, 2022	484	350	$ 15.36	$ 9

During the year ended December 31, 2022 the Company granted stock options to officers, directors, employees and consultants to purchase a total of 158,012 shares of common stock. The options have an exercise price of $5.04 per share, expire in ten years, and vest as follows: one half vests on the one-year anniversary of the grant date and the remainder will vest in eight equal quarterly increments with the first such quarterly increment vesting on September 30, 2022. The total fair value of these options at the grant date was approximately $633,000 using the Black-Scholes Option pricing model. The Black-Scholes option pricing model includes the following weighted average assumptions for grants made during the year ended December 31, 2022:

Assumptions:	
Weighted average per share grant date fair value	$ 12.01
Risk-free interest rate	2.89%
Expected dividend yield	0.00%
Expected volatility	111.96%
Expected terms (in years)	5.83

During the year ended December 31, 2021 the Company granted stock options to officers, directors, employees and consultants to purchase a total of 86,170 shares of common stock. The options have an exercise price of $13.32 per share, expire in ten years, and vest as follows: one half vests on the one-year anniversary of the grant date and the remainder will vest in eight equal quarterly increments with the first such quarterly increment vesting on September 30, 2021. The total fair value of these options at the grant date was approximately $965,000 using the Black-Scholes Option pricing model. The Black-Scholes option pricing model includes the following weighted average assumptions for grants made during the year ended December 31, 2021:

Assumptions:	
Weighted average per share grant date fair value	$ 11.16
Risk-free interest rate	0.91%
Expected dividend yield	0.00%
Expected volatility	114.62%
Expected terms (in years)	5.83

For the years ended December 31, 2022 and 2021, equity-based compensation expense for options vesting during the period was $855,000 and $724,000, respectively.

As of December 31, 2022, there was $1,052,000 of total unrecognized compensation expense related to non-vested stock options that is expected to be recognized over a weighted average period of 2.8 years. For options granted and outstanding, there were 349,901 options outstanding which were fully vested or expected to vest, with an aggregate intrinsic value of $0, a weighted average exercise price of $14.98, and weighted average remaining contractual term of 8.4 years at December 31, 2022. For vested and exercisable options, outstanding shares totaled 140,359, with an aggregate intrinsic value of $0.00. These options had a weighted-average exercise price of $26.53 per share and a weighted-average remaining contractual term of 7.2 years at December 31, 2022.

The aggregate intrinsic value of outstanding and exercisable options at December 31, 2022 was calculated based on the closing price of the Company's common stock as reported on the Nasdaq Capital Market on December 31, 2022 of approximately $1.95 per share less the exercise price of the options. The aggregate intrinsic value is calculated based on the positive difference between the closing fair market value of the Company's common stock and the exercise price of the underlying options.

Common Stock Reserved for Future Issuance

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

	2022	2021
Stock options issued and outstanding	350	206
Shares authorized for future option grants	484	628
Warrants outstanding	20	20
Total	854	854

9. 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, 2022 and 2021 (table in thousands):

	Warrants Accounted for as: Equity	**Warrants Accounted for as: Liabilities**		
	May 2018 Warrants	October 2013 Warrants	January 2014 Warrants	Total
Outstanding, December 31, 2020	7	2	11	20
Exercised	-	-	-	-
Granted	-	-	-	-
Expired	-	-	-	-
Outstanding, December 31, 2021	7	2	11	20
Exercised	-	-	-	-
Granted	-	-	-	-
Expired	(7)	-	-	(7)
Outstanding, December 31, 2022	-	2	11	13
Expiration date	Oct 27, 2022	Oct 24, 2023	Jan 16, 2024	

Warrants outstanding as of December 31, 2022 and 2021 included warrants with the potential to be settled in cash, which are liability-classified warrants. As of December 31, 2021, 13,268 warrants are accounted for as liabilities and 6,732 warrants are accounted for as equity. During the year ended December 31, 2022, the 6,732 warrants accounted as equity expired and the 13,268 warrants accounted for as liabilities remained outstanding as of December 31, 2022.

Warrants Classified as Liabilities

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

The estimated fair value of outstanding warrants accounted for as liabilities is determined at each balance sheet date. Any decrease or increase in the estimated fair value of the warrant liability since the most recent balance sheet date is recorded in the consolidated statement of operations as changes in fair value of derivative liabilities. The fair value of the warrants classified as liabilities is estimated using the Black-Scholes option-pricing model with the following inputs as of December 31, 2022:

	October 2013 Warrants	January 2014 Warrants
Strike price	$ 180.00	$ 180.00
Expected dividend yield	0.00%	0.00%
Expected term (years)	0.8	1.0
Cumulative volatility	143.06%	145.00%
Risk-free rate	4.42%	4.40%
Fair value (in thousands)	$ -	$ -

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, 2021:

	October 2013 Warrants	January 2014 Warrants
Strike price	$ 180.00	$ 180.00
Expected dividend yield	0.00%	0.00%
Expected term (years)	1.8	2.0
Cumulative volatility	129.65%	128.17%
Risk-free rate	0.06%	0.08%
Fair value (in thousands)	$ 2	$ 10

The Company estimates volatility using its own historical stock price volatility based upon the range of periods consistent with the expected life of the warrants. 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.

10. Licenses and Collaborations

Merck Sharp & Dohme Corp.

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

The Company did not recognize revenue for the years ended December 31, 2022 and 2021 As of December 31, 2022 and 2021, the Company did not report accounts receivable from Merck.

Kansas State University Research Foundation

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

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

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

On April 17, 2020, the Company entered into an Agreement with Foundation effective April 1, 2020. Pursuant to the terms of the Agreement, the Foundation granted the Company an exclusive for human use a royalty bearing license to practice under certain patent rights, including a patent and a patent application covering antiviral compounds against coronaviruses and norovirus, and related know-how, to make and sell therapeutic, diagnostic and prophylactic products.

The Company agreed to pay the Foundation a one-time non-refundable license initiation fee in the amount of $110,000 and an annual license maintenance fee in the amount of $20,000 per year for the first seven (7) years and $50,000 per year thereafter and agreed to reimburse the Foundation for third party expenses associated with the filing, prosecution and maintenance of the patent rights in question. The Company also agreed to make certain future milestone payments up to $4,150,000, dependent upon the progress of clinical trials, regulatory approvals, and initiation of commercial sales in the United States and certain countries outside the United States. As of December 31, 2022, no milestone payments were due under the agreement.

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

Phase 2a Clinical Trial

On August 3, 2022 the Company engaged hVIVO, a subsidiary of London-based Open Orphan plc (AIM: ORPH), a rapidly growing specialist contract research organization (CRO), to conduct a Phase 2a clinical trial with the Company's novel, broad-spectrum, orally administered antiviral influenza candidate. The Company paid a reservation fee of $1.7 million upon execution of the agreement for a Phase 2a clinical trial that is scheduled to begin in 2023, which has been recorded under prepaid expenses and other current assets on the accompanying December 31,2022 balance sheet. The total estimated cost of the agreement (including the reservation fee) is approximately $7.2 million.

11. Income Taxes

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

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

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

Significant components of the Company's deferred income taxes at December 31, 2022 and 2021 are shown below (table in thousands):

	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 21,368	$ 19,993
Compensation	474	846
Research and development tax credits	2,710	2,423
Capitalized and Research Expenditures	2,595	-
Other	487	466
Total deferred tax assets	27,633	23,728
Deferred tax liabilities:		
Property and equipment	(27)	(21)
Other	(60)	(105)
Total deferred tax liabilities	(87)	(126)
Total deferred taxes, net	27,546	23,602
Valuation allowance	(27,546)	(23,602)
Deferred tax liability, net	$ -	$ -

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.

On March 27, 2020, the United States enacted the Coronavirus Aid, Relief and Economic Security Act ("CARES Act"). The CARES Act is an emergency economic stimulus package that includes spending and tax breaks to strengthen the United States economy and fund a nationwide effort to curtail the effect of COVID-19. While the CARES Act provides sweeping tax changes in response to the COVID-19 pandemic, some of the more significant provisions are the extension of the carryback period of certain losses to five years, and increasing the ability to deduct interest expense from 30 percent to 50 percent of modified taxable income. The CARES Act also provides for a credit against employee wages, the opportunity to defer payment of a portion of federal payroll taxes to December 2021 and December 2022 and enhanced small business loans to assist business impacted by the pandemic. The Company's tax provision and financial position was not materially impacted by the CARES Act.

On December 27, 2020, the United States enacted the Consolidated Appropriations Act which extended and modified many of the tax related provisions of the CARES Act. The Company does not anticipate a material impact of the Consolidated Appropriations Act on its tax provision or financial position.

At December 31, 2022, the Company has federal and state net operating losses ("NOL") carryforwards of approximately $99.4 million and $5.8 million, respectively. The federal and Florida NOL generated after 2017 of $37.7 million and $5.8 million, respectively, will carryforward indefinitely. Under the CARES Act, the Internal Revenue Code was amended to allow for federal NOL carrybacks for five years to offset previous income, or can be carried forward indefinitely to offset 100% of the taxable income for the tax year 2020 and 80% of the taxable income for the tax years 2021 and thereafter. The federal NOL carryforwards begin to expire in 2026.

At December 31, 2022, the Company had federal research credit carryforwards of approximately $2.7 million that expire in 2028.

At December 31, 2022, the Company had federal and state capital loss carryforwards of approximately $1.07 million that expire in 2023.

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

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

	2022	2021
Statutory federal income tax rate	21.0%	21.0%
Goodwill impairment	(10.3)%	0%
Research credits	0.7%	1.9%
Change in valuation allowance	(10.2)%	(22.3)%
Equity	(1.4)%	0.0%
Other tax, credit and adjustments	0.2%	(0.6)%
Effective income tax rate	0.0%	0.0%

12. Lease Commitments

Operating Leases

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

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

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

	Year Ended December 31, 2022
Lease Cost	
Operating lease cost (included in operating expenses in the Company's consolidated statement of operations)	$ 233
Other Information	
Cash paid for amounts included in the measurement of lease liabilities	$ 232
Weighted average remaining lease term – operating leases (in years)	1.5
Average discount rate – operating leases	7.1%

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

	At December 31, 2022	At December 31, 2021
Operating leases		
Long-term right-of-use assets of which $99 and $153 relates to related party, net of accumulated amortization of $592 and $388	$ 274	$ 478
Short-term operating lease liabilities, of which $59 and $53 relates to related party	233	209
Long-term operating lease liabilities, of which $42 and $101 relates to related party	57	291
Total operating lease liabilities	$ 290	$ 500

Year ending December 31,	(in thousands)
2023	246
2024	58
2025 and thereafter	-
Total minimum operating lease payments	$ 304
Less: present value discount	(14)
Total operating lease liabilities	290

The minimum lease payments above do not include common area maintenance (CAM) charges, which are contractual obligations under the Company's Bothell, Washington lease, but are not fixed and can fluctuate from year to year. CAM charges for the Bothell, Washington facility are calculated and billed based on total common expenses for the building incurred by the lessor and apportioned to tenants based on square footage. In 2022 and 2021, approximately $98,000 and $75,000 of CAM charges for the Bothell, Washington lease were included in operating expenses in the consolidated statements of operations, respectively.

On September 1, 2018, the Company entered into a lease agreement with a limited liability company controlled by Dr. Phillip Frost, a director, and a principal stockholder of the Company for the lease of its Miami office (see Note 13 – Transactions with Related Parties). On September 1, 2021, the Company extended this lease agreement into additional three-year with monthly lease payments under this lease total $186,000 through September 2024. The minimum lease payments above include taxes and fees, which are expected to be approximately $9,000 annually. As of December 31, 2022, the remaining right of use asset relating to this lease was $99,000 and the remaining lease obligation was $99,000.

Rent expense, excluding capital leases and CAM charges, for 2022 and 2021 totaled $233,000 and $230,000, respectively.

Finance Leases

In November 2018, the Company entered into two lease agreements to acquire equipment with 18 monthly payments of $18,000 payable through May 27, 2020 and 36 monthly payments of $1,000 payable through November 21, 2021. The lease agreements have an effective interest rate of 8.00%.

The leased lab equipment is included under property and equipment and depreciable over five years. Total assets and accumulated depreciation recognized, net, under finance leases was $194,000 and $158,000 as of December 31, 2022, respectively. Total assets and accumulated depreciation recognized, net, under finance leases was $194,000 and $143,000 as of December 31, 2021.

13. Commitments and 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.

Liberty Insurance Underwriters Inc. filed suit against us in federal court in Delaware seeking a declaratory judgment that there was no insurance coverage for any settlement, judgment, or defense costs in the class and derivative litigation, that the monies totaling approximately $1 million it paid to the Company in connection with the SEC investigation were not covered by insurance, and for recoupment of the monies already paid. We have retained counsel to defend us which has filed an answer to the complaint denying its material allegations, as well as a counterclaim against Liberty for breach of contract, declaratory judgment, bad faith and violation of the Washington State Consumer Protection Act, alleging among other things that Liberty wrongfully denied the Company's claims for coverage of the class and derivative litigations, and seeking money damages. Liberty Insurance Underwriters, Inc. filed suit against us in federal court in Delaware seeking a declaratory judgement that there was no insurance coverage for any settlement, judgement, or defense costs in the class and derivative litigation, the monies totaling approximately $1 million it paid to the Company in connection with the SEC request for information in an investigation was not covered by insurance, and for the recoupment of the monies already paid. On June 7, 2022, the court filed a Stipulation and Order for Entry of Judgment in the amount of $1,359,063.72 in favor of Liberty (the "Judgment") following summary judgment granted by the court to Liberty on all but one of the matters at issue in the case. The Company filed an appeal in July 2022. Pending the outcome of the appeal, the Company paid $1.6 million into the registry of the court which stayed execution of the Judgment. The United States Court of Appeals for the Third Circuit (the "Third Circuit Court") held oral argument on the appeal on March 8, 2023. As of the date of this Report, the Third Circuit Court has not issued a ruling on the appeal.

In November 2017, Lee Pederson, a former Biozone lawyer, filed a lawsuit in the U.S. District Court in Minnesota against co-defendants the Company, Dr. Phillip Frost, OPKO Health, Inc. and Brian Keller alleging that defendants engaged in wrongful conduct related to Biozone, including causing Biozone to enter into an allegedly improper licensing agreement and engaged in alleged market manipulation ("Pederson I"). On September 13, 2018, the United States District Court granted the Company and its co-defendants' motion to dismiss Pederson's amended complaint in Pederson I for lack of personal jurisdiction in Minnesota. On October 11, 2018, Pederson filed a notice of appeal with the United States Court of Appeals for the Eighth Circuit. The plaintiff's appeal was denied and the dismissal of Pederson I affirmed in March 2020. Meanwhile, in July 2019, Lee Pederson had filed another lawsuit in the U.S. District Court in Minnesota against co-defendants the Company, Dr. Frost, and Daniel Fisher ("Pederson II"). In his complaint in Pederson II, Pederson alleges tortious interference by the Company and Dr. Frost with an alleged collaboration agreement between Mr. Pederson and Mr. Fisher. In Pederson II, Mr. Pederson seeks damages in the amount of $800,000 or such other amount as may be determined at trial. Pederson II had previously been stayed by the court, pending disposition of Pederson I. With that first lawsuit having been dismissed and appeal denied, the stay was lifted in Pederson II, and the Company and all other defendants in that case filed Motions to Dismiss the (then amended) complaint. On November 19, 2020 the Magistrate Judge recommended dismissal of Pederson II, and further recommended that Pederson be restricted from filing any other actions in the District of Minnesota against defendants on the same or similar allegations as those in Pederson II, and on January 4, 2021 the District Court Judge adopted those recommendations and ordered dismissal of Pederson II. On February 1, 2021 Pederson filed a Notice of Appeal from the order of dismissal of Pederson II in the Eighth Circuit, and on December 29, 2021 the Eighth Circuit affirmed the decision of the District Court. Thereafter, on or about January 11, 2022 Pederson sought via petition, re-hearing en banc by the Eighth Circuit. On October 3, 2022, the U.S. Supreme Court denied Pederson's petition for a writ of certiorari.

COVID-19

Our administrative and finance activities are fully functional out of our Miami, Florida location and our research laboratory in Bothell, Washington remained open for essential operations while meeting COVID-19 quarantine challenges. Our scientists are also able to continue working remotely and we remain committed to meeting our corporate and development milestones throughout the year. We have experienced delays in our supply chain and with service partners as a result of the COVID-19 pandemic, including recent raw material and test animal shortages affecting our research and development efforts. Also because of the unknown impact from COVID-19, it may have unanticipated material adverse effects on us in a number of ways including:

- If our scientists and other personnel (or their family members) are infected with the virus, it may hamper our ability to engage in ongoing research activities;
- Similarly, we rely on third parties who have been and may in the future be adversely impacted;
- If these third parties are and/or continue to be adversely affected by COVID-19, they may focus on other activities which they may devote their limited time to other priorities rather than to our joint research, which has caused and may in the future cause material delays in our research and development efforts;
- We have experienced and may experience in the future shortages of laboratory materials and other resources which impact our research activities;
- As a result of the continuing impact of the virus, we may fail to get access to third party laboratories which would impact our research activities; and
- In addition to the problems described above, we may sustain problems due to the serious short-term and possible longer term serious economic disruptions as our economy faces unprecedented uncertainty.

14. Transactions with Related Parties

In September 2018, the Company leased administrative offices from a limited liability company owned by one of the Company's directors and principal stockholder, Dr. Phillip Frost. The lease term is three years with an optional three-year extension. On an annualized basis, rent expense, including taxes and fees, for this location would be approximately $62,000. The Company paid a lease deposit of $4,000 and total rent and other expenses paid in connection with this lease were $61,000 and $60,000 for the years ended December 31, 2022 and 2021 respectively.

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

Not applicable.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, have evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2022. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms of the Securities and Exchange Commission. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on this evaluation, management concluded that our disclosure controls and procedures were effective as of December 31, 2022.

Management's Annual Report on Internal Control Over Financial Reporting

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

Our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2022, based on the framework in the Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "2013 Internal Control-Integrated Framework"). Based on our evaluation under the 2013 Internal Control-Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2022.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting as defined in Rule 13a-15(f) or 15d-15(f) under the Exchange Act that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

The information required by Item 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 2022 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of December 31, 2022.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(1) Financial Statements: See Part II, Item 8 of this report.
(2) Exhibits: See Index to Exhibits below.

EXHIBIT INDEX

Exhibit No.	Exhibit Description	Incorporated by Reference			Filed or Furnished Herewith
		Form	Date	Number	
3.1	Certificate of Incorporation, as amended	10-Q	8/16/21	3.1	
3.1(a)	Certificate of Amendment to the Certificate of Incorporation	8-K	10/3/22	3.1	
3.2	Amended and Restated Bylaws	8-K	2/19/21	3.1	
4.1	Description of Capital Stock	10-K	3/27/20	4.1	
10.1	2015 Equity Incentive Plan*	DEF 14A	6/1/15	Annex A	
10.1(a)	Amendment to 2015 Equity Incentive Plan*	DEF 14A	4/30/19	Annex A	
10.1(b)	Amendment to 2015 Equity Incentive Plan*	DEF14A	4/26/2021	Annex B	
10.2	Sam Lee Employment Agreement*	8-K	1/8/14	10.2	
10.2(a)	Amendment to Sam Lee Employment Agreement*	10-K	3/31/15	10.6	
10.3	James Martin Consulting Agreement*	8-K	2/24/17	10.1	
10.4	Chief Financial Officer Offer Letter dated May 26, 2017 - James Martin*	8-K	6/1/17	10.1	
10.5	Form of Underwriter's Warrant	8-K	5/2/18	4.1	
10.6	Exclusive License and Research Collaboration Agreement between the Company and Merck Sharp & Dohme Corp., dated January 2, 2019***	10-K	4/1/19	10.12	
10.7	Placement Agency Agreement, dated January 29, 2020	8-K	1/31/20	1.1	
10.8	Form of Securities Purchase Agreement**	8-K	1/31/20	10.1	
10.9	Engagement Letter, dated February 26, 2020	8-K	3/4/20	10.2	
10.10	Form of Securities Purchase Agreement, dated February 27, 2020**	8-K	3/4/20	10.1	
10.11	Form of Securities Purchase Agreement, dated March 9, 2020**	8-K	3/13/20	10.1	
10.12	License Agreement, dated February 18, 2020, between the Company and Kansas State University Research Foundation****	10-Q	5/13/20	10.7	
10.13	License Agreement, dated April 19, 2020, between the Company and Kansas State University Research Foundation****	10-Q	8/6/20	10.1	
10.14	At-The-Market Offering Agreement, dated July 1, 2020, by and between the Company and H.C. Wainwright & Co., LLC	8-K	7/2/20	1.1	
10.15	Underwriting Agreement, dated as of May 4, 2021 by and between Cocrystal Pharma, Inc. and H.C. Wainwright & Co., LLC**	8-K	5/5/21	1.1	
10.16	Consulting and Scientific Advisory Board Agreement, dated April 13, 2021 with Roger Kornberg	10-Q	8/16/21	10.1	

21.1	Subsidiaries	10-K	3/27/20	21.1	
23.1	Consent of Weinberg & Company				Filed
31.1	Certification of Principal Executive Officer (302)				Filed
31.2	Certification of Principal Executive Officer (302)				Filed
31.3	Certification of Principal Financial Officer (302)				Filed
32.1	(906)+				Furnished
101.INS	XBRL Instance Document				Filed
101.SCH	XBRL Taxonomy Extension Schema Document				Filed
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				Filed
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				Filed
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				Filed
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				Filed

* Represents management contracts or compensatory plan or arrangement.
** Exhibits have been omitted. The Company undertakes to furnish the omitted exhibits to the Commission upon request.
*** Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been submitted separately to the SEC.
**** Portions of this exhibit have been omitted as permitted by the rules of the SEC. The information excluded is both (i) not material and (ii) would be competitively harmful if publicly disclosed. The Company undertakes to submit a marked copy of this exhibit for review by the SEC staff, to the extent it has not been previously provided, and provide supplemental materials to the SEC staff promptly upon request.
+ 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 stockholders who make a written request to our Corporate Secretary at Cocrystal Pharma, Inc., 19805 N. Creek Parkway Bothell, WA 98011.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

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

COCRYSTAL PHARMA, INC.

March 29, 2023

By: */s/ James Martin*
James Martin
Co-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.

SIGNATURE	TITLE	DATE
/s/ Roger Kornberg Roger Kornberg	*Chairman*	March 29, 2023
/s/ Phillip Frost Phillip Frost	Director	March 29, 2023
/s/ Steven Rubin Steven Rubin	Director	March 29, 2023
/s/Richard Pfenniger Richard Pfenniger	Director	March 29, 2023
/s/ Anthony Japour Anthony Japour	Director	March 29, 2023
/s/ James Martin James Martin	Chief Financial Officer and Co-Interim Chief Executive Officer (Principal Financial, Accounting and Executive Officer)	March 29, 2023
/s/ Sam Lee Sam Lee	President and Co-Interim Chief Executive Officer (Principal Executive Officer)	March 29, 2023

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Cocrystal Pharma, Inc.
Bothell, Washington

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-231022 and No. 333-237738) and on Form S-8 (No. 333-193161 and No. 333-224869) of Cocrystal Pharma, Inc. of our report dated March 29, 2023, relating to the consolidated financial statements, which appears in this Annual Report on Form 10-K.

/s/ Weinberg & Company

Los Angeles, California
March 29, 2023

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, James Martin, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 29, 2023

/s/ James Martin

James Martin
Co-Interim Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Sam Lee, 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 29, 2023

/s/ Sam Lee
Sam Lee
Co-Interim Chief Executive Officer

Exhibit 31.3

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, James Martin, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 29, 2023

/s/ James Martin

James Martin
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the report of Cocrystal Pharma, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof, I, James Martin, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and

2. The information contained in the report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ James Martin
James Martin
Chief Financial Officer and Co-Interim Chief Executive Officer
(Principal Financial Officer and Principal Executive Officer)
Dated: March 29, 2023

In connection with the report of Cocrystal Pharma, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof, I, James Martin, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and

2. The information contained in the report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Sam Lee
Sam Lee
Co-Interim Chief Executive Officer
(Principal Executive Officer)
Dated: March 29, 2023