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

FORM 10-K

(Mark One)

☒ **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 FOR THE TRANSITION PERIOD FROM _____ TO _____ .**

Commission File Number 001-37348

Corbus Pharmaceuticals Holdings, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**46-4348039**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
500 River Ridge Drive Norwood, Massachusetts	**02062**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 963-0100

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 $0.0001 per share	**CRBP**	**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 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, 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 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 Section 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 ☒

As of June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the common stock held by non-affiliates of the registrant was approximately $31,475,349, based on the closing price of the registrant's common stock on June 30, 2022.

As of March 3, 2023, the number of shares outstanding of the registrant's common stock, $0.0001 par value per share, was 4,171,297.

Documents incorporated by reference

Portions of the registrant's proxy statement for the 2023 annual meeting of stockholders to be filed pursuant to Regulation 14A within 120 days after the registrant's fiscal year ended December 31, 2022, are incorporated by reference in Part III of this Form 10-K.

CORBUS PHARMACEUTICALS HOLDINGS, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2022
TABLE OF CONTENTS

PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report on Form 10-K contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include statements with respect to our beliefs, plans, objectives, goals, expectations, anticipations, assumptions, estimates, intentions and future performance, and involve known and unknown risks, uncertainties and other factors, which may be beyond our control, and which may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through our use of words such as "may," "can," "anticipate," "assume," "should," "indicate," "would," "believe," "contemplate," "expect," "seek," "estimate," "continue," "plan," "point to," "project," "predict," "could," "intend," "target," "potential" and other similar words and expressions of the future.

There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by us. These factors include, but are not limited to:

- our history of operating losses;
- our current and future capital requirements and our ability to satisfy our capital needs;
- our ability to complete required clinical trials of our product candidates and obtain approval from the FDA or other regulatory agents in different jurisdictions;
- our ability to internally develop new product candidates, intellectual property, and other product candidates we may acquire and/or license;
- our ability to maintain or protect the validity of our patents and other intellectual property;
- our ability to retain key executive members;
- the potential impact of the COVID-19 pandemic and other geographical events, including the war in Ukraine and their effects on our operations, including on our clinical development plans and timelines;
- interpretations of current laws and the passages of future laws;
- acceptance of our business model by investors;
- the accuracy of our estimates regarding expenses and capital requirements; and
- our ability to adequately support growth.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipate in our forward-looking statements. Please see "Risk Factors" for additional risks which could adversely impact our business and financial performance.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this report or the date of the document incorporated by reference into this report. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise. We have expressed our expectations, beliefs and projections in good faith and we believe they have a reasonable basis. However, we cannot assure you that our expectations, beliefs or projections will result or be achieved or accomplished.

Item 1. BUSINESS

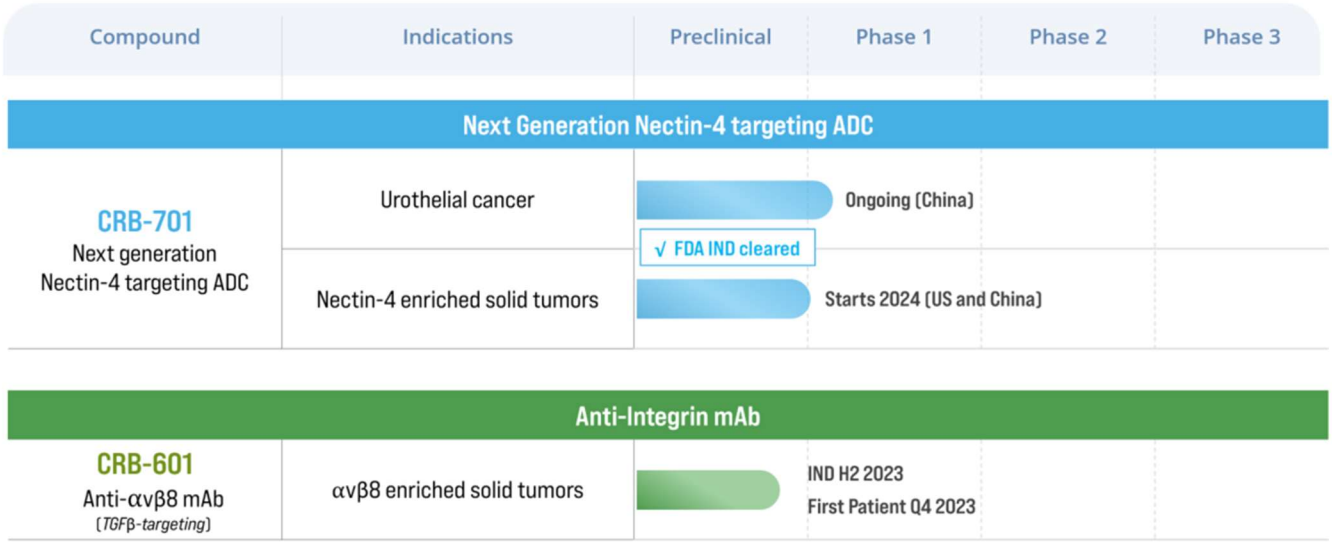
All references in this report to "Corbus," the "Company," "we," "us," or "our" mean Corbus Pharmaceuticals Holdings, Inc., and its subsidiaries unless we state otherwise, or the context otherwise indicates.

Overview

Corbus Pharmaceuticals Holdings, Inc. (the "Company" or "Corbus") is a precision oncology company committed to helping people defeat serious illness by bringing innovative scientific approaches to well understood biological pathways. Corbus' internal development pipeline includes CRB-701, a next generation antibody drug conjugate (ADC) that targets the expression of Nectin-4 on cancer cells to release a cytotoxic payload and CRB-601, an anti-integrin monoclonal antibody that blocks the activation of TGFβ expressed on cancer cells. The Company has also developed CRB-913, an endocannabinoid small molecule drug, for the treatment of obesity and is seeking partners to fund further development.

Corbus' precision oncology internal development pipeline:

- CRB-701 is a next generation ADC that targets the expression of Nectin-4 on cancer cells to release a cytotoxic payload. In February 2023, the Company obtained a license from CSPC Megalith Biopharmaceutical Co., Ltd ("CSPC"), a subsidiary of CSPC Pharmaceutical Group Limited, to develop and commercialize the drug in the United States ("U.S."), Canada, the European Union (including the European Free Trade Area), the United Kingdom, and Australia (the "CSPC License Agreement"). The Investigational New Drug (IND) application for CRB-701 has been cleared by the U.S. FDA and the drug is currently being investigated by CSPC in a Phase 1 dose escalation clinical trial in patients with advanced solid tumors in China. Corbus is planning to bridge data from this Phase 1 trial to support a U.S. clinical trial starting in mid-2024.
- CRB-601 is an anti-αvβ8 monoclonal antibody that blocks the activation of TGFβ expressed on cancer cells in the tumor microenvironment. In pre-clinical models, CRB-601 demonstrates enhanced anti-tumor activity when combined with anti-PD-1 checkpoint inhibitor therapy compared to either single agent alone. Pre-clinical data suggests that blockade of latent TGFβ production by CRB-601 can lead to changes in immune cell infiltration in the tumor microenvironment, potentially enhancing the benefit of PD-1 blockade. CRB-601 is being developed as a potential treatment for patients with solid tumors in combination with existing therapies, including checkpoint inhibitors, and is scheduled for an IND submission in the second half of 2023. The Company expects to enroll the first patient in the Phase 1 study by the end of 2023.



Corbus' endocannabinoid pipeline:

- CRB-913 is a second-generation cannabinoid receptor type 1 (CB1) inverse agonist designed to treat obesity and related metabolic diseases. In the diet-induced obesity mice model (DIO), CRB-913 demonstrates a reduction in weight and food consumption, improvement in insulin resistance and leptinemia, and reduced fat deposits in the liver. The CRB-913 program is in the pre-clinical stage, and we are seeking partnerships to fund further development.
- Lenabasum is a novel, synthetic, oral molecule that selectively activates cannabinoid receptor type 2 (CB2) for the treatment of inflammation and fibrosis. The drug completed Phase 3 studies in dermatomyositis and systemic sclerosis and these studies failed to meet their primary endpoints. In November 2022, the National Institutes of Health released results for the Phase 2 study it sponsored in systemic lupus erythematosus and lenabasum failed to demonstrate efficacy versus placebo. We do not plan to conduct additional clinical studies for lenabasum.

CRB-701

CRB-701 is a novel clinical stage ADC that targets the expression of Nectin-4 on cancer cells to release a cytotoxic payload of monomethyl auristatin E (MMAE). In February 2023, the Company obtained a license from CSPC, a subsidiary of CSPC Pharmaceutical Group Limited, to develop and commercialize the drug in the United States, Canada, the European Union (including the European Free Trade Area), the United Kingdom, and Australia. The IND for CRB-701 has been cleared by the U.S. FDA and the drug is currently being investigated by CSPC in a Phase 1 dose escalation clinical trial in patients with advanced solid tumors in China. Corbus is planning to bridge data from the Phase 1 trial in China to support a U.S. clinical trial starting in mid-2024. During 2023, we plan on conducting pre-clinical translational studies and, in partnership with CSPC, plan to develop a companion diagnostic to identify tumors other than urothelial cancer that express lower levels of Nectin-4. The companion diagnostic is expected to help identify patients who are likely to respond to the therapy.

The targeting of Nectin-4 on cancer cells to release the cytotoxic payload MMAE is a clinically validated target as Enfortumab vedotin (PADCEV®) has been approved for the treatment of urothelial cancer (Figure 1). However, PADCEV® is also associated with serious adverse events and has a corresponding black box warning in its label. PADCEV® toxicity and safety limitations include serious and potentially life-threatening skin reactions and peripheral neuropathy, which negatively impact tolerability and dose intensity (Figure 2).

Figure 1: Nectin-4 is a clinically validated target with untapped potential

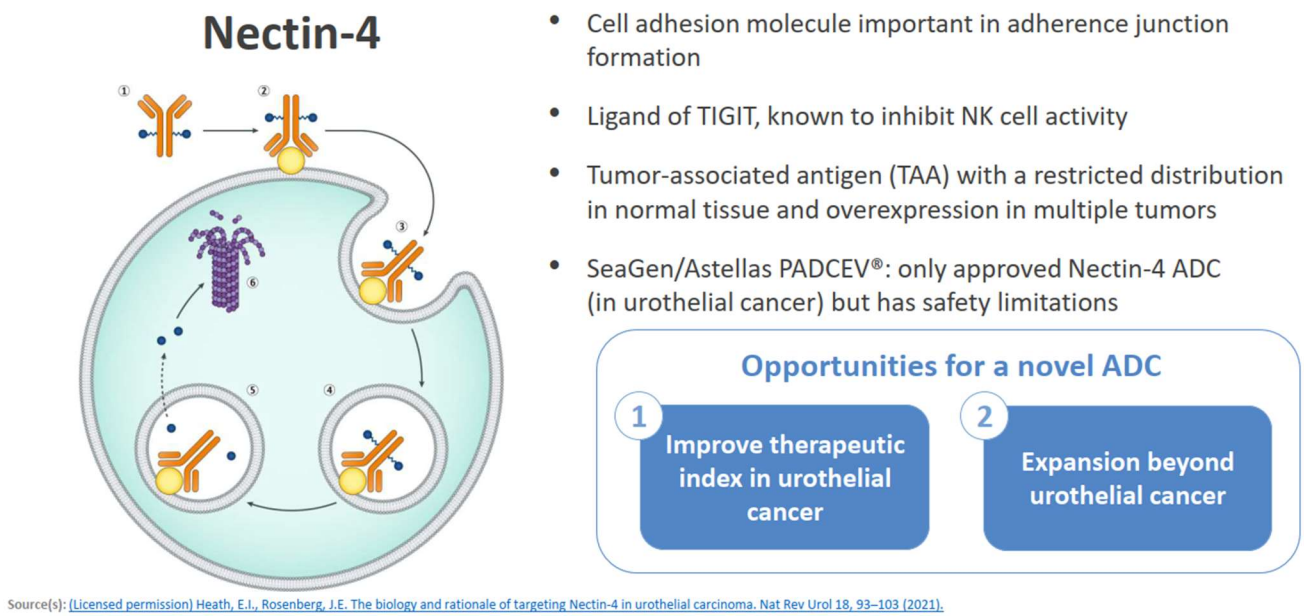
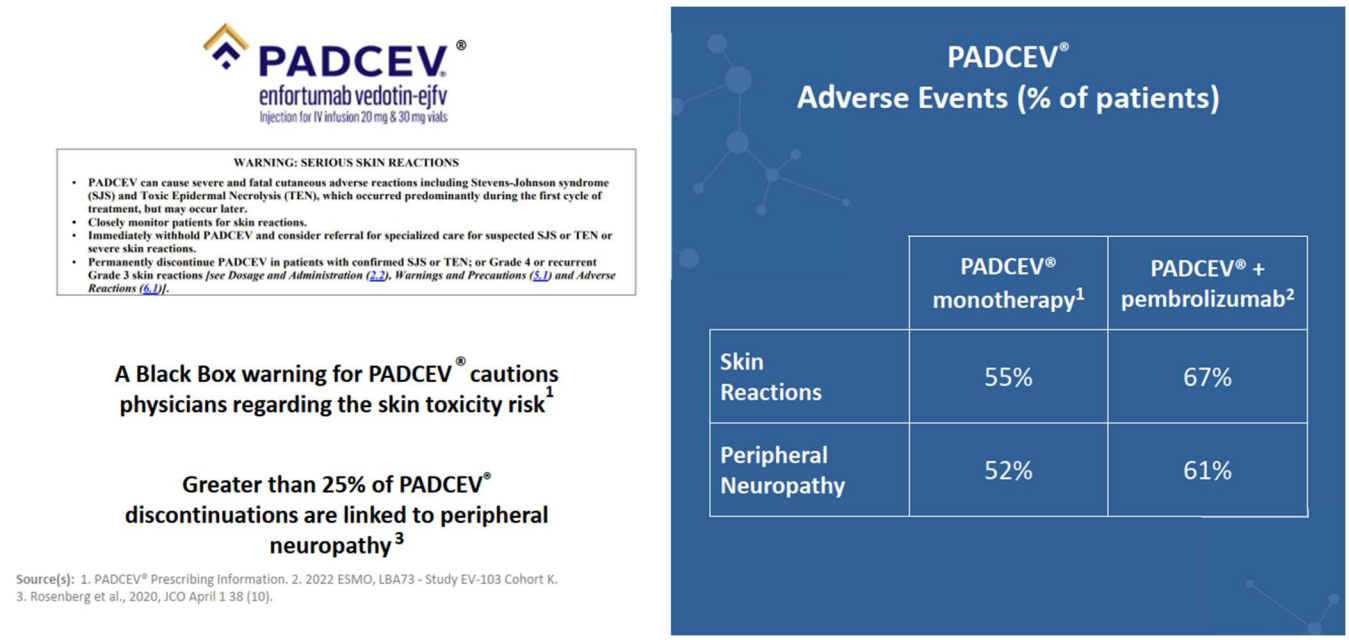
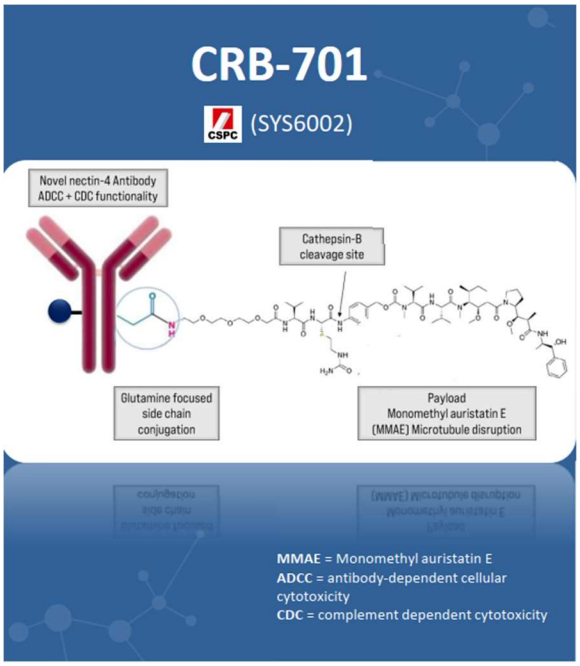


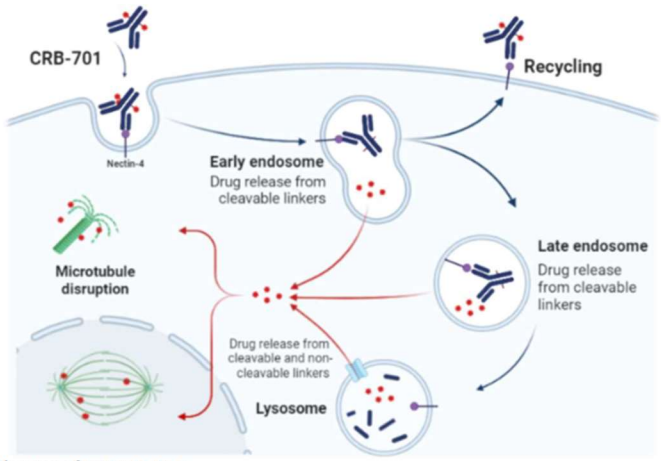
Figure 2: PADCEV® safety limitations



CRB-701 is designed to be an improved next generation site-specific Nectin-4 targeting ADC (Figure 3). The drug leverages site specific conjugation and novel linker technology to enable homogeneous payload incorporation. The linker technology attaches the MMAE cytotoxic payload to the monoclonal antibody and is designed to keep the MMAE attached to the monoclonal antibody until it binds to the Nectin-4 receptor on the target cell. MMAE is then released upon internalization within the target cell. The targeted delivery of CRB-701 is designed to maximize delivery of MMAE while minimizing toxicity to normal tissues. CRB-701's longer half-life and low free plasma payload supports less frequent dosing. The complexity and cost of manufacturing for CRB-701 has also been reduced by the drug's single enzyme and improved linker technology. CRB-701 may also offer immune-mediated tumor destruction functionality. The antibody for CRB-701 binds to the Fc receptor to trigger innate immune-mediated destruction as a secondary mechanism of action (Figure 4). Pre-clinical data suggest that CRB-701 has a comparative advantage versus standard of care for urothelial cancer and thus provides Corbus with the opportunity to develop an improved Nectin-4 targeting ADC with a differentiated profile (Figure 5).

Figure 3: CRB-701 Next generation site-specific Nectin-4 targeting ADC





Mechanism of CRB-701 ADC

1. Selective binding of CRB-701 to Nectin-4
2. Internalization of CRB-701/Nectin-4 complex via endocytosis
3. Intracellular cytosol release of MMAE (payload) due to lysosomal trafficking
4. MMAE cytotoxic effect – tubulin polymerization inhibition – G2/M cell cycle arrest - apoptosis
5. Bystander effect: Nearby tumor cells exposed to MMAE/ADC released from targeted cell also undergo apoptosis

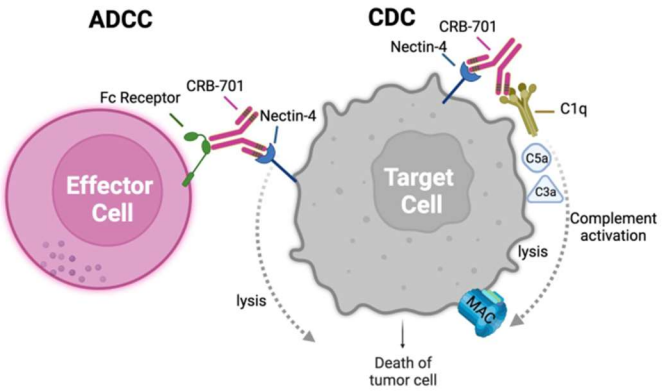
Source(s): Modified image from Corbus data on file

Figure 4: CRB-701 differentiated by immune-mediated tumor destruction functionality

The CRB-701 antibody has built-in Fc receptor binding activity → innate immune mediated tumor destruction

CRB-701 has demonstrated potency against FcγR1, C1q and FcRn

This additional antibody functionality is designed to increase efficacy of CRB-701 via a secondary mechanism

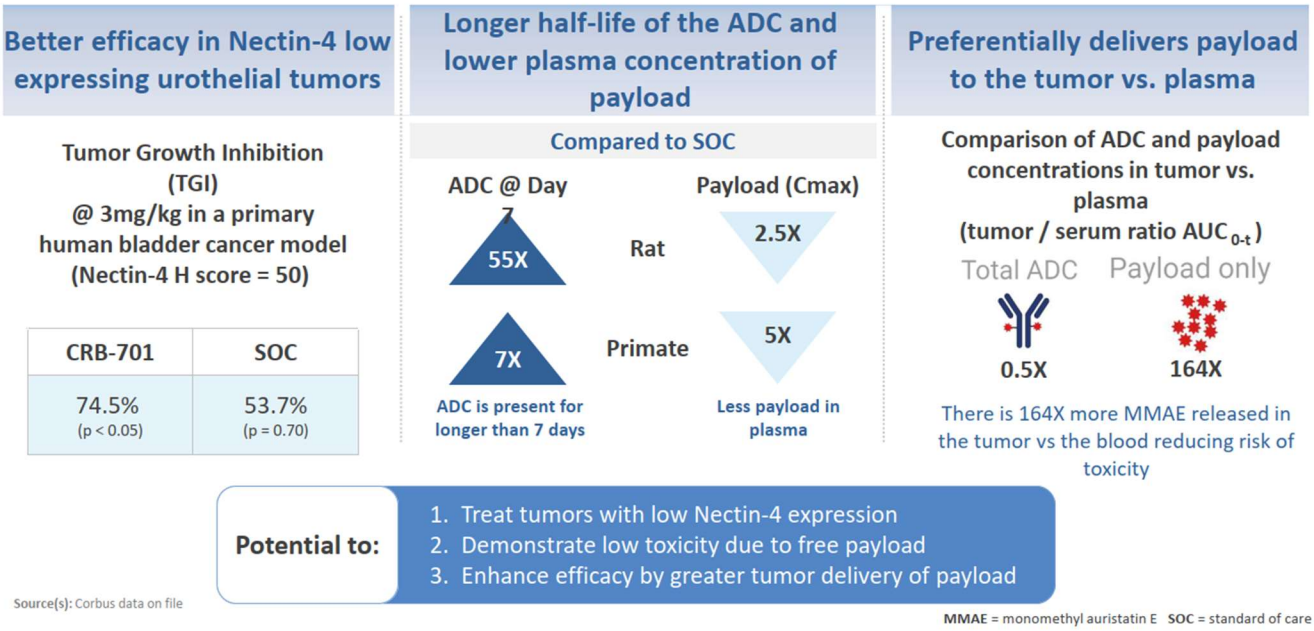


CRB-701
Antibody-dependent cellular cytotoxicity
(ADCC)
< 1 nM

CRB-701
Complement-dependent cytotoxicity
(CDC)
< 10 nM

Source(s): Corbus data on file ADCC = antibody-dependent cellular cytotoxicity CDC = complement dependent cytotoxicity

Figure 5: CRB-701 pre-clinical data suggests a differentiated Nectin-4 targeting ADC



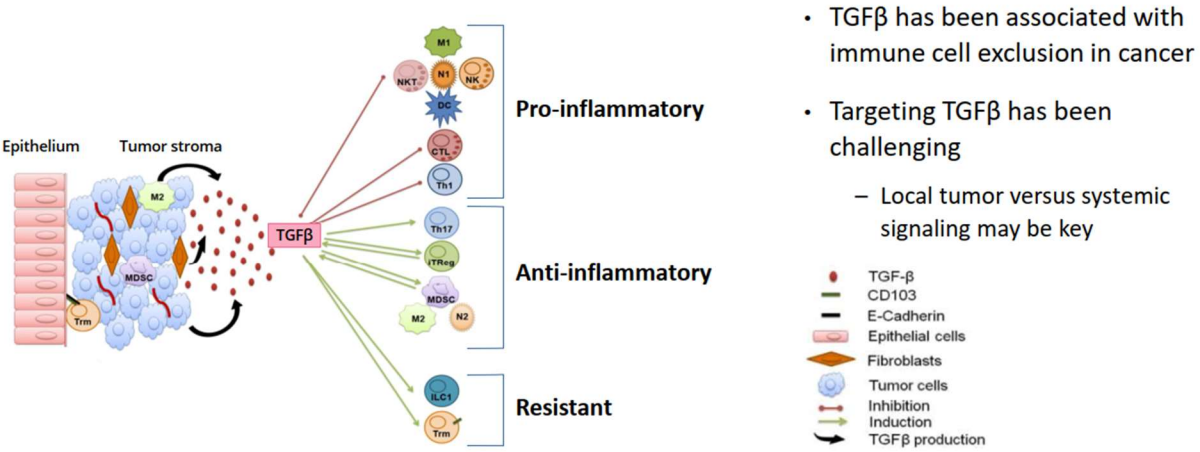
CRB-601

We are developing CRB-601, an anti-αvβ8 integrin mAb for the treatment of solid tumors. The Company in-licensed the intellectual property for CRB-601 from Dr. Stephen Nishimura's laboratory at the University of California, San Francisco.

TGFβ is a multifunctional cytokine involved in many cellular processes, including cell growth and differentiation, immune response, wound healing, and tissue repair. In cancer, TGFβ mediates immune evasion (Figure 6) and plays a key role in promoting cancer cell growth and metastasis via its immunosuppressive effects in the tumor microenvironment. When overexpressed in the tumor milieu, TGFβ is linked to poor clinical outcomes (Figure 7). Similarly, the αvβ8 integrin appears to be the only TGFβ activating integrin expressed on regulatory T-cells, highlighting the key contribution of this integrin to immunosuppression. Tumor cells can also evade host immunity by activating TGFβ via integrin αvβ8.

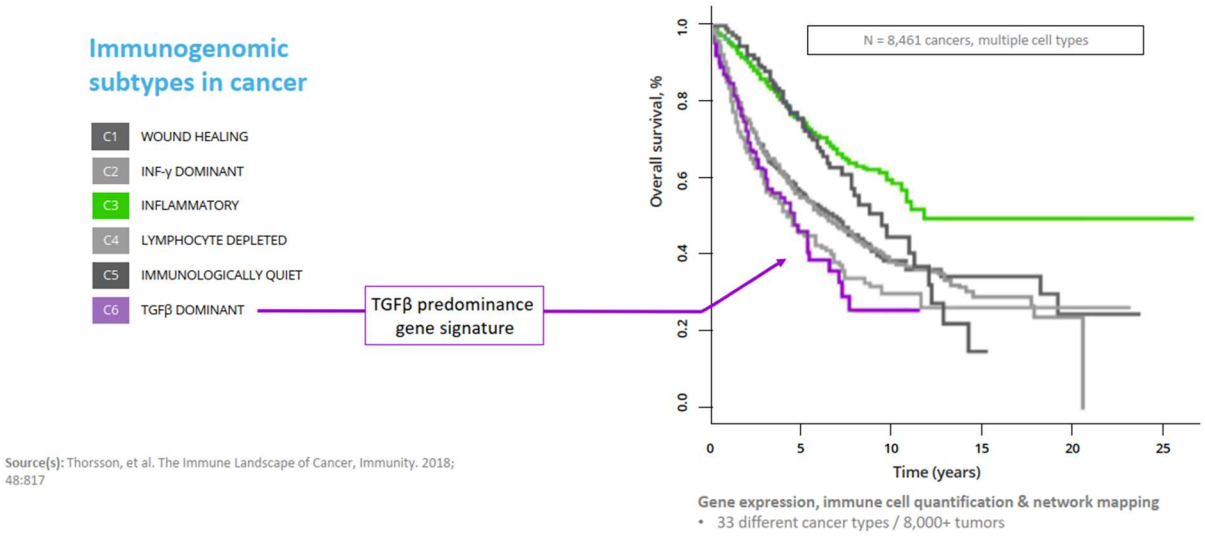
The αvβ8 integrin is a key regulator of TGFβ that is co-opted in many late-stage metastatic cancers to function as a pro-cancer cytokine. TGFβ is normally stored in the extracellular matrix as an inactive latent pro-protein complex. TGFβ is held in an inactive state in association with latency associate peptide (LAP) and is presented on cell surfaces by latent transforming growth factor β binding proteins (e.g., LTBP1, GARP); these three components comprising the large latent complex (LLC). Upon binding of the LAP-TGFβ complex to the αvβ8 integrin TGFβ is released and can now activate the TGFβ receptor and the associated SMAD signaling pathway that leads to a related transcription translation program of TGFβ target genes. CRB-601 was specifically designed to bind at the TGFβ activation site on αvβ8 (Figure 8), thereby blocking αvβ8-dependent activation.

Figure 6: TGFβ is believed to play a central role in immunoregulation and cancer



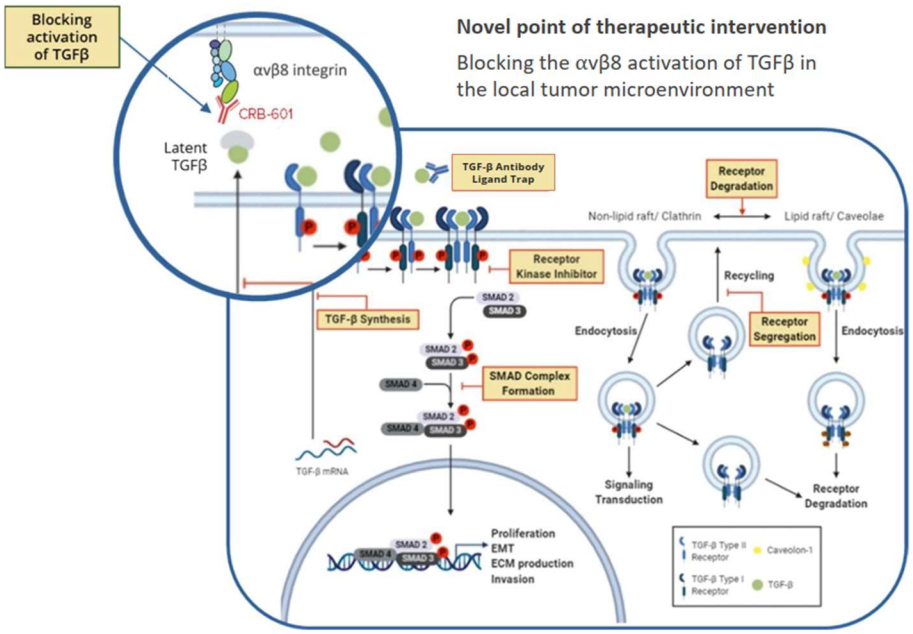
Source(s): Dahmani A, Delisle JS. TGF-β in T Cell Biology: Implications for Cancer Immunotherapy. *Cancers (Basel)*. 2018;10(6):194. Published 2018 Jun 11. doi:10.3390/cancers10060194

Figure 7: TGFβ predicts poor clinical outcomes in a subset of cancer patients



Source(s): Thorsson, et al. The Immune Landscape of Cancer, Immunity. 2018; 48:817

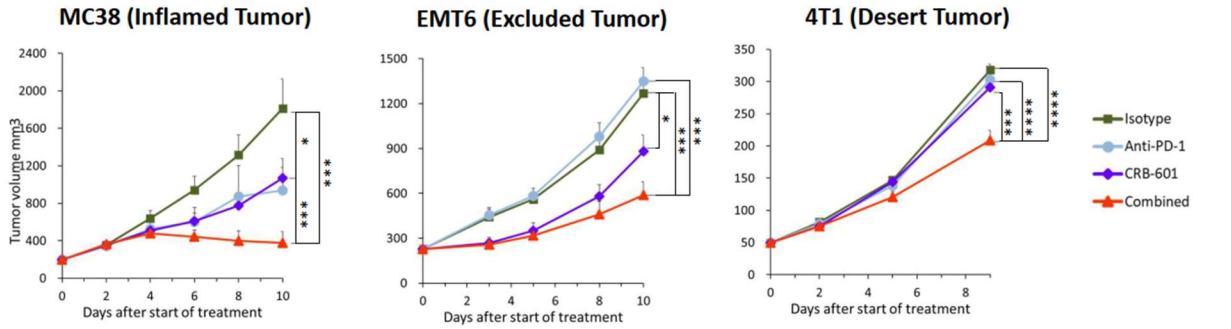
Figure 8: Targeting the integrin αvβ8 represents a novel approach to regulating TGFβ



Source(s): Huang et al., 2021. Recent progress in TGFβ inhibitors for cancer therapy.

While checkpoint inhibitors (CPIs) have led to dramatic improvements in survival rates for certain cancer patients, there is still a significant subset of patients who do not respond to this class of medicine. In resistant murine tumor models, CRB-601 has demonstrated that it enhanced the effect of anti-PD-1 checkpoint therapy (Figure 9).

Figure 9: CRB-601 enhancements



Source(s): Corbus data on file

Checkpoint blockade sensitivity

Sensitive **Resistant**

% TGI	MC38	EMT6	4T1
Anti-PD-1	54	-8	6
CRB-601	46	37	10
Combo	89	65	41

CRB-601: 10 mg/kg BIW
Anti-PD-1: 10 mg/kg BIW
10 animals / group
Animals randomized at 50-80 mm³
Comparisons across arms
*p<0.05, ***p<0.001, ****p<0.0001

Endocannabinoid Pipeline

CRB-913

Corbus has developed CRB-913, a second-generation cannabinoid receptor type 1 (CB1) inverse agonist designed to treat obesity and related metabolic diseases. In the diet-induced obesity mice model (DIO), CRB-913 demonstrates a reduction in weight, food consumption, and fat deposits in the liver and improvement in insulin resistance and leptinemia. CRB-913 induces weight loss both as a monotherapy (Figure 10) and in combination with the incretin analogs liraglutide (Saxenda™), semaglutide (Wegovy™) and tirzepatide (Mounjaro™) (Figure 11). The CRB-913 program is in the pre-clinical stage, and we are seeking partnerships to fund further development.

Figure 10: CRB-913 demonstrate significant reduction in body weight

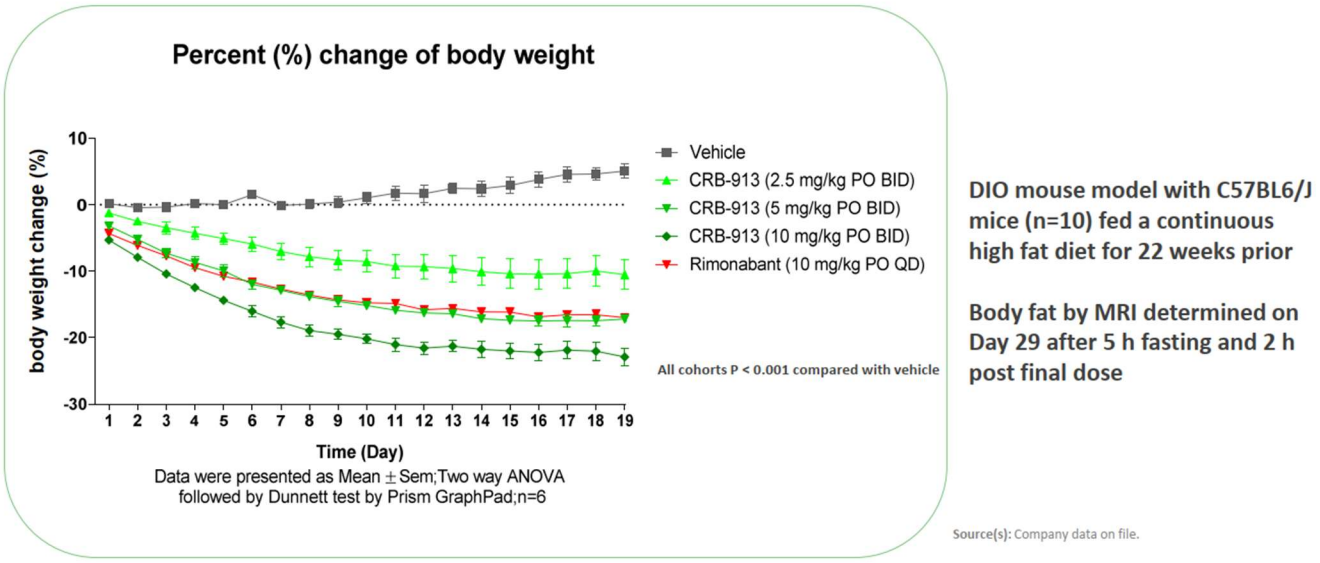
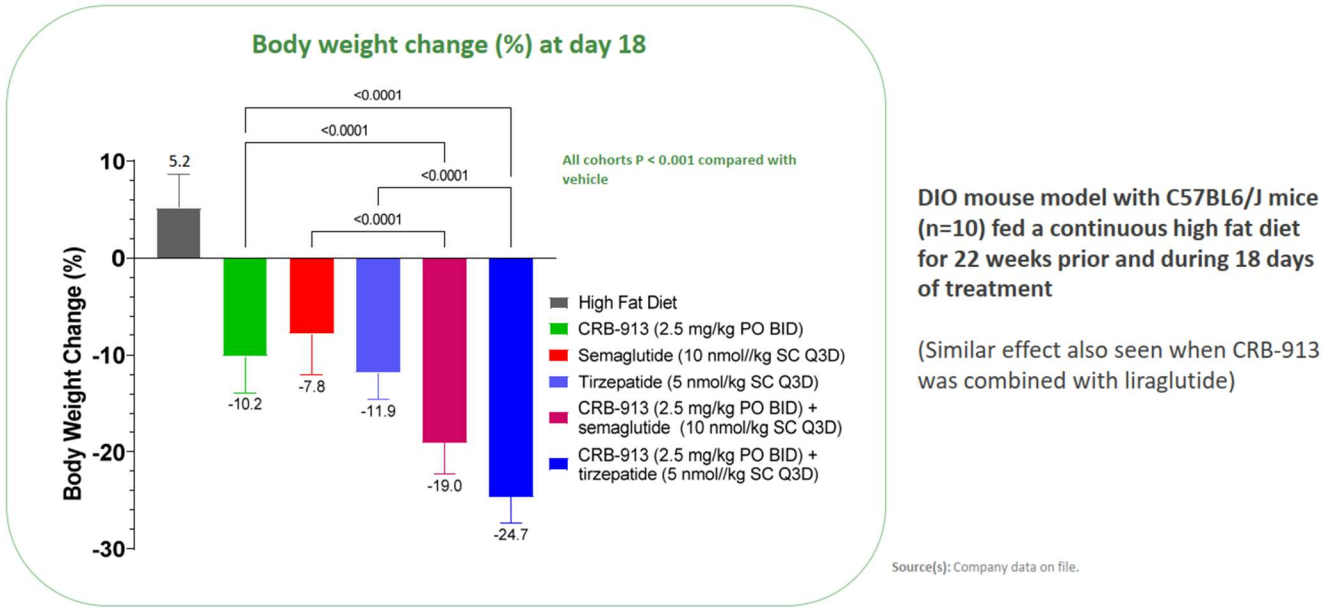


Figure 11: CRB-913 enhanced combo effect



Lenabasum

Lenabasum is a novel, synthetic, oral molecule that selectively activates cannabinoid receptor type 2 (CB2) for the treatment of inflammation and fibrosis. The drug completed Phase 3 studies in dermatomyositis and systemic sclerosis and these studies failed to meet their primary endpoints. In November 2022, the National Institutes of Health released results for the Phase 2 study it sponsored in systemic lupus erythematosus and lenabasum failed to demonstrate efficacy versus placebo. We do not plan to conduct additional clinical studies for lenabasum.

Our Business Development Strategy

Our goal is to develop novel therapeutics in oncology for well understood biological pathways by utilizing precision medicine to identify the genetic drivers and biomarkers for each specific type of cancer and then develop companion diagnostics that will better identify patient populations that will be most likely to benefit from our therapies. Our key business goals are as follows:

- Develop a companion diagnostic and perform translational validation studies for CRB-701 in 2023 followed by the first U.S. clinical study in mid-2024.
- File an IND for CRB-601 in the third quarter 2023 and initiate a Phase 1 trial for CRB-601 by the end of 2023.
- Expand and diversify our precision oncology pipeline through a licensing and acquisition strategy.
- Enter into partnerships for our endocannabinoid drug CRB-913 to fund further development.

Research and Development

We incurred expenses of approximately $16,137,000 and $36,445,000 for research and development activities for the years ended December 31, 2022 and 2021, respectively. These expenses include cash and non-cash expenses relating to the development of our clinical and pre-clinical programs for our pipeline. Research and development expenses are incurred for the development of our drug candidates and consist primarily of payroll and payments to contract research and development companies. To date, these costs are related to generating pre-clinical data and the cost of manufacturing drug product for clinical trials and conducting clinical trials.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain patent and other proprietary protection for our technologies, products and processes, including proprietary protection for CRB-701, CRB-601, CRB-913, and lenabasum.

CRB-701: Antibody Drug Conjugate (ADC) Targeting Nectin-4

The Company entered into the CSPC License Agreement with CSPC effective February 12, 2023. Pursuant to the CSPC License Agreement, the Company received an exclusive license to CRB-701 for the prevention and treatment of all oncology indications in the United States, Canada, the European Union (including the European Free Trade Area), the United Kingdom, and Australia. The last of the licensed patent applications, if granted, is projected to expire in 2042.

CRB-601: Anti-Integrin Monoclonal Antibody

The Company entered into a license agreement (the "UCSF License Agreement") with the Regents of the University of California ("The Regents") effective May 26, 2021, as amended to include additional inventions effective November 17, 2022. Pursuant to the UCSF License Agreement, the Company received an exclusive worldwide license to certain patent applications relating to humanized antibodies against integrin αvβ8, an antibody for diagnostic use, along with non-exclusive licenses to certain related know-how and materials. The last of the licensed patent applications, if granted, is projected to expire in 2043.

CRB-913: Second Generation CB1 Inverse Agonist

On September 20, 2018, we entered into an exclusive license agreement with Jenrin Discovery, LLC which provides us with an exclusive worldwide license to develop and market cannabinoid compounds covered by the Jenrin issued patents and patent applications that cover the composition and method of use of selective cannabinoid receptor modulators. The Jenrin intellectual property portfolio includes eight granted United States patents and nine granted patents outside of the United States. The portfolio includes U.S. Patent No. 8,853,252 which granted with claims relating to the cannabinoid receptor blocker CRB-913 and methods of using the same for treating obesity, diabetes, hepatic disorders, and/or cardiometabolic disorders. The licensed intellectual property portfolio provides intellectual property protection in the United States for CRB-913 and these uses through November 2028. Corbus owns a patent application covering CRB-913 that can result in patent rights projected to expire in 2043.

Lenabasum Program

We have filed patent applications directed to lenabasum, compositions and methods for treating disease using lenabasum. If granted, the resulting patents would expire on dates ranging from 2031 to 2040, subject to extension under certain circumstances. The patent application filings are directed to:

- Compositions including an improved ultrapure version of lenabasum and uses of the compositions for the treatment of fibrotic conditions and inflammatory conditions;
- The use of lenabasum in the treatment of fibrotic diseases;
- Lenabasum formulations and uses of the formulations for the treatment of disease; and
- Lenabasum polymorphs and uses of the polymorphs for the treatment of the disease.

On August 6, 2019, the U.S. Patent and Trademark Office ("USPTO") issued U.S. Patent No. 10,369,131 to the Company with claims covering the use of pharmaceutical compositions comprising lenabasum for the treatment of dermatomyositis. The patent provides exclusivity in the U.S. for this use of lenabasum to February 12, 2034.

On December 18, 2018, USPTO issued U.S. Patent No. 10,154,986 to the Company with claims covering pharmaceutical compositions of lenabasum. The patent provides exclusivity in the U.S. for these lenabasum compositions to February 12, 2034.

On October 3, 2018, the USPTO issued U.S. Patent No. 10,085,964 to the Company with claims covering the use of pharmaceutical compositions comprising lenabasum for the treatment of all fibrotic diseases, encompassing Corbus' lead indications systemic sclerosis, cystic fibrosis and others. The patent provides exclusivity in the U.S. for this use of lenabasum to February 12, 2034.

On October 31, 2017, the USPTO issued U.S. Patent No. 9,801,849 to the Company with claims covering the use of pharmaceutical compositions comprising lenabasum, for the treatment of all inflammatory diseases. The patent provides exclusivity in the U.S. for this use of lenabasum to February 12, 2034.

On November 27, 2017, the USPTO issued U.S. Patent No. 9,820,964 to the Company with claims covering the use of pharmaceutical compositions comprising lenabasum for the treatment of all fibrotic diseases, encompassing the Company's lead indications systemic sclerosis, cystic fibrosis and others. The patent provides intellectual property protection in the United States for this use of lenabasum to February 12, 2034.

On July 6, 2021, the USPTO issued U.S. Patent No. 11,052,066 to the Company with claims covering pharmaceutical compositions of lenabasum and their use in treating fibrotic and inflammatory diseases, encompassing the Company's lead indications systemic sclerosis, cystic fibrosis and others. The patent provides intellectual property protection in the United States for this use of lenabasum to February 12, 2034.

Lenabasum has been granted Orphan Drug Designation for cystic fibrosis, dermatomyositis and systemic sclerosis in the U.S. and in the European Union and for systemic sclerosis in Japan. In addition, in systemic sclerosis and in cystic fibrosis, lenabasum has been granted a Fast Track Designation by the FDA. Orphan designation for lenabasum may be pursued for other inflammatory diseases in the U.S., Europe, and Japan. Orphan drug status provides seven years of market exclusivity in the U.S. and ten years in Europe and Japan beginning on the date of drug approval.

Other Intellectual Property Matters

Our commercial success depends in part on our ability to obtain and maintain patent and other proprietary protection for our technologies and to operate without infringing the proprietary right of others and to prevent others from infringing our proprietary rights. We strive to protect our intellectual property through a combination of patents and trademarks as well as through the confidentiality provisions in our contracts. With respect to our candidates, we endeavor to obtain and maintain patent protection in the U.S. and internationally on all patentable aspects of each product candidate. We cannot be sure that the patents will be granted with respect to any patent applications we may own or license in the future, nor can we be sure that any patents issued or licensed to us in the future will be useful in protecting our technology. For this and more comprehensive risks related to our intellectual property, please see "Risk Factors—Risks Relating to Our Intellectual Property Rights."

In addition to patent protection, we rely on trade secrets and know-how to develop and maintain our competitive position. For example, aspects of our proprietary technology platform are based on unpatented trade secrets and know-how related to the manufacturing of our product candidates. Trade secrets and know-how can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and commercial partners. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

We also seek and will continue to seek trademark protection in the United States and outside of the United States where available and when appropriate. We use and intend to use these registered marks in connection with our pharmaceutical research and development as well as our product candidates.

Manufacturing and Supply of CRB-701, CRB-601, and CRB-913

We do not own or operate manufacturing facilities and rely on third-party contract manufacturing organizations or licensing partners to supply Corbus with drugs for pre-clinical and clinical studies.

CRB-701 is designed to be an improved next generation site-specific Nectin-4 targeting antibody drug conjugate. CRB-701 is a monoclonal antibody attached to an MMAE cytotoxic payload using a proprietary linker technology. CSPC has developed a manufacturing process under current good manufacturing practice ("cGMP") to produce batches of drug substance and drug product for pre-clinical and clinical studies. CSPC will supply drug substance and drug product in support of clinical and commercial activities.

CRB-601 is a monoclonal antibody and we are in the process of developing a manufacturing process under cGMP to produce batches of drug substance and drug product for pre-clinical and clinical studies. Drug substance for CRB-601 will be produced by a contract manufacturer through recombinant DNA technology utilizing genetically engineered host cells, upstream cell culture processes and downstream purification methods as required to manufacture the drug substance.

CRB-913 is a second-generation cannabinoid receptor type 1 (CB1) inverse agonist and we have developed a manufacturing process under cGMP to produce batches of drug substance for pre-clinical and IND-enabling studies. Drug substance for CRB-913 has been produced by a contract manufacturer to initiate drug product studies.

Competition

The biotechnology and pharmaceutical industries are characterized by a rapid pace of new innovation and discoveries, fierce competition and strong defense of intellectual property. We face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others.

Competitors to CRB-701 who are targeting Nectin-4 include Seagen, Bicycle Therapeutics, and Mabwell. Competitors to CRB-601 who are also targeting the TGFβ pathway in cancer include Bristol Meyers, Merck KGaA, Pfizer, Sanofi, Argenx, Morphic, Pliant and Scholar Rock. Competitors to CRB-913 who are also targeting obesity include Eli Lilly, Novo Nordisk, Amgen, and Pfizer.

Regulatory Matters

Government Regulation

The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Any product development activities related to products that we may develop or acquire in the future will be subject to extensive regulation by various government authorities, including the FDA, other federal, state and local agencies and comparable regulatory authorities in other countries, which regulate the design, research, clinical and pre-clinical development, testing, manufacturing, storage, distribution, import, export, labeling, advertising and marketing of pharmaceutical products and devices. Generally, before a new drug can be sold, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific to each regulatory authority, submitted for review and approved by the regulatory authority. The data are often generated in two distinct development states: pre-clinical and clinical.

Development of Drugs in the United States

Products that we may develop or acquire in the future must be approved by the FDA before they may be legally marketed in the United States. For new chemical entities, the pre-clinical development stage generally involves synthesizing the active component, developing the formulation and determining the manufacturing process, and drug stability as well as carrying out non-human toxicology, pharmacology and drug metabolism studies that support subsequent clinical testing. These pre-clinical laboratory and animal tests are often performed under the FDA's Good Laboratory Practices regulations. A drug's sponsor must submit the result of the pre-clinical tests, together with manufacturing information, analytical data and any available clinical data or literature and a proposed clinical protocol to the FDA as part of an IND application, which is a request for authorization from the FDA to administer an investigational drug or biological product to humans. Similar filings are required in other countries.

The clinical stage of development can generally be divided into three sequential phases that may overlap: Phase 1, Phase 2, and Phase 3 clinical trials. In Phase 1, generally, small numbers of healthy volunteers are initially exposed to single escalating doses and then multiple escalating doses of the product candidate. The primary purpose of these studies is to assess the metabolism, pharmacologic action and general safety of the drug. Phase 2 trials typically involve studies in disease-affected patients to determine the dose required to produce the desired benefits, common short-term side effects and risks. Phase 2 studies are typically well-controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects. Phase 3 trials are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 studies usually include from several hundred to several thousand subjects and are closely controlled and monitored. In addition to these Phase 1-3 trials, other trials may be conducted to gather additional safety, pharmacokinetic and pharmacodynamic information. Pharmaceutical products with active ingredients equal or similar to those already approved by the FDA often have more streamlined development programs than compounds entirely new to the agency, often skipping Phase 1 and 2 trials.

A clinical plan must be submitted to the FDA prior to commencement of a clinical trial. If the FDA has concerns about the clinical plan or the safety of the proposed studies, they may suspend or terminate the study at any time. Studies must be conducted in accordance with good clinical practice and reporting of study progress and any adverse experiences is required. Studies are also subject to review by independent institutional review boards responsible for overseeing studies at particular sites and protecting human research study subjects. An independent institutional review board may also suspend or terminate a study once initiated. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that once begun, issues will not arise that could cause the trial to be suspended or terminated.

Post-approval studies, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. Sometimes, these studies are used to gain additional experience from the treatment of patients in the intended therapeutic condition. In certain instances, the FDA may mandate the performance of Phase 4 studies. In other situations, post-approval studies aim to gain additional indications for a medication or develop new dosage forms for a medication.

Special Protocol Assessment

The Federal Food, Drug, and Cosmetic Act directs the FDA to meet with sponsors, pursuant to a sponsor's written request, for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an efficacy claim in a New Drug Application (NDA) or a Biologic Licensing Application (BLA). If an agreement is reached, the FDA will reduce the agreement to writing and make it part of the administrative record. This agreement is called a special protocol assessment (SPA). While the FDA's guidance on SPAs states that documented SPAs should be considered binding on the review division, the FDA has latitude to change its assessment if certain exceptions apply. Exceptions include public health concerns emerging that were unrecognized at the time of the protocol assessment, identification of a substantial scientific issue essential to the safety or efficacy testing that later comes to light, a sponsor's failure to follow the protocol agreed upon, or the FDA's reliance on data, assumptions or information that are determined to be wrong.

Review and Approval in the United States

Following pivotal or Phase 3 trial completion, data are analyzed to determine safety and efficacy. Data are then filed with the FDA in an NDA or BLA, along with proposed labeling for the product and information about the manufacturing and testing processes and facilities that will be used to ensure product quality. In the United States, FDA approval of an NDA or BLA must be obtained before marketing a pharmaceutical product. The NDA or BLA must contain proof of safety, purity, potency, and efficacy, which entails extensive pre-clinical and clinical testing.

The FDA will likely re-analyze the clinical trial data, which could result in extensive discussions between the FDA and us during the review process. The review and evaluation of applications by the FDA is extensive and time consuming and may take several years to complete. The FDA may conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with current good manufacturing practice requirements and may also audit data from clinical and pre-clinical trials.

There is no assurance that the FDA will act favorably or quickly in making such reviews and significant difficulties or costs may be encountered in our efforts to obtain FDA approvals. The FDA may require that certain contraindications, warnings or precautions be included in the product labeling, or may condition the approval of the NDA or BLA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing or clinical trials and surveillance programs to monitor the safety of approved products that have been commercialized. Further, the FDA may place conditions on approvals including the requirement for a risk evaluation and mitigation strategy, or REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS; the FDA will not approve the NDA or BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan product designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of regulatory review and approval process. In addition to the potential period of exclusivity, orphan designation makes a company eligible for grant funding of up to $400,000 per year for four years to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as (i) the drug's orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant's product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. If a drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity. We have received orphan drug designation for lenabasum for cystic fibrosis, systemic sclerosis, and dermatomyositis. There can be no assurance that we will receive orphan drug designation for our products.

Drug Development in Europe

In the European Union, our future products may also be subject to extensive regulatory requirements. Similar to the U.S., the marketing of medicinal products is subject to the granting of marketing authorizations by regulatory agencies. Also, as in the U.S., the various phases of pre-clinical and clinical research in the European Union are subject to significant regulatory controls.

Review and Approval in the European Union

In the European Union, approval of new medicinal products can be obtained through one of three processes: the mutual recognition procedure, the centralized procedure, and the decentralized procedure. We intend to determine which process we will follow, if any, in the future.

Mutual Recognition Procedure: An applicant submits an application in one European Union member state, known as the reference member state. Once the reference member state has granted the marketing authorization, the applicant may choose to submit applications in other concerned member states, requesting them to mutually recognize the marketing authorizations already granted. Under this mutual recognition process, authorities in other concerned member states have 55 days to raise objections, which must then be resolved by discussion among the concerned member states, the reference member state and the applicant within 90 days of the commencement of the mutual recognition procedure. If any disagreement remains, all considerations by authorities in the concerned member states are suspended and the disagreement is resolved through an arbitration process. The mutual recognition procedure results in separate national marketing authorizations in the reference member state.

Centralized Procedure: This procedure is currently mandatory for products developed by means of a biotechnological process and optional for new active substances and other "innovative medicinal products with novel characteristics." Under this procedure, an application is submitted to the European Agency for the Evaluation of Medical Products. Two European Union member states are appointed to conduct an initial evaluation of each application. These countries each prepare an assessment report that is then used as the basis of a scientific opinion of the Committee on Proprietary Medical Products. If this opinion is favorable, it is sent to the European Commission, which drafts a decision. After consulting with the member states, the European Commission adopts a decision and grants a marketing authorization, which is valid throughout the European Union and confers the same rights and obligations in each of the member states as a marketing authorization granted by that member state.

Decentralized Procedure: The most recently introduced of the three processes for obtaining approval of new medicinal processes in the European Union, the decentralized procedure is similar to the mutual recognition procedure described above, but with differences in the timing that key documents are provided to concerned member states by the reference member state, the overall timing of the procedure and the possibility of, among other things, "clock stops" during the procedure.

Post-Marketing Requirements

Following approval of a new product, a pharmaceutical company and the approved product are subject to continuing regulation by the FDA and other federal and state regulatory authorities, including, among other things, monitoring and recordkeeping activities, reporting to applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations not described in the drug's approved labeling (known as "off-label use"), and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses. Modifications or enhancements to the products or labeling or changes of site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process. The FDA regulations require the products be manufactured in specific approved facilities and in accordance with current good manufacturing practices, and NDA and BLA holders must list their products and register their manufacturing establishments with the FDA. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with current good manufacturing practice and other laws. NDA and BLA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms. These firms are subject to inspections by the FDA at any time, and the discovery of violative conditions could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of Health and Human Services, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, and state and local governments. These regulations include:

- the federal healthcare program anti-kickback law which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims 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 government reimbursement programs that are false or fraudulent. The government may assert that a claim including items or services resulting from a violation of the federal healthcare program anti-kickback law or related to off-label promotion constitutes a false or fraudulent claim for purposes of the federal false claims laws;
- the Federal Physician Payments Sunshine Act within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members; and
- the Health Insurance Portability and Accountability Act, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates"—independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.
- applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act.
- The Lanham Act and federal antitrust laws.
- state 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 laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

Distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, traceability, and storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products

The handling of any controlled substances must comply with the U.S. Controlled Substances Act and the Controlled Substances Import and Export Act. In the U.S., our product candidate, lenabasum, is currently classified as Schedule I controlled substance as defined in the Controlled Substance Act (the "CSA").

Schedule I controlled substances are pharmaceutical products subject to specific regulations under the CSA, that establishes, among other things, certain registration, manufacturing quotas, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. All parties responsible for the manufacturing, distribution and testing the drug in clinical studies must apply for and obtain a license from the DEA before they are permitted to perform these activities with lenabasum. Furthermore, these parties must have the security, control, recordkeeping, reporting and inventory mechanisms required by the DEA to prevent drug loss and diversion. All licensed facilities are required to renew their registrations annually if they intend to continue to work with our drug. The DEA conducts periodic inspections of certain registered establishments that handle controlled substances. We have been working with our manufacturers, distributors, exporters and clinical sites to obtain the necessary licenses to work with lenabasum. The parties responsible for the manufacturing, distribution and export of lenabasum have already applied for and have been granted DEA licenses and a number of institutions responsible for conducting our current clinical studies have also been granted DEA licenses.

Individual states have also established controlled substance laws and regulations. Though state-controlled substances laws often mirror federal law because the states are separate jurisdictions, they may separately schedule drugs, as well. While some states automatically schedule a drug based on federal action, other states schedule drugs through rulemaking or a legislative action. The requirement for state registrations could also result in delay of the manufacturing, distribution of lenabasum or in the completion of our current clinical studies. We and our manufacturing vendors and clinical sites must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

Third-Party Payer Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any of our drug candidates that ultimately may obtain regulatory approval. In both the United States and foreign markets, our ability to commercialize our product candidates successfully, and to attract commercialization partners for our product candidates, depends in significant part on the availability of adequate financial coverage and reimbursement from third-party payers, including, in the United States, governmental payers such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. Medicare is a federally funded program managed by the CMS, through local fiscal intermediaries and carriers that administer coverage and reimbursement for certain healthcare items and services furnished to the elderly and disabled. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels and who are otherwise uninsured that is both federally and state funded and managed by each state. The federal government sets general guidelines for Medicaid and each state creates specific regulations that govern its individual program. Each payer has its own process and standards for determining whether it will cover and reimburse a procedure or particular product. Private payers often rely on the lead of the governmental payers in rendering coverage and reimbursement determinations. Therefore, achieving favorable CMS coverage and reimbursement is usually a significant gating issue for successful introduction of a new product. The competitive position of some of our products will depend, in part, upon the extent of coverage and adequate reimbursement for such products and for the procedures in which such products are used. Prices at which we or our customers seek reimbursement for our product candidates can be subject to challenge, reduction or denial by the government and other payers.

The United States Congress and state legislatures may, from time to time, propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our product candidates profitably. For example, the two-year spending law signed by the President of United States on February 9, 2018 includes a provision raising the manufacturer discount to 70% in 2019 in the Medicare Part D coverage gap, also known as the "donut hole." Under prior law, manufacturers were required to provide a 50% discount on prescription drugs purchased in the donut hole. Manufacturers of branded drugs will face much higher liabilities from donut hole payments beginning in 2019, estimated at multiple billions of dollars for some of the largest companies.

The cost of pharmaceuticals continues to generate substantial governmental and third-party payer interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Our results of operations could be adversely affected by current and future healthcare reforms.

Some third-party payers also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and operate profitably.

In addition, in some foreign countries, 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. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

Employees

We had 33 full-time employees at December 31, 2022. All our employees are engaged in administration, finance, clinical, manufacturing, regulatory and business development functions. We believe our relations with our employees are good. In addition, we utilize and will continue to utilize consultants, clinical research organizations and third parties to perform our pre-clinical studies, clinical studies, manufacturing, and regulatory functions.

Corporate Information

Corbus Pharmaceuticals, Inc. (formerly known as JB Therapeutics Inc.), was incorporated on April 24, 2009 under the laws of the State of Delaware. On April 11, 2014, JB Therapeutics, Inc. completed a merger with Corbus Pharmaceuticals Holdings, Inc. and changed its name to Corbus Pharmaceuticals, Inc. Upon the consummation of the merger, Corbus Pharmaceuticals, Inc. became a wholly-owned subsidiary of Corbus Pharmaceuticals Holdings, Inc. which continues to operate the business of Corbus Pharmaceuticals, Inc. Our principal executive offices are located at 500 River Ridge Drive, Norwood, Massachusetts 02062, and our telephone number is (617) 963-0100. Our website address is www.corbuspharma.com.

We make available free of charge through the Investor Relations link on our website, www.corbuspharma.com, access to press releases and investor presentations, as well as all materials that we file electronically with the SEC, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports, filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after electronically filing such materials with, or furnishing them to, the SEC. During the period covered by this Form 10-K, we made all such materials available through our website as soon as reasonably practicable after filing such materials with the SEC. In addition, the SEC maintains an Internet website, www.sec.gov, that contains reports, proxy and information statements and other information that we file electronically with the SEC.

This report and the information incorporated herein by reference contain references to trademarks, service marks and trade names owned by us or other companies. Solely for convenience, trademarks, service marks and trade names referred to in this report and the information incorporated herein, including logos, artwork, and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks, service marks and trade names. We do not intend our use or display of other companies' trade names, service marks or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies. Other trademarks, trade names and service marks appearing in this report are the property of their respective owners.

ITEM 1A. RISK FACTORS

An investment in our common stock is speculative and illiquid and involves a high degree of risk including the risk of a loss of your entire investment. You should carefully consider the risks and uncertainties described below and the other information contained in this report and our other reports filed with the Securities and Exchange Commission. The risks set forth below are not the only ones facing us. Additional risks and uncertainties may exist that could also adversely affect our business, operations and financial condition. If any of the following risks actually materialize, our business, financial condition and/or operations could suffer. In such event, the value of our common stock could decline, and you could lose all or a substantial portion of the money that you pay for our common stock.

Summary of Risks Associated with Our Business

Our business and an investment in our company is subject to numerous risks and uncertainties, including those highlighted in the section titled "Risk Factors" immediately following this summary. Some of these risks include:

- We have never generated any product revenues;
- We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability;
- We will need substantial additional funding, and certain terms included in our financing transactions may restrict our ability to raise such capital at the times and in the manner we may require;
- We expect that we will rely on third parties to assist us in conducting clinical trials for our drug candidates, and if these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business would be substantially harmed;
- Changes in geopolitical conditions, U.S.-China trade relations and other factors beyond our control may adversely impact our business and operating results;
- We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of our product candidates;
- Clinical trials are very expensive, time-consuming, difficult to design and implement and involve an uncertain outcome;
- If we are not able to obtain any required regulatory approvals for our drug candidates, we will not be able to commercialize our product candidates and our ability to generate revenue will be limited;
- We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively;
- We do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of our product candidates;
- We are, and will be, completely dependent on third parties to manufacture our drug candidates, and our commercialization of our drug candidates could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of our drug candidates or fail to do so at acceptable quality levels or prices;
- We have in-licensed a portion of our intellectual property, and if we fail to comply with our obligations under these arrangements, we could lose such intellectual property rights or owe damages to the licensor of such intellectual property; and
- We do not currently intend to pay dividends on our common stock in the foreseeable future, and consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

Risk Related to our Company and our Business

Risks Related to Our Financial Position and Need for Capital

We are a biopharmaceutical company with a limited operating history.

We are a biopharmaceutical company with a limited operating history. All of our product candidates that we do not intend to out-license are in the discovery stage, pre-clinical, or clinical development stage. We must complete clinical studies and other development activity and receive regulatory approval of an NDA or BLA, before commercial sales of a product can commence. The likelihood of success of our business plan must be considered in light of the problems, substantial expenses, difficulties, complications and delays frequently encountered in connection with developing and expanding early-stage businesses and the regulatory and competitive environment in which we operate. Pharmaceutical product development is a highly speculative undertaking, involves a substantial degree of risk and is a capital-intensive business.

Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially clinical pharmaceutical companies such as ours. Potential investors should carefully consider the risks and uncertainties that a company with a limited operating history will face. In particular, potential investors should consider that we cannot assure you that we will be able to:

- successfully implement or execute our current business plan, and we cannot assure you that our business plan is sound;
- successfully manufacture our clinical products and establish commercial drug supply;
- successfully complete the pre-clinical and clinical trials necessary to obtain regulatory approval for the marketing of our drug candidates;
- secure market exclusivity and/or adequate intellectual property protection for our drug candidates;
- attract and retain an experienced management and advisory team;
- secure acceptance of our drug candidates in the medical community and with third party payors and consumers;
- launch commercial sales of our drug candidates, whether alone or in collaboration with others; and
- raise sufficient funds in the capital markets to effectuate our business plan.

If we cannot successfully execute any one of the foregoing, our business may not succeed, and your investment will be adversely affected.

We have incurred operating losses in each year since our inception and expect to continue to incur substantial losses for the foreseeable future. We may never become profitable or, if we achieve profitability, be able to sustain profitability.

We expect to incur substantial expenses without corresponding revenues unless and until we are able to obtain regulatory approval and successfully commercialize any of our drug candidates. To date, we have not generated any revenue from our drug candidates, and we expect to incur significant expense to complete our pre-clinical and clinical program for our drug candidates in the United States and elsewhere. We may never be able to obtain regulatory approval for the marketing of our drug candidates in any indication in the United States or internationally. Even if we are able to commercialize our drug candidates, there can be no assurance that we will generate significant revenues or ever achieve profitability. Our net losses for the years ended December 31, 2022 and December 31, 2021 were approximately $42,347,000 and $45,640,000, respectively. As of December 31, 2022, we had an accumulated deficit of approximately $392.1 million.

We may elect to pursue FDA approval for our drug candidates, which will result in significant additional research and development expenses. As a result, we expect to continue to incur substantial losses for the foreseeable future, and these losses will increase. We are uncertain when or if we will be able to achieve or sustain profitability. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable would impair our ability to sustain operations and adversely affect the price of our common stock and our ability to raise capital.

Our cash, cash equivalents, or investments will only fund our operations for a limited time, and we will need to raise additional capital to support our development and commercialization efforts.

We are currently operating at a loss and expect our operating costs will increase significantly as we incur further costs related to pre-clinical development and the clinical trials for our drug candidates. As of December 31, 2022, we held cash, cash equivalents, and investments of approximately $59.2 million.

We expect the cash, cash equivalents, and investments of approximately $59.2 million at December 31, 2022 to be sufficient to meet our operating and capital requirements through the second quarter of 2024, based on planned expenditures.

We may seek additional capital through a combination of private and public equity offerings, debt financings and strategic collaborations. Debt financing, if obtained, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, and could increase our expenses and require that our assets secure such debt.

Equity financing, if obtained, could result in dilution to our then existing stockholders and/or require such stockholders to waive certain rights and preferences. If such financing is not available on satisfactory terms, or is not available at all, we may be required to delay, scale back or eliminate the development of business opportunities and our operations and financial condition may be materially adversely affected. We can provide no assurances that any additional sources of financing will be available to us on favorable terms, if at all. In addition, if we are unable to secure sufficient capital to fund our operations, we may choose to pursue, as an alternative, strategic collaborations that could require us to share commercial rights to our drug candidates with third parties in ways that we currently do not intend or on terms that may not be favorable to us. If we choose to pursue additional indications and/or geographies for our drug candidates or otherwise expand more rapidly than we presently anticipate we may also need to raise additional capital sooner than expected.

Our Loan and Security Agreement contains restrictive and financial covenants that may limit our operating flexibility.

On July 28, 2020, we entered into a Loan and Security Agreement ("the Loan and Security Agreement") with our subsidiary, Corbus Pharmaceuticals, Inc., as borrower, us, as guarantor, and each lender party thereto (the "Lenders"), K2 HealthVentures LLC, an unrelated third party, as administrative agent for the Lenders, and Ankura Trust Company, LLC, an unrelated third party, as collateral agent for the Lenders, pursuant to which K2HV may provide us with term loans in an aggregate principal amount of up to $50,000,000. The Loan and Security Agreement is secured by a lien covering substantially all of our personal property, excluding intellectual property.

The Loan and Security Agreement contains customary representations, warranties, and covenants. including restrictive covenants by the Company and Borrower limiting additional indebtedness, liens, mergers and acquisitions, dispositions, investments, distributions, subordinated debt, transactions with affiliates and fundamental changes. We therefore may not be able to engage in any of the foregoing types of transactions unless we obtain the consent of K2 HealthVentures or prepay the outstanding amount under the Loan and Security Agreement. The Loan and Security Agreement also contains certain financial covenants, including requirements to maintain unrestricted cash in the amount of $10,000,000 or the amount of all principal loans outstanding if certain regulatory and developmental milestones do not occur.

The restrictions and covenants in the Loan and Security Agreement, as well as those contained in any future debt financing agreements that we may enter into, may restrict our ability to finance our operations and engage in, expand or otherwise pursue our business activities and strategies. Our ability to comply with these covenants and restrictions may be affected by events beyond our control, and breaches of these covenants and restrictions could result in a default under the loan agreement and any future financing agreements that we may enter into.

Risks Related to Product Development, Regulatory Approval, Manufacturing and Commercialization

Our success is dependent upon successful development of our drug candidates in our pipeline or that we may acquire. If we are unable to generate revenues from any product candidates, our ability to create stockholder value will be limited.

We do not generate revenues from any FDA approved drug products. Our current business currently depends on the successful development, regulatory approval, and commercialization of our pre-clinical drug candidates, which may never occur.

CRB-701 is currently in a Phase 1 clinical trial being conducted by CSPC in China. We are completing pre-clinical testing for CRB-601 in the U.S. and we expect to file an IND in 2023. We note that most drug candidates never reach the clinical development stage and even those that do have only a small chance of successfully completing clinical development and gaining regulatory approval. Notably, we advanced our product candidate lenabasum to a phase 3 study. In June 2021, we announced that the primary endpoint in our DETERMINE phase 3 study of lenabasum for treatment of dermatomyositis was not met. We will continue to face risks related to the uncertainty of clinical trials and success in early phases of pre-clinical and clinical trials does not ensure that later clinical trials will be successful.

Drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Our pre-clinical and clinical trials may be unsuccessful, which would materially harm our business. Even if our initial trials are successful, we will be required to conduct additional trials to establish the safety and efficacy of our drug candidates before an NDA or BLA can be filed with the FDA for marketing approval of any of our drug candidates.

Drug testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in early phases of pre-clinical and clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, the drug testing process that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates. The research, testing, manufacturing, labeling, packaging, storage, approval, sale, marketing, advertising and promotion, pricing, export, import and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. We are not permitted to market any of our drug candidates as prescription pharmaceutical products in the United States until we receive approval of an NDA or BLA from the FDA or in foreign markets until we receive the requisite approval from comparable regulatory authorities in such countries. In the United States, the FDA generally requires the completion of pre-clinical and clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before an NDA or BLA is approved. Regulatory authorities in other jurisdictions impose similar requirements. Of the large number of drugs in development, only a small percentage result in the submission of an NDA or BLA to the FDA and even fewer are eventually approved for commercialization. We have never submitted an NDA or BLA to the FDA or any comparable applications to other regulatory authorities. If our development efforts for our drug candidates, including regulatory approval, are not successful for our planned indications, or if adequate demand for our drug candidates is not generated, our business will be harmed.

Receipt of necessary regulatory approval is subject to a number of risks, including the following:

- pre-clinical testing may not yield results that justify progressing to clinical testing;
- the FDA or comparable foreign regulatory authorities or institutional review boards, or IRBs, may disagree with the design or implementation of our clinical trials;
- we may not be able to provide acceptable evidence of the safety and efficacy of our drug candidates;
- the results of our clinical trials may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA, the European Medicines Agency, or EMA, or other comparable foreign regulatory authorities for marketing approval;
- the dosing of our drug candidates in a particular clinical trial may not be at an optimal level;
- patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to our drug candidates;
- the data collected from clinical trials may not be sufficient to support the submission of an NDA, BLA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; and
- the FDA or comparable foreign regulatory authorities may decide that the clinical trial endpoints we have chosen, the statistical analysis plans that we use, or any other parameter that we rely on to show the safety and efficacy of our drugs, are not parameters that can be used to support approval of our products.

Failure to obtain regulatory approval for any of our drug candidates for the foregoing or any other reasons will prevent us from commercializing such product candidate as a prescription product, and our ability to generate revenue will be materially impaired. We cannot guarantee that regulators will agree with the endpoints that we have chosen to use in our clinical trials, our assessment of the results of our clinical trials or that such trials will be considered by regulators to have shown safety or efficacy of our product candidates. The FDA, EMA and other regulators have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional clinical trials, or pre-clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate.

We have only limited experience in filing the applications necessary to gain regulatory approvals and expect to rely on consultants and third-party contract research organizations, or CROs, with expertise in this area to assist us in this process. Securing FDA approval requires the submission of pre-clinical, clinical and/or pharmacokinetic data, information about product manufacturing processes and inspection of facilities and supporting information to the FDA for each therapeutic indication to establish a product candidate's safety and efficacy for each indication. Our drug candidates may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use with respect to one or all intended indications.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the product candidates involved, the jurisdiction in which regulatory approval is sought and the substantial discretion of regulatory authorities. Changes in the regulatory approval policy during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for a submitted product application may cause delays in the approval or rejection of an application. Regulatory approval obtained in one jurisdiction does not necessarily mean that a product candidate will receive regulatory approval in all jurisdictions in which we may seek approval, but the failure to obtain approval in one jurisdiction may negatively impact our ability to seek approval in a different jurisdiction. Failure to obtain regulatory marketing approval for any of our drug candidates in any indication will prevent us from commercializing such product candidates, and our ability to generate revenue will be materially impaired.

If we are not able to obtain any required regulatory approvals for our drug candidates, we will not be able to commercialize our product candidates and our ability to generate revenue will be limited.

Drug testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Our drug candidates are in various stages of discovery, pre-clinical, and clinical testing. Pre-clinical tests are performed at an early stage of a product's development and provide information about a drug candidate's safety and effectiveness on laboratory animals. Pre-clinical tests can last years. If a product passes its pre-clinical tests satisfactorily and we determine that further development is warranted, we would file an IND application for the product with the FDA, and if the FDA gives its approval, we would begin Phase 1 clinical tests. If Phase 1 test results are satisfactory and the FDA gives its approval, we can begin Phase 2 clinical tests. If Phase 2 test results are satisfactory and the FDA gives its approval, we can begin Phase 3 pivotal studies. Once clinical testing is completed and an NDA or BLA is filed with the FDA, it may take more than a year to receive FDA approval.

The results of pre-clinical studies and early clinical trials may not be predictive of the results of later-stage clinical trials. We cannot assure you that the FDA will view the results as we do or that any future trials of our drug candidates will achieve positive results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Any future clinical trial results for our drug candidates may not be successful.

In all cases, we must show that a drug candidate is both safe and effective before the FDA, or drug approval agencies of other countries where we intend to sell the product, will approve it for sale. Our research and testing programs must comply with drug approval requirements both in the United States and in other countries, since we are developing our drug candidates with the intention to, or could later decide to, commercialize them both in the U.S. and abroad. A product may fail for safety or effectiveness at any stage of the testing process. A major risk we face is the possibility that none of our products under development will come through the testing process to final approval for sale, with the result that we cannot derive any commercial revenue from them after investing significant amounts of capital in multiple stages of pre-clinical and clinical testing. In addition, a number of factors could contribute to a lack of favorable safety and efficacy results for our drug candidates. For example, our trials could result in increased variability due to varying site characteristics, such as local standards of care, differences in evaluation period and surgical technique, and due to varying patient characteristics, including demographic factors and health status.

Even if we receive regulatory approval for our drug candidates, we still may not be able to successfully commercialize any of our products, and the revenue that we generate from sales, if any, may be limited.

If approved for marketing, the commercial success of our drug candidates will depend upon their acceptance by the medical community, including physicians, patients and health care payors. The degree of market acceptance of our drug candidates will depend on a number of factors, including:

- demonstration of clinical safety and efficacy;
- relative convenience, pill burden and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe our drug candidates and of the target patient population to try new therapies;
- safety, tolerability and efficacy of our drug candidates compared to competing products;
- safety of competing products may impact our drug candidates;
- the introduction of any new products that may in the future become available to treat indications for which our drug candidates may be approved;
- new procedures or methods of treatment that may reduce the incidences of any of the indications in which our drug candidates may show utility;
- pricing and cost-effectiveness;
- the inclusion or omission of our drug candidates in applicable treatment guidelines;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in FDA-approved labeling;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement.

If any of our drug candidates are approved, but do not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of our drug candidates may require significant resources and may never be successful.

In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our drug candidates successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render our drug candidates not commercially viable. For example, regulatory authorities may approve our drug candidates for fewer or more limited indications than we request, may not approve the prices we intend to charge for our drug candidates, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve our drug candidates with labels that do not include the labeling claims necessary or desirable for the successful commercialization of a particular indication. Further, the FDA or comparable foreign regulatory authorities may place conditions on approvals, such as risk management plans and a Risk Evaluation and Mitigation Strategy, or REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS; the FDA will not approve the NDA or BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA may also require a REMS for an approved product when new safety information emerges. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of our drug candidates. Moreover, product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of our drug candidates.

Even if we obtain marketing approval for our drug candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our drug candidates could be subject to labeling and other restrictions and withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our drug candidates.

Even if we obtain United States regulatory approval of our drug candidates for an indication, the FDA may still impose significant restrictions on their indicated uses or marketing or the conditions of approval or impose ongoing requirements for potentially costly and time-consuming post-approval studies, including Phase 4 clinical trials, and post-market surveillance to monitor safety and efficacy. Our drug candidates will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post-market information. These requirements include registration with the FDA, continued compliance with current Good Clinical Practices regulations, or cGCPs, for any clinical trials that we conduct post-approval, continued compliance with the CSA and ongoing review by the DEA. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current Good Manufacturing Practices, or cGMP, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents.

With respect to sales and marketing activities by us or any future partner, advertising and promotional materials must comply with FDA rules in addition to other applicable federal, state and local laws in the United States and similar legal requirements in other countries. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific/educational grant programs. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

In addition, if any of our drug candidates are approved for an indication, our product labeling, advertising, and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for any of our drug candidates, physicians may nevertheless legally prescribe such products to their patients in a manner that is inconsistent with the approved label. However, if we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed.

If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured, or if we or our manufacturers fail to comply with applicable regulatory requirements, we may be subject to the following administrative or judicial sanctions:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- issuance of warning letters or untitled letters;
- injunctions or the imposition of civil or criminal penalties or monetary fines;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- suspension of, or imposition of restrictions on, operations, including costly new manufacturing requirements; or
- product seizure or detention or refusal to permit the import or export of product.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our drug candidates and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase our product liability exposure.

We have entered into, and may in the future enter into, collaboration agreements for the licensing, development, and ultimate commercialization of some of our drug candidates. In such cases, we will depend greatly on our third-party collaborators to license, develop and commercialize such drug candidates, and they may not meet our expectations.

We may enter into co-development and commercialization partnerships for our drug candidates where appropriate. The process of identifying collaborators and negotiating collaboration agreements for the licensing, development, and ultimate commercialization of some of our drug candidates may cause delays and increased costs. We may not be able to enter into collaboration agreements on terms favorable to us or at all. Furthermore, some of those agreements may give substantial responsibility over our drug candidates to the collaborator. Some collaborators may be unable or unwilling to devote sufficient resources to develop our drug candidates as their agreements require. They often face business risks similar to ours, and this could interfere with their efforts. Also, collaborators may choose to devote their resources to products that compete with ours. If a collaborator does not successfully develop any one of our products, we will need to find another collaborator to do so. The success of our search for a new collaborator will depend on our legal right to do so at the time and whether the product remains commercially viable.

If we enter into collaboration agreements for one or more of our drug candidates, the success of such drug candidates will depend in great part upon our and our collaborators' success in promoting them as superior to other treatment alternatives. We believe that our drug candidates can be proven to offer disease treatment with notable advantages over drugs in terms of patient compliance and effectiveness. However, there can be no assurance that we will be able to prove these advantages or that the advantages will be sufficient to support the successful commercialization of our drug candidates.

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

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors in a number of jurisdictions, many of which have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than we have. Established competitors may invest heavily to quickly discover and develop novel compounds that could make our drug candidates obsolete or uneconomical. Any new product that competes with an approved product may need to demonstrate compelling advantages in efficacy, cost, convenience, tolerability and safety to be commercially successful. Other competitive factors, including generic competition, could force us to lower prices or could result in reduced sales. In addition, new products developed by others could emerge as competitors to our drug candidates. If we are not able to compete effectively against our current and future competitors, our business will not grow, and our financial condition and operations will suffer.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our drug candidates. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In the United States, under the Medicare Modernization Act, or MMA, Medicare Part D provides coverage to the elderly and disabled for outpatient prescription drugs by approving and subsidizing prescription drug plans offered by private insurers. The MMA also authorizes Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. The Part D plans use their formulary leverage to negotiate rebates and other price concessions from drug manufacturers. Also under the MMA, Medicare Part B provides coverage to the elderly and disabled for physician-administered drugs on the basis of the drug's average sales price, a price that is calculated according to regulatory requirements and that the manufacturer reports to Medicare quarterly.

Both Congress and the Centers for Medicare & Medicaid Services (CMS), the agency that administers the Medicare program, from time to time consider legislation, regulations, or other initiatives to reduce drug costs under Medicare Parts B and D. For example, under the 2010 Affordable Care Act, drug manufacturers are required to provide a 50% discount on prescriptions for branded drugs filled while the beneficiary is in the Medicare Part D coverage gap, also known as the "donut hole." There have been legislative proposals to repeal the "non-interference" provision of the MMA to allow CMS to leverage the Medicare market share to negotiate larger Part D rebates. Further cost reduction efforts could decrease the coverage and price that we receive for our drug candidates and could seriously harm our business. Private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement under the Medicare program may result in a similar reduction in payments from private payors.

The 2010 Affordable Care Act is intended to broaden access to health insurance and reduce or constrain the growth of healthcare spending. Further, the Affordable Care Act imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also increased the amount of the rebates drug manufacturers must pay to state Medicaid programs, required that Medicaid rebates be paid on managed Medicaid utilization, and increased the additional rebate on "line extensions" (such as extended-release formulations) of solid oral dosage forms of branded products. The law also contains substantial provisions affecting fraud and abuse compliance and transparency, which may require us to modify our business practices with healthcare practitioners and incur substantial costs to ensure compliance.

In addition, other legislative changes that affect the pharmaceutical industry have been proposed and adopted in the United States since the ACA was enacted. For example, the Inflation Reduction Act of 2022 included, among other things, a provision that authorizes CMS to negotiate a "maximum fair price" for a limited number of high-cost, single-source drugs every year, and another provision that requires drug companies to pay rebates to Medicare if prices rise faster than inflation. In addition, various states have adopted or are considering adopting laws that require pharmaceutical companies to provide notice prior to raising prices and to justify price increases. We expect that additional healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability.

Our future growth depends, in part, on our ability to enter into and succeed in markets outside of the United States, where we may choose to rely on third party collaborations and will be subject to additional regulatory and commercial burdens, risks and other uncertainties.

Our future profitability will depend, in part, on our ability to gain approval of and commercialize our drug candidates in non-U.S. markets. In some or all of these non-U.S. markets, we intend to enter into licensing and contractual collaborations with third parties to handle some or all of the tasks and responsibilities necessary to succeed. Our activities in non-U.S. markets are subject to additional risks and uncertainties, including:

- our ability to enter into favorable licensing and contractual arrangements with our partners;
- our ability to select partners who are capable of achieving success at the tasks they agree to perform;
- obtaining timely and sufficient favorable approval terms for our drug candidates;
- obtaining favorable pricing and reimbursement;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

International sales of our drug candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, and trade restrictions and changes in tariffs, any of which may adversely affect our results of operations.

If we market our drug candidates in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.

The FDA enforces laws and regulations which require that the promotion of pharmaceutical products be consistent with the approved prescribing information. While physicians may prescribe an approved product for a so-called "off label" use, it is unlawful for a pharmaceutical company to promote its products in a manner that is inconsistent with its approved label and any company which engages in such conduct may be subject to significant liability. Similarly, industry codes in the European Union and other foreign jurisdictions prohibit companies from engaging in off-label promotion and regulatory agencies in various countries enforce violations of the code with civil penalties. While we intend to ensure that our promotional materials are consistent with our label, regulatory agencies may disagree with our assessment and may issue untitled letters, warning letters or may institute other civil or criminal enforcement proceedings. In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include the U.S. Anti-Kickback Statute, U.S. False Claims Act and similar state laws. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

The U.S. Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not, in all cases, meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, recent health care reform legislation has strengthened these laws. For example, the Health Care Reform Law, among other things, amends the intent requirement of the U.S. Anti-Kickback Statute and criminal health care fraud statutes; a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Health Care Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the U.S. Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the U.S. False Claims Act. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid.

Over the past few years, pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicare or Medicaid for non-covered, off-label uses; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Most states also have statutes or regulations similar to the U.S. Anti-Kickback Statute and the U.S. False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include substantial civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, substantial criminal fines and imprisonment.

We are, and will be, completely dependent on third parties to manufacture our drug candidates, and our commercialization of our drug candidates could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of our drug candidates or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture the active pharmaceutical ingredients of our drug candidates, or the finished drug products, for use in our clinical trials or for commercial product, if any. As a result, we will be obligated to rely on contract manufacturers if and when our drug candidates are approved for commercialization.

We currently rely on a single contract supplier for manufacturing monoclonal antibodies. We have limited experience contracting third parties to manufacture monoclonal antibodies and do not control the manufacturing processes of, and are completely dependent on, our two contract manufacturing partners for compliance with cGMPs for manufacture of all active drug substances and finished drug products. These cGMP regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to our drug candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our drug candidates, if approved.

Our contract manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. We will not have control over our contract manufacturers' compliance with these regulations and standards. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market our drug candidates, delays, suspensions or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In addition, we will not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect our ability to develop, obtain regulatory approval for or market our drug candidates.

If, for any reason, these third parties are unable or unwilling to perform, we may not be able to terminate our agreements with them, and we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our active pharmaceutical ingredient, or API, or our finished products or should cease doing business with us, we could experience significant interruptions in the supply of our drug candidates or may not be able to create a supply of our drug candidates at all. Were we to encounter manufacturing issues, our ability to produce a sufficient supply of our drug candidates might be negatively affected. Our inability to coordinate the efforts of our third-party manufacturing partners, or the lack of capacity available at our third-party manufacturing partners, could impair our ability to supply our drug candidates at required levels. Because of the significant regulatory requirements that we would need to satisfy in order to qualify a new bulk or finished product manufacturer, if we face these or other difficulties with our current manufacturing partners, we could experience significant interruptions in the supply of our drug candidates if we decided to transfer the manufacture of our drug candidates to one or more alternative manufacturers in an effort to deal with the difficulties.

Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture our potential products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability, and quality. Any unanticipated disruption to a future contract manufacturer caused by problems at suppliers could delay shipment of our drug candidates, increase our cost of goods sold and result in lost sales.

We cannot guarantee that our manufacturing and supply partners will be able to manufacture our drug candidates at commercial scale on a cost-effective basis. If the commercial-scale manufacturing costs of our drug candidates are higher than expected, these costs may significantly impact our operating results. In order to reduce costs, we may need to develop and implement process improvements. However, in order to do so, we will need, from time to time, to notify or make submissions with regulatory authorities, and the improvements may be subject to approval by such regulatory authorities. We cannot be sure that we will receive these necessary approvals or that these approvals will be granted in a timely fashion. We also cannot guarantee that we will be able to enhance and optimize output in our commercial manufacturing process. If we cannot enhance and optimize output, we may not be able to reduce our costs over time.

There are risks associated with scaling up manufacturing to commercial scale. If our contract manufacturers are unable to manufacture our drug candidates on a commercial scale, this could potentially delay regulatory approval and commercialization or materially adversely affect our results of operations.

There are risks associated with scaling up manufacturing to commercial volumes including, among others, cost overruns, technical problems with process scale-up, process reproducibility, stability issues, and lot consistency. We have limited experience contracting with third parties to manufacture monoclonal antibodies and will need to be able to successfully scale up and produce a batch of CRB-601 to commence clinical studies. We are dependent on our licensing partner, CSPC, to manufacture antibody drug conjugates and we do not have control over their chemistry, manufacturing, and control strategy for CRB-701 to ensure successful development and supply of drug to commence clinical studies. Even if we obtain regulatory approval for our drug candidates, there is no assurance that our contract manufacturers or licensing partners will be able to manufacture the approved products to specifications acceptable to the FDA or other regulatory authorities, to produce them in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities of approved products for commercialization, either on a timely basis or at all, our commercialization efforts would be impaired, which would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We expect that we will rely on third parties to assist us in conducting clinical trials for our drug candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business would be substantially harmed.

We expect to enter into agreements with third-party CROs to assist us in conducting and managing our clinical programs, including contracting with clinical sites to perform our clinical studies. We plan to rely on these parties for execution of clinical studies for our drug candidates and we will control only certain aspects of conducting the clinical studies. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs and clinical sites will not relieve us of our regulatory responsibilities. We and our CROs will be required to comply with cGCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces these cGCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with cGCPs. In addition, our clinical trials must be conducted with products produced under cGMP regulations and will require a large number of test subjects. Our failure or the failure of our CROs or clinical sites to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties.

Although we intend to design the clinical trials for our drug candidates in consultation with CROs, we expect that the CROs will manage and assist us with the clinical trials conducted at contracted clinical sites. As a result, many important aspects of our drug development programs would be outside of our direct control. In addition, the CROs and clinical sites may not perform all of their obligations under arrangements with us or in compliance with regulatory requirements. If the CROs or clinical sites do not perform clinical trials in a satisfactory manner, or if they breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of our drug candidates for the subject indications may be delayed or our development program materially and irreversibly harmed. We cannot control the amount and timing of resources these CROs and clinical sites will devote to our program or our drug candidates. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of our clinical trials, which could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party CROs or clinical sites terminate, we may not be able to enter into arrangements with alternative CROs or clinical sites. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any such clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our financial results and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Any termination or suspension of or delays in the commencement or completion of any necessary studies of our drug candidates for any indications could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

The commencement and completion of clinical studies can be delayed for a number of reasons, including delays related to:

- the FDA failing to grant permission to proceed and placing the clinical study on hold;
- subjects failing to enroll or remain in our trials at the rate we expect;
- a facility manufacturing any of our drug candidates being ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of cGMP requirements or other applicable requirements, or cross-contaminations of product in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- subjects choosing an alternative treatment for the indications for which we are developing our drug candidates, or participating in competing clinical studies;
- subjects experiencing severe or unexpected drug-related adverse effects;
- reports of similar technologies and products raising safety and/or efficacy concerns;
- third-party clinical investigators losing their license or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or employing methods consistent with the clinical trial protocol, cGCP requirements, or other third parties not performing data collection and analysis in a timely or accurate manner;
- inspections of clinical study sites by the FDA or IRBs finding regulatory violations that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study, or that prohibit us from using some or all of the data in support of our marketing applications;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or any of the data produced by such contractors in support of our marketing applications;
- one or more IRBs refusing to approve, suspending or terminating the study at an investigational site precluding enrollment of additional subjects, or withdrawing its approval of the trial; reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- deviations of the clinical sites from trial protocols or dropping out of a trial;
- adding new clinical trial sites;
- the inability of the CRO to execute any clinical trials for any reason;
- government or regulatory delays or "clinical holds" requiring suspension or termination of a trial; and
- delays related to the impacts of COVID-19, including slowdowns in enrollment or our ability complete our clinical trials on our expected timeline.

Product development costs for our drug candidates will increase if we have delays in testing or approval or if we need to perform more or larger clinical studies than planned. Additionally, changes in regulatory requirements and policies may occur and we may need to amend study protocols to reflect these changes. Amendments may require us to resubmit our study protocols to the FDA and IRBs for reexamination, which may impact the costs, timing or successful completion of that study. If we experience delays in completion of, or if we, the FDA or other regulatory authorities, any IRBs, or other reviewing entities, or any of our clinical study sites suspend or terminate any of our clinical studies of our drug candidates, our commercial prospects may be materially harmed and our ability to generate product revenues will be delayed. Any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical studies may also ultimately lead to the denial of regulatory approval of our drug candidates. In addition, if one or more clinical studies are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of our drug candidates could be significantly reduced.

We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.

We may seek orphan drug designation in the United States and in the European Union for our product candidates. Upon receipt of regulatory approval, orphan drug status will provide us with seven years of market exclusivity in the United States under the Orphan Drug Act. However, there is no guarantee that the FDA will grant orphan drug designation for any of our drug candidates for any future indication, which would make us ineligible for the additional exclusivity and other benefits of orphan drug designation. Moreover, there can be no assurance that another company also holding orphan drug designation for the same indication, or which may receive orphan drug designation in the future will not receive approval prior to us, in which case our competitor would have the benefit of the seven years of market exclusivity, and we would be unable to commercialize our product for the same indication until the expiration of such seven-year period. Even if we are the first to obtain approval for the orphan drug indication, there are circumstances under which a competing product may be approved for the same indication during our seven-year period of exclusivity.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug available in the Unites States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of regulatory review and approval process. In addition to the potential period of exclusivity, orphan designation makes a company eligible for grant funding of up to $400,000 per year for four years to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as (i) the drug's orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant's product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. If a drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity. There can be no assurance that we will receive orphan drug designation for any of our drug candidates for any additional indications if we elect to seek such designation. Even if orphan designation is granted it may be withdrawn by the FDA for non-compliance with regulations.

Third-party coverage and reimbursement and health care cost containment initiatives and treatment guidelines may constrain our future revenues.

Our ability to successfully market our drug candidates will depend in part on the level of reimbursement that government health administration authorities, private health coverage insurers and other organizations provide for the cost of our products and related treatments. Countries in which our drug candidates are expected to be sold through reimbursement schemes under national health insurance programs frequently require that manufacturers and sellers of pharmaceutical products obtain governmental approval of initial prices and any subsequent price increases. In certain countries, including the United States, government-funded and private medical care plans can exert significant indirect pressure on prices. We may not be able to sell our drug candidates profitably if adequate prices are not approved or coverage and reimbursement is unavailable or limited in scope. Increasingly, third-party payors attempt to contain health care costs in ways that are likely to impact our development of products including:

- failing to approve or challenging the prices charged for health-care products;
- introducing reimportation schemes from lower priced jurisdictions;
- limiting both coverage and the amount of reimbursement for new therapeutic products;
- denying or limiting coverage for products that are approved by the regulatory agencies but are considered to be experimental or investigational by third-party payors; and
- refusing to provide coverage when an approved product is used in a way that has not received regulatory marketing approval.

Our collaboration partners are conducting and may intend to conduct additional clinical trials for certain of our drug candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations or may require additional U.S.-based trials.

Our collaboration partners are currently conducting and may intend in the future to conduct clinical trials outside the United States, particularly in China where CSPC is conducting a Phase 1 trial. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted by qualified investigators in accordance with current good clinical practices, or GCPs, including review and approval by an independent ethics committee and receipt of informed consent from trial patients. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical trial conducted outside of the United States must be representative of the population for which we intend to seek approval in the United States. In addition, while these clinical trials are subject to applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also comply with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from our clinical trials conducted outside the United States, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay or permanently halt our ability to develop and market these or other drug candidates in the United States. In addition, there are risks inherent in conducting clinical trials in jurisdictions outside the United States including:

- regulatory and administrative requirements of the jurisdiction where the trial is conducted that could burden or limit our ability to conduct clinical trials;
- foreign exchange fluctuations;
- manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- the risk that patient populations in such trials are not considered representative as compared to patient populations in the United States and other markets.

Risks Relating to Our Intellectual Property Rights

It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights.

Our success will depend, in part, on maintaining and obtaining additional patent protection for our technologies, products and processes, successfully defending these patents against third-party challenges, and successfully enforcing these patents against third party competitors. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowable in our pending applications or, the enforceability of our existing and future patents. Our pending patent applications may never be approved by United States or foreign patent offices and the existing patents and patent applications relating to our product candidates may be challenged, invalidated, or circumvented by third parties and may not protect us against competitors with similar products or technologies.

The degree of our current and future protection for our proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect our rights, permit us to gain or keep our competitive advantage, or provide us with any competitive advantage at all. For example, others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical, or competitive to our product candidates, or important to our business. We cannot be certain that any patents or patent application owned by a third party will not have priority over patents and patent applications filed by us, or that we will not be involved in interference, opposition or invalidity proceedings before United States or foreign patent offices.

We also rely on trade secrets to protect technology, especially in cases when we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we require employees, academic collaborators, consultants, and other contractors to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary or licensed information. Typically, research collaborators and scientific advisors have rights to publish data and information in which we may have rights. If we cannot maintain the confidentiality of our proprietary technology and other confidential information, our ability to receive patent protection and our ability to protect valuable information owned by us may be imperiled. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts are sometimes less willing to protect trade secrets than patents. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how.

If we fail to maintain or obtain additional patent protection or trade secret protection for our product candidates or our technologies, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and attain profitability.

We may also rely on the trademarks we may develop to distinguish our products from the products of our competitors. We cannot guarantee that any trademark applications filed by us, or our business partners will be approved. Third parties may also oppose such trademark applications, or otherwise challenge our use of the trademarks. In the event that the trademarks we use are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. Further, we cannot provide assurance that competitors will not infringe the trademarks we use, or that we will have adequate resources to enforce these trademarks.

We have in-licensed a portion of our intellectual property, and if we fail to comply with our obligations under these arrangements, we could lose such intellectual property rights or owe damages to the licensor of such intellectual property.

We are a party to license agreements with Jenrin, The Regents, and Milky Way BioPharma, LLC ("Milky Way") pursuant to which we licensed exclusive worldwide rights to develop, manufacture and market drug candidates. These agreements are important to our business, and we may enter into additional license agreements in the future. Certain of our in-licensed intellectual property covers, or may cover, potential cannabinoid and monoclonal antibody developmental candidates. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If there is any conflict, dispute, disagreement or issue of non-performance between us and our licensing partners regarding our rights or obligations under the license agreements, including any such conflict, dispute or disagreement arising from our failure to satisfy payment obligations under any such agreement, we may owe damages, our licensor may have a right to terminate the affected license, and our ability to utilize the affected intellectual property in our product discovery and development efforts and our ability to enter into collaboration or marketing agreements for an affected product candidate may be adversely affected.

We are a party to a license agreement with CSPC pursuant to which we licensed the exclusive rights in the United States, Canada, the European Union (including the European Free Trade Area), the United Kingdom, and Australia to develop and market a drug candidate from CSPC. This agreement is important to our business, and we may enter into additional license agreements in the future. Certain of our in-licensed intellectual property covers, or may cover, potential antibodies, monoclonal antibody, and antibody drug conjugate developmental candidates. Our existing license agreement imposes, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, and other obligations on us. If there is any conflict, dispute, disagreement or issue of non-performance between us and our licensing partners regarding our rights or obligations under the license agreements, including any such conflict, dispute or disagreement arising from our failure to satisfy payment obligations under any such agreement, we may owe damages, our licensor may have a right to terminate the affected license, and our ability to utilize the affected intellectual property in our product discovery and development efforts and our ability to enter into collaboration or marketing agreements for an affected product candidate may be adversely affected.

Our product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts.

Our success depends in part on avoiding infringement of the proprietary technologies of others. The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Identification of third-party patent rights that may be relevant to our proprietary technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases, and the difficulty in assessing the meaning of patent claims. Additionally, because patent applications are maintained in secrecy until the application is published, we may be unaware of third-party patents that may be infringed by any of our product candidates. There may be certain issued patents and patent applications claiming subject matter that we may be required to license in order to research, develop or commercialize our product candidates, and we do not know if such patents and patent applications would be available to license on commercially reasonable terms, or at all. Any claims of patent infringement asserted by third parties would be time-consuming and may:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- prevent us from commercializing a product until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to cease or modify our use of the technology and/or develop non-infringing technology; or
- require us to enter into royalty or licensing agreements.

Although no third party has asserted a claim of infringement against us, others may hold proprietary rights that could prevent our product candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our product candidates or our processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market our product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign any product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates, which could harm our business, financial condition, and operating results.

A number of companies, including several major pharmaceutical companies, have conducted research on anti-inflammatory, cancer, and anti-fibrosis therapies which resulted in the filing of many patent applications related to this research. If we were to challenge the validity of these or any issued United States patent in court, we would need to overcome a statutory presumption of validity that attaches to every issued United States patent. This means that, in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims.

If we were to challenge the validity of these or any issued United States patent in an administrative trial before the Patent Trial and Appeal Board in the United States Patent and Trademark Office, we would have to prove that the claims are unpatentable by a preponderance of the evidence. There is no assurance that a jury and/or court would find in our favor on questions of infringement, validity, or enforceability.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is commonplace in our industry, we employ individuals who were previously employed at other pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject in the future to claims that our employees or prospective employees are subject to a continuing obligation to their former employers (such as non-competition or non-solicitation obligations) or claims that we or our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

We are, and may become, subject to claims that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets that, regardless of merit, could result in significant expense and loss of our intellectual property rights.

We have entered into and may in the future enter into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, potential partners and other third parties. We may become subject to litigation where a third-party asserts that we or our employees inadvertently or otherwise breached the agreements and used or disclosed trade secrets or other information proprietary to the third parties. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from developing, marketing or otherwise commercializing our product candidates. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Parties making claims against us may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, operating results, financial condition and prospects.

On November 18, 2021, Venn Therapeutics, LLC ("Venn"), filed a complaint (the "Complaint") against us in the U.S. District Court for the Middle District of Florida. The Complaint asserted claims for trade secret misappropriation under federal law and state law, a claim for breach of contract, and state law claims for unfair competition, misrepresentation, unjust enrichment, and intentional interference with advantageous business relations. On May 12, 2022, we entered into a binding term sheet (the "Settlement") with Venn to resolve the claims by Venn against us, our Chief Executive Officer, and a former employee. Under the terms of the Settlement, we made a $5 million payment to Venn on May 26, 2022, and Venn dismissed with prejudice all claims against us, our Chief Executive Officer and a former employee.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

Although we are not aware of any asserted third-party claims challenging inventorship on our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, strategic partners, commercial counterparties or other third parties associated with us or one of our predecessors in ownership have an interest in our patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we cannot fully control the enforcement of these policies by third parties with which we contract, nor can we be certain that assignment agreements between us and our employees, between us and our counterparties, or between our counterparties and their employees or between our predecessors of ownership and their employees and counterparties, will effectively protect our interests as to any party who conceives or develops intellectual property that we regard as our own. Among other issues, the assignment of intellectual property rights may not be self-executing, the assignment agreements may be breached, or we may have disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. As we approach potential commercialization of our product candidates, we are more closely analyzing all facts that we believe might be used to assert an inventorship claim against us. Determinations like these involve complex sets of fact and applications of sometimes-unsettled patent law, resulting in inherent uncertainties regarding ownership rights. Determining the history of development of certain of our intellectual property is made more difficult by the fact that certain of our intellectual property was developed by other companies for other indications before being acquired by us. Consequently, we cannot be sure that we have all of the documentary records relevant to such an analysis. In the course of our analysis, we identified a potential issue regarding incomplete inventorship on certain aspects of our lenabasum portfolio that were developed prior to our acquisition of lenabasum. Since identifying this potential issue, we reached agreement with the relevant third-party co-inventors and received assignments of such co-inventors' rights in and to the relevant patents.

If claims challenging inventorship are made against us, we may need to resort to litigation to resolve those claims. If we fail in defending against any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of valuable intellectual property rights or the right to assert those rights against third-parties marketing competing products. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

General Company-Related Risks

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2022, we had 33 full-time employees. As our development and commercialization plans and strategies develop, we will need to expand the size of our employee base for managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate, and integrate additional employees. In addition, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize our drug candidates and our ability to compete effectively will depend, in part, on our ability to effectively manage our future growth.

Future capital raises may dilute our existing stockholders' ownership and/or have other adverse effects on our operations.

If we raise additional capital by issuing equity securities, our existing stockholders' percentage ownership will be reduced, and these stockholders may experience substantial dilution. We may also issue equity securities that provide for rights, preferences, and privileges senior to those of our common stock. If we raise additional funds by issuing debt securities, these debt securities would have rights senior to those of our common stock and the terms of the debt securities issued could impose significant restrictions on our operations, including liens on our assets. If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our technologies or candidate products, or to grant licenses on terms that are not favorable to us.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. In addition, the loss of the services of certain key employees, including Yuval Cohen, our Chief Executive Officer, Rachael Brake, our Chief Scientific Officer, and Sean Moran, our Chief Financial Officer would adversely impact our business prospects.

Our ability to compete in the highly competitive pharmaceuticals industry depends in large part upon our ability to attract highly qualified managerial, scientific, and medical personnel. In order to induce valuable employees to remain with us, we intend to provide employees with stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in the price of our common stock that we will not be able to control and may at any time be insufficient to counteract more lucrative offers from other companies.

Our management team has expertise in many different aspects of drug development and commercialization. However, we will need to hire additional personnel as we further develop our drug candidates. Competition for skilled personnel in our market is intense and competition for experienced scientists may limit our ability to hire and retain highly qualified personnel on acceptable terms. Despite our efforts to retain valuable employees, members of our management, scientific and medical teams may terminate their employment with us on short notice. We have entered into employment agreements with certain of our executive officers. However, these employment arrangements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. The loss of the services of any of our executive officers or other key employees could potentially harm our business, operating results, or financial condition. In particular, we believe that the loss of the services of Yuval Cohen, Ph.D., our Chief Executive Officer, Rachael Brake, Ph.D., our Chief Scientific Officer, and Sean Moran, C.P.A., M.B.A., our Chief Financial Officer, would have a material adverse effect on our business. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level, and senior managers as well as junior, mid-level, and senior scientific and medical personnel.

Other pharmaceutical companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles, and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can develop and commercialize product candidates would be limited.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our drug candidates.

We face a potential risk of product liability as a result of the clinical testing of our drug candidates and will face an even greater risk if we commercialize our drug candidates. For example, we may be sued if any product we develop or any materials that we use in our products allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing, or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our drug candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- the inability to commercialize our drug candidates; and
- a decline in the value of our stock.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We intend to obtain product liability insurance covering our clinical trials. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

We may acquire businesses, assets, or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.

We may acquire additional businesses, assets, or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing, and marketing any new delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

Significant disruptions of information technology systems or breaches of data security could materially adversely affect our business, results of operations and financial condition.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store, and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have established physical, electronic, and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors, and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization.

The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments, and cyber-terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged.

In addition, such a breach may require notification to governmental agencies, the media, or individuals pursuant to various federal and state privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Clinical Health Act of 2009, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws.

Under the EU regulation and notably the General Data Protection Regulation, or GDPR, No. 2016/679, which entered into force on May 25, 2018 and is applicable personal data that we process in relation to our presence in the EU, the offering of products or services to individuals in the EU or the monitoring of the behavior of individuals in the EU, we have also a legal responsibility to report personal data breaches to the competent supervisory authority. The EU data protection regulation includes a broad definition and a short deadline for the notification of personal data breaches, which may be difficult to implement in practice and requires that we implement robust internal processes. Under this regulation, we have to report personal data breaches to the competent supervisory authority within 72 hours of the time we become aware of a breach "unless the personal data breach is unlikely to result in a risk to the right and freedoms of natural persons" (Article 33 of the GDPR). In addition, the GDPR requires that we communicate the breach to the Data Subject if the breach is "likely to result in a high risk to the rights and freedoms of natural persons" (Article 34 of the GDPR). In order to fulfill these requirements, we have to implement specific internal processes to be followed in case of a personal data breach, which will allow us to (a) contain and recover the breach, (b) assess the risk to the data subjects, (c) notify, and possibly communicate the breach to the data subjects, (d) investigate and respond to the breach. The performance of these processes implies substantial costs in resources and time.

Moreover, as we may rely on third parties that will also process as processor the data for which we are a data controller—for example, in the context of the manufacturing of our drug candidates or for the conduct of clinical trials, we must contractually ensure that strict security measures, as well as appropriate obligations including an obligation to report in due delay any security incident are implemented, in order to allow us fulfilling our own regulatory requirements.

We would also be exposed to a risk of loss or litigation and potential liability for any security breach on personal data for which we are data controller. The costs of above-mentioned processes together with legal penalties, possible compensation for damages and any resulting lawsuits arising from a breach may be extensive and may have a negative impact on reputation and materially adversely affect our business, results of operations and financial condition.

Changes in geopolitical conditions, U.S.-China trade relations and other factors beyond our control may adversely impact our business and operating results.

Our operations and performance depend in part on global and regional economic and geopolitical conditions, given our current third-party license agreement with CSPC, which is headquartered in China. Changes in U.S.-China trade policies, and a number of other economic and geopolitical factors both in China and abroad could have a material adverse effect on our business, financial condition, results of operations or prospects. Such factors may include:

- instability in political or economic conditions, such as inflation, recession, foreign currency exchange restrictions and devaluations, restrictive governmental controls on the movement and repatriation of earnings and capital, and actual or anticipated military or political conflicts, particularly in emerging markets;
- expanded jurisdiction of the Committee for Foreign Investment in the United States (CFIUS); and
- intergovernmental conflicts or actions, such as armed conflict, trade wars, retaliatory tariffs, and acts of terrorism or war.

As a result of these events, our ability to obtain data or regulatory support from our China-based licensing partner may be limited or adversely affected, and we may ourselves be subject to sanctions, diminished public perception and operational constraints.

Disruptions in the global economy and supply chains may have a material adverse effect on our business, financial condition and results of operations.

The disruptions to the global economy in 2020 and into 2021 have impeded global supply chains, resulting in longer lead times and also increased critical component costs and freight expenses. We have taken and may have to take steps to minimize the impact of these disruptions in lead times and increased costs by working closely with our suppliers and other third parties on whom we rely for the conduct of our business. Despite the actions we have undertaken or may have to undertake to minimize the impacts from disruptions to the global economy, there can be no assurances that unforeseen future events in the global supply chain will not have a material adverse effect on our business, financial condition and results of operations.

Furthermore, inflation can adversely affect us by increasing the costs of clinical trials, the research and development of our product candidates, as well as administration and other costs of doing business. We may experience increases in the prices of labor and other costs of doing business. In an inflationary environment, cost increases may outpace our expectations, causing us to use our cash and other liquid assets faster than forecasted. If this happens, we may need to raise additional capital to fund our operations, which may not be available in sufficient amounts or on reasonable terms, if at all, sooner than expected.

Adverse global conditions, including economic uncertainty, may negatively impact our financial results.

Global conditions, dislocations in the financial markets, any negative financial impacts affecting United States as a result of tax reform or changes to existing trade agreements or tax conventions, may adversely impact our business.

In addition, the global macroeconomic environment could be negatively affected by, among other things, COVID-19 or other pandemics or epidemics, instability in global economic markets, increased U.S. trade tariffs and trade disputes with other countries, instability in the global credit markets, supply chain weaknesses, instability in the geopolitical environment as a result of the withdrawal of the United Kingdom from the European Union, the Russian invasion of Ukraine and other political tensions, and foreign governmental debt concerns. Such challenges have caused, and may continue to cause, uncertainty and instability in local economies and in global financial markets.

Risks Related to our Common Stock

An active, liquid trading market for our common stock may not be sustained.

Presently, our common stock is traded on The Nasdaq Capital Market, or Nasdaq, and an investment in our company may require a long-term commitment, with no certainty of return. If we are unable to maintain an active, liquid active trading market:

- investors may have difficulty buying and selling or obtaining market quotations;
- market visibility for shares of our common stock may be limited; and
- a lack of visibility for shares of our common stock may have a depressive effect on the market price for shares of our common stock.

The lack of an active market could impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire additional intellectual property assets by using our shares as consideration.

We are currently listed on The Nasdaq Capital Market. If we are unable to maintain listing of our securities on The Nasdaq Capital Market or any stock exchange, our stock price could be adversely affected and the liquidity of our stock and our ability to obtain financing could be impaired and it may be more difficult for our stockholders to sell their securities.

Although our common stock is currently listed on The Nasdaq Capital Market, we may not be able to continue to meet the exchange's minimum listing requirements or those of any other national exchange. If we are unable to maintain listing on Nasdaq or if a liquid market for our common stock does not develop or is sustained, our common stock may remain thinly traded.

The Listing Rules of Nasdaq require listing issuers to comply with certain standards in order to remain listed on its exchange. If, for any reason, we should fail to maintain compliance with these listing standards and Nasdaq should delist our securities from trading on its exchange and we are unable to obtain listing on another national securities exchange, a reduction in some or all of the following may occur, each of which could have a material adverse effect on our stockholders:

- the liquidity of our common stock;
- the market price of our common stock;
- our ability to obtain financing for the continuation of our operations;
- the number of institutional and general investors that will consider investing in our common stock;
- the number of investors in general that will consider investing in our common stock;
- the number of market makers in our common stock;
- the availability of information concerning the trading prices and volume of our common stock; and
- the number of broker-dealers willing to execute trades in shares of our common stock.

Our failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our common stock

On January 3, 2022, we received a letter (the "Notice") from the Listing Qualifications Staff (the "Staff) of the Nasdaq Stock Market, LLC ("Nasdaq") indicating that, based upon the closing bid price of our common stock for the last 30 consecutive business days, we are not in compliance with the requirement to maintain a minimum bid price of $1.00 per share for continued listing on the Nasdaq Global Market, as set forth in Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). We were provided a compliance period of 180 calendar days from the date of the Notice, or until July 5, 2022, to regain compliance with the minimum closing bid requirement, pursuant to Nasdaq Listing Rule 5810(c)(3)(A). On July 6, 2022, we transferred to The Nasdaq Capital Market, and we were afforded the remainder of The Nasdaq Capital Market's second 180 calendar day compliance period, or until January 3, 2023, to regain compliance with the Minimum Bid Price Requirement.

On December 20, 2022, we held a special meeting of stockholders at which our stockholders approved the adoption and approval of an amendment to our Charter to effect a reverse stock split of the shares of our common stock, issued and outstanding or held by the Company in treasury, at a specific ratio, ranging from 1:4 to 1:40, with the exact ratio to be determined by our board of directors without further approval or authorization of the Company's stockholders. On February 9, 2023, our board of directors approved a 1:30 reverse stock split (the "Reverse Stock Split") which became effective on February 14, 2023.

On January 4, 2023, we received notice from the Staff that due to our continued non-compliance with the Minimum Bid Price Requirement, it had determined to delist our securities from The Nasdaq Capital Market unless we timely request a hearing before the Nasdaq Hearings Panel (the "Panel"). We timely requested a hearing before the Panel and appeared before the Panel on February 23, 2023. On March 7, 2023, we received notice that we had regained compliance with the Minimum Bid Price Requirement.

There can be no assurance that we will continue to maintain compliance with the Minimum Bid Price Requirement or maintain compliance with the other Nasdaq listing requirements. A delisting could substantially decrease trading in our common stock, adversely affect the market liquidity of our common stock as a result of the loss of market efficiencies associated with Nasdaq and the loss of federal preemption of state securities laws, adversely affect our ability to obtain financing on acceptable terms, if at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. Additionally, the market price of our common stock may decline further, and stockholders may lose some or all of their investment.

The market price of our common stock may be significantly volatile.

The market price for our common stock may be volatile and subject to wide fluctuations in response to factors including the following:

- actual or anticipated fluctuations in our quarterly or annual operating results;
- changes in financial or operational estimates or projections;
- conditions in markets generally;
- changes in the economic performance or market valuations of companies similar to ours; and
- general economic or political conditions in the United States or elsewhere.

In particular, the market prices of biotechnology companies like ours have been highly volatile due to factors, including, but not limited to:

- any delay or failure to conduct a clinical trial for our product or receive approval from the FDA and other regulatory agencies;
- developments or disputes concerning a company's intellectual property rights;
- technological innovations of such companies or their competitors;
- changes in market valuations of similar companies;
- announcements by such companies or their competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies, or patents; and
- failure to complete significant transactions or collaborate with vendors in manufacturing a product.

The securities market has from time-to-time experienced significant price and volume fluctuations that are not related to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of shares of our common stock.

Future sales of shares by existing stockholders could cause our stock price to decline.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock.

As of December 31, 2022, we had outstanding options to purchase an aggregate of 617,996 shares of our common stock at a weighted average exercise price of $88.99 per share and warrants to purchase an aggregate of 50,207 shares of our common stock at a weighted average exercise price of $283.81 per share. The exercise of such outstanding options and warrants will result in further dilution of your investment. If our existing stockholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our common stock, even if there is no relationship between such sales and the performance of our business.

We do not currently intend to pay dividends on our common stock in the foreseeable future, and consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We have never declared or paid cash dividends on our common stock and do not anticipate paying any cash dividends to holders of our common stock in the foreseeable future. Consequently, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our investors have purchased their shares.

There may be limitations on the effectiveness of our internal controls, and a failure of our control systems to prevent error or fraud may materially harm our company.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by our management on, among other things, the effectiveness of our internal control over financial reporting. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

Effective internal control over financial reporting is necessary for us to provide reliable and timely financial reports and, together with adequate disclosure controls and procedures, are designed to reasonably detect and prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

We do not expect that our disclosure controls or internal control over financial reporting will prevent or detect all error or all fraud. We may in the future discover weaknesses in our system of internal control over financial reporting that could result in a material misstatement of our financial statements. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. If we identify one or more material weaknesses in our internal controls, investors could lose confidence in the reliability of our financial statements, the market price of our stock could decline and we could be subject to sanctions or investigations by The Nasdaq Stock Market, the SEC or other regulatory authorities. Failure of our control systems to detect or prevent error or fraud could materially adversely impact us.

We may be unable to complete our analysis of our internal controls over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may adversely affect investor confidence in our company and, as a result, the value of our common stock.

We may not be able to complete our evaluation and testing of our internal control over financial reporting and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective.

If we are unable to assert that our internal control over financial reporting is effective, or, if applicable, our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal controls, we could lose investor confidence in the accuracy and completeness of our financial reports, which would cause the price of our common stock to decline, and we may be subject to investigation or sanctions by the SEC. We will also be required to disclose changes made in our internal control and procedures on a quarterly basis.

If we identify a material weakness, our remediation efforts may not enable us to avoid a material weakness in our internal control over financial reporting in the future. Any of the foregoing occurrences, should they come to pass, could negatively impact the public perception of our company, which could have a negative impact on our stock price.

Upon dissolution of our company, you may not recoup all or any portion of your investment.

In the event of a liquidation, dissolution or winding-up of our company, whether voluntary or involuntary, the proceeds and/or assets of our company remaining after giving effect to such transaction, and the payment of all of our debts and liabilities and distributions required to be made to holders of any outstanding preferred stock will then be distributed to the stockholders of common stock on a pro rata basis. There can be no assurance that we will have available assets to pay to the holders of common stock, or any amounts, upon such a liquidation, dissolution or winding-up of our Company. In this event, you could lose some or all of your investment.

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

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Unused federal net operating losses for tax years beginning before January 1, 2018 may be carried forward to offset future taxable income, if any, until such unused net operating losses expire. Under legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, or the Tax Act, as modified by legislation enacted on March 27, 2020, entitled the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, federal net operating losses incurred in tax years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such federal net operating losses in tax years beginning after December 31, 2020 is limited to 80% of taxable income. In addition, as a result of our merger in April 2014 with Corbus Pharmaceuticals, Inc., our wholly-owned subsidiary, our ability to utilize our federal net operating loss, carryforwards and federal tax credit prior to that date may be limited under Sections 382 of the Internal Revenue Code. The limitations apply if an "ownership change," as defined by Section 382, occurs. Generally, an ownership change occurs if the percentage of the value of the stock that is owned by one or more direct or indirect "five percent shareholders" increases by more than 50 percentage points over their lowest ownership percentage at any time during the applicable testing period (typically three years). In addition, future changes in our stock ownership, which may be outside of our control, may trigger an "ownership change" and, consequently, Section 382 limitations. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other tax attributes to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

Legislation or other changes in U.S. tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many changes have been made to applicable tax laws and changes are likely to continue to occur in the future. For example, the Tax Act, made significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%; limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses); and, subject to certain changes in tax law made by the CARES Act as discussed above, limitation of the deduction of net operating losses generated in tax years beginning after December 31, 2017 to 80% of taxable income, indefinite carryforward of net operating losses generated in tax years after 2018 and elimination of net operating loss carrybacks generated in tax years ending after December 31, 2017; changes in the treatment of offshore earnings regardless of whether they are repatriated; current inclusion in U.S. federal taxable income of certain earnings of controlled foreign corporations, mandatory capitalization of research and development expenses beginning in 2022; immediate deductions for certain new investments instead of deductions for depreciation expense over time; further deduction limits on executive compensation; and modifying, repealing and creating many other business deductions and credits, including the reduction in the orphan drug credit from 50% to 25% of qualifying expenditures. We continue to examine the impact this tax reform legislation may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. This periodic report does not discuss any such tax legislation or the manner in which it might affect us or our stockholders in the future. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation. In addition, the CARES Act included certain changes in tax law intended to stimulate the U.S. economy in light of the COVID-19 outbreak, including temporary beneficial changes to the treatment of net operating losses, interest deductibility limitations and payroll tax matters.

It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

Our certificate of incorporation, as amended, allows for our board to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our common stock.

Our board of directors has the authority to fix and determine the relative rights and preferences of preferred stock. We anticipate that our board of directors will have the authority to issue up to 10,000,000 shares of our preferred stock without further stockholder approval. As a result, our board of directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation and the right to receive dividend payments before dividends are distributed to the holders of common stock. In addition, our board of directors could authorize the issuance of a series of preferred stock that has greater voting power than our common stock or that is convertible into our common stock, which could decrease the relative voting power of our common stock or result in dilution to our existing stockholders.

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

Our principal offices are located at 500 River Ridge Drive, Norwood, MA 02062 and consists of 63,256 square feet of leased office space at December 31, 2022. The lease term for this office space ends on November 30, 2026. Effective August 26, 2021, the Company entered into a sublease agreement with a third party to sublease 12,112 square feet of the first floor. The sublease term ends on October 31, 2026.

Item 3. LEGAL PROCEEDINGS

We are not currently subject to any material legal proceedings. However, we may from time to time become a party to various legal proceedings arising in the ordinary course of our business.

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 currently listed on The Nasdaq Capital Market under the symbol "CRBP." Our shares of common stock began trading on The Nasdaq Global Market under the symbol "CRBP" effective April 16, 2015. Effective July 8, 2022, our shares of common stock were transferred to The Nasdaq Capital Market under the same symbol "CRBP."

Dividends

We have never declared or paid cash dividends on our common stock. We do not intend to declare or pay cash dividends on our common stock for the foreseeable future, but currently intend to retain any future earnings to fund the development and growth of our business. The payment of cash dividends if any, on the common stock will rest solely within the discretion of our board of directors and will depend, among other things, upon our earnings, capital requirements, financial condition, and other relevant factors.

Record Holders

As of March 3, 2023 there are approximately 86 record holders of shares of our common stock.

Item 6. RESERVED

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and the related notes and the other financial information included elsewhere in this Annual Report. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed below and elsewhere in this Annual Report, particularly those under "Risk Factors."

Overview

Corbus Pharmaceuticals Holdings, Inc. (the "Company" or "Corbus") is a precision oncology company committed to helping people defeat serious illness by bringing innovative scientific approaches to well understood biological pathways. Corbus' internal development pipeline includes CRB-701, a next generation antibody drug conjugate (ADC) that targets the expression of Nectin-4 on cancer cells to release a cytotoxic payload and CRB-601, an anti-integrin monoclonal antibody that blocks the activation of TGFβ expressed on cancer cells. The Company has also developed CRB-913, an endocannabinoid small molecule drug, for the treatment of obesity and is seeking partners to fund further development.

Corbus' precision oncology internal development pipeline:

- CRB-701 is a next generation ADC that targets the expression of Nectin-4 on cancer cells to release a cytotoxic payload. In February 2023, the Company obtained a license from CSPC Megalith Biopharmaceutical Co., Ltd ("CSPC"), a subsidiary of CSPC Pharmaceutical Group Limited, to develop and commercialize the drug in the United States ("U.S."), Canada, the European Union (including the European Free Trade Area), the United Kingdom, and Australia (the "CSPC License Agreement"). The Investigational New Drug (IND) application for CRB-701 has been cleared by the U.S. FDA and the drug is currently being investigated by CSPC in a Phase 1 dose escalation clinical trial in patients with advanced solid tumors in China. Corbus is planning to bridge data from this Phase 1 trial to support a U.S. clinical trial starting in mid-2024.
- CRB-601 is an anti-αvβ8 monoclonal antibody that blocks the activation of TGFβ expressed on cancer cells in the tumor microenvironment. In pre-clinical models, CRB-601 demonstrates enhanced anti-tumor activity when combined with anti-PD-1 checkpoint inhibitor therapy compared to either single agent alone. Pre-clinical data suggests that blockade of latent TGFβ production by CRB-601 can lead to changes in immune cell infiltration in the tumor microenvironment, potentially enhancing the benefit of PD-1 blockade. CRB-601 is being developed as a potential treatment for patients with solid tumors in combination with existing therapies, including checkpoint inhibitors, and is scheduled for an IND submission in the second half of 2023. The Company expects to enroll the first patient in the Phase 1 study by the end of 2023.

Corbus' endocannabinoid pipeline:

- CRB-913 is a second-generation cannabinoid receptor type 1 (CB1) inverse agonist designed to treat obesity and related metabolic diseases. In the diet-induced obesity mice model (DIO), CRB-913 demonstrates a reduction in weight and food consumption, improvement in insulin resistance and leptinemia, and reduced fat deposits in the liver. The CRB-913 program is in the pre-clinical stage, and we are seeking partnerships to fund further development.
- Lenabasum is a novel, synthetic, oral molecule that selectively activates cannabinoid receptor type 2 (CB2) for the treatment of inflammation and fibrosis. The drug completed Phase 3 studies in dermatomyositis and systemic sclerosis and these studies failed to meet their primary endpoints. In November 2022, the National Institutes of Health released results for the Phase 2 study it sponsored in systemic lupus erythematosus and lenabasum failed to demonstrate efficacy versus placebo. We do not plan to conduct additional clinical studies for lenabasum.

Financial Operations Overview

We are a precision oncology company and have not generated any revenues from the sale of products. We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain regulatory approval for the marketing of one of our product candidates, which we expect will take a number of years and is subject to significant uncertainty. We have never been profitable and at December 31, 2022, we had an accumulated deficit of approximately $392,081,000. Our net losses for the years ended December 31, 2022 and December 31, 2021 were approximately $42,347,000 and $45,640,000, respectively.

We expect to continue to incur significant expenses for the foreseeable future. We expect our expenses to increase in 2023 as compared to 2022 as assets in our pipeline move into the clinical phase. We will continue to incur significant operating losses and accordingly we will need additional financing to support our continuing operations. We will seek to fund our operations through public or private equity, debt financings or other sources, which may include government grants and collaborations with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenues to achieve profitability, and we may never do so.

We expect to continue to incur operating losses for at least the next several years in connection with our ongoing activities, as we:

- conduct pre-clinical and clinical trials for our product candidates;
- continue our research and development efforts; and
- manufacture drugs for clinical studies.

Recent Developments

CSPC License Agreement

On February 12, 2023, we entered into the CSPC License Agreement with CSPC pursuant to which we received an exclusive license to obtain certain exclusive rights to develop and commercialize CRB-701 (SYS6002), a novel clinical stage antibody drug conjugate targeting Nectin-4. The CSPC License Agreement covers exclusive commercialization rights to CRB-701 in the United States, Canada, the European Union (including the European Free Trade Area), the United Kingdom, and Australia.

We will pay CSPC an upfront payment of $7.5 million ($5.0 million at signing followed by a $2.5 million payment after eighteen months). CSPC will also be eligible to receive low double-digit royalties on net sales and up to $130 million in potential development and regulatory milestone payments and $555 million in potential commercial milestone payments.

Series A Preferred Stock

On October 12, 2022, the Board of Directors (the "Board"), declared a dividend of 0.008 of a share of Series A Preferred Stock ("Series A Preferred Stock"), for each outstanding share of Common Stock to stockholders of record at 5:00pm Eastern Time on October 22, 2022. The Certificate of Designation of Series A Preferred Stock was filed with the Delaware Secretary of State and became effective on October 12, 2022. The dividend was based on the number of outstanding shares of common stock prior to the Reverse Stock Split. This resulted in 1,002,247.048 shares of preferred stock being issued. The outstanding shares of Series A Preferred Stock were entitled to vote together with the outstanding shares of common stock as a single class exclusively with respect to any proposal to adopt an amendment to the Company's Amended and Restated Certificate of Incorporation, as amended (the "Certificate of Incorporation"), to reclassify the outstanding shares of Common Stock into a smaller number of shares of Common Stock at a ratio specified in or determined in accordance with the terms of such amendment (the "Reverse Stock Split"), as well as any proposal to adjourn any meeting of stockholders called for the purpose of voting on the Reverse Stock Split Proposal (the "Adjournment Proposal").

The Company held a special meeting of stockholders on December 20, 2022 (the "Special Meeting") for the purpose of voting on the Reverse Stock Split and an Adjournment Proposal. All shares of Series A Preferred Stock that were not present in person or by proxy at the Special Meeting, which totaled 500,894.04 shares, were automatically redeemed by the Company immediately prior to the opening of the polls at Special Meeting (the "Initial Redemption"). All shares that were not redeemed pursuant to the Initial Redemption would be redeemed if ordered by the Board or automatically upon the effectiveness of the amendment to the Certificate of Incorporation implementing the Reverse Stock Split (the "Subsequent Redemption" and together with the Initial Redemption, the "Redemption"). Each share of Series A Preferred Stock is entitled to receive $0.001 in cash for each 10 whole shares of Series A Preferred Stock immediately prior to the Redemption.

At the Special Meeting, both the Reverse Stock Split and Adjournment Proposal were approved.

Upon issuance of the Series A Preferred Stock, the Company was not solely in control of the Redemption of the shares of Series A Preferred Stock since the holders had the option of deciding whether to attend or return a proxy card for the Special Meeting, which determined whether a given holder's shares of Series A Preferred Stock were redeemed in the Initial Redemption. Since the Redemption of the Series A Preferred Stock was not solely in the control of the Company, the shares of Series A Preferred Stock are classified within mezzanine equity. The shares of Series A Preferred Stock were initially recorded at redemption value, which approximated fair value.

After the Special Meeting upon approval of the Reverse Stock Split, the remaining 501,353.008 shares outstanding of Series A Preferred Stock would be considered mandatorily redeemable and reclassified to a current liability. As of December 31, 2022, the fair value of the Series A Preferred Stock were included in accrued expenses. As of December 31, 2022, there were 0 shares of Series A Preferred Stock issued and outstanding within the consolidated balance sheet, however, the Series A Preferred Stock were redeemed on February 14, 2023, upon the effectiveness of the amendment to the Certificate of Incorporation implementing the Reverse Stock Split pursuant to the terms of the Certificate of Designation of the Series A Preferred Stock.

Reverse Stock Split

On February 9, 2023, the Board of Directors approved a 1-for-30 reverse stock split, and we filed the Amendment for the Reverse Stock Split with the Secretary of State of the State of Delaware. The Reverse Stock Split became effective in accordance with the terms of the Amendment on February 14, 2023. The Amendment did not change the number of authorized shares of common stock or the par value. All references in the consolidated financial statements to shares, share prices, exercise prices, and other per share information in all periods have been adjusted, on a retroactive basis, to reflect the split.

Amended Loan and Security Agreement with K2 HealthVentures LLC

On October 25, 2022, we, with our subsidiary, Corbus Pharmaceuticals, Inc., as borrower, entered into an amendment to the Loan and Security Agreement (the "Amended Loan and Security Agreement") dated as of July 28, 2020 with K2 HealthVentures LLC ("K2HV"), an unrelated third party, to defer the commencement of principal repayments by a one year period from September 1, 2022 to September 1, 2023. If we raise at least $30 million in net proceeds through capital raising transactions, the commencement of principal repayments will be deferred by an additional six months to March 1, 2024. Pursuant to the Amended Loan and Security Agreement, we paid $119,000 at the time of entering into the Amended Loan and Security Agreement and will pay $400,000 at the maturity of the loan. In addition, pursuant to the initial Loan and Security Agreement, the Lenders may jointly elect at any time and from time to time prior to the payment in full of the loans to convert any portion (in a minimum amount of $500,000) of the principal amount of the loans then outstanding into shares of our common stock at a conversion price of $282.00 per share, provided that the aggregate principal amount of loans converted by the Lenders into common stock may not exceed $5,000,000. The Amended Loan and Security Agreement adjusts the conversion price of a $2,000,000 portion of the maximum $5,000,000 convertible amount by adjusting the conversion price of $875,000 of the loan from $282.00 per share to $4.50 per share, and $1,125,000 of the loan from $282.00 per share to $7.875 per share.

Critical Accounting Policies

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period.

On an ongoing basis, we evaluate our estimates and judgments for all assets and liabilities, including those related to accrued research and development expense, stock-based compensation expense, and operating lease right of use assets and liabilities. We base our estimates and judgments on historical experience, current economic and industry conditions and on various other factors that are believed to be reasonable under the circumstances. This forms the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. See Note 3 "Significant Accounting Policies" to the consolidated financial statements included under Part II, Item 8 of this Annual Report on Form 10-K for information about our significant accounting policies.

We believe that full consideration has been given to all relevant circumstances that we may be subject to, and the consolidated financial statements accurately reflect our best estimate of the results of operations, financial position and cash flows for the periods presented.

Accrued Research and Development Expenses

As part of the process of preparing financial statements, we are required to estimate and accrue expenses, the largest of which are research and development expenses. This process involves: communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost; estimating and accruing expenses in our financial statements as of each balance sheet date based on facts and circumstances known to us at the time; and periodically confirming the accuracy of our estimates with selected service providers and making adjustments, if necessary.

Examples of estimated research and development expenses that we accrue include:

- fees paid to CROs and research institutions in connection with pre-clinical studies;
- fees paid to contract manufacturers in connection with the production of drugs for studies and clinical trials;
- fees paid to CROs and research institutions in connection with conducting of clinical studies; and
- professional service fees for consulting and related services.

We base our expense accruals related to pre-clinical and clinical activities on our estimates of the services performed pursuant to contracts with multiple research institutions and clinical research organizations that conduct and manage pre-clinical and clinical work on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors, such as the successful animal trials and the completion of study milestones. Our service providers invoice us monthly in arrears for services performed. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If we do not identify costs that we have begun to incur, or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

To date, we have not experienced significant changes in our estimates of accrued research and development expenses following each applicable reporting period. However, due to the nature of estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information regarding the status or conduct of our pre-clinical and clinical studies and other research activities.

Stock-Based Compensation

Stock options are granted with an exercise price at no less than fair market value at the date of the grant. The stock options normally expire ten years from the date of grant. Stock option awards vest upon terms determined by our board of directors.

We recognize compensation costs resulting from the issuance of stock-based awards to employees, members of our Board of directors and consultants. The fair value of each option grant was estimated as of the date of grant using the Black-Scholes option-pricing model. The fair value is amortized as compensation cost on a straight-line basis over the requisite service period of the awards, which is generally the vesting period. We estimate volatility by analyzing the volatility of the trading price of our common stock. We use historical data, as well as subsequent events occurring prior to the issuance of the consolidated financial statements, to estimate option exercise and employee forfeitures within the valuation model. The expected term of options granted to employees under our stock plans is based on the average of the contractual term (generally 10 years) and the vesting period (generally 48 months). The expected term of options granted under the 2014 Plan, all of which qualify as "plain vanilla" per SEC Staff Accounting Bulletin 107, is based on the average of the 6.25 years. For non-employee options, the expected term is the contractual term. The risk-free rate is based on the yield of a U.S. Treasury security with a term consistent with the option. We estimate the forfeiture rate at the time of grant and revise it, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on management's expectation through industry knowledge and historical data. We have never paid dividends on our common stock and do not anticipate paying dividends on our common stock in the foreseeable future. Accordingly, we have assumed no dividend yield for purposes of estimating the fair value of our share-based compensation.

The following assumptions were used to estimate the fair value of employee stock options granted using the Black-Scholes option pricing model for the years ended December 31, 2022 and 2021 is as follows:

	Twelve Months Ended December 31,	
	2022	2021
Risk free interest rate	1.99%	0.76%
Expected dividend yield	0%	0%
Expected term in years	6.25	6.23
Expected volatility	98.08%	102.96%
Estimated forfeiture rate	12.43%	9.12%

Leases

We lease our office space. We determine if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use ("ROU") assets and operating lease liabilities, current and noncurrent in our consolidated balance sheets. 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. ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As our leases do not provide an implicit rate, we use an incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. This is the rate we would have to pay if borrowing on a collateralized basis over a similar term to each lease. The ROU asset also includes any lease payments made and excludes lease incentives. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

The Company has subleased a portion of its leased facility under an agreement considered to be an operating lease according to GAAP. The Company has not been legally released from its primary obligations under the original lease and therefore it continues to account for the original lease as it did before commencement of the sublease. The Company will record both fixed and variable payments received from the sublessee in its statement of operations on a straight-line basis as an offset to rent expense.

Recently Issued Accounting Pronouncements

Recent accounting pronouncements which may be applicable to us are described in Note 3 "Significant Accounting Policies" to our Consolidated Financial Statements included under Part II, Item 8 of this Annual Report on Form 10-K.

Results of Operations

Comparison of Year Ended 2022 to 2021

Revenue from Awards. We have recognized approximately $0 and $882,000 of revenue from awards in the years ended December 31, 2022 and 2021, respectively, in accordance with GAAP. No revenue from licenses was recognized for the years ended December 31, 2022 and 2021.

Amounts recognized in revenue from awards for the year ended December 31, 2021 was in connection with our entry on January 26, 2018 into the Cystic Fibrosis Program Related Investment Agreement ("Investment Agreement) with the Cystic Fibrosis Foundation ("CFF"), a non-profit drug discovery and development corporation, pursuant to which we received a development award for up to $25 million in funding (the "2018 CFF Award") to support a Phase 2b Clinical Trial (the "Phase 2b Clinical Trial") of lenabasum in patients with cystic fibrosis. We received cash payments in an aggregate of $12,500,000 during the year ended December 31, 2018, an additional $5,000,000 during the year ended December 31, 2019, $5,000,000 in the third quarter of 2020, and $2,500,000 in the fourth quarter of 2021 upon our achievement of a milestone related to the progress of the Phase 2b Clinical Trial, as set forth in the Investment Agreement. We received the entire $25 million from the CFF and have recorded a total of $18,784,775 in revenue to date less the fair value of $6,215,225 associated with the CFF Warrant (see note 11 and 16). We will not be recognizing revenue in the future from the 2018 CFF award and do not currently have any other award agreements.

Research and Development. Research and development expenses for the year ended December 31, 2022 totaled approximately $16,137,000, a decrease of $20,308,000 over the $36,445,000 recorded for the year ended December 31, 2021. The decrease in fiscal 2022 as compared to fiscal 2021 was primarily attributable to lower clinical expenses of approximately $8,015,000 and a reduction in data analysis expenses associated with the completion of lenabasum clinical studies of $1,574,000. There were also decreases of $7,428,000 in compensation costs and $2,160,000 in consulting costs as clinical and manufacturing headcount was reduced due to the completion of the lenabasum clinical studies. License payments decreased $1,889,000 as the licensing payments were made to UCSF and PRI in 2021. These decreases are offset by an increase in toxicology costs of $2,055,000 as CRB-601 is prepared for clinical trials.

Research and development expenses are expected to increase in 2023 as the assets in our pipeline move into the clinical phase beginning in 2023.

During 2018, the Company formed a subsidiary in each of the United Kingdom and Australia and approximately 43% and 25% of research and development expenses recorded for the years ended December 31, 2022 and December 31, 2021 respectively was recorded in these entities.

General and Administrative. General and Administrative expense for the year ended December 31, 2022 totaled approximately $18,699,000, a decrease of $1,726,000 from the $20,425,000 recorded for the year ended December 31, 2021. The decrease in fiscal 2022 as compared to fiscal 2021 was primarily attributable to decreases of approximately $2,414,000 of compensation costs due to reductions in headcount as the Company transitioned to the pre-clinical phase and needed less support staff. This decrease was partially offset by an increase in legal expenses of $926,000 relating to the Venn Settlement and exploring business development opportunities.

We expect our general and administrative expenses to decrease in 2023 as compared to 2022 as we do not expect litigation costs to recur.

Litigation Settlement. Litigation Settlement expense for the year ended December 31, 2022 totaled $5,000,000 as a result of the settlement with Venn Therapeutics, LLC. There was no litigation settlement for the year ended December 31, 2021.

We do not expect to incur any litigation settlement costs in 2023.

Other Income (Expense), Net. Other income (expense), net for 2022 was an expense of approximately $2,511,000 as compared to income of approximately $10,349,000 recorded for 2021. The decrease of $12,860,000 in 2022 as compared to 2021 was primarily attributable to a decrease in refundable research and development credits from a foreign tax authority of approximately $12,300,000 as compared to the prior year. The current year refundable research and development credits are expected to be realized in the first half of 2023.

In addition to refundable research and development tax credits that were earned on certain research and development expenses incurred primarily outside of the United States, other income (expense), net consists of interest income we earn on interest-bearing accounts, realized investment gains and losses, interest expense incurred on our outstanding debt, changes in derivative liabilities, and realized and unrealized foreign currency exchange gains and losses.

We expect other income (expense), net to increase in 2023 due to the receipt of the current year refundable research and development credits along with the application and receipt of next year's refundable research and development credits.

Liquidity and Capital Resources

Since inception, we have experienced negative cash flows from operations. We have financed our operations primarily through sales of equity-related securities. At December 31, 2022, our accumulated deficit since inception was approximately $392,081,000.

At December 31, 2022, we had total current assets of approximately $60,181,000 and current liabilities of approximately $12,640,000 resulting in working capital of approximately $47,541,000. Of our total cash, cash equivalents, investments, and restricted cash of $59,867,000 at December 31, 2022, $57,062,000 was held within the United States.

Net cash used in operating activities for the year ended December 31, 2022 was approximately $37,544,000 which includes a net loss of approximately $42,347,000, adjusted for non-cash expenses of approximately $8,826,000, principally related to stock-based compensation expense of $5,720,000, depreciation and amortization expense of $763,000, amortization of debt discount of $742,000, operating lease right of use asset amortization of $725,000, and loss on foreign exchange of $649,000, and approximately $4,024,000 of cash used by net working capital items, principally related to the decreases in accrued expenses of $4,094,000 and operating lease liabilities of $1,136,000. These decreases in working capital were offset by a decrease in prepaid expenses of $1,573,000.

Cash provided by investing activities for the year ended December 31, 2022 totaled approximately $30,074,000, which was largely due to the proceeds from sales and maturities of investments, net of purchases.

Cash used in financing activities for the year ended December 31, 2022 totaled approximately $534,000, which related to the repayment of short-term borrowings of approximately $867,000 in connection with our loan agreement with a financing company to fund D&O insurance premiums. This was offset by proceeds from the issuance of a new notes payable of approximately $452,000 to fund D&O insurance premiums, which the terms of the loan stipulate equal monthly payments of principal and interest payments of approximately $51,000 over a nine-month period. Interest accrues on this loan at an annual rate of 5.40%. Finally, the Company began making principal payments on its Loan and Security Agreement with K2HV in September 2022, however, as part of the Amended Loan and Security Agreement effective October 2022, principal repayments were deferred by one year, therefore, these principal payments were returned net of fees of $119,000.

We expect our cash, cash equivalents, and investments of approximately $59.2 million at December 31, 2022 will be sufficient to meet our operating and capital requirements through the second quarter of 2024 based on current planned expenditures.

We will need to raise significant additional capital to continue to fund operations, including the discovery and pre-clinical costs for our product candidates. If we are unable to raise sufficient capital in the future, we may be required to undertake cost-cutting measures, including delaying or discontinuing certain clinical activities. We may seek to sell common stock, preferred stock, or convertible debt securities, enter into a credit facility or another form of third-party funding or seek other debt financing. In addition, we may seek to raise cash through collaborative agreements or from government grants. The sale of equity and convertible debt securities may result in dilution to our stockholders and certain of those securities may have rights senior to those of our common shares. If we raise additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these securities or other debt could contain covenants that would restrict our operations. Any other third-party funding arrangement could require us to relinquish valuable rights.

The source, timing and availability of any future financing will depend principally upon market conditions, and, more specifically, on the progress of our clinical development programs.

Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us, among other things, to delay, scale back or eliminate expenses including some or all of our planned clinical trials.

Contractual Obligations and Commitments

Our contractual obligations as of December 31, 2022 consists of our amended lease agreement (“February 2019 Lease Agreement”) for an aggregate total of 62,756 square feet of leased office space (“Total Premises”) through November 30, 2026. Total rent expense for the year ended December 31, 2022 was $1,652,563 and we do not expect any significant changes in future periods. In addition, the Company entered into a sublease agreement with a third party to sublease 12,112 square feet of our leased space. The sublease commenced on October 1, 2021 and ends October 31, 2026. Rent expense for the twelve months ended December 31, 2022 was offset by $220,531 of sublease income and we do not expect any significant changes in future periods.

We may enter into contracts in the normal course of business with clinical research organizations for clinical trials and clinical supply manufacturing and with vendors for pre-clinical research studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore, we believe that our non-cancelable obligations under these agreements are not material. As of December 31, 2022, other than our leases, we had no material Contractual Obligations or Commitments that will affect our future liquidity.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors, other than future royalty payments under development award agreements discussed as follows:

License Agreement with Jenrin

Pursuant to the terms of the Jenrin License Agreement, we are obligated to pay potential milestone payments to Jenrin totaling up to $18.4 million for each compound we elect to develop based upon the achievement of specified development and regulatory milestones. In addition, we are obligated to pay Jenrin royalties in the mid, single digits based on net sales of any Licensed Products, as defined in the Jenrin License Agreement, subject to specified reductions.

The Jenrin License Agreement terminates on a country-by-country basis and product-by-product basis upon the expiration of the royalty term for such product in such country. Each royalty term begins on the date of the first commercial sale of the licensed product in the applicable country and ends on the later of seven years from such first commercial sale or the expiration of the last to expire of the applicable patents in that country. The Jenrin License Agreement may be terminated earlier in specified situations, including termination for uncured material breach of the Jenrin License Agreement by either party, termination by Jenrin in specified circumstances, termination by Corbus with advance notice and termination upon a party's insolvency or bankruptcy.

License Agreement with Milky Way

Pursuant to the terms of the Milky Way License Agreement, we are obligated to pay potential milestone payments to Milky Way totaling up to $53.0 million based upon the achievement of specified development and regulatory milestones. In addition, we are obligated to pay Milky Way royalties in the lower, single digits based on net sales of any Licensed Products, as defined in the Milky Way License Agreement.

The Milky Way License Agreement will remain in effect on a Licensed Product-by-License Product and country-by-country basis, until the expiration of the Royalty Term of the Licensed Product in the country. The "Royalty Term" means the period beginning from the First Commercial Sale of the Licensed Product in the country until the expiration of the last-to-expire Valid Claim in any Licensor Patent in the country that Covers the composition of matter of the Licensed product, the manufacture of the Licensed Product in the country, or a method of use of the Licensed Product for an indication for which Regulatory Approval has been obtained in the country. The Milky Way License Agreement may be terminated earlier in specified situations, including termination for material breach or termination by Corbus with advance notice.

License Agreement with UCSF

Pursuant to the terms of the UCSF License Agreement, we are obligated to pay potential milestone payments to UCSF totaling up to $153.15 million based upon the achievement of specified development and regulatory milestones, excluding indication milestones for antibodies used for diagnostic products and services that will be an additional $50,000 for each new indication. In addition, we are obligated to pay UCSF royalties in the lower, single digits based on net sales of any Licensed Products, as defined in the UCSF License Agreement, and any diagnostic products and services.

The UCSF License Agreement will remain in effect until the expiration or abandonment of the last of the Patent Rights licensed. The Royalty Term is the duration of Patent Rights in that country covering the applicable Licensed Product or Licensed Services Sold in the country. The UCSF License Agreement may be terminated earlier in specified situations, including termination for material breach, termination by Corbus with advance notice and termination upon a party's bankruptcy.

License Agreement with CSPC

Pursuant to the terms of the CSPC License Agreement, we are obligated to pay potential milestone payments to CSPC totaling up to $130 million based upon the achievement of specified development and regulatory milestones and $555 million in potential commercial milestone payments. In addition, we are obligated to pay CSPC royalties in the low double digits based on net sales of any Licensed Products, as defined in the CSPC License Agreement.

The CSPC License Agreement will remain in effect on a Licensed Product and on a country-by-country basis, until the expiration of the Royalty Term of the Licensed Product in the country. The Royalty Term is the period beginning from the First Commercial Sale of the Licensed Product in the country until the later of the expiration of the last-to-expire Valid Claim in any Licensor Patent in the country that Covers the Licensed product, 10 years after the date of the First Commercial Sale in the country, or expiration of the Regulatory Exclusivity for the Licensed Product in the country. The CSPC License Agreement may be terminated earlier in specified situations, including termination for material breach, termination by Corbus with advance notice and termination upon a party's bankruptcy.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is limited to our cash and cash equivalents, all of which have maturities of three months or less. The primary objectives of our investment activities are to preserve principal, provide liquidity and maximize income without significantly increasing risk. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operation.

Foreign Exchange Risk

The majority of our operations are based in the United States and, accordingly our transactions are denominated in U.S. Dollars. However, we have foreign currency exposures related to our cash valued in the United Kingdom in British Pounds and Euros and our cash valued in Australia in Australian Dollars because our functional currency is the U.S. Dollar in our foreign-based subsidiaries. Our foreign denominated assets and liabilities are remeasured each reporting period with any exchange gains and losses recorded in our consolidated statements of operations and comprehensive income.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See pages F-67 through F-94 following the Exhibit Index of this Annual Report on Form 10-K.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Our Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that material information required to be disclosed in our periodic reports filed under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, our principal executive officer and our principal financial officer, to allow timely decisions regarding required disclosure. Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act, as amended) as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that the information required to be disclosed by us in such reports is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal controls over financial reporting, as such term is defined in Rule 13a-15(f) of the Exchange Act. Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in the "Internal Control-Integrated Framework (2013)" issued by the Committee of Sponsoring Organization of the Treadway Commission. Based on this assessment, management concluded that, as of December 31, 2022, our internal control over financial reporting was effective. This annual report does not include an attestation report of our registered public accounting firm on internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the period to which this report relates that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Item 9B. OTHER INFORMATION

None.

Item 9C. DISCLOSURE REGARDING FOREIGN JURISDICTION THAT PREVENTS INSPECTIONS

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by this item is incorporated by reference to our Proxy Statement for the 2023 Annual Meeting of Stockholders.

Item 11. EXECUTIVE COMPENSATION

Information required by this item is incorporated herein by reference to our Proxy Statement for the 2023 Annual Meeting of Stockholders.

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

Information required by this item is incorporated by reference to our Proxy Statement for the 2023 Annual Meeting of Stockholders.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Information required by this item is incorporated by reference to our Proxy Statement for the 2023 Annual Meeting of Stockholders.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information required by this item is incorporated by reference to our Proxy Statement for the 2023 Annual Meeting of Stockholders.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) List of Documents filed as part of this Report

(1) Consolidated Financial Statements

The financial statements and related notes, together with the report of EisnerAmper LLP (PCAOB ID: 274) appear at pages F-67 through F-94 following the Exhibit List as required by Part II, Item 8 "Financial Statements and Supplementary Data" of this Form 10-K.

(2) Financial Statement Schedules.

Schedules are omitted because they are either not required, not applicable, or the information is otherwise included.

(3) Exhibits

The Company has filed with this report or incorporated by reference herein certain exhibits as specified below pursuant to Rule 12b-32 under the Exchange Act. See Exhibit Index following the signature page to this report for a complete list of documents filed with this report.

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Company, as amended.*
3.2	Amended and Restated Bylaws of the Company.*
4.1	Form of Merger Warrant (incorporated by reference to Exhibit 4.1 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014).
4.2	Form of Replacement Warrant (incorporated by reference to Exhibit 4.2 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014).
4.3	Form of Investor Warrant (incorporated by reference to Exhibit 4.3 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014).
4.4	Form of Additional Replacement Warrant (incorporated by reference to Exhibit 4.4 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014).
4.5	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.5 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014).
4.6	Registration Rights Agreement (incorporated by reference to Exhibit 4.6 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014).
4.7	Specimen Common Stock Certificate, $0.0001 par value (incorporated herein by reference to Exhibit 4.1 of the Company's Registration Statement on Form S-3 filed with the SEC on November 10, 2015).
4.8	Warrant to Purchase Common Stock, dated as of January 26, 2018, issued to the Cystic Fibrosis Foundation (incorporated herein by reference to Exhibit 4.8 of the Company's Annual Report on Form 10-K filed with the SEC on March 12, 2018).
4.9	Form of Warrant to Purchase Common Stock (incorporated herein by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on July 29, 2020).
4.10	Description of Capital Stock*
10.1	2014 Equity Compensation Plan (incorporated by reference to Exhibit 10.5 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014). †

10.2	Form of Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.6 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014). †
10.3	Form of Non-Qualified Stock Option Agreement (incorporated by reference to Exhibit 10.7 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014). †
10.4	Form of Restricted Stock Agreement (incorporated by reference to Exhibit 10.8 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014). †
10.5	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.15 of the Company's Registration Statement on Amendment No. 1 to Form S-1 filed with the SEC on September 30, 2014). †
10.6	Award Agreement, dated April 9, 2015, between Cystic Fibrosis Foundation Therapeutics, Inc. and the Company (incorporated herein by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed with the SEC on May 13, 2015).#
10.7	Consulting Agreement, dated September 20, 2016, between Company and Orchestra Medical Ventures, LLC (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on September 21, 2016).
10.8	Lease, dated May 30, 2014, between Corbus Pharmaceuticals, Inc. and River Ridge Limited Partnership (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on November 10, 2016).
10.9	First Amendment to Lease, dated August 27, 2015, between Corbus Pharmaceuticals, Inc. and River Ridge Limited Partnership (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed with the SEC on November 10, 2016).
10.10	Second Amendment to Lease, dated March 30, 2016, between Corbus Pharmaceuticals, Inc. and River Ridge Limited Partnership (incorporated by reference to Exhibit 10.4 of the Company's Current Report on Form 8-K filed with the SEC on November 10, 2016).
10.11	Third Amendment to Lease, dated September 13, 2016, between Corbus Pharmaceuticals, Inc. and River Ridge Limited Partnership (incorporated by reference to Exhibit 10.5 of the Company's Current Report on Form 8-K filed with the SEC on November 10, 2016).
10.12	Lease Agreement, dated August 21, 2017, by and between Corbus Pharmaceuticals, Inc. and River Ridge Limited Partnership (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on August 22, 2017).
10.13	Guarantee, dated August 21, 2017, by Corbus Pharmaceuticals Holdings, Inc. (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on August 22, 2017).
10.14	Cystic Fibrosis Program Related Investment Agreement, dated January 26, 2018, between Cystic Fibrosis Foundation Therapeutics, Inc. and the Company (incorporated herein by reference to Exhibit 10.33 of the Company's Annual Report on Form 10-K filed with the SEC on March 12, 2018).#
10.15	License Agreement, dated as of September 20, 2018, between Corbus Pharmaceuticals, Inc. and Jenrin Discovery, LLC (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed with the SEC on November 8, 2018).#
10.16	Lease Amendment No. 1, dated as of February 26, 2019, among River Ridge Limited Partnership, Corbus Pharmaceuticals, Inc. and Corbus Pharmaceuticals Holdings, Inc. (incorporated by reference to Exhibit 10.40 of the Company's Annual Report on Form 10-K filed with the SEC on March 12, 2019).
10.17	Separation and General Release Agreement between Corbus Pharmaceuticals Holdings, Inc. and Mark Tepper, dated March 31, 2019 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on April 1, 2019).

10.18	Lease Amendment No. 2, dated as of October 25, 2019, among River Ridge Limited Partnership, Corbus Pharmaceuticals, Inc. and Corbus Pharmaceuticals Holdings, Inc. (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed with the SEC on November 7, 2019)
10.19	Loan and Security Agreement, dated as of July 28, 2020, by and between Corbus Pharmaceuticals Holdings, Inc., Corbus Pharmaceuticals, Inc., K2 HealthVentures LLC and Ankura Trust Company, LLC (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on July 29, 2020).
10.20	Separation and Release Agreement between the Company and Robert Discordia, dated November 30, 2020 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on December 4, 2020).†
10.21	License Agreement between the Company and Milky Way BioPharma, LLC, dated May 25, 2021 (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed with the SEC on August 12, 2021).#
10.22	License Agreement between the Company and The Regents of the University of California, dated May 26, 2021 (incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q filed with the SEC on August 12, 2021).#
10.23	Separation and General Release Agreement between the Company and Barbara White, dated September 17, 2021 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on September 22, 2021). †
10.24	Employment Agreement between the Company and Rachael Brake, effective as of December 6, 2021(incorporated herein by reference to Exhibit 10.31 of the Company's Annual Report on Form 10-K filed with the SEC on March 8, 2022). †
10.25	Form of Fourth Amended and Restated Employment Agreement between Corbus Pharmaceuticals Holdings, Inc. and Yuval Cohen (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on April 15, 2022). †
10.26	Form of Fifth Amended and Restated Employment Agreement between Corbus Pharmaceuticals Holdings, Inc. and Sean Moran (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on April 15, 2022). †
10.27	Form of Second Amended and Restated Employment Agreement between Corbus Pharmaceuticals Holdings, Inc. and Craig Millian (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on April 15, 2022). †
10.28	Second Amendment to Loan and Security Agreement, dated as of July 28, 2020, by and between Corbus Pharmaceuticals Holdings, Inc., Corbus Pharmaceuticals, Inc., K2 HealthVentures LLC and Ankura Trust Company, LLC (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on October 31, 2022).
10.29	License Agreement between the Company and CSPC Megalith Biopharmaceutical Co., Ltd.*
21.1	List of Subsidiaries of the Company.*
23.1	Consent of EisnerAmper LLP.*
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).*
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).*
32.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(b) or Rule 15d-14(b).**
32.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(b) or Rule 15d-14(b).**

101.INS	Inline XBRL Instance Document.* – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.*
104	The cover page from the Company's Annual Report on Form 10-K for the year ended December 31, 2020, has been formatted in Inline XBRL*

* Filed herewith.

** Furnished, not filed.

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

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

Item 16. FORM 10-K SUMMARY

None.

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.

CORBUS PHARMACEUTICALS HOLDINGS, INC.

Date: March 7, 2023

By: */s/ YUVAL COHEN*
Name: Yuval Cohen
Title: Chief 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/ YUVAL COHEN Yuval Cohen	Chief Executive Officer and Director (Principal Executive Officer)	March 7, 2023
/s/ SEAN MORAN Sean Moran	Chief Financial Officer (Principal Financial and Accounting Officer)	March 7, 2023
/s/ ALAN HOLMER Alan Holmer	Director	March 7, 2023
/s/ ANNE ALTMEYER Anne Altmeyer	Director	March 7, 2023
/s/ AVERY CATLIN Avery Catlin	Director	March 7, 2023
/s/ RACHELLE JACQUES Rachelle Jacques	Director	March 7, 2023
/s/ JOHN JENKINS John Jenkins	Director	March 7, 2023
/s/ PETER SALZMANN Peter Salzmann	Director	March 7, 2023
/s/ YONG BEN Yong Ben	Director	March 7, 2023

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Corbus Pharmaceuticals Holdings, Inc.

Opinion on the Financial Statements

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

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the 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 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 was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accruals for Research and Development Expenses

As described in Note 3 to the consolidated financial statements, at each balance sheet date, the Company estimates its accrued pre-clinical expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants in connection with performing pre-clinical work in preparation for clinical trials, and in making that estimate, may depend on factors such as successful enrollment of certain numbers of patients, site initiation, and the completion of contract milestones. The Company accounts for research and development expenses based on services that have been performed on the Company's behalf and estimating the level of service performed and the associated cost incurred for the service when an invoice has not been received or the Company has not otherwise been notified of the actual cost. The Company estimates the time period over which services will be performed and the level of effort to be expended in each period. The Company's accrual for pre-clinical and clinical trial expenses of $2,385,000 is included in Accrued expenses on the December 31, 2022 consolidated balance sheet. The amounts recorded for pre-clinical and clinical trial expenses represent the Company's estimate of the unpaid pre-clinical and clinical trial expenses based on the information available to the Company at that time. The estimation of pre-clinical and clinical trial expenses was also identified as a critical accounting estimate by management.

We identified the accruals for research and development expenses as a critical audit matter due to the significant judgment and estimation required by management in determining progress or state of completion of trials or services completed. This in turn led to a high degree of auditor subjectivity and significant audit effort was required in performing our procedures and evaluating audit evidence relating to estimates made by management.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. We obtained an understanding and evaluated the design of controls over the Company's estimation of pre-clinical and clinical trial expenses, including the process of estimating the expenses incurred to date based on the status of the pre-clinical and clinical work. Our procedures also included, among others, reading agreements and contract amendments entered into with vendors in connection with conducting pre-clinical trials, evaluating the significant assumptions described above and the methods used in developing the pre-clinical trial estimates and calculating the amounts that were unpaid at the balance sheet date. We confirmed the assumptions directly with the third parties involved in performing the research and development services on behalf of the Company, where applicable. We also made direct inquiries of financial and pre-clinical client personnel regarding status, and progress towards completion, of pre-clinical trials and description of future commitments, and verified amounts paid to date under each contract by vouching to invoices and payment support. We also assessed the historical accuracy of management's estimates, and compared the current estimate of expenses incurred to estimates previously made by management.

/s/ EisnerAmper LLP

We have served as the Company's auditor since 2014.

EISNERAMPER LLP
Philadelphia, Pennsylvania
March 7, 2023

Corbus Pharmaceuticals Holdings, Inc.
Consolidated Balance Sheets

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,002,715	$ 25,006,632
Investments	42,194,296	72,640,520
Restricted cash	192,475	192,475
Prepaid expenses and other current assets	791,616	2,365,010
Total current assets	60,181,102	100,204,637
Restricted cash	477,425	477,425
Property and equipment, net	1,613,815	2,392,696
Operating lease right of use assets	3,884,252	4,609,110
Other assets	155,346	46,385
Total assets	$ 66,311,940	$ 107,730,253
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable	$ 353,323	$ 767,938
Accounts payable	2,173,963	1,782,277
Accrued expenses	5,999,252	10,093,312
Derivative liability	36,868	133,710
Operating lease liabilities, current	1,280,863	1,136,948
Current portion of long-term debt	2,795,669	3,093,344
Total current liabilities	12,639,938	17,007,529
Long-term debt, net of debt discount	15,984,426	15,636,275
Other long-term liabilities	22,205	22,205
Operating lease liabilities, noncurrent	4,675,354	5,956,217
Total liabilities	33,321,923	38,622,226
Stockholders' equity		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2022 and December 31, 2021. See Note 13	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized, 4,171,297 and 4,169,631 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	417	416
Additional paid-in capital	425,196,359	418,903,820
Accumulated deficit	(392,080,667)	(349,733,764)
Accumulated other comprehensive loss	(126,092)	(62,445)
Total stockholders' equity	32,990,017	69,108,027
Total liabilities and stockholders' equity	$ 66,311,940	$ 107,730,253

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

Corbus Pharmaceuticals Holdings, Inc.
Consolidated Statements of Operations and Comprehensive Loss

	For the Twelve Months Ended December 31,	
	2022	**2021**
Revenue from awards	$ —	$ 881,705
Operating expenses:		
Research and development	16,136,826	36,445,285
General and administrative	18,698,619	20,425,444
Litigation settlement	5,000,000	—
Total operating expenses	39,835,445	56,870,729
Operating loss	(39,835,445)	(55,989,024)
Other income (expense), net:		
Other income (expense), net	(48,773)	11,899,992
Interest income (expense), net	(2,132,091)	(1,830,486)
Change in fair value of derivative liability	96,842	663,290
Foreign currency exchange gain (loss), net	(427,436)	(384,198)
Other income (expense), net	(2,511,458)	10,348,598
Net loss	$ (42,346,903)	$ (45,640,426)
Net loss per share, basic and diluted	$ (10.15)	$ (11.15)
Weighted average number of common shares outstanding, basic and diluted	4,170,675	4,094,935
Comprehensive loss:		
Net loss	$ (42,346,903)	$ (45,640,426)
Other comprehensive income (loss):		
Change in unrealized gain (loss) on marketable debt securities	(63,647)	(62,445)
Total other comprehensive income (loss)	(63,647)	(62,445)
Total comprehensive loss	$ (42,410,550)	$ (45,702,871)

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

Corbus Pharmaceuticals Holdings, Inc.
Consolidated Statements of Stockholders' Equity

	For the Year Ended December 31, 2022							
	Mezzanine Equity		Stockholders' Equity					
	Series A Redeemable Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Loss	Equity
Balance at December 31, 2020	—	$—	3,290,358	$329	$349,367,934	$(304,093,338)	$—	$45,274,925
Issuance of common stock, net of issuance costs of $1,820,437	—	—	851,320	85	59,110,715	—	—	59,110,800
Stock-based compensation expense	—	—	—	—	9,480,373	—	—	9,480,373
Issuance of common stock upon exercise of stock options	—	—	27,953	2	944,798	—	—	944,800
Change in unrealized gain (loss) on marketable debt securities	—	—	—	—	—	—	(62,445)	(62,445)
Net loss	—	—	—	—	—	(45,640,426)	—	(45,640,426)
Balance at December 31, 2021	—	$—	4,169,631	$416	$418,903,820	$(349,733,764)	$(62,445)	$69,108,027
Issuance of common stock, net of issuance costs of $0	—	—	1,666	1	—	—	—	1
Issuance of Series A Redeemable Preferred Stock	1,002,247	100	—	—	(100)	—	—	—
Redemption of Series A Redeemable Preferred Stock	(1,002,247)	(100)	—	—	—	—	—	(100)
Stock-based compensation expense	—	—	—	—	5,719,637	—	—	5,719,637
Change in fair value of debt conversion feature	—	—	—	—	573,002	—		573,002
Change in unrealized gain (loss) on marketable debt securities	—	—	—	—	—	—	(63,647)	(63,647)
Net loss	—	—	—	—	—	(42,346,903)	—	(42,346,903)
Balance at December 31, 2022	—	$—	4,171,297	$417	$425,196,359	$(392,080,667)	$(126,092)	$32,990,017

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

Corbus Pharmaceuticals Holdings, Inc.
Consolidated Statements of Cash Flows

	Twelve Months Ended December 31,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (42,346,903)	$ (45,640,426)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	5,719,637	9,480,373
Depreciation and amortization	762,995	999,817
Loss on impairment of fixed assets	—	606,078
Net amortization on premium of investments	124,875	698,254
Stock consideration in connection with PRI License Agreement	—	250,000
Loss on foreign exchange	648,520	342,424
Operating lease right of use asset amortization	724,858	639,415
Amortization of debt discount	742,478	700,613
Realized loss on investments	178,222	—
Change in fair value of derivative liability	(96,842)	(663,290)
Loss on sale of property and equipment	21,235	99,520
Changes in operating assets and liabilities:		
Decrease in prepaid expenses	1,573,394	1,347,851
Decrease in contract asset	—	1,618,296
(Increase) decrease in other assets	(108,961)	187,652
Decrease in accounts payable	(256,835)	(5,956,297)
Decrease in accrued expenses	(4,094,160)	(11,912,120)
Increase in other long-term liabilities	—	22,205
Decrease in operating lease liabilities	(1,136,948)	(1,004,062)
Net cash used in operating activities	(37,544,435)	(48,183,697)
Cash flows from investing activities:		
Purchases of investments	(86,341,894)	(87,266,596)
Proceeds from sales and maturities of investments	116,421,376	13,880,343
Purchases of property and equipment	(13,449)	(54,172)
Proceeds from sale of property and equipment	8,100	23,900
Net cash provided by (used in) investing activities	30,074,133	(73,416,525)
Cash flows from financing activities:		
Proceeds from issuance of notes payable	452,250	984,375
Repayment of short-term borrowings	(866,865)	(926,595)
Proceeds from issuance of long-term borrowings	1,381,729	—
Repayment of long-term borrowings	(1,500,729)	—
Proceeds from issuance of common stock	—	62,586,070
Issuance costs paid for common stock financings	—	(1,820,437)
Net cash (used in) provided by financing activities	(533,615)	60,823,413
Net decrease in cash, cash equivalents, and restricted cash	(8,003,917)	(60,776,809)
Cash, cash equivalents, and restricted cash at beginning of the period	25,676,532	86,453,341
Cash, cash equivalents, and restricted cash at end of the period	$ 17,672,615	$ 25,676,532
Supplemental disclosure of cash flow information and non-cash transactions:		
Cash paid during the period for interest	$ 1,969,583	$ 1,740,878
Write off of fully depreciated property and equipment	—	544,752

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

1. NATURE OF OPERATIONS

Business

Corbus Pharmaceuticals Holdings, Inc. ("the Company" or "Corbus") is a precision oncology company committed to helping people defeat serious illness by bringing innovative scientific approaches to well understood biological pathways. Corbus' pipeline being developed internally includes CRB-701, a next generation antibody drug conjugate that targets the expression of Nectin-4 on cancer cells to release a cytotoxic payload, and CRB-601, an anti-integrin monoclonal antibody which blocks the activation of TGFβ expressed on cancer cells. The Company also has a pipeline of endocannabinoid small molecule drugs and is seeking partners to fund further development. Since its inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets and raising capital. The Company's business is subject to significant risks and uncertainties and the Company will be dependent on raising substantial additional capital before it becomes profitable, and it may never achieve profitability.

2. LIQUIDITY

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company has incurred recurring losses since inception and as of December 31, 2022, had an accumulated deficit of approximately $392,081,000. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research funding, development of its product candidates and its pre-clinical and clinical programs, strategic alliances and the development of its administrative organization. The Company expects the cash, cash equivalents, and investments of approximately $59,197,000 at December 31, 2022 will be sufficient to meet its operating and capital requirements at least 12 months from the issuance of these consolidated financial statements.

The source, timing and availability of any future financing will depend principally upon market conditions, and, more specifically, on the progress of the Company's clinical development programs. Funding may not be available when needed, at all, or on terms acceptable to the Company. Lack of necessary funds may require the Company to, among other things, delay, scale back or eliminate some or all of the Company's planned clinical or pre-clinical trials.

On August 7, 2020, the Company entered into an Open Market Sale Agreement℠ (the "August 2020 Sale Agreement") with Jefferies LLC ("Jefferies"), as sales agent, pursuant to which the Company may issue and sell, from time to time, through Jefferies, shares of its common stock, and pursuant to which Jefferies may sell its common stock by any method permitted by law deemed to be an "at the market offering" as defined by Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. The Company will pay Jefferies a commission of 3.0% of the aggregate gross proceeds from each sale of common stock and have agreed to provide Jefferies with customary indemnification and contribution rights. The Company has also agreed to reimburse Jefferies for certain specified expenses. As of August 7, 2020, the Company is authorized to offer and sell up to $150 million of its common stock pursuant to the August 2020 Sale Agreement. During the year ended December 31, 2021, the Company sold 846,390 shares of its common stock under the August 2020 Sale Agreement for which the Company received gross proceeds of approximately $60,681,238, less issuance costs incurred of approximately $1,820,437. The Company has sold no additional shares of our common stock under the August 2020 Sale Agreement subsequent to December 31, 2022 (see Note 14).

3. SIGNIFICANT ACCOUNTING POLICIES

A summary of the significant accounting policies followed by the Company in the preparation of the consolidated financial statements is as follows:

Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

Reverse Stock Split

On February 14, 2023, the Company completed a 1-for-30 reverse split of its outstanding common stock. The Reverse Split did not change the number of authorized shares of common stock or par value. All references in these consolidated financial statements to shares, share prices, exercise prices, and other per share information in all periods have been adjusted, on a retroactive basis, to reflect the split (see Note 14).

Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany transactions and accounts have been eliminated in consolidation.

Use of Estimates

The process of preparing financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates and changes in estimates may occur. The most significant estimates are related to stock-based compensation expense, the accrual of research, product development and clinical obligations, the recognition of revenue under the Investment Agreement (see Note 11), the valuation of warrants (see Note 9 and Note 16), and the derivative liability associated with the K2 Loan and Security Agreement (see Note 17).

Cash, Cash Equivalents, and Restricted Cash

The Company considers only those investments which are highly liquid, readily convertible to cash, and that mature within three months from date of purchase to be cash equivalents. At December 31, 2022 and 2021, cash equivalents were comprised of money market funds, commercial paper, and other debt securities with maturities less than three months from the date of purchase.

Restricted cash as of December 31, 2022 included security for a stand-by letter of credit issued in favor of a landlord for $669,900 of which $192,475 was classified in current assets and $477,425 was classified in noncurrent assets as of December 31, 2022.

Cash and cash equivalents consist of the following:

	December 31, 2022	December 31, 2021
Cash	$3,805,156	$6,751,593
Cash Equivalents	13,197,559	18,255,039
Cash and cash equivalents	$17,002,715	$25,006,632
Restricted cash, current	192,475	192,475
Restricted cash, noncurrent	477,425	477,425
Restricted cash	669,900	669,900
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	$17,672,615	$25,676,532

As of December 31, 2022, all of the Company's cash and cash equivalents was held in the United States, except for approximately $2,805,000 of cash which was held principally in our subsidiary in the United Kingdom. As of December 31, 2021, all of the Company's cash and cash equivalents was held in the United States, except for approximately $5,752,000 of cash which was held principally in our subsidiary in the United Kingdom.

Investments

Investments consist of investments in debt securities and term deposits with maturities greater than 90 days at their acquisition date. The Company has classified its investments with maturities beyond one year as current, based on their highly liquid nature and because such investments represent the investment of cash that is available for current operations.

The Company classifies all of its marketable debt securities as available-for-sale securities. The Company's marketable debt securities are measured and reported at fair value using quoted prices in active markets for similar securities. Unrealized gains and losses on available-for-sale debt securities that are not impairment related are reported as accumulated other comprehensive gain or loss, which is a separate component of stockholders' equity. The cost of debt securities sold is determined on a specific identification basis, and realized gains and losses are included in other income (expense), net in the consolidated statements of operations and comprehensive loss.

The Company evaluates its marketable debt securities with unrealized losses for other-than-temporary impairment. When assessing marketable debt securities for other-than-temporary declines in value, the Company considers such factors as, among other things, how significant the decline in value is as a percentage of the original cost, how long the market value of the investment has been less than its original cost, the Company's ability and intent to retain the investment for a period of time sufficient to allow for any anticipated recovery in fair value and market conditions in general. If any adjustment to fair value reflects a decline in the value of the investment that the Company considers to be "other than temporary," the Company reduces the investment to fair value through a charge to the statement of operations and comprehensive loss. No such adjustments were necessary during the periods presented.

Concentrations of Credit Risk

The Company has no significant off-balance-sheet concentration of credit risk such as foreign exchange contracts, option contracts or other hedging arrangements. The Company may, from time to time, have cash in banks in excess of Federal Deposit Insurance Corporation insurance limits. However, the Company believes the risk of loss is minimal as these banks are large financial institutions.

Financial Instruments

The carrying values of the notes payable and debt approximate their fair value due to the fact that they are at market terms.

Fair Value Measurements

The valuation of the Company's debt and embedded derivatives are determined primarily by an income approach that considers the present value of net cash flows of the debt with and without prepayment and default features. These embedded debt features, which are determined to be classified as derivative liabilities are marked-to-market each reporting period, with a corresponding non-cash gain or loss charged to the current period. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, there exists a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1 – Unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access as of the measurement date

Level 2 – Inputs other than quoted prices included within Level 1 that are directly observable for the asset or liability or indirectly observable through corroboration with observable market data

Level 3 – Unobservable inputs for the asset or liability only used when there is little, if any, market activity for the asset or liability at the measurement date

The Company's investments, debt, and its derivative liabilities are carried at fair value determined according to the fair value hierarchy described above. The carrying values of the Company's prepaid expenses and other current assets, and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

To determine the fair value of our embedded derivatives, management evaluates assumptions regarding the probability of certain future events. Other factors used to determine fair value include the discount rate, risk-free interest rate, and derivative term. The fair value recorded for the derivative liability varies from period to period. This variability may result in the actual derivative liability for a period either above or below the estimates recorded on our consolidated financial statements, resulting in fluctuations in other income (expense) because of the corresponding non-cash gain or loss recorded.

Property and Equipment

The estimated life for the Company's property and equipment is as follows: three years for computer hardware and software and three to five years for office furniture and equipment. The Company's leasehold improvements and assets under capital lease are amortized over the shorter of their useful lives or the respective leases. See Note 7 for details of property and equipment and Note 8 for operating and capital lease commitments.

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use ("ROU") assets, other current liabilities, and operating lease liabilities in the Company's consolidated balance sheets.

ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As the Company's leases do not provide an implicit rate, the Company uses an incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. This is the rate the Company would have to pay if borrowing on a collateralized basis over a similar term to each lease. The ROU asset also includes any lease payments made and excludes lease incentives. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

The Company has subleased a portion of its leased facility under an agreement considered to be an operating lease according to U.S. GAAP. The Company has not been legally released from its primary obligations under the original lease and therefore it continues to account for the original lease as it did before commencement of the sublease. The Company will record both fixed and variable payments received from the sublessee in its statement of operations on a straight-line basis as an offset to rent expense.

Accruals for Research and Development Expenses and Clinical Trials

As part of the process of preparing its financial statements, the Company is required to estimate its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment terms that do not match the periods over which materials or services are provided under such contracts. The Company's objective is to reflect the appropriate expenses in its financial statements by matching those expenses with the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the timing of various aspects of the expenses. The Company determines the accrual estimates by taking into account discussions with applicable personnel and outside service providers as to the progress of clinical trials, or the services completed. During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low for any particular period. For the years ended December 31, 2022 and 2021, there were no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials.

Revenue Recognition

We recognize revenue in accordance with Accounting Standards Codification ("ASC") 606, Revenue from Contracts with Customers ("ASC 606"), which applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements, and financial instruments. Under ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Research and Development Expenses

Costs incurred for research and development are expensed as incurred.

Nonrefundable advance payments for goods or services that have the characteristics that will be used or rendered for future research and development activities pursuant to executory contractual arrangements with third party research organizations are deferred and recognized as an expense as the related goods are delivered or the related services are performed.

Asset Acquisitions

We account for asset acquisitions under the accounting standards for business combinations and research and development, as applicable. In-process research and development acquired in an asset acquisition is expensed immediately unless there is an alternative future use. Subsequent payments made for the achievement of milestones are evaluated to determine whether they have an alternative future use or should be expensed.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions regarding resource allocation and assessing performance. To date, the Company has viewed its operations and manages its business as principally one operating segment, which is developing and commercializing therapeutics for autoimmunity, fibrosis, and cancer. As of December 31, 2022, all of the Company's assets were located in the United States, except for approximately $2,805,000 of cash, cash equivalents, and investments, $136,000 of prepaid expenses and other assets, and $0 of property and equipment, net which were held outside of the United States, principally in our subsidiary in the United Kingdom. As of December 31, 2021, all of the Company's assets were located in the United States, except for approximately $5,752,000 of cash, $16,752,000 of investments, $973,000 of prepaid expenses and other assets, and $1,000 of property and equipment, net which were held outside of the United States, principally in our subsidiary in the United Kingdom.

Income Taxes

For federal and state income taxes, deferred tax assets and liabilities are recognized based upon temporary differences between the financial statement and the tax basis of assets and liabilities. Deferred income taxes are based upon prescribed rates and enacted laws applicable to periods in which differences are expected to reverse. A valuation allowance is recorded to reduce a net deferred tax benefit when it is not more likely than not that the tax benefit from the deferred tax assets will be realized. Accordingly, given the cumulative losses since inception, the Company has provided a valuation allowance equal to 100% of the deferred tax assets in order to eliminate the deferred tax assets amounts.

Tax positions taken or expected to be taken in the course of preparing the Company's tax returns are required to be evaluated to determine whether the tax positions are "more-likely-than-not" of being sustained by the applicable tax authority. Tax positions not deemed to meet a more-likely-than-not threshold, as well as accrued interest and penalties, if any, would be recorded as a tax expense in the current year. There were no uncertain tax positions that require accrual or disclosure to the financial statements as of December 31, 2022 or 2021.

Impairment of Long-lived Assets

The Company continually monitors events and changes in circumstances that could indicate that carrying amounts of long-lived assets may not be recoverable. An impairment loss is recognized when expected undiscounted cash flows of an asset are less than an asset's carrying value. Accordingly, when indicators of impairment are present, the Company evaluates the carrying value of such assets in relation to the operating performance and future undiscounted cash flows of the underlying assets. An impairment loss equal to the excess of the fair value of the asset over its carrying amount, is recorded when it is determined that the carrying value of the asset may not be recoverable. The Company recognized an impairment loss of approximately $606,000 in the third quarter of 2021 to write down the value of leasehold improvements as a result of entering into a sublease. The Company notes no impairment charges were taken in 2022. See Note 8 for more details on sublease agreement.

Stock-based Payments

The Company recognizes compensation costs resulting from the issuance of stock-based awards to employees, non-employees and directors as an expense in the statement of operations over the service period based on a measurement of fair value for each stock-based award. The fair value of each option grant is estimated as of the date of grant using the Black-Scholes option-pricing model, net of estimated forfeitures. The fair value is amortized as compensation cost on a straight-line basis over the requisite service period of the awards, which is generally the vesting period.

Foreign Currency

Transaction gains and losses arising from currency exchange rate fluctuations on transactions denominated in a currency other than the U.S. Dollar functional currency are recorded in the Company's statement of operations and comprehensive loss. Such transaction gains and losses may be realized or unrealized depending upon whether the transaction settled during the period or remains outstanding at the balance sheet date. The functional currency of the Company's foreign subsidiaries is the U.S. dollar.

Net Loss Per Common Share

Basic and diluted net loss per share of the Company's common stock has been computed by dividing net loss by the weighted average number of shares outstanding during the period. For years in which there is a net loss, options and warrants are anti-dilutive and therefore excluded from diluted loss per share calculations. The following table sets forth the computation of basic and diluted earnings per share for the years ended December 31, 2022 and 2021:

	Year Ended December 31,	
	2022	2021
Net loss	$ (42,346,903)	$ (45,640,426)
Weighted average number of common shares-basic	4,170,675	4,094,935
Net loss per share of common stock-basic	$ (10.15)	$ (11.15)

Warrants and options that have not been exercised have been excluded from the diluted calculation as all periods presented have a net loss and the impact of these securities would be anti-dilutive.

Recently Adopted Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board (the "FASB") issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* which is intended to simplify various aspects related to accounting for income taxes. The Company's adoption of ASU 2019-12 as of January 1, 2021 had no impact on the Company's financial statements and related disclosures.

In May 2021, the FASB issued ASU 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging— Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options* which is intended to clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after modification of exchange. The Company's adoption of ASU 2021-04 as of January 1, 2022 had no material impact on the Company's financial statements and disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13")*, which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. These changes may result in earlier recognition of credit losses. In November 2018, the FASB issued ASU No. 2018-19, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses*, which narrowed the scope and changed the effective date for non-public entities for ASU 2016-13. The FASB subsequently issued supplemental guidance within ASU No. 2019-05, *Financial Instruments—Credit Losses (Topic 326): Targeted Transition Relief ("ASU 2019-05")*. ASU 2019-05 provides an option to irrevocably elect the fair value option for certain financial assets previously measured at amortized cost basis. The Company's adoption of ASU 2016-13 as of January 1, 2023 had no impact on the Company's financial statements as there are no assets held at amortized cost on the balance sheet and there are no credit losses associated with our available-for-sale debt securities.

As a result of the adoption of ASU 2016-13, the Company has updated its significant accounting policy related to investments, specifically available-for-sale debt securities, and allowance for credit losses effective January 1, 2023 as follows:

The Company evaluates its marketable debt securities with unrealized losses for impairment. When assessing marketable debt securities for potential impairment, the Company considers available evidence, including the extent to which fair value is less than cost, whether an allowance for credit loss is required, and adverse factors that could affect the value of the securities. An impairment has occurred if the Company does not expect to recover the entire amortized cost basis of the marketable debt security. If the Company does not intend to sell the impaired debt security and it is not more likely than not required to sell the debt security before the recovery of its amortized cost basis, the amount of the impairment related to credit losses is recognized in an allowance for credit losses with an offsetting entry to Other income (expense), net. The remaining portion of the impairment related to other factors is recognized in Other comprehensive loss. Realized gains and losses for debt securities are included in Other income (expense), net.

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* which is intended to simplify various aspects of GAAP for certain financial instruments with characteristics of liabilities and equity. The Company's early adoption of ASU 2020-06 as of January 1, 2023 had no impact on the Company's financial statements and disclosures.

Recently Issued Accounting Pronouncements

The Company considers the applicability and impact of all ASUs. Management determined that recently issued ASUs are not expected to have a material impact on its consolidated financial statements.

4. INVESTMENTS

The following table summarizes the Company's investments as of December 31, 2022 (in thousands):

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Losses	Fair Value
Debt Securities:				
Commercial paper	$12,174	$—	$—	$12,174
Corporate debt securities	30,146	—	(126)	30,020
Total	$42,320	$—	$(126)	$42,194

The following table summarizes the amortized cost and fair value of the Company's available-for-sale marketable debt securities by contractual maturity as of December 31, 2022 (in thousands):

	Amortized Cost	Fair Value
Maturing in one year or less	$42,320	$42,194
Maturing after one year but less than three years	—	—
	$42,320	$42,194

The following table summarizes the Company's investments as of December 31, 2021 (in thousands):

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Losses	Fair Value
Commercial paper	$12,794	$—	$—	$12,794
Corporate debt securities	32,922	—	(58)	32,864
Asset backed securities	10,235	—	(4)	10,231
Term deposits	16,752	—	—	16,752
Total	$72,703	$—	$(62)	$72,641

The following table summarizes the amortized cost and fair value of the Company's available-for-sale marketable debt securities by contractual maturity as of December 31, 2021 (in thousands):

	Amortized Cost	Fair Value
Maturing in one year or less	$44,859	$44,848
Maturing after one year but less than three years	11,092	11,041
	$55,951	$55,889

5. FAIR VALUE OF FINANCIAL ASSETS AND LIABILITIES

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values as of December 31, 2022 (in thousands):

	Level 1	Level 2	Level 3	Total
Assets:				
Cash Equivalents:				
Money market funds	$8,471	$—	$—	$8,471
Commercial paper	—	1,495	—	1,495
Corporate debt securities	—	3,232	—	3,232
Investments:				
Commercial paper	—	12,174	—	12,174
Corporate debt securities	—	30,020	—	30,020
	$8,471	$46,921	$—	$55,392
Liabilities:				
Derivative liabilities	$—	$—	$37	$37

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values as of December 31, 2021 (in thousands):

	Level 1	Level 2	Level 3	Total
Assets:				
Cash Equivalents:				
Money Market funds	$18,255	$—	$—	$18,255
Investments:				
Term deposits	16,752	—	—	16,752
Commercial paper	—	12,794	—	12,794
Corporate debt securities	—	32,864	—	32,864
Asset backed securities	—	10,231	—	10,231
	$35,007	$55,889	$—	$90,896
Liabilities:				
Derivative liabilities	$—	$—	$134	$134

6. LICENSE AGREEMENTS

The Company entered into a license agreement (the "Jenrin License Agreement") with Jenrin Discovery, LLC, a privately held Delaware limited liability company ("Jenrin"), effective September 20, 2018. Pursuant to the Jenrin License Agreement, Jenrin granted the Company exclusive worldwide rights to develop and commercialize the Licensed Products (as defined in the Jenrin Agreement) which includes the Jenrin library of over 600 compounds and multiple issued and pending patent filings. The compounds are designed to treat inflammatory and fibrotic diseases by targeting the endocannabinoid system.

In consideration of the license and other rights granted by Jenrin, the Company paid Jenrin a $250,000 upfront cash payment and is obligated to pay potential milestone payments to Jenrin totaling up to $18,400,000 for each compound it elects to develop based upon the achievement of specified development and regulatory milestones. In addition, Corbus is obligated to pay Jenrin royalties in the mid, single digits based on net sales of any Licensed Products, subject to specified reductions.

The Company entered into a license agreement (the "Milky Way License Agreement") with Milky Way BioPharma, LLC ("Milky Way"), a subsidiary of Panorama Research Inc., effective May 25, 2021. Pursuant to the Milky Way License Agreement, the Company received an exclusive license, under certain patent rights and know-how owned or controlled by Milky Way, to develop, commercialize, and otherwise exploit products containing antibodies against integrin αvβ6 and/or integrin αvβ8 ("Licensed Products"), one of which the Company is referring to as CRB-602. Under the terms of the Milky Way License Agreement, the Company will have sole responsibility for research, development, and commercialization of any Licensed Products, and Company has agreed to use commercially reasonable efforts to perform these activities. The Milky Way Agreement may be terminated earlier in specified situations, including termination for material breach or termination by Corbus with advance notice.

In consideration for the license and other rights granted to the Company under the Milky Way License Agreement, the Company paid Milky Way an upfront payment of $500,000 and issued to Milky Way 147,875 shares of its common stock. The Company is obligated to pay up to $53,000,000 in potential milestone payments for the achievement of certain development, regulatory, and sales milestones. At the Company's election, the Company may satisfy a portion of certain milestone payments by issuing shares of its common stock. In addition, the Company is obligated to pay royalties in the low, single digits on sales of Licensed Products during the life of the applicable licensed patents on a country-by-county and product-by-product basis, which is subject to a minimum annual royalty obligation, as well as a percentage share of certain payments received by Company from sublicensees.

The Company entered into a license agreement (the "UCSF License Agreement") with the Regents of the University of California ("The Regents") effective May 26, 2021. Pursuant to the UCSF License Agreement, the Company received an exclusive license to certain patents relating to humanized antibodies against integrin αvβ8, one of which the Company is referring to as CRB-601, along with non-exclusive licenses to certain related know-how and materials. In consideration for the license and other rights granted to the Company under the UCSF License Agreement, the Company paid The Regents a license issue fee of $1,500,000.

The Company amended the UCSF License Agreement with The Regents effective November 17, 2022 adding additional antibody patents to the agreement. In consideration for the additional antibody patents granted to the Company, the Company will pay The Regents a license issue fee of $750,000, payable in two equal installments of $375,000 (first payment due within 7 days of the Amendment Effective Date and the second payment due on the first anniversary of the Amendment Effective Date).

In addition to the license issuance fees, the Company is obligated to pay an annual license maintenance fee, as well as up to $153,150,000 in potential milestone payments, excluding indication milestones for antibodies used for diagnostic products and services that will be an additional $50,000 for each new indication, for the achievement of certain development, regulatory, and sales milestones. In addition, the Company is obligated to pay royalties in the low, single digits on sales of products falling within the scope of the licensed patents, which is subject to a minimum annual royalty obligation, and a percentage share of certain payments received by Company from sublicensees or in connection with the sale of the licensed program.

The Company determined that substantially all of the fair value of the Jenrin License Agreement was attributable to a single in-process research and development asset which did not constitute a business. The Company determined that substantially all of the fair value of the Milky Way License Agreement and the UCSF License Agreement was attributable to separate groups of in-process research and development assets which did not constitute a business. The Company concluded that it did not have any alternative future use for the acquired in-process research and development assets. Thus, the Company recorded the various upfront payment to research and development expenses in the quarter the license deals became effective. The Company will account for the development, regulatory, and sales milestone payments in the period that the relevant milestones are achieved as either research and development expense or as an intangible asset as applicable.

7. PROPERTY AND EQUIPMENT

Property and Equipment consisted of the following:

	December 31, 2022	December 31, 2021
Computer hardware and software	$ 262,203	$ 248,754
Office furniture and equipment	1,113,980	1,185,329
Leasehold improvements	3,330,855	3,330,855
Property and equipment, gross	4,707,038	4,764,938
Less: accumulated depreciation	(3,093,223)	(2,372,242)
Property and equipment, net	$ 1,613,815	$ 2,392,696

Depreciation expense was approximately $763,000 and $1,000,000 for the years ended December 31, 2022 and 2021, respectively.

8. COMMITMENTS AND CONTINGENCIES

Operating Lease Commitment

On August 21, 2017, the Company entered into a lease agreement ("August 2017 Lease Agreement") for commercial lease of office space, pursuant to which the Company agreed to lease 32,733 square feet of office space ("Leased Premises"). The initial term of the August 2017 Lease Agreement was for a period of seven years which began with the Company's occupancy of the Leased Premises in February 2018. The base rent for the Leased Premises ranged from approximately $470,000 for the first year to approximately $908,000 for the seventh year. Per the terms of the August 2017 Lease Agreement, the landlord agreed to reimburse the Company for approximately $1,080,000 of leasehold improvements. The reimbursements had been deferred and were to be recognized as a reduction of rent expense over the term of the lease. Additionally, the August 2017 Lease Agreement required a standby irrevocable letter of credit of $400,000, which was to be reduced, if the Company is not in default under the August 2017 Lease Agreement, to $300,000 and $200,000 on the third and fourth anniversary of the commencement date, respectively, The Company entered into an unsecured letter of credit for $400,000 in connection with the August 2017 Lease Agreement.

The Company adopted ASU 2016-02, *Leases (Topic 842),* as amended ("ASU 2016-02") using the effective date method as of January 1, 2019 and recorded a lease liability of approximately $3,811,000, and a right-of-use asset of approximately $2,400,000, with no operations adjustment to the accumulated deficit related to the Leased Premises. Operating leases are included in operating lease right-of-use assets ("ROU"), operating lease liabilities, current and operating lease liabilities, noncurrent in the Company's consolidated balance sheets.

ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. ROU assets and liabilities are recognized at the date of adoption based on the present value of lease payments over the lease term. As the Company's leases do not provide an implicit rate, the Company uses an incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments, which was 9%. This is the rate the Company would have to pay if borrowing on a collateralized basis over a similar term to each lease. The ROU asset also includes any lease payments made and excludes lease incentives. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

On February 26, 2019, the Company amended its lease ("February 2019 Lease Agreement") pursuant to which an additional 30,023 square feet of office space ("New Premises") will be leased by the Company in the same building for an aggregate total of 62,756 square feet of leased office space ("Total Premises"). The February 2019 Lease Agreement constitutes a modification as it extends the original lease term and increases the scope of the lease (additional space provided under the amendment), which requires evaluation of the remeasurement of the lease liability and corresponding ROU asset. Accordingly, the Company reassessed the classification of the Leased Premises and remeasured the lease liability on the basis of the extended lease term using the 20 additional monthly rent payments and the incremental borrowing rate at the effective date of the modification of 9%. The remeasurement for the modification resulted in an increase to the lease liability and the ROU asset of approximately $855,000. The Company determined that the New Premises will be treated as a new standalone operating lease and recorded a lease liability and a right-of-use asset of approximately $2,700,000 for this lease.

Per the terms of the February 2019 Lease Agreement, the landlord agreed to reimburse the Company for approximately $991,000 of leasehold improvements. The reimbursements are being recognized as a reduction of rent expense over the term of the lease. Additionally, the February 2019 Lease Agreement required a standby irrevocable letter of credit of $369,900, which may be reduced, if the Company is not in default under the February 2019 Lease Agreement, to $277,425 and $184,950 on the third and fourth anniversary of the commencement date, respectively.

On October 25, 2019, the Company amended its lease ("October 2019 Lease Amendment") pursuant to which the term of the lease was extended through November 30, 2026 and the existing office space under lease was expanded by 500 square feet for an aggregate total of 63,256 square feet of leased office space ("Amended Total Premises"). The October 2019 Lease Amendment constitutes a modification as it extends the original lease term and increases the scope of the lease (additional space provided under the amendment), which requires evaluation of the remeasurement of the lease liability and corresponding ROU asset. The additional space did not result in a separate contract as the rent increase was determined not to be commensurate with the standalone price for the additional right of use. Accordingly, the Company reassessed the classification of the Amended Total Premises, which resulted in operating classification, and remeasured the lease liability on the basis of the extended lease term using the additional monthly rent payments and the incremental borrowing rate at the effective date of the modification of 8%. The remeasurement for the modification resulted in an increase to the lease liability and the ROU asset of approximately $381,000 that was recorded in the fourth quarter of 2019.

The following table contains a summary of the lease costs recognized under ASC 842 and other information pertaining to the Company's operating leases for the year ended December 31, 2022 and 2021:

	2022	2021
Lease cost		
Operating lease cost	$ 1,240,473	$ 1,240,473
Total lease cost	$ 1,240,473	$ 1,240,473
Other information		
Weighted average remaining lease term	3.8 years	4.8 years
Weighted average discount rate	8.00%	8.00%

Total rent expense for the years ended December 31, 2022 and 2021 was $1,652,563 and $1,185,341, respectively. Rent expense for the twelve months ended December 31, 2022 and 2021 was offset by $220,531 and $55,133, respectively, of sublease income.

Pursuant to the terms of the Company's non-cancelable lease agreements in effect at December 31, 2022, the following table summarizes the Company's maturities of operating lease liabilities as of December 31, 2022:

2023	$1,700,005
2024	1,747,447
2025	1,794,889
2026	1,688,145
Total lease payments	$6,930,486
Less: imputed interest	(974,269)
Total	$5,956,217

Sublease Commitment

Effective August 26, 2021, the Company entered into a sublease agreement with a third party to sublease 12,112 square feet of the 30,023 square feet currently being leased under one of its two existing lease agreements. The sublease commences on October 1, 2021 and ends October 31, 2026. The Company notes sublease income of $220,531 and $55,133 was recognized and offset against rent expense for the years ended December 31, 2022 and 2021, respectively.

Undiscounted sublease cash inflows have been summarized in the following table:

2023	185,717
2024	278,576
2025	290,688
2026	252,333
Total sublease payments	$1,007,314

For commitments under the Company's development award agreements refer to Note 11.

9. NOTES PAYABLE

D&O Financing

In November 2021, the Company entered into a loan agreement with a financing company for $984,375 to finance one of the Company's insurance policies. The terms of the loan stipulate equal monthly payments of principal and interest payments of $111,041 over a nine-month period. Interest accrues on this loan at an annual rate of 3.64%. This loan was fully repaid in July 2022.

In November 2022, the Company entered into a loan agreement with a financing company for $452,250 to finance one of the Company's insurance policies. The terms of the loan stipulate equal monthly payments of principal and interest payments of $51,387 over a nine-month period. Interest accrues on this loan at an annual rate of 5.4%. Prepaid expenses as of December 31, 2022, included approximately $418,750 related to the underlying insurance policy being financed.

Loan and Security Agreement with K2 HealthVentures LLC

On July 28, 2020, the Company, with its subsidiary, Corbus Pharmaceuticals, Inc., as borrower, entered into a $50,000,000 secured Loan and Security Agreement with K2HV, an unrelated third party (the "Loan and Security Agreement") and received the first $20,000,000 tranche upon signing. The second tranche of $20,000,000 and the third tranche of $10,000,000 will be made available at the Company's option subject to the achievement of certain clinical and regulatory milestones. The loan matures on August 1, 2024 and the Company is obligated to make interest only payments for the first 24 months and then interest and equal principal payments for the next 24 months commencing on September 1, 2022. The Company entered into an Amendment to the Loan and Security Agreement (the "Amended Loan and Security Agreement") on October 25, 2022. The Amended Loan and Security Agreement defers the commencement of principal repayments by a one-year period from September 1, 2022 to September 1, 2023 and if the Company raises at least $30 million in net proceeds through capital raising transactions, the commencement of principal repayments will be deferred by an additional six months to March 1, 2024. Interest accrues at a variable annual rate equal to the greater of (i) 8.5% and (ii) the rate of interest noted in The Wall Street Journal, Money Rates section, as the "Prime Rate" plus 5.25%, in each case, subject to a step-down of 25 basis points upon the funding of the second tranche. The interest rate used at December 31, 2022 was 12.75%.

In accordance with ASC Topic No. 470-50, *"Debt – Modifications and Extinguishments"* (Topic No. 470), the amendment noted above was determined to be a modification, thus no gain or loss was recorded.

Pursuant to the Loan and Security Agreement, the Lenders may jointly elect to convert up $5,000,000 of the outstanding loan balance into shares of the Company's common stock at a conversion price of $282.00 per share. The Amended Loan and Security Agreement adjusts the conversion price of $2,000,000 of the maximum $5,000,000 convertible amount by adjusting the conversion price of $875,000 of the loan from $282.00 per share to $4.50 per share, and $1,125,000 of the loan from $282.00 per share to $7.875 per share. The remaining $3,000,000 will continue to have a conversion price of $282.00 per share. The decrease in the conversion price resulted in an increase in the fair value of the conversion option of $573,000, which was recorded as an increase to the debt discount and additional paid in capital.

In connection with the Loan and Security Agreement, on July 28, 2020, the Company issued the Lenders a warrant to purchase up to 2,874 common shares (the "K2 Warrant") at an exercise price of $208.80 (the "Warrant Price"). The K2 Warrant may be exercised either for cash or on a cashless "net exercise" basis and expires on July 28, 2030. The total proceeds attributed to the K2 Warrant was approximately $472,000 based on the relative fair value of the K2 Warrant as compared to the sum of the fair values of the K2 Warrant, prepayment feature, default feature, and debt. Total proceeds attributed to the prepayment and default features was approximately $546,000. The Company also incurred approximately $1,244,000 of debt issuance costs from the Loan and Security Agreement. In connection with entering into the Amended Loan and Security Agreement, the Company incurred an additional $119,000 of debt issuance costs. The proceeds attributed to the K2 Warrant, the prepayment and default features, and the debt issuance costs are all included in the debt discount. The Company is required to make a final payment in excess of the stated principal equal to approximately $1,590,000. See Note 16 for more detail on assumptions used in the valuation of the K2 warrant and see Note 17 for more information on the assumptions used in valuation of the default and prepayment features.

The total principal amount of the loan under the Amended Loan and Security Agreement outstanding at December 31, 2022, including the $1,590,000 final payment discussed above, is $21,590,000.

Upon the occurrence of an Event of Default (as defined in the Loan and Security Agreement), and during the continuance of an Event of Default, the applicable rate of interest, described above, will be increased by 5.00% per annum. The secured term loan maturity date is August 1, 2024, and the Loan and Security Agreement includes both financial and non-financial covenants. The Company was in compliance with these covenants as of December 31, 2022. The obligations under the Loan and Security Agreement are secured on a senior basis by a lien on substantially all of the assets of the Company and its subsidiaries. The subsidiaries of the Company are guarantors of the obligations of the Company under the Loan and Security Agreement.

The total debt discount related to Lenders of approximately $2,954,000 is being charged to interest expense using the effective interest method over the term of the debt. At December 31, 2022, the fair value of our outstanding debt, which is considered Level 3 in the fair value hierarchy, approximates carrying value. Interest expense for the year ended December 31, 2022 was approximately $3,097,000. Interest expense for the year ended December 31, 2021 was approximately $2,709,000.

The net carrying amounts of the liability components consists of the following:

	December 31, 2022	December 31, 2021
Principal	$ 20,000,000	$ 20,000,000
Less: debt discount	(2,954,390)	(2,262,388)
Accretion of debt discount	1,734,485	992,007
Net carrying amount	$ 18,780,095	$ 18,729,619
Less: current portion of long-term debt	$ (2,795,669)	$ (3,093,344)
Total long-term debt, net of discount	$ 15,984,426	$ 15,636,275

The following table summarizes the future principal payments due under long-term debt:

	Principal Payments and final payment on Loan Agreement
2023	$2,977,268
2024	18,612,732
Total	$21,590,000

10. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	December 31, 2022	December 31, 2021
Accrued pre-clinical and clinical costs	$ 2,137,317	$ 5,435,464
Accrued product development costs	247,500	203,676
Accrued compensation	2,224,951	2,715,368
Accrued administrative costs	473,376	1,213,699
Accrued interest	916,108	525,105
Total	$ 5,999,252	$ 10,093,312

11. DEVELOPMENT AWARDS AND DEFERRED REVENUE

2018 CFF Award

On January 26, 2018, the Company entered into the Cystic Fibrosis Program Related Investment Agreement with the CFF ("Investment Agreement"), a non-profit drug discovery and development corporation, pursuant to which the Company received an award for up to $25 million in funding (the "2018 CFF Award") to support a Phase 2b Clinical Trial (the "Phase 2b Clinical Trial") of lenabasum in patients with cystic fibrosis, of which the Company has received $25 million in the aggregate through December 31, 2022 upon the Company's achievement of milestones related to the progress of the Phase 2b Clinical Trial, as set forth in the Investment Agreement.

Pursuant to the terms of the Investment Agreement, the Company is obligated to make certain royalty payments to CFF, including a royalty payment of one and one-half times the amount of the 2018 CFF Award, payable in cash within sixty days upon the first receipt of approval of lenabasum in the United States and a second royalty payment of one and one-half times the amount of the 2018 CFF Award upon approval in another major market, as set forth in the Investment Agreement (the "Approval Royalty"). At the Company's election, the Company may satisfy the first of the two Approval Royalties in registered shares of the Company's common stock.

Additionally, the Company is obligated to make (i) royalty payments to CFF of two and one-half percent of net sales from lenabasum due within sixty days after any quarter in which such net sales occur in the Field, as defined in the Investment Agreement, (ii) royalty payments to CFF of one percent of net sales of Non-Field Products, as defined in the Investment Agreement due within sixty days after any quarter in which such net sales occur, and (iii) royalty payments to CFF of ten percent of any amount the Company and its stockholders receive in connection with the license, sale, or other transfer to a third party of lenabasum, if indicated for the treatment or prevention of CF, or a change of control transaction, except that such payment shall not exceed five times the amount of the 2018 CFF Award, with such payments to be credited against any other net sales royalty payments due. Accordingly, the Company will owe to CFF a royalty payment equal to 10% of any amounts the Company receives as payment under the collaboration agreement with Kaken, provided that the total royalties that the Company will be required to pay under the Investment Agreement resulting from income from licenses or sales subject to the Investment Agreement are capped at five times the total amount of the 2018 CFF Award, and the Company may credit such royalties against any royalties on net sales otherwise owed to CFF under the Investment Agreement. Accordingly, the Company was required to pay CFF $2,700,000 in May 2019 as a result of its receipt of the $27,000,000 upfront cash payment from Kaken.

Either CFF or the Company may terminate the Investment Agreement for cause, which includes the Company's material failure to achieve certain commercialization and development milestones. The Company's payment obligations survive the termination of the Investment Agreement.

Pursuant to the terms of the Investment Agreement, the Company issued a warrant to CFF to purchase an aggregate of 33,333 shares of the Company's common stock (the "CFF Warrant"). The CFF Warrant is exercisable at a price equal to $396 per share and is immediately exercisable for 16,667 shares of the Company's common stock. Upon completion of the final milestone set forth in the Investment Agreement and receipt of the final payment from CFF to the Company pursuant to the Investment Agreement, the CFF Warrant will be exercisable for the remaining 16,667 shares of the Company's common stock. The CFF Warrant expires on January 26, 2025. Any shares of the Company's common stock issued upon exercise of the CFF Warrant will be unregistered and subject to a one-year lock-up.

Under the Investment Agreement, the Company recorded $0 and $881,705 of revenue during the years ended December 31, 2022 and 2021, respectively. The Company assessed the 2018 CFF Award for accounting under ASC 606, which it adopted in the first quarter of 2018. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, CFF, is a customer. The Company identified the following material promise under the arrangement: research and development activities and related services under the Phase 2b Clinical Trial. Based on these assessments, the Company identified one performance obligation at the outset of the Investment Agreement, which consists of: Phase 2b Clinical Trial research and development activities and related services.

To determine the transaction price, the Company included the total aggregate payments under the Investment Agreement which amount to $25 million and reduced the revenue to be recognized by the payment to the customer of $6,215,225 in the form of the CFF Warrant representing its fair value, leaving the remaining $18,784,775 as the transaction price as of the outset of the arrangement, which was recognized as revenue over the performance period as discussed below. The $6,215,225 fair value of the warrant was also recorded as an increase to additional paid in capital.

The Company has invoiced and received $25,000,000 in milestone payments, including $12,500,000 in 2018, $5,000,000 in 2019, $5,000,000 in 2020, and $2,500,000 in 2021. The Company notes there are no further development milestones under this agreement.

The CFF Warrant is accounted for as a payment to the customer. See Note 16 for further information related to the CFF Warrant. The Company notes that the Investment Agreement contains an initial payment that was received upon contract execution and subsequent milestone payments, which are a form of variable consideration that require evaluation for constraint considerations. The Company concluded that the related performance milestones are generally within the Company's control and as result are considered probable. Revenue associated with the performance obligation is being recognized as revenue as the research and development services are provided using an input method, according to the costs incurred as related to the research and development activities on each program and the costs expected to be incurred in the future to satisfy the performance obligation. The transfer of control occurs over this time period and, in management's judgment, is the best measure of progress towards satisfying the performance obligation. The research and development services related to this performance obligation were performed over an approximately three-year period and were completed as of December 31, 2021. The amounts recognized as revenue, but not received or invoiced were recognized as a contract asset on the Company's consolidated balance sheet.

12. INCOME TAXES

No provision or benefit for federal or state income taxes has been recorded, as the Company has incurred a net loss for all of the periods presented, and the Company has provided a full valuation allowance against its deferred tax assets.

The components of the Company's net loss are as follows:

	December 31,	
	2022	2021
United States	$(34,842,427)	$(48,713,664)
United Kingdom	(7,550,356)	3,016,100
Australia	45,880	57,138
Total	$(42,346,903)	$(45,640,426)

At December 31, 2022 and 2021, the Company had federal net operating loss carryforwards of approximately $197,846,000 and $186,267,000 respectively, of which federal carryforwards will expire in varying amounts beginning in 2029. Of the federal net operating loss carryforwards of $197,846,000, approximately $141,494,000 are from periods after 2017 and have no expiration date. Net operating loss carryforwards starting in 2021 are limited to 80% of taxable income. At December 31, 2022 and 2021, the Company had State net operating loss carryforwards of approximately $188,273,000 and $177,171,000, respectively. Utilization of net operating losses may be subject to substantial annual limitations due to the "change in ownership" provisions of the Internal Revenue Code, and similar state provisions. The annual limitations may result in the expiration of net operating losses before utilization. The Company has not yet conducted a study to determine if any such changes have occurred that could limit the Company's ability to use the net operating losses and tax credit carryforwards. The Company also had research and development tax credit carryforwards at December 31, 2022 and 2021 of approximately $9,376,000 and $8,656,000, respectively, of which will begin to expire in varying amounts beginning in 2033.

Significant components of the Company's net deferred tax asset are as follows:

	December 31,	
	2022	2021
U.S. and state net operating loss carryforwards	$ 53,438,141	$ 50,311,967
Foreign net operating loss carryforwards	7,267,176	5,846,372
Tax credit carryforward	9,132,973	8,392,989
Stock based compensation	8,661,477	9,102,630
Capitalized research and development	3,925,743	-
Accrued expenses	503,124	559,876
Other temporary differences	1,202,364	1,284,347
Subtotal	84,130,998	75,498,181
Valuation allowance	(84,130,998)	(75,498,181)
Net deferred tax asset	$ —	$ —

The Tax Cuts and Jobs Act ("TCJA") requires taxpayers to capitalize and amortize research and development ("R&D") expenditures under section 174 for tax years beginning after December 31, 2021. This rule became effective for us during 2022 and resulted in capitalized R&D costs of $14,523,000 as of December 31, 2022. We will amortize these costs for tax purposes over 5 years for R&D performed in the U.S. and over 15 years for R&D performed outside the U.S.

The Company has maintained a full valuation allowance against its deferred tax assets in all periods presented. A valuation allowance is required to be recorded when it is not more likely than not that some portion or all the net deferred tax assets will be realized. Since the Company cannot determine that it is more likely than not that it will generate taxable income, and thereby realize the net deferred tax assets, a full valuation allowance has been provided. The valuation allowance increased by $8,633,000 and $1,052,000 in 2022 and 2021, respectively, due to increased net operating loss carryforwards and increased capitalization of R&D expenditures in 2022 as required by changes to the tax laws from the TCJA as described above. The Company has no uncertain tax positions at December 31, 2022 and 2021 that would affect its effective tax rate. Since the Company is in a loss carryforward position, the Company is generally subject to U.S. federal and state income tax examinations by tax authorities for all years for which a loss carryforward is available.

Income tax benefits computed using the federal statutory income tax rate differs from the Company's effective tax rate primarily due to the following:

	December 31,	
	2022	2021
Tax provision at statutory rate	21.00%	21.00%
State income tax, net of federal benefit	5.53%	4.98%
Permanent differences	(1.72)%	(3.56)%
Foreign expected tax	4.08%	(1.21)%
Tax credits	1.87%	2.62%
Income tax rate change	—	(0.20)%
NOL Adjustments	—	(4.10)%
Other	(5.99)%	(17.37)%
Change in valuation reserve	(24.77)%	(2.16)%
Total	—%	—%

13. PREFERRED STOCK

The Company has authorized 10,000,000 shares of preferred stock, $0.0001 par value per share, of which 0 shares were issued and outstanding as of December 31, 2022 and 2021.

On October 12, 2022, the Board of Directors (the "Board"), declared a dividend of 0.008 of a share of Series A Preferred Stock ("Series A Preferred Stock"), for each outstanding share of Common Stock to stockholders of record at 5:00pm Eastern Time on October 22, 2022. The Certificate of Designation of Series A Preferred Stock was filed with the Delaware Secretary of State and became effective on October 12, 2022. The dividend was based on the number of outstanding shares of common stock prior to the Reverse Stock Split. This resulted in 1,002,247.048 shares of preferred stock being issued. The outstanding shares of Series A Preferred Stock were entitled to vote together with the outstanding shares of common stock as a single class exclusively with respect to any proposal to adopt an amendment to the Company's Amended and Restated Certificate of Incorporation, as amended (the "Certificate of Incorporation"), to reclassify the outstanding shares of Common Stock into a smaller number of shares of Common Stock at a ratio specified in or determined in accordance with the terms of such amendment (the "Reverse Stock Split"), as well as any proposal to adjourn any meeting of stockholders called for the purpose of voting on the Reverse Stock Split Proposal (the "Adjournment Proposal").

The Company held a special meeting of stockholders on December 20, 2022 (the "Special Meeting") for the purpose of voting on the Reverse Stock Split and an Adjournment Proposal. All shares of Series A Preferred Stock that were not present in person or by proxy at the Special Meeting, which totaled 500,894.04 shares, were automatically redeemed by the Company immediately prior to the opening of the polls at Special Meeting (the "Initial Redemption"). All shares that were not redeemed pursuant to the Initial Redemption would be redeemed if ordered by the Board or automatically upon the effectiveness of the amendment to the Certificate of Incorporation implementing the Reverse Stock Split (the "Subsequent Redemption" and together with the Initial Redemption, the "Redemption"). Each share of Series A Preferred Stock is entitled to receive $0.001 in cash for each 10 whole shares of Series A Preferred Stock immediately prior to the Redemption.

At the Special Meeting, both the Reverse Stock Split and Adjournment Proposal were approved.

Upon issuance of the Series A Preferred Stock, the Company was not solely in control of the Redemption of the shares of Series A Preferred Stock since the holders had the option of deciding whether to attend or return a proxy card for the Special Meeting, which determined whether a given holder's shares of Series A Preferred Stock were redeemed in the Initial Redemption. Since the Redemption of the Series A Preferred Stock was not solely in the control of the Company, the shares of Series A Preferred Stock are classified within mezzanine equity. The shares of Series A Preferred Stock were initially recorded at redemption value, which approximated fair value.

After the Special Meeting upon approval of the Reverse Stock Split, the remaining 501,353.008 shares outstanding of Series A Preferred Stock would be considered mandatorily redeemable and reclassified to a current liability. As of December 31, 2022, the fair value of the Series A Preferred Stock were included in accrued expenses. As of December 31, 2022, there were 0 shares of Series A Preferred Stock issued and outstanding within the consolidated balance sheet, however, the Series A Preferred Stock were redeemed on February 14, 2023, upon the effectiveness of the amendment to the Certificate of Incorporation implementing the Reverse Stock Split pursuant to the terms of the Certificate of Designation of the Series A Preferred Stock.

14. COMMON STOCK

On February 14, 2023, the Company completed a 1-for-30 reverse split of its outstanding common stock. The Reverse Split did not change the number of authorized shares of common stock or par value. All references in these consolidated financial statements to shares, share prices, exercise prices, and other per share information in all periods have been adjusted, on a retroactive basis, to reflect the split.

The Company has authorized 300,000,000 shares of common stock, $0.0001 par value per share, of which 4,171,297 shares were issued and outstanding as of December 31, 2022. The Company had 300,000,000 shares authorized, and 4,169,631 shares were issued and outstanding as of December 31, 2021.

On August 7, 2020, the Company entered into the August 2020 Sale Agreement with Jefferies pursuant to which Jefferies is serving as the Company's sales agent to sell shares of the Company's common stock through an "at the market offering." As of August 7, 2020, the company was authorized to sell up to $150,000,000 of shares of the Company's common stock pursuant to the August 2020 Sale Agreement. During the year ended December 31, 2022, the Company did not sell any shares of its common stock under the August 2020 Sale Agreement. During the year ended December 31, 2021, the Company sold 846,390 shares of its common stock under the August 2020 Sale Agreement for which the Company received gross proceeds of approximately $60,681,000, less issuance costs incurred of approximately $1,820,437 through December 31, 2021. During the year ended December 31, 2020, the Company sold 518,205 shares of its common stock under the August 2020 Sale Agreement for which the Company received gross proceeds of approximately $21,404,000, less issuance costs incurred of approximately $642,000 through December 31, 2020.

During the year ended December 31, 2021, the Company issued 27,953 shares of common stock upon the exercise of stock options to purchase common stock and the Company received proceeds of approximately $945,000 from these exercises, respectively.

During the year ended December 31, 2022, the Company issued 1,666 shares of restricted common stock pursuant to a professional services agreement with an investor relations service provider.

During the year ended December 31, 2021, the Company issued 4,929 shares of restricted common stock pursuant to the Milky Way License Agreement.

No warrants were exercised during the years ended December 31, 2022 and 2021.

15. STOCK OPTIONS

In April 2014, the Company adopted the Corbus Pharmaceuticals Holdings, Inc. 2014 Equity Incentive Plan (the "2014 Plan"). Pursuant to the 2014 Plan, the Company's Board of Directors may grant incentive and nonqualified stock options and restricted stock to employees, officers, directors, consultants, and advisors.

Pursuant to the terms of an annual evergreen provision in the 2014 Plan, the number of shares of common stock available for issuance under the 2014 Plan shall automatically increase on January 1 of each year by at least seven percent (7%) of the total number of shares of common stock outstanding on December 31st of the preceding calendar year, or, pursuant to the terms of the 2014 Plan, in any year, the Board of Directors may determine that such increase will provide for a lesser number of shares.

On January 1, 2022, pursuant to an annual evergreen provision contained in the 2014 Plan, the number of shares reserved for future grants was increased by 292,205 shares, which was seven percent (7%) of the outstanding shares of common stock on December 31, 2021. As of January 1, 2022 there was a total of 1,144,567 shares reserved for issuance under the 2014 Plan and there were 558,671 shares available for future grants. Options issued under the 2014 Plan generally vest over 4 years from the date of grant in multiple tranches and are exercisable for up to 10 years from the date of issuance.

In accordance with the terms of the 2014 Plan, effective as of January 1, 2023, the number of shares of common stock available for issuance under the 2014 Plan increased by 291,991 shares, such amount being seven percent (7%) of the outstanding shares of common stock on December 31, 2022 (see Note 18). As of January 1, 2023, the 2014 Plan had a total reserve of 1,436,558 shares and there were 741,870 shares available for future grants.

Share-based Compensation

For stock options issued and outstanding for the years ended December 31, 2022 and 2021, the Company recorded non-cash, stock-based compensation expense of $5,719,637 and $9,480,373, respectively, net of estimated forfeitures.

	Twelve Months Ended December 31,	
	2022	2021
Research and development expenses	$577,472	$2,969,347
General and administrative expenses	5,142,165	6,511,026
Total stock-based compensation	$5,719,637	$9,480,373

The fair value of each option award for employees and non-employees is estimated on the date of grant using the Black-Scholes option pricing model that uses the assumptions noted in the following table, except for the expected term for non-employees as noted in the following. The Company uses historical data, as well as subsequent events occurring prior to the issuance of the financial statements, to estimate option exercises and employee terminations in order to estimate its forfeiture rate. The expected term of options granted under the 2014 Plan, all of which qualify as "plain vanilla" per SEC Staff Accounting Bulletin 107, is determined based on the simplified method due to the Company's limited operating history and is 6.25 years based on the average between the vesting period and the contractual life of the option. For non-employee options, the expected term is the contractual term. The risk-free rate is based on the yield of a U.S. Treasury security with a term consistent with the option.

The weighted average assumptions used principally in determining the fair value of options granted were as follows:

	Twelve Months Ended December 31,	
	2022	2021
Risk free interest rate	1.99%	0.76%
Expected dividend yield	0%	0%
Expected term in years	6.25	6.23
Expected volatility	98.08%	102.96%
Estimated forfeiture rate	12.43%	9.12%

A summary of option activity for years ended December 31, 2022 and 2021 is presented below:

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Intrinsic Value
Outstanding at December 31, 2020	476,321	154.50		
Granted	245,793	70.80		
Exercised	(27,953)	33.90		
Forfeited or canceled	(182,655)	151.20		
Expired	(636)	209.10		
Outstanding at December 31, 2021	510,870	$ 121.90		
Granted	185,169	12.90		
Exercised	—	—		
Forfeited or canceled	(56,019)	107.13		
Expired	(22,024)	166.53		
Outstanding at December 31, 2022	617,996	$ 88.99	6.78	$ 11,195,964
Exercisable at December 31, 2022	358,611	$ 125.97	5.37	$ 3,177,014
Vested and expected to vest at December 31, 2022	584,143	$ 92.55	6.66	$ 9,969,530

The weighted average grant-date fair value of options granted during the years ended December 31, 2022 and 2021 was $10.20 and $57.30 per share, respectively. The aggregate intrinsic value of options exercised during the years ended December 31, 2022 and 2021 was approximately $0 and $1,769,714, respectively. As of December 31, 2022, there was approximately $6,302,350 of total unrecognized compensation expense, related to non-vested share-based compensation arrangements. The unrecognized compensation expense is estimated to be recognized over a period of 2.05 years at December 31, 2022.

As summary of non-vested stock options for the years ended December 31, 2022 and 2021 is presented below:

Options	Shares	Weighted Average Fair Value
Non-vested December 31, 2020	144,576	$ 124.20
Granted	245,793	57.30
Vested	(74,731)	120.60
Forfeited	(105,135)	84.00
Non-vested at December 31, 2021	210,503	$ 67.80
Granted	185,169	10.19
Vested	(107,269)	67.54
Forfeited	(29,019)	43.06
Non-vested at December 31, 2022	259,384	$ 29.59

16. WARRANTS

No warrants were exercised during the years ended December 31, 2022 and 2021.

At December 31, 2022, there were warrants outstanding to purchase 50,207 shares of common stock with a weighted average exercise price of $283.81 and a weighted average remaining life of 2.60 years.

The Company issued a warrant to CFF to purchase an aggregate of 33,334 shares of the Company's common stock (the "CFF Warrant"). The CFF Warrant is exercisable at a price equal to $396 per share and is immediately exercisable for 16,667 shares of the Company's common stock. Upon completion of the final milestone set forth in the Investment Agreement and receipt of the final payment from CFF to the Company pursuant to the Investment Agreement, the CFF Warrant will be exercisable for the remaining 16,667 shares of the Company's common stock. The CFF Warrant expires on January 26, 2025. Any shares of the Company's common stock issued upon exercise of the CFF Warrant will be unregistered and subject to a one-year lock-up. The CFF Warrant is classified as equity as it meets all the conditions under U.S. GAAP for equity classification. In accordance with U.S. GAAP, the Company has calculated the fair value of the warrant for initial measurement and will reassess whether equity classification for the warrant is appropriate upon any changes to the warrants or capital structure, at each balance sheet date. The weighted average assumptions used in determining the $6,215,225 fair value of the CFF Warrant were as follows:

Risk free interest rate	2.60%
Expected dividend yield	—%
Expected term in years	7.00
Expected volatility	83.5%

On July 28, 2020, the Company entered into the Loan and Security Agreement with K2HV pursuant to which K2HV may provide the Company with term loans in an aggregate principal amount of up to $50,000,000. On July 28, 2020, in connection with the funding of the first $20,000,000 tranche, the Company issued a warrant exercisable for 2,874 shares of the Company's common stock (the "K2 Warrant") at an exercise price of $208.80 per share. The K2 warrant is immediately exercisable for 2,874 shares and expires on July 28, 2030. Any shares of the Company's common stock issued upon exercise of the K2 Warrant are permitted to be settled in unregistered shares. The K2 Warrant is classified as equity as it meets all the conditions under U.S. GAAP for equity classification. In accordance with U.S. GAAP, the Company has calculated the fair value of the warrant for initial measurement and will reassess whether equity classification for the warrant is appropriate upon any changes to the warrants or capital structure, at each balance sheet date. The weighted average assumptions used in determining the $472,409 fair value of the K2 Warrant were as follows:

Risk free interest rate	0.60%
Expected dividend yield	—%
Expected term in years	10.00
Expected volatility	80.0%

On October 16, 2020, the Company entered into a professional services agreement with an investor relations service provider. Pursuant to the agreement, the Company issued warrants exercisable for a total of 14,000 shares of the Company's common stock (the "Warrants") at an exercise price of $32.10 per share. The Warrants were fully vested on October 19, 2021. Any shares of the Company's common stock issued upon exercise of the Warrants are permitted to be settled in unregistered shares. The Warrants are classified as equity as they meet all the conditions under U.S. GAAP for equity classification. In accordance with U.S. GAAP, the Company has calculated the fair value of the warrants for initial measurement and will reassess whether classification for the warrant is appropriate upon any changes to the warrants or capital structure, at each balance sheet date. The weighted average assumptions used in determining the $334,740 fair value of the Warrants were as follows:

Risk free interest rate	0.90%
Expected dividend yield	—%
Expected term in years	5.00
Expected volatility	100.6%

17. DERIVATIVE LIABILITY

On July 28, 2020, the Company, with its subsidiary, Corbus Pharmaceuticals, Inc., as borrower, entered into a $50,000,000 secured Loan and Security Agreement with K2HV, an unrelated third party (the "Loan and Security Agreement") and received the first $20,000,000 tranche upon signing. The Company has determined that a prepayment feature and default feature needed to be separately valued and mark to market each reporting period after assessing the agreement under ASC 815.

The value of these features is determined each reporting period by taking the present value of net cash flows with and without the prepayment features. The significant assumption used to determine the fair value of the debt without any features is the discount rate which has been estimated by using published market rates of triple CCC rated public companies. All other inputs are taken from the Loan and Security Agreement. The additional significant assumptions used when valuing the prepayment feature is the probability of a change of control event. The Company has determined the probability from December 31, 2020 to December 31, 2022 has stayed consistent. The additional significant assumption used when valuing the default feature is the probability of defaulting on the repayment of loan. The Company has determined the probability from December 31, 2021 to December 31, 2022 has remained consistent. The value of these features was determined to be approximately $133,710 at December 31, 2021 and $36,868 at December 31, 2022 which resulted in $96,842 of other income in 2022. The Company considers the fair value of the derivative liability to be Level 3 under the three-tier fair value hierarchy.

A roll forward of the fair value of the derivative liability for the year ended December 31, 2022 is presented below.

	December 31, 2022
Beginning balance, December 31, 2021	$133,710
Change in fair value of derivative liabilities	(96,842)
Ending balance, December 31, 2022	$36,868

18. SUBSEQUENT EVENTS

Evergreen Provision

Pursuant to the terms of an annual evergreen provision in the 2014 Plan, the number of shares of common stock available for issuance under the 2014 Plan shall automatically increase on January 1 of each year by at least seven percent (7%) of the total number of shares of common stock outstanding on December 31st of the preceding calendar year, or, pursuant to the terms of the 2014 Plan, in any year, the Board of Directors may determine that such increase will provide for a lesser number of shares. In accordance with the terms of the 2014 Plan, effective as of January 1, 2023, the number of shares of common stock available for issuance under the 2014 Plan increased by 291,991 shares, such amount being seven percent (7%) of the outstanding shares of common stock on December 31, 2022. As of January 1, 2023, the 2014 Plan had a total reserve of 1,436,558 shares and there were 741,870 shares available for future grants.

Reverse Stock Split

At the 2022 Special Meeting on December 20, 2022, the Company's stockholders granted the Company's Board of Directors the discretion to effect a reverse stock split of the Company's its issued and outstanding common stock through an amendment to its Certificate of Incorporation, as amended and restated to date, at a ratio of not less than 1-for-4 and not more than 1-for-40, such ratio to be determined by the Board. On February 9, 2023, the Board of Directors approved a 1-for-30 reverse stock split, and the Company filed the Amendment for the Reverse Stock Split with the Secretary of State of the State of Delaware. The Reverse Stock Split became effective in accordance with the terms of the Amendment on February 14, 2023. The Amendment did not change the number of authorized shares of common stock or the par value.

CSPC License Agreement

On February 12, 2023, the Company entered into an Exclusive License Agreement with CSPC Megalith Biopharmaceutical Co., Ltd. ("CSPC"), pursuant to which the Company received an exclusive license to obtain certain exclusive rights to develop and commercialize CRB-701 (SYS6002), a novel clinical stage antibody drug conjugate targeting Nectin-4. The License Agreement covers exclusive commercialization rights to CRB-701 in the United States, Canada, the European Union (including the European Free Trade Area), the United Kingdom, and Australia.

The Company will pay CSPC an upfront payment of $7.5 million ($5.0 million at signing followed by a $2.5 million payment after eighteen months). CSPC will also be eligible to receive low double-digit royalties on net sales and up to $130 million in potential development and regulatory milestone payments and $555 million in potential commercial milestone payments.