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, 2020

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: 001-38326

COHBAR, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**26-1299952**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

1455 Adams Drive, Suite 2050
Menlo Park, CA 94025
(Address of principal executive offices, including zip code)

(650) 446-7888
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	CWBR	Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act: N/A

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 ☐
Non-accelerated filer ☒

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. ☐

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

The aggregate market value of voting and non-voting common equity held by non-affiliates as of the last business day of the Registrant's most recently completed second fiscal quarter (June 30, 2020) was $50,525,285 based upon the last price of the Registrant's common stock as reported on the Nasdaq Capital Market on such date. As of March 25, 2021, the registrant had outstanding 61,788,325 shares of common stock.

Documents Incorporated by Reference

The registrant has incorporated by reference into Part III of this Form 10-K portions of its Proxy Statement for its 2021 Annual Meeting of Shareholders. Such Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2020.

COHBAR, INC.

2020 FORM 10-K ANNUAL REPORT

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PART I

Forward-Looking Statements

This report, including the sections entitled "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains forward-looking statements regarding future events and our future results that are based on our current expectations, estimates, forecasts and projections about our business, our results of operations, the industry in which we operate and the beliefs and assumptions of our management. Words such as "may", "will", "should", "could", "anticipate", "believe", "expect", "intend", "plan", "potential", "continue" and similar expressions are intended to identify these forward-looking statements. Examples of such forward-looking statements include statements regarding:

- our future results of operations and financial position, business strategy, market size and potential growth opportunities:
- preclinical and clinical development activities;
- efficacy and safety profiles of our clinical candidates;
- the anticipated therapeutic properties of our MBT drug development candidates;
- expectations regarding our ability to effectively protect our intellectual property; and
- expectations regarding our ability to attract and retain qualified employees and key personnel.

These statements reflect our current beliefs and are based on information currently available to us. Forward-looking statements involve significant risks and uncertainties, including without limitation, those listed in the "Risk Factors" section. A number of factors could cause actual results to differ materially from the results discussed in the forward-looking statements including, but not limited to, changes in general economic and market conditions and the risk factors disclosed under "Risk Factors". Although the forward-looking statements contained in this report are based upon what we believe to be reasonable assumptions, we cannot assure you that actual results will be consistent with these forward-looking statements. Investors should not place undue reliance on forward-looking statements. These forward-looking statements are made as of the date hereof and we assume no obligation to update or revise them to reflect new events or circumstances, except as required by applicable law.

Item 1. Business

OVERVIEW

CohBar ("CohBar," "we," "us," "our," "its" or the "Company") is a clinical stage biotechnology company focused on the research and development of mitochondria based therapeutics (MBTs), an emerging class of drugs for the treatment of chronic and age-related diseases. Mitochondria based therapeutics originate from the discovery by CohBar's founders of a novel group of naturally occurring mitochondrial-derived peptides within the mitochondrial genome that regulate metabolism and cell death, and whose biological activity declines with age. To date, the Company has discovered more than 100 mitochondrial-derived peptides. CohBar's efforts focus on the development of these peptides into therapeutics that offer the potential to address a broad range of diseases, including nonalcoholic steatohepatitis (NASH), obesity, fibrotic diseases including idiopathic pulmonary fibrosis (IPF), acute respiratory distress syndrome (ARDS) including COVID-19 associated ARDS, cancer, type 2 diabetes (T2D), cardiovascular and neurodegenerative diseases. The Company's lead compound, CB4211, is in the Phase 1b stage of a Phase 1a/1b clinical trial for NASH and obesity. In addition, CohBar has four preclinical programs, including one in fibrotic diseases, one in ARDS and two in cancer.

We substantially expanded our preclinical pipeline in 2020. Our expanded pipeline greatly strengthens our belief that there are potentially multiple novel therapeutics that can be developed from peptides encoded in the mitochondrial genome.

The application of MBTs originates from almost two decades of research by our founders, resulting in their discovery of a novel group of mitochondrial-derived peptides (MDPs) encoded within the mitochondrial genome. Some of these naturally occurring MDPs and their analogs have demonstrated a range of biological activity and therapeutic potential in research models across multiple diseases including NASH, obesity, cancer, fibrotic diseases including IPF, ARDS, T2D, cardiovascular and neurodegenerative diseases. Many chronic and age-related diseases are associated with a decrease in number and function of mitochondria.

Mitochondrial dysfunction can result in decreased levels of mitochondrially encoded peptides, some of which are secreted and have been shown to regulate cellular, metabolic, immunologic and other key processes, ranging from energy homeostasis to cytoprotection. We believe MBTs, which are novel modified analogs of mitochondrially derived peptides, represent an entirely new frontier and an emerging new class of potential drugs for the treatment of chronic and age-related diseases.

We believe CohBar is the first mover in exploring the mitochondrial genome for therapeutically relevant peptides, and has developed a proprietary MBT technology platform, using cell-based assays and animal models of disease, to rapidly identify naturally occurring MDPs with promising biological activity. Once identified, we deploy powerful development techniques to improve the drug-like properties of our MBT candidates, enabling us to match the most biologically promising peptides to disease indications that have substantial unmet medical needs. Our ongoing research and development activities focus on discovery and development of novel improved MDP analogs that have the greatest therapeutic and commercial potential.

Our first clinical candidate, CB4211, is a potential treatment for NASH and obesity. It is a novel peptide initially developed from a MOTS-c MDP. In July 2018, we initiated a Phase 1a/1b clinical study of CB4211, which was designed to initially assess the safety, tolerability and pharmacokinetics of CB4211 following single and multiple-ascending doses in healthy subjects.

In November 2019, the double-blind, placebo-controlled Phase 1a stage was completed and the blinded safety and tolerability data supported advancement to the Phase 1b stage of the study.

In November 2019, we initiated recruitment for the Phase 1b stage, which is designed to assess the safety, tolerability and activity of CB4211 in obese subjects with non-alcoholic fatty liver disease (NAFLD). Assessments will include changes in liver fat assessed by MRI-PDFF, body weight and biomarkers relevant to NASH and obesity. On March 30, 2020, we announced a delay in the completion of our Phase 1b study due to the COVID-19 pandemic. The delay was a result of a pause by some of our clinical research organization partners in all of their activities related to the study in response to COVID-19. On July 7, 2020, we announced the resumption of our Phase 1b study. In March 2021, we completed the enrollment for the Phase 1b clinical trial. Based on positive clinical results and additional funding from potential partnerships and general fundraising, we plan to initiate preparations for a Phase 2 study of CB4211 in 2021 and initiate a Phase 2 study in 2022.

Our internal discovery efforts have resulted in the identification of more than 100 previously unidentified peptides encoded within the mitochondrial genome. Many of these MDPs and their analogs have demonstrated various degrees of biological activity in cell based and/or animal models relevant to a wide range of diseases, such as NASH, obesity, fibrotic diseases, ARDS, cancer and T2D. Our research efforts have further identified and focused on certain of these MDPs and their analogs that have demonstrated the greatest therapeutic potential for treating indications related to those diseases. CohBar has four preclinical programs: CB5138 Analogs for IPF and other Fibrotic Diseases; CB5064 Analogs for ARDS, including COVID-19 Associated ARDS; CB5046 Analogs for Cancer and Other Disease Indications and MBT3 Analogs for Cancer Immunotherapy.

We Have a Seasoned Management and Drug Development Team

Our Chief Executive Officer, Steven Engle, has over two decades of experience leading public biotech companies in developing products for metabolic, inflammatory, autoimmune, and oncologic diseases. Mr. Engle served as Chairman and CEO of XOMA Corporation, a leader in the development of therapeutic antibodies, and of La Jolla Pharmaceutical Company, which discovered the biology of B cell tolerance and developed the first B cell toleragen candidate for lupus patients. Earlier, he helped to gain FDA approval and to launch Nicotrol for smoking cessation while Vice President of Marketing for Cygnus. He has been a board member of several biotechnology companies, and industry associations including Biotechnology Innovation Organization (BIO), BayBio Institute and Biocom.

Our research and development efforts are conducted under the leadership of our Chief Scientific Officer, Dr. Kenneth Cundy, former Chief Scientific Officer at Xenoport, Inc. and Senior Director of Biopharmaceutics at Gilead Sciences, Inc. Dr. Cundy is the co-inventor of several approved drugs, including tenofovir, an antiretroviral drug that is marketed globally in various combinations with other drugs for the treatment of HIV infection (Atripla®, Viread®, Complera®, Stribild®, Truvada®), gabapentin enacarbil (Horizant®) for the treatment of RLS and post-herpetic neuralgia, and Nanocrystal® technology, employed in several other approved drugs.

Our scientific team also includes the expertise of our founders who serve on our board of directors, Dr. Pinchas Cohen, Dean of the Davis School of Gerontology at the University of Southern California, Dr. Nir Barzilai, Professor of Medicine and Genetics and Director of the Institute for Aging Research at the Albert Einstein College of Medicine, as well as our co-founders and advisors Dr. David Sinclair, Professor of Genetics at Harvard Medical School and Dr. John Amatruda, former Senior Vice President and Franchise Head for Diabetes and Obesity at Merck Research Laboratories.

We have filed more than 65 patent applications with claims directed to both compositions comprising and methods of using our novel proprietary MDPs and their analogs. We are the exclusive licensee from the Regents of the University of California and the Albert Einstein College of Medicine of six issued U.S. Patents, three pending U.S. applications, five issued foreign patents, and four pending foreign applications. Our licensed patents and patent applications include claims that are directed to compositions comprising MDPs and their analogs and/or methods of their use in the treatment of indicated diseases.

We believe that the proprietary capabilities of our technology platform combined with our scientific expertise and intellectual property portfolio provide a competitive advantage in our mission to treat chronic and age-related diseases through the advancement of MBTs as a new class of transformative drugs.

We believe our technology platform provides multiple opportunities for value creation. Our peptide optimization process is designed to discover numerous potential drug candidate opportunities. These drug candidates may be internally developed by CohBar or advanced through strategic partnerships with larger biopharmaceutical companies. Our strategy of capturing the most valuable MBT space by aggressively filing for broad intellectual property coverage is designed to secure CohBar's leadership role in the field and protect our ability to create additional value in the future.

We were formed as a limited liability company in the state of Delaware in 2007, and converted to a Delaware corporation in 2009. We completed our initial public offering of common stock in January 2015 and our common stock is listed for trading on the Nasdaq Capital Market (CWBR).

Our corporate headquarters and laboratory are located in Menlo Park, California.

BUSINESS STRATEGY

Our strategic objective is to secure, maintain and exploit a leading scientific, commercial and intellectual property position in the arena of mitochondria based therapeutics, with best-in-class treatments for chronic and age-related diseases. The key elements of our strategy include:

- advancing CB4211 through clinical trials;
- further evaluating and optimizing analogs of CB5138 and CB5064 for potential clinical candidacy;
- developing strategic partnerships with leading biopharmaceutical companies and other organizations to advance our research programs and future development and commercialization efforts;
- maintaining sufficient financial runway to fund our operations, research and clinical development programs;
- minimizing operating costs and related funding requirements for our research and development activities through careful program management and cost-efficient relationships with academic partners, consultants and contract research organizations (CROs);
- continuing to strategically expand our intellectual property portfolio to capture all novel therapeutically relevant peptides encoded within the mitochondrial genome and improved analogs; and
- increasing awareness and recognition of our team, assets, capabilities and opportunities within the investment and scientific communities.

OUR PIPELINE

Our research efforts are focused on identifying, assessing and optimizing new analogs of biologically active MDPs and advancing those candidates with the greatest therapeutic and commercial potential. Our pipeline includes a number of novel peptide analogs of MDPs in different stages of research evaluation as potential MBTs, and one MBT currently in clinical development.

CB4211

In July 2018, we announced the initiation of the Phase 1a stage of a double-blind, placebo-controlled Phase 1a/1b clinical study of our first lead MBT candidate, CB4211, for the potential treatment of NASH and obesity. The Phase 1a stage of the clinical study is designed to initially assess the safety, tolerability and pharmacokinetics of CB4211 following single and multiple-ascending doses in healthy subjects. The Phase 1b stage of the clinical study is an assessment of safety, tolerability and activity in obese subjects with non-alcoholic fatty liver disease (NAFLD). Assessments will include changes in liver fat assessed by MRI-PDFF, body weight and biomarkers relevant to NASH and obesity.

In November 2018, we announced a temporary suspension of the Phase 1a stage of our Phase 1a/1b clinical study of CB4211 to address mild, but persistent injection site reactions. These injection site reactions were generally seen as painless bumps at the injection site that can be felt under the skin, but in most cases would be otherwise undetectable. Based on the data accumulated and expert review, we believe that some of the administered dose of CB4211 remained localized in the tissue at the injection site, thereby causing these bumps to occur. In May 2019, we received regulatory feedback on our plan to address this issue, and in June 2019, we resumed the trial. Since the study resumed, we have not observed any persistent injection site bumps.

In November 2019, we announced the completion of the Phase 1a portion of the clinical trial, with the drug being well-tolerated, and the commencement of the recruiting phase of the final Phase 1b stage of the study. On March 30, 2020, we announced a delay in the completion of our Phase 1b study due to the COVID-19 pandemic. The delay was a result of a pause by some of our clinical research organization partners in all of their activities related to the study in response to COVID-19. On July 7, 2020, we announced the resumption of our Phase 1b study. In March 2021, we completed the enrollment for the Phase 1b clinical trial. While topline data is expected at the end of the second quarter of 2021, it is dependent upon a number of factors such as the last patient visit, and therefore, we cannot predict with certainty when such data will be available.

CB4211, discovered by CohBar, is a novel, enhanced analog of MOTS-c, a naturally occurring mitochondrial peptide discovered by Dr. Pinchas Cohen and his academic collaborators in 2012. Their research in cell-based assays and animal models indicated that MOTS-c plays a significant role in the regulation of metabolism. Certain of the original MOTS-c studies were published in an article entitled "The Mitochondrial-Derived Peptide, MOTS-c, Promotes Metabolic Homeostasis and Reduces Obesity and Insulin Resistance," which appeared in the March 3, 2015 edition of the journal *Cell Metabolism*.

In preclinical studies conducted by CohBar, CB4211 demonstrated significant therapeutic potential for the treatment of NASH, showing improvements in triglyceride levels, as well as favorable effects on liver enzyme markers associated with NAFLD and NASH. CB4211 also demonstrated significant therapeutic potential for the treatment of obesity, demonstrating significantly greater weight loss together with more selective reduction of fat mass versus lean mass in comparison to a market-leading obesity drug in DIO mice. The therapeutic effects of CB4211 have been further evaluated in the well-established Stelic Animal Model (STAM™) of NASH. In this model, treatment with CB4211 resulted in a significant reduction of the non-alcoholic fatty liver disease activity score, or NAS, a composite measure of steatosis (fat accumulation), inflammation and hepatocyte ballooning (cellular injury). Data from these studies were presented at the American Association for the Study of Liver Disease (AASLD) 2017 Liver Meeting® in October, 2017.

In addition to the therapeutic potential indicated by the preclinical models described above, data were presented at the 2018 American Diabetes Association meeting providing in vitro evidence that CB4211 inhibits adipocyte lipolysis, a process that is foundational in the development of liver steatosis, through an insulin-dependent mechanism. These data provide a potential mechanistic explanation for previous observations in vivo, including efficacy of CB4211 in animal models of NASH, and anti-steatotic effects on livers of mice on a high fat diet, where a corresponding reduction in circulating fat and biomarkers of liver damage was also observed. The activity of CB4211 appears to involve sensitizing insulin action on the insulin receptor.

Research Programs

Our research activities are focused on discovering, developing and prioritizing MDP analogs for development as potential MBTs. Our criteria include examining MDP analogs with the greatest commercial and therapeutic potential, the most suitable development and clinical resources, and the broadest intellectual property protection and exploitation opportunities.

We have substantially expanded our preclinical pipeline in the last year. This expanded pipeline greatly strengthens our belief that there are potentially multiple novel therapeutics that can be developed from peptides encoded in the mitochondrial genome.

CohBar Discovered MDPs and Analogs

Our discovery efforts have resulted in the identification of more than 100 previously unidentified peptides encoded within the mitochondrial genome. Many of these MDPs and their analogs have demonstrated various degrees of biological activity in cell based and/or animal models relevant to a wide range of diseases, such as NASH, obesity, fibrotic diseases including IPF, ARDS, cancer, T2D, cardiovascular and neurodegenerative diseases. Our research efforts have further identified and focused on certain of these MDPs and their analogs that have demonstrated greatest therapeutic potential for treating indications related to those diseases.

CB5138 Analogs for IPF and other Fibrotic Diseases: Our discovery efforts have identified CB5138 Analogs, a family of novel peptides with potential for use as treatments for fibrotic diseases. In co-cultures of human lung cells, CB5138-1 decreased the expression of key fibrosis biomarkers, including alpha smooth muscle actin (αSMA), and collagen types I and III. CB5138-1 also decreased the transformation of healthy lung cells into fibrotic cells after induction by TGF-beta1, resulting in reduced production of the fibrotic components αSMA and pro-collagen I alpha 1. In vivo, CB5138-1 decreased lung fibrosis and inflammation in both the prophylactic mouse model of IPF, initiating treatment with the peptide immediately after fibrosis induction by bleomycin, and in the therapeutic mouse model of IPF, starting peptide treatment one week after induction. In addition, using the more exacting therapeutic model of IPF, two new analogs of CB5138 (CB5138-2 and CB5138-3) significantly reduced lung fibrosis assessed by the Ashcroft Score, reduced inflammation, and decreased fibrosis-related changes in lung weight, collagen deposition in lung tissue, and collagen secretion into lung fluid. In addition, we have demonstrated that a CB5138 Analog has enhanced effects when combined with nintedanib, the leading treatment for Idiopathic Pulmonary Fibrosis (IPF), suggesting potential utility for combination therapy in IPF. In the first quarter of 2021, we identified CB5138-3 as the lead clinical candidate in this program and our goal is to initiate IND-enabling activities with the potential to file an IND in 2022.

CB5064 Analogs for COVID-19 Associated Acute Respiratory Distress Syndrome (ARDS) and ARDS: Our internal discovery efforts have identified CB5064 Analogs, a family of peptides that are agonists of the apelin receptor with potential for use as therapeutics for COVID-19 associated ARDS and ARDS in general. In May 2020, we initiated testing of CB5064 Analogs in preclinical models of ARDS. In the preclinical studies, acute lung injury was induced in mice by administration of lipopolysaccharide (LPS), a bacterial toxin that produces similar symptoms to other causes of ARDS, including fluid accumulation and cytokine secretion. A single dose of CB5064 Analog was administered one hour prior to the LPS exposure, and effects on lung weight and levels of pro-inflammatory cytokines were measured at 4 hours after LPS exposure. Treatment with CB5064 Analogs reduced fluid accumulation in the lungs and a corresponding broad reduction in levels of key pro-inflammatory cytokines secreted into the lung fluid, when compared to treatment with a placebo control. We previously demonstrated the beneficial effects of this novel family of peptides on glucose tolerance, insulin sensitivity, and weight loss in an obese mouse model of T2D, as presented at the American Diabetes Association in 2019. In January 2021, we signed a Non-Clinical Evaluation Agreement (NCEA) with the National Institute of Allergy and Infectious Diseases (NIAID) initiating a collaboration to evaluate the potential of CB5064 Analogs for the treatment of COVID-19 associated Acute Respiratory Distress Syndrome (ARDS). In parallel with the work being conducted by NIAID, we are currently performing the required studies in this program to select a candidate. Based on successful outcomes of those studies and additional funding, we will nominate a clinical candidate followed by initiation of pre-IND work in 2021, with the longer-term goal of initiating a Phase 1 study.

CB5046 Analogs for Cancer and Other Disease Indications: Our internal discovery efforts have identified CB5046 Analogs, a family of novel potent and selective peptide inhibitors of CXCR4, a key chemokine receptor involved in tumor growth, metastasis and avoidance of immune surveillance that is overexpressed in 75% of human tumors. CXCR4 is also involved in localization of healthy stem cells and in certain genetic diseases. We have demonstrated positive effects of one of the CB5046 Analogs when administered in combination with chemotherapy in an animal model of aggressive melanoma. We are screening multiple peptide analogs for in vitro activity and plan to explore the potential for use initially in stem cell mobilization and hematologic cancers.

MBT3 Analogs for Cancer Immunotherapy: Our discovery efforts identified a novel peptide family, MBT3 Analogs. We have demonstrated the enhanced killing of cancer cells by human immune cells in the presence of an MBT3 Analog, and plan to further explore the therapeutic potential of this analog family for treatment of cancer, subject to resource availability and the requirements of our more-advanced programs.

CohBar Licensed MDPs and Analogs

SHLP Analogs: Our founders and their academic collaborators discovered several MDPs encoded within the mitochondrial genome; we refer to these as small humanin-like peptides, or SHLPs. In cancer treatment models in cell culture and in mice, SHLP-6 demonstrated suppression of cancer progression via mechanisms involving both suppression of tumor angiogenesis (blood vessel development) and induction of apoptosis (cancer cell death). There is also in vivo research evidence to suggest that SHLP-2 has protective effects against neuronal toxicity.

Humanin Analogs: Our founders and others have demonstrated the protective effects of the humanin MDP in various animal models of age-related diseases, including Alzheimer's disease, atherosclerosis, myocardial and cerebral ischemia and T2D. Humanin levels in humans have been shown to decline with age, and elevated levels of humanin together with lower incidence of age-related diseases have been observed in centenarians as well as their offspring.

All of our pipeline peptides, except for CB4211, our first clinical candidate and CB5138-3, our second clinical candidate, are in various stages of research. There is no guarantee that any additional MDP analog will be advanced to clinical development, or that the activity demonstrated in preclinical research models will be shown in human testing.

OUR TECHNOLOGY PLATFORM

Our proprietary technology platform is designed to rapidly identify therapeutically relevant peptides encoded within the mitochondrial genome, to evaluate their biological activity, and to develop these peptides into novel refined MBTs that have the potential to treat diseases with major unmet medical needs. We use a broad range of proprietary activity screens to assess the therapeutic potential of our novel peptides and to prioritize our development opportunities. Some of our novel peptides have demonstrated promising biological effects in a variety of in vitro and/or in vivo models of age-related diseases. We are prioritizing the research and development of our novel peptides by assessing their activity in a variety of areas such as metabolic regulation, oxidative stress, cellular energy levels, cell proliferation, cell death, cellular protection, carbohydrate metabolism, lipid metabolism, body weight regulation, regulation of body fat, insulin sensitivity, regulation of glucose, glucose tolerance, liver function, regulation of fibrotic processes, immunomodulatory effects, tumor growth, etc.

Disease Focus

Our research and development focus is on chronic diseases. Our research to date suggests multiple potential therapeutic disease indications for some of our pipeline MDPs. While we believe our current and future MBT drug candidates we identify would initially be advanced against one of the following diseases as a primary indication, it is possible that we may determine to advance a drug candidate for treatment of a different disease as a primary indication. We may determine to advance any future drug candidate against an alternative primary disease indication if, for example, additional data suggests greater therapeutic potential for the drug candidate against the alternative indication, or we determine that the development, approval or commercialization pathway may be more favorable for a drug candidate targeted against the alternative indication.

NAFLD and NASH – Non-alcoholic fatty liver disease (NAFLD) is the build-up of extra fat in liver cells that is not due to alcohol consumption and tends to develop in people who are overweight or obese or have diabetes, high cholesterol or high levels of triglycerides. Non-alcoholic steatohepatitis (NASH) is a more severe form of NAFLD characterized by swelling of the liver that eventually may lead to scarring (cirrhosis) and over time to liver cancer or liver failure. NAFLD affects between 30-40% of the U.S. adult population while as many as 12% of U.S. adults may have NASH. Currently, there are no FDA approved treatments for NAFLD/NASH.

Obesity — Obesity is now recognized as the most prevalent metabolic disease world-wide, reaching epidemic proportions in both developed and developing countries and affecting all age groups. More than one-third of the U.S. adult population, and over 45% of U.S. age groups between 45 and 75, have obesity. The prevalence of class III, or morbid, obesity (body mass index ≥40) has increased dramatically in several countries and currently affects approximately 8% of adults in the U.S., with an estimated increase of 130% over the next two decades. It is expected that by 2030 approximately 50% of the U.S. adult population will be obese and one in four will have severe obesity. Obesity is a major risk factor for age-related diseases such as heart disease, stroke, T2D and certain types of cancer.

Fibrotic Diseases – Fibrosis describes the formation of fibrous connective tissue in an organ or tissue as a reparative response to an injury or damage. "Scarring" occurs when fibrosis develops in response to injury. Fibrotic diseases include diseases that result in fibrosis, such as lung or pulmonary fibrosis, liver fibrosis, cardiac fibrosis, skin fibrosis, systemic sclerosis and others.

Acute Respiratory Distress Syndrome - ARDS can be triggered by viral or bacterial pneumonia, sepsis, trauma or other events and represents a major cause of morbidity and mortality. There is a high unmet need for a safe and effective treatment of ARDS due to its high mortality rate and lack of effective drug treatments, affecting three million patients annually. ARDS also prolongs hospital stays and requires convalescence in the hospital and rehabilitation. An effective therapy would reduce time on ventilators and in the ICU, reduce mortality, and improve quality of life.

Cancer – Cancer is a generic term for a large group of diseases that can affect any part of the body. One defining feature of cancer is the rapid creation of abnormal cells that grow beyond their usual boundaries, and which can then invade adjoining parts of the body and spread to other organs. This process is referred to as metastasis. Metastases are a major cause of death from cancer. Cancer is a leading cause of death worldwide. Cancer treatments such as chemotherapy, hormone therapy and other treatments are used to destroy cancer cells. The goal of cancer drugs is to cure the disease or, when a cure is not possible, to prolong life or improve quality of life for patients with incurable cancer.

Other Potential Disease Indications for MBTs

Previous preclinical studies have demonstrated potential utility of certain MDPs or their analogs in models of the following disease indications:

Neurodegenerative disease – In the brain, neurons connect and communicate at synapses, where tiny bursts of chemicals called neurotransmitters carry information from one cell to another. Alzheimer's, a neurodegenerative disease, disrupts this process and eventually destroys synapses and kills neurons, damaging the brain's communication network. There is no cure, and medications on the market today treat only the symptoms of Alzheimer's disease and do not have the ability to stop its onset or its progression. There is an urgent and unmet need for both a disease-modifying drug for Alzheimer's disease as well as for better symptomatic treatments.

Cardiovascular – Heart disease is a leading cause of death for both men and women in the United States. Atherosclerosis is a cardiovascular disease commonly referred to as a "hardening" or furring of the arteries. It is caused by the formation of multiple atheromatous plaques within the arteries. This process is the major underlying risk for developing myocardial infarction (heart attack) as those plaques will either narrow the vessel or rupture the vessel, preventing blood flow in the coronary artery to parts of the heart muscle. Cholesterol lowering drugs are considered the main preventive approach to treat atherosclerosis, however these drugs are estimated to prevent only one-third of incidences of myocardial infarction, and there is significant unmet need for additional therapeutic options.

Type 2 diabetes mellitus – T2D is a chronic disease characterized by a relative deficiency in insulin production and secretion by the pancreas and an inability of the body to respond to insulin normally, i.e. insulin resistance. Hyperglycemia, or raised blood sugar, is a common effect of uncontrolled diabetes and over time leads to serious damage to many of the body's systems, especially the nerves, kidneys, eyes and blood vessels.

COMPETITION

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our scientific knowledge, technology, and research and development experience provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies, and public and private research institutions. Many of our competitors may have significantly greater financial resources and capabilities for research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do.

There are no approved therapies for the treatment of NAFLD and NASH, but numerous therapies are in development for NASH. These potential therapies are varied in modality and mechanism of action and may provide significant competition, if approved, for any of our product candidates for which we obtain market approval. Competitive products or therapies for NASH that are in development may become available and provide efficacy, safety, convenience and other benefits that could provide significant competition for any of our product candidates for which we obtain market approval.

If a CohBar MBT is developed and approved for the treatment of patients with obesity, it may compete with products currently approved for obesity, such as Saxenda, Contrave, phentermine (Adipex) and other sympathomimetic amines approved for short term use (a few weeks) such as benzphetamine (Didex), diethyoproprion (Tenuate) and phendimetrazine (Bontril), Xenical and Alli, and Qsymia, as well as several investigational therapies that are currently being studied for the treatment of obesity. The list of investigational therapies, while not exhaustive, includes such potential therapies as CB1-receptor-antagonists, 5-HT receptor agonists, SGLT-2 antagonists, GLP-1 agonists, Adenylate Cyclase 3 activators, GLP1 and GIP co-agonists, GLP1, Glucagon co-agonists and activin II receptor antibodies, plus other centrally acting drugs, triple agonists, other gut hormone derived drugs, amylin mimetics such as davalintide, dual amylin and calcitonin receptor agonists, peptide YY, leptin analogues such as combination pramlintide-metreleptin, and other products such as the methionine aminopeptidase 2 inhibitors, the lipase inhibitor, cetilistat, the triple monoamine reuptake inhibitor, tesofensine, fibroblast growth factor 21 and anti-obesity vaccines against ghrelin, somatostatin, and adenovirus36.

If a CohBar MBT is developed and approved for treatment of patients with NASH, it may compete with several investigational therapies that are currently being studied for the treatment of NAFLD/NASH including, for example, FXR activators, PXR activators, ACC1/2 inhibitors, PPAR-α, -γ and -δ activators, SREBP2/MIR-33a inhibitors, DGAT1 or 2 inhibitors, CCR2/5 antagonists, TRbeta agonists, uncouplers, GLP1 agonists and dual and triple incretin agonists, SGLT2 inhibitors, FGF19 and 21 analogs, galectin 3 antagonists, CXCR3 antagonists and numerous other potential therapeutics.

If a CohBar MBT is developed and approved for the treatment of patients with a fibrotic disease, it would compete with all approved therapies for the disease it is approved to treat. Since the specific fibrotic disease that these investigational therapies might be approved to treat is unknown, and approved therapies for fibrotic diseases are often studied in other types of fibrotic disease for which the sponsor may seek approval, they would theoretically compete with any pharmaceutical agent that is approved to treat fibrotic disease. Both new and existing drugs are being studied for the treatment of fibrotic diseases. If these investigational indications were approved, they could also compete with an MBT developed and approved for the treatment of the fibrotic disease.

If a CohBar MBT is developed and approved for treatment of patients with IPF, it would compete with drugs that are approved to treat IPF, including nintedanib (Ofev) and Pirfenidone (Esbriet). In addition, there are several classes of investigational drugs being studied to treat IPF, and if these investigational therapies were approved, they would also compete with an MBT developed and approved for IPF.

If a CohBar MBT is developed and approved for the treatment of patients with cancer, it would compete with all approved therapies for the cancer it is approved to treat. Since the specific cancer that these investigational therapies might be approved to treat is unknown, and approved therapies for cancer are often studied in multiple other cancers for which the sponsor may seek approval, they would theoretically compete with any pharmaceutical agent that is approved to treat cancer. Both new and existing drugs are being studied for the treatment of cancer, and if these investigational indications were approved, they could also compete with an MBT developed and approved for the treatment of cancer.

If a CohBar MBT is developed and approved for the treatment of patients with Alzheimer's disease or other neurodegenerative diseases, it would compete with all approved therapies to treat Alzheimer's disease including donepezil (Aricept), galantamine (Razadyne), memantine (Namenda), rivastigmine (Exelon) and tacrine (Cognex). In addition, there are several investigational drugs being studied to treat Alzheimer's and other neurodegenerative diseases that, if approved, would also compete with an MBT developed and approved for the treatment of Alzheimer's and other neurodegenerative diseases.

If a CohBar MBT is developed and approved for treatment of patients with T2DM, it would compete with several classes of drugs for T2DM that are approved to improve glucose control, including sulfonylureas, glinides, PPAR gamma agonists, biguanides including metformin, alpha glucosidase inhibitors, DPP IV inhibitors, GLP1 agonists, SGLT2 inhibitors, bromocriptine and insulin. Insulin sensitizing agents approved to treat T2D are the PPAR gamma agonists pioglitazone and rosiglitazone. Some of the agents approved to treat T2DM are not generic, are oral once-daily pills and are effective in lowering glucose and A1C. Drugs approved for obesity as well as surgical management of obesity and approved and investigational devices used in GI tract may also be used to treat T2D. In addition, there are several investigational drugs being studied to treat T2D, and if these investigational therapies were approved, they would also compete with an MBT developed and approved for T2D.

FINANCING

Our business strategy and plans for research and development of our MDPs and MBT candidates includes periodic infusion of new capital to our Company. We may seek to obtain funding for our business through partnership agreements with pharmaceutical and biotechnology companies or through the issuance and sale of debt or equity securities in capital raising transactions.

PARTNERING

We believe our technology platform provides multiple opportunities for value creation. Our multiplexed peptide optimization process is designed to discover numerous potential drug candidate opportunities with near term value. These drug candidates can be internally developed by CohBar or advanced through strategic partnerships with larger biopharmaceutical companies. At the same time, our strategy of capturing the most valuable MBT space by aggressively filing for broad intellectual property coverage is designed to secure CohBar's leadership role in the field and protect our ability to create additional value in the future.

EMPLOYEES AND HUMAN CAPITAL RESOURCES

As of March 25, 2021, we had 12 employees, eleven full-time and one part-time. In addition to our employees, our founders consult directly with our employees and scientific staff from time to time to advance our research programs. Our founders provide advisory services in the areas of peptide research, genetics, aging and age-related diseases, drug discovery, development and commercialization, and other areas relevant to our business. Additionally, from time to time we engage other subject-matter experts on a consulting basis in specific areas of our research and development efforts. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We have not experienced any work stoppages and we consider our relations with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

RESEARCH AND DEVELOPMENT

Research and development activities are central to our business model. Our research programs include activities related to discovery of novel MDPs, investigational research to evaluate the potential therapeutic effects of certain discovered MDPs in research and preclinical studies and engineering novel, improved analogs of certain discovered MDPs with characteristics suitable for further development as potential MBT drug candidates and advancing our identified MBT candidate through clinical studies. Depending on factors of capability, cost, efficiency and intellectual property rights, we conduct our research programs independently at our laboratory facility. We also outsource some research and development activities pursuant to contractual arrangements with CROs or under collaborative arrangements with academic institutions.

INTELLECTUAL PROPERTY

Patents

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our novel biological discoveries and therapeutic methods, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. We seek to protect our proprietary position by, among other methods, licensing and/or filing patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business.

Our intellectual property and patent strategy is focused on our MDPs, their analogs and our MBT candidates. Our strategy is generally to seek patent protection in the United States and, where applicable, in those international jurisdictions we identify as holding significant potential market opportunity for any drug we may develop and in which patent protection is available. We also rely on trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position. With respect to new biologically active MDPs that we identify within the mitochondrial genome, we typically file provisional patent applications and seek composition of matter and method of treatment patents for our MDPs, their analogs, and prospective MBTs as well as methods of use based on research and preclinical evaluation of therapeutic potential. We intend to file non-provisional patent applications for those MDPs and analogs within our pipeline based on further assessment of their therapeutic and commercial potential, as well as strategic and competitive considerations. We believe that the opportunity to engineer analogs or create combination therapies will afford us the opportunity to strengthen IP protection for our drug development candidates as they advance through our development pipeline and to broaden our IP protection internationally.

As of December 31, 2020, CohBar has filed more than 65 patent applications, including 8 international Patent Cooperation Treaty (PCT) applications, with claims directed to both composition of matter and methods of use of novel proprietary MDP analogs. Our patent applications include filings in the United States, Europe and a number of other foreign countries, with projected expiration dates ranging from 2037 to 2041. Additionally, we are the exclusive worldwide licensee from the Regents of the University of California (the Regents) of twelve issued patents that will expire between 2028 and 2034, along with six pending patent applications. Other licensed intellectual property is described below.

Terms for individual patents extend for varying periods of time generally depending on the date of filing of the patent application and the legal term of patents in the countries in which they are obtained. Generally, patents issued from applications filed in the United States are effective for twenty years from the earliest non-provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period; however, the restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed fourteen years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also twenty years from the earliest international filing date. In certain instances, extension of patent term due to regulatory approval activities is available in foreign countries.

National and international patent laws concerning peptide therapeutics remain highly unsettled. Policies regarding the patent eligibility or breadth of claims allowed in such patents are currently in flux in the United States and other countries. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries can diminish our ability to protect our inventions and enforce our intellectual property rights. Accordingly, we cannot predict the breadth or enforceability of claims that may be granted in our patents or in third-party patents. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Our ability to maintain and solidify our proprietary position for our drugs and technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of the patent applications that we may file or license from third parties will result in the issuance of any patents. The issued patents that we own, license, or may license or own in the future, may be challenged, invalidated or circumvented, and the rights granted under any issued patents may not provide us with sufficient protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may be able to independently develop and commercialize similar drugs or duplicate our technology, business model or strategy without infringing our patents. Because of the extensive time required for clinical development and regulatory review of a drug we may develop, it is possible that, before any of our drugs can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of any such patent.

Summaries of our owned and licensed patent positions are described below.

CohBar Owned IP

As of December 31, 2020, CohBar has filed more than 65 patent applications, including applications relating to CB4211, CB5138 Analogs and other CohBar-identified MDPs and Analogs.

MOTS-c Analog Patent Coverage

CohBar has filed over 20 U.S. and foreign patent applications, including in Europe and Asia, directed to novel refined analogs of MOTS-c with improved properties, including claims directed to composition of matter and methods of use as well as to formulations containing these peptides. These applications also cover our lead product candidate CB4211. If issued, these patents would expire in 2037 and 2039.

CB5138 Analog Patent Coverage

CohBar has filed an international PCT application covering a CohBar-identified MDP (CB5138) and novel, improved analogs, including claims directed to composition of matter and methods of use, with a projected expiration date of 2040.

Other CohBar Identified MDPs and Analog Coverage

CohBar has also filed more than 45 patent applications that cover additional CohBar-identified MDPs and their novel, improved analogs, including claims directed to composition of matter and methods of use, with expiration dates of 2040 and 2041. A number of these filings relate to our programs and, in particular, MBT programs, including CB5064 analogs, and CB5046 analogs. The applications also include 8 international PCT applications. We intend to file additional non-provisional patent applications for MDPs and analogs within our pipeline based on further assessments of their therapeutic and commercial potential, as well as strategic and competitive considerations.

CohBar Licensed IP

MOTS-c Patent Coverage

We are the exclusive licensee from the Regents to intellectual property rights related to MOTS-c, including two issued U.S. patents corresponding foreign applications and granted foreign patents filed in multiple countries and regions. These issued patents and applications include composition of matter claims directed to MOTS-c and certain analogs of MOTS-c, as well as methods of use claims for MOTS-c or certain analogs of MOTS-c as a treatment for type 1 diabetes, T2D, fatty liver, obesity and cancer. Patents related to these filings have been granted in the United States, Europe, Japan and several other countries.

SHLP-2 and SHLP-6 Patent Coverage

We are the exclusive licensee from the Regents to intellectual property for SHLP-2 and SHLP-6 and their analogs. This intellectual property includes an issued U.S. patent and pending application with a term expiring in 2029.

Humanin and Humanin Analogs Patent Coverage

We are the exclusive licensee from the Regents and the Albert Einstein College of Medicine of Yeshiva University of two U.S. issued patents covering humanin and humanin analogs for treatment of disease which expire in 2028 and 2029.

Trade Secrets

In addition to patents, we rely upon unpatented trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our commercial partners, collaborators, employees and consultants and invention assignment agreements with our employees. 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. These agreements 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 commercial partners, collaborators, employees and consultants 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.

Trademarks

We consider COHBAR™ to be our common law trademark and are pursuing registration in the United States Patent & Trademark Office.

In-licenses

MOTS-c Exclusive License

On August 6, 2013, we entered into an exclusive license agreement with the Regents of the University of California (the "Regents") to obtain worldwide, exclusive rights under patent filings and other intellectual property rights in inventions developed by Dr. Cohen and academic collaborators at the University of California, Los Angeles. The intellectual property includes the U.S. and foreign patents and patent applications described above under "*MOTS-c Patent Coverage*".

We agreed to pay the Regents specified development milestone payments aggregating up to $765,000 for the first product sold under the license. Milestone payments for additional products developed and sold under the license are reduced by 50%. We are also required to pay annual maintenance fees to the licensors. Aggregate maintenance fees for the first three years following execution of the agreement were $7,500. Thereafter, we are required to pay maintenance fees of $5,000 annually until the first sale of a licensed product. In addition, we are required to pay the Regents royalties equal to 2% of our worldwide net sales of drugs, therapies or other products developed from claims covered by the licensed patent, subject to a minimum royalty payment of $75,000 annually, beginning after the first commercial sale of a licensed product. We are required to pay the Regents royalties ranging from 8% of worldwide sublicense sales of covered products (if the sublicense is entered after commencement of Phase II clinical trials) to 12% of worldwide sublicense sales (if the sublicense is entered prior to commencement of Phase I clinical trials). The agreement also requires us to meet certain diligence and development milestones, including filing of an Investigational New Drug (IND) Application for a product covered by the agreement on or before the seventh anniversary of the agreement date.

Under the agreement, the license rights granted to us are subject to any rights the U.S. Government may have in such licensed rights due to its sponsorship of research that led to the creation of the licensed rights. The agreement also provides that if the Regents become aware of a third-party's interest in exploiting the licensed technologies in a field that we are not actively pursuing, then we may be obligated either to issue a sublicense for use in the unexploited field to the third-party on substantially similar terms or to actively pursue the unexploited field subject to appropriate diligence milestones. The agreement terminates upon the expiration of the last valid claim of the licensed patent rights. We may terminate the agreement at any time by giving the Regents advance written notice. The agreement may also be terminated by the Regents in the event of our continuing material breach after notice of such breach and the opportunity to cure.

Humanin and SHLPs Exclusive License

On November 30, 2011, we entered into an exclusive license agreement with the Regents and the Albert Einstein College of Medicine at Yeshiva University to obtain worldwide, exclusive rights under patent filings and other intellectual property rights in inventions developed by Drs. Cohen and Barzilai and their academic collaborators. The intellectual property includes the U.S. patents and patent applications described above under "Humanin and Humanin Analogs Patent Coverage" and "SHLP-2 and SHLP-6 Patent Coverage".

We agreed to pay the licensors specified development milestone payments aggregating up to $765,000 for the first product sold under the license. Milestone payments for additional products developed and sold under the license are reduced by 50%. We are also required to pay annual maintenance fees to the licensors. Aggregate maintenance fees for the first five years following execution of the agreement were $80,000. Thereafter, we are required to pay maintenance fees of $50,000 annually until the first sale of a licensed product. In addition, we are required to pay the licensors royalties equal to 2% of our worldwide net sales of drugs, therapies or other products developed from claims covered by the licensed patents, subject to a minimum royalty payment of $75,000 annually, beginning after the first commercial sale of a licensed product. We are required to pay royalties ranging from 8% of worldwide sublicense sales of covered products (if the sublicense is entered after commencement of Phase II clinical trials) to 12% of worldwide sublicense sales (if the sublicense is entered prior to commencement of Phase I clinical trials). The agreement also requires us to meet certain diligence and development milestones, including filing of an IND for a product covered by the agreement on or before the seventh anniversary of the agreement date.

Under the agreement, the license rights granted to us are subject to any rights the U.S. Government may have in such licensed rights due to its sponsorship of research that led to the creation of the licensed rights. The agreement terminates upon the expiration of the last valid claim of the licensed patent rights. We may terminate the agreement at any time by giving the Regents advance written notice. The agreement may be modified or terminated on a product by product basis by the Regents if we materially fail to meet certain diligence requirements and development milestones. The agreement may also be terminated by the Regents in the event of our continuing material breach after notice of such breach and the opportunity to cure. In October 2020, the Regents accepted our payment for an additional year of license maintenance.

ENVIRONMENTAL AND OTHER REGULATORY MATTERS

Government Regulation

The preclinical studies and clinical testing, manufacture, labeling, storage, record keeping, advertising, promotion, export, marketing and sales, among other things, of our therapeutic candidates and future products, are subject to extensive regulation by governmental authorities in the United States and other countries. In the United States, pharmaceutical products are regulated by the Food and Drug Administration (the "FDA") under the Federal Food, Drug, and Cosmetic Act (the "FDCA") and other laws. Biologics are subject to regulation by the FDA under the FDCA, the Public Health Service Act, and related regulations, and other federal, state and local statutes and regulations. Biological products include, among other things, viruses, therapeutic serums, vaccines and most protein products. Product development and approval within these regulatory frameworks takes a number of years, and involves the expenditure of substantial resources.

Regulatory approval will be required in all major markets in which we, or our licensees, seek to test our products in development. At a minimum, such approval requires evaluation of data relating to quality, safety and efficacy of a product for its proposed use. The specific types of data required and the regulations relating to these data differ depending on the territory, the drug involved, the proposed indication and the stage of development.

In general, new chemical entities are tested in animal models to determine whether the product is reasonably safe for initial human testing. Additional preclinical testing continues during the clinical development stage. Clinical trials for new products are typically conducted in three sequential phases that may overlap. Phase 1 trials typically involve the initial introduction of the pharmaceutical into healthy human volunteers and focus on testing for safety, dosage tolerance, metabolism, distribution, excretion and clinical pharmacology. In the case of serious or life-threatening diseases, such as cancer, initial Phase 1 trials are often conducted in patients directly, with preliminary exploration of potential efficacy. Phase 2 trials involve clinical trials to evaluate the effectiveness of the drug for a particular disease indication or indications in patients with the disease or condition under study and to determine appropriate dosages and dose regimens and the common short-term side effects and risks associated with the drug. Phase 2 trials are typically closely monitored and conducted in a relatively small number of patients, usually involving no more than several hundred subjects. Phase 3 trials are generally expanded, well-controlled clinical trials. They are performed after preliminary evidence suggesting effectiveness, as well as the appropriate dose and dose ranges of the drug, have been obtained, and 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.

In the United States, specific research and preclinical data, chemical data and a proposed clinical study protocol, as described above, must be submitted to the FDA as part of an Investigational New Drug application, or IND, which, unless the FDA objects, will become effective 30 days following receipt by the FDA. Phase 1 trials may commence only after the IND application becomes effective. Following completion of Phase 1 trials, further submissions to regulatory authorities are necessary in relation to Phase 2 and 3 trials to update the existing IND. Authorities may require additional data before allowing the trials to commence and could demand discontinuation of studies at any time if there are significant safety issues. In addition to regulatory review, a clinical trial involving human subjects has to be approved by an independent body. The exact composition and responsibilities of this body differ from country to country. In the United States, for example, each clinical trial is conducted under the auspices of an Institutional Review Board for any institution at which the clinical trial is conducted. This board considers among other factors, the design of the clinical trial, ethical factors, the safety of the human subjects and the possible liability risk for the institution.

Information generated in this process is susceptible to varying interpretations that could delay, limit, or prevent regulatory approval at any stage of the approval process. Failure to demonstrate adequately the quality, safety and efficacy of a therapeutic drug under development would delay or prevent regulatory approval of the product.

In order to gain marketing approval, we must submit a new drug application, or NDA, for review by the FDA. The NDA must include a substantial amount of data and other information concerning safety and effectiveness of the drug compound from laboratory, animal and clinical testing, as well as data and information on manufacturing, product stability, and proposed product labeling.

There can be no assurance that if clinical trials are completed that we or any future collaborative partners will submit an NDA or similar applications outside of the United States for required authorizations to manufacture or market potential products, or that any such applications will be reviewed or approved in a timely manner. Approval of an NDA, if granted at all, can take several months to several years, and the approval process can be affected by a number of factors. Additional studies or clinical trials may be requested during the review and may delay marketing approval and involve unbudgeted costs. Regulatory authorities may conduct inspections of relevant facilities and review manufacturing procedures, operating systems and personnel qualifications. In addition to obtaining approval for each product, in many cases each drug manufacturing facility must be approved. Further, inspections may occur over the life of the product. An inspection of the clinical investigation sites by a competent authority may be required as part of the regulatory approval procedure. As a condition of marketing approval, the regulatory agency may require post-marketing surveillance to monitor adverse effects, or other additional studies as deemed appropriate. After approval for the initial disease indication, further clinical studies are usually necessary to gain approval for additional indications. The terms of any approval, including labeling content, may be more restrictive than expected and could affect product marketability.

Holders of an approved NDA are required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain requirements concerning advertising and promotional labeling for their products. Moreover, quality control and manufacturing procedures must continue to conform to current good manufacturing practices (“cGMP”) after approval, and the FDA periodically inspects manufacturing facilities to assess cGMP compliance. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. We expect to continue to rely upon third-party manufacturers to produce commercial supplies of any products which are approved for marketing. We cannot be sure that those manufacturers will remain in compliance with applicable regulations, or that future FDA inspections will not identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct.

Any of our future products approved by the FDA will likely be purchased principally by patients through a pharmacy benefit plan or by pharmacies that typically bill various third-party payers, such as governmental programs (e.g., Medicare and Medicaid), private insurance plans and managed care plans, for the pharmaceuticals provided to patients. The ability of customers to obtain appropriate reimbursement for the products they purchase is crucial to the success of new drug and biologic products. The availability of reimbursement affects which products customers purchase and the prices they are willing to pay. Reimbursement varies from country to country and can significantly impact the acceptance of new products. Even if we were to develop a promising new product, we may find limited demand for the product unless reimbursement approval is obtained from private and governmental third-party payers.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system and efforts to control health care costs, including drug prices, that could significantly affect the development of our business, including preventing, limiting or delaying regulatory approval of our drug candidates and reducing the sales and profits derived from our products once they are approved. For example, in the United States, the Patient Protection and Affordable Care Act of 2010 ("ACA") substantially changed the way health care is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. There is continued uncertainty about the implementation of ACA, including the potential for further amendments to the ACA and legal challenges to or efforts to repeal the ACA. We cannot be sure whether additional legislative changes will be enacted, or whether government regulations, guidance or interpretations will be changed, or what the impact of such changes would be on the marketing approvals, sales, pricing, or reimbursement of our drug candidates or products, if any, may be.

If the FDA approves any of our future products and reimbursement for those products is approved by any federal or state healthcare programs, then we will be subject to federal and state laws, such as the Federal False Claims Act, state false claims acts, the illegal remuneration provisions of the Social Security Act, and federal and state anti-kickback laws that govern financial and other arrangements among drug manufacturers and developers and the physicians and other practitioners or facilities that purchase or prescribe products. Among other things, these laws prohibit kickbacks, bribes and rebates, as well as other direct and indirect payments that are intended to induce the use or prescription of medical products or services payable by any federal or state healthcare program, and prohibit presenting a false or misleading claim for payment under a federal or state program. Possible sanctions for violation of any of these restrictions or prohibitions include loss of eligibility to participate in federal and state reimbursement programs and civil and criminal penalties. If we fail to comply, even inadvertently, with any of these requirements, we could be required to alter our operations, enter into corporate integrity, deferred prosecution or similar agreements with state or federal government agencies, and could become subject to significant civil and criminal penalties.

AVAILABLE INFORMATION

Our common stock is listed on the Nasdaq Capital Market and trades under the symbol "CWBR." Our principal executive offices are located at 1455 Adams Drive, Suite 2050, Menlo Park, California 94025, and our telephone number is (650) 446-7888. The internet address of our corporate website is http://www.cohbar.com.

We file annual reports, quarterly reports, current reports, proxy statements and other information with the Securities and Exchange Commission (the "SEC") under the Securities Exchange Act of 1934, as amended. Our filings with the SEC are available free of charge on the SEC's website at www.sec.gov and on our website under the "Investors" tab as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

The contents of our corporate website are not incorporated into, or otherwise to be regarded as part of, this Annual Report on Form 10-K.

Item 1A. Risk Factors

Summary of Risk Factors

An investment in our common stock involves various risks, and prospective investors are urged to carefully consider the matters discussed in the section titled "Risk Factors" prior to making an investment in our common stock. These risks include, but are not limited to, the following:

- We will need additional funding and may be unable to raise additional capital when needed, which would force us to delay, reduce or eliminate our research and development activities.
- The outbreak of the novel strain of coronavirus, SARS-CoV-2, which causes COVID-19, could adversely impact our business, including our clinical trials and preclinical studies.
- We have had a history of losses and no revenue.
- We are an early-stage biotechnology company and may never be able to successfully develop marketable products or generate any revenue. We have a very limited relevant operating history upon which an evaluation of our performance and prospects can be made. There is no assurance that our future operations will result in profits. If we cannot generate sufficient revenues, we may suspend or cease operations.
- If we fail to demonstrate efficacy or safety in our research and clinical trials, our future business prospects, financial condition and operating results will be materially adversely affected.
- If our current and any future clinical trials are delayed, suspended or terminated, we may be unable to develop our product candidates on a timely basis, which would adversely affect our ability to obtain regulatory approvals, increase our development costs and delay or prevent commercialization of any approved products.
- If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed and, as a result, our stock price may decline.
- Our future success depends on key members of our scientific team and our ability to attract, retain and motivate qualified personnel.
- We may seek to establish development and commercialization collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.
- We may not be successful in our efforts to identify or discover potential drug development candidates.
- Our research and development plans will require substantial additional future funding which could impact our operational and financial condition. Without the required additional funds, we will likely cease operations.

- Even if we are able to develop our potential drugs, we may not be able to obtain regulatory approval, or if approved, we may not be able to generate significant revenues or successfully commercialize our products, which will adversely affect our financial results and financial condition, and we will have to delay or terminate some or all of our research and development plans, which may force us to cease operations.

- If we do not maintain the support of qualified scientific collaborators, our revenue, growth and profitability will likely be limited, which would have a material adverse effect on our business.

- We expect to rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing. These third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or preclinical testing.

- We contract with third parties for the manufacture of our peptide materials for research and preclinical testing and expect to continue to do so for any future product candidate advanced to clinical trials and commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our research peptide materials, product candidates or medicines, or that such supply will not be available to us at an acceptable cost, which could delay, prevent or impair our research, development or commercialization efforts.

- We may not be able to develop drug candidates, market or generate sales of our products to the extent anticipated. Our business may fail, and investors could lose all of their investment in our Company.

- Interim and preliminary or topline data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

- We expect to expand our drug development and regulatory capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

- The use of any of our products in clinical trials may expose us to liability claims, which may cost us significant amounts of money to defend against or pay out, causing our business to suffer.

CohBar operates in an environment that involves a number of risks and uncertainties. The risks and uncertainties described in this Annual Report on Form 10-K are not the only risks and uncertainties that we face. Additional risks and uncertainties that presently are not considered material or are not known to us, and therefore are not mentioned herein, may impair our business operations. If any of the risks described in this Annual Report on Form 10-K actually occur, our business, operating results and financial position could be adversely affected.

Risks Related to Our Financial Position and Need for Additional Capital

We will need additional funding and may be unable to raise additional capital when needed, which would force us to delay, reduce or eliminate our research and development activities.

Our operations to date have consumed substantial amounts of cash, and we expect our capital and operating expenditures to continue to increase in the next few years. We may not be able to generate significant revenues for several years, if at all. Until we can generate significant revenues, if ever, we expect to satisfy our future cash needs through equity or debt financing, and/or through any future development collaborations with commercial partners. We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital and, in light of our current market capitalization, it may be more difficult to raise the amount of capital needed to support planned development of our product candidates. In addition, the ongoing COVID-19 pandemic has led to, and may continue to create, global economic disruption, uncertainty and volatility in the global financial markets. These effects may make it increasingly difficult to raise additional capital. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may be required to significantly delay, reduce the scope of, or eliminate one or more of our research and development activities. If we are unable to secure additional capital, a Phase 2 clinical trial of CB4211 will be delayed or discontinued. We could also be required to seek collaborators for our product candidate at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to such product candidates.

The outbreak of the novel strain of coronavirus, SARS-CoV-2, which causes COVID-19, could adversely impact our business, including our clinical trials and preclinical studies.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. In response to the global COVID-19 pandemic, we have modified our business practices by restricting nonessential travel, implementing a partial work from home policy for our employees and instituting new safety protocols for our lab to enable essential on-site work to continue. We continue to monitor the impact of COVID-19 on ongoing activities at our external research and development partner sites.

Timely enrollment in our clinical trials is dependent upon global clinical trial sites, which may be adversely affected by global health matters, such as pandemics. We are currently conducting a clinical trial for our lead product candidate in the United States, which is currently, and may continue to be, affected by COVID-19. For example, enrollment for our CB4211 Phase 1b study was delayed due to suspension of study activities at some of our clinical sites. Although enrollment resumed, we have experienced delays and withdrawals in enrollment due to COVID-19. These and any additional delays in our CB4211 Phase 1b study could increase our development costs, delay or prevent the availability of topline data expected to be available from the trial, delay our product development and regulatory submission process, result in the termination of the trial or make it difficult to raise additional capital.

As a result of the COVID-19 outbreak, or similar pandemics, we may experience disruptions that could severely impact our business, clinical trials and preclinical studies, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays or disruptions in non-clinical experiments and investigational new drug application-enabling good laboratory practice standard toxicology studies due to unforeseen circumstances in the supply chain;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19, being forced to quarantine or not accepting home health visits;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;

- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (particularly any procedures that may be deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;

- interruption or delays in the operations of the U.S. Food and Drug Administration ("FDA") and comparable foreign regulatory agencies, which may impact approval timelines;

- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people, an increased reliance on working from home or mass transit disruptions;

- disruptions in the supply chain and the manufacture or shipment of both drug substance and finished drug product for our product candidates for preclinical testing and clinical trials

- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems; and

- reduced ability to engage with the medical and investor communities due to the cancellation of conferences scheduled throughout the year.

In addition, the trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic and the resulting impact on economic activity. As a result, we may face difficulties raising capital through sales of our common stock or other equity-linked securities, and any such sales may be on unfavorable terms to us and potentially dilutive to existing stockholders.

The extent to which the pandemic may impact our business, clinical trials and preclinical studies will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, the impact of vaccinations, travel restrictions and actions to contain the virus or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

We have had a history of losses and no revenue.

We have generated substantial accumulated losses since our inception. We have not generated any revenues from our operations to date and do not expect to generate any revenue in the near future. As a result, our management expects the business to continue to experience negative cash flow for the foreseeable future. We can offer no assurance that we will ever operate profitably or that we will generate positive cash flow in the future.

Until we can generate significant revenues, if ever, we expect to satisfy our future cash needs through equity or debt financing. We will need to raise additional funds, and such funds may not be available on commercially acceptable terms, if at all. If we are unable to raise funds on acceptable terms, we may not be able to execute our business plan, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements. This may seriously harm our business, financial condition and results of operations. In the event we are not able to continue operations, investors will likely suffer a complete loss of their investments in our securities.

We are an early-stage biotechnology company and may never be able to successfully develop marketable products or generate any revenue. We have a very limited relevant operating history upon which an evaluation of our performance and prospects can be made. There is no assurance that our future operations will result in profits. If we cannot generate sufficient revenues, we may suspend or cease operations.

We are an early-stage company. Our operations to date have been limited to organizing and staffing our Company, business planning, raising capital, identifying MDPs for further research, developing our intellectual property portfolio, performing research on identified MDPs and advancing our lead MBT candidate into and through clinical studies. We have not generated any revenues to date. All of our MBTs are in the concept, research or early clinical stages. Moreover, we cannot be certain that our research and development efforts will be successful or, if successful, that our MBTs will ever be approved by the FDA. Typically, it takes 10-12 years to develop one new medicine from the time it is discovered to when it is available for treating patients, and longer timeframes are not uncommon. Even if approved, our products may not generate commercial revenues. We have no relevant operating history upon which an evaluation of our performance and prospects can be made. We are subject to all of the business risks associated with a new enterprise, including, but not limited to, risks of unforeseen capital requirements, failure of potential drug candidates either in research, preclinical testing or in clinical trials, and failure to establish business relationships and competitive advantages against other companies. If we fail to become profitable, we may be forced to suspend or cease operations.

If we fail to demonstrate efficacy or safety in our research and clinical trials, our future business prospects, financial condition and operating results will be materially adversely affected.

The success of our research and development efforts will greatly depend on our ability to demonstrate efficacy of MBTs in non-clinical studies, as well as in clinical trials. Non-clinical studies involve testing potential MBTs in appropriate non-human disease models to demonstrate efficacy and safety. Regulatory agencies evaluate these data carefully before they will approve clinical testing in humans. If certain non-clinical data reveals potential safety issues or the results are inconsistent with an expectation of the potential drug's efficacy in humans, the program may be discontinued or the regulatory agencies may require additional testing before allowing human clinical trials. This additional testing will increase program expenses and extend timelines. We may decide to suspend further testing on our potential drugs if, in the judgment of our management and advisors, the non-clinical test results do not support further development.

Moreover, success in research, preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and non-clinical testing. The clinical trial process may fail to demonstrate that our potential drug candidates are safe for humans and effective for indicated uses. This failure would cause us to abandon a drug candidate and may delay development of other potential drug candidates. Any delay in, or termination of, our non-clinical testing or clinical trials will delay the filing of an investigational new drug application and new drug application with the FDA or the equivalent applications with pharmaceutical regulatory authorities outside the United States and, ultimately, our ability to commercialize our potential drugs and generate product revenues. In addition, we expect that our early clinical trials will involve small patient populations. Because of the small sample size, the results of these early clinical trials may not be indicative of future results.

Risks Related to Discovery, Development and Commercialization

If our current and any future clinical trials are delayed, suspended or terminated, we may be unable to develop our product candidates on a timely basis, which would adversely affect our ability to obtain regulatory approvals, increase our development costs and delay or prevent commercialization of any approved products.

We cannot predict whether we will encounter problems with our ongoing, planned or any future clinical trials that will cause regulatory agencies, institutional review boards, or us to suspend or delay a trial. For example, in November 2018, the Company announced the temporary suspension of the Phase 1 clinical trial for CB4211, our lead MBT candidate, in order to address injection site reactions, and we resumed the trial in June 2019. In November 2019, we announced the completion of the Phase 1a portion of the clinical trial and the commencement of the recruiting phase of the final Phase 1b stage of the study. However, in March 2020, we announced a delay in the completion of our Phase 1b study for NASH and obesity. The delays were caused by a pause by some of our clinical research organization partners in all of their activities related to the study in response to developments relating to the COVID-19 pandemic. We announced the resumption of our Phase 1b study in July 2020. In response to a routine annual development safety update report (the "DSUR") we submitted to the FDA on August 6, 2020, the FDA requested additional details regarding injection site reaction safety data presented in the DSUR. The additional information was provided to the FDA. FDA's review of such information could result in the delay or suspension of our Phase 1b study to address any concerns. Clinical trials and clinical data collection protocols can be delayed for a variety of reasons, including:

- unanticipated consequences of the formulation of the product candidate requiring us to pause the trial to investigate alternative formulations;
- the occurrence of unacceptable drug-related side effects or adverse events experienced by participants in our clinical trials;
- discussions with the FDA regarding the scope or design of our clinical trials and clinical data collection protocols;
- delays or the inability to obtain required approvals from institutional review boards or other responsible entities at clinical sites selected for participation in our existing or future clinical trials;
- adverse findings in clinical or nonclinical studies related to the safety of our product candidates in humans;
- the amendment of clinical trial or data collection protocols to reflect changes in regulatory requirements and guidance or other reasons, as well as subsequent re-examination of amendments of clinical trial or data collection protocols by institutional review boards or other responsible bodies; and
- the need to repeat or conduct additional clinical trials as a result of inconclusive or negative results, failure to replicate positive early clinical data in subsequent clinical trials, failure to deliver an efficacious dose of a product candidate, poorly executed testing, a failure of a clinical site to adhere to the clinical protocol, an unacceptable study design or other problems.

In addition, a clinical trial or development program may be suspended or terminated by us, institutional review boards, the FDA or other responsible bodies due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;

- inability to resume a suspended trial in a timely manner (which we cannot predict with certainty), if at all;
- unforeseen safety issues or any determination that a trial presents unacceptable health risks;
- inability to deliver an efficacious dose of a product candidate; and
- lack of adequate funding to continue the clinical trial.

If the results of our clinical trials are not available when we expect or if we encounter any delay in the analysis of data from our clinical trials, we may be unable to conduct additional clinical trials on the schedule we anticipate. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any delays in completing a clinical trial could increase our development costs, delay or prevent the availability of topline data expected to be available from the trial, delay our product development and regulatory submission process or make it difficult to raise additional capital.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed and, as a result, our stock price may decline.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions, including positive clinical and preclinical results, the addition of a corporate partner for the CB4211 program, and sufficient funding from partnering and general fundraising. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, our revenue may be lower than expected, the commercialization of our products may be delayed or never achieved and, as a result, our stock price may decline.

Our future success depends on key members of our management and scientific teams and our ability to attract, retain and motivate qualified personnel.

Recruiting and retaining qualified senior management and scientific, clinical, and operations management and personnel will be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

We are highly dependent on our key management and scientific teams, including our Chief Executive Officer, Chief Financial Officer and Chief Scientific Officer who are all employed "at will," meaning they may terminate the employment relationship at any time. We do not maintain "key person" insurance for any of the key members of our team. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Our consultants and advisors, including our founders, may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Our founders, Dr. Pinchas Cohen and Dr. Nir Barzilai, are members of our board of directors and provide oversight and guidance on scientific, research and development topics in that capacity. In addition, we rely on other consultants and advisors from time to time, including drug discovery and development advisors, to assist us in formulating our research and development strategy. Agreements with these advisors typically may be terminated by either party, for any reason, on relatively short notice.

We may seek to establish development and commercialization collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our potential drug development programs and the potential commercialization of our drug candidates will require substantial additional cash to fund expenses. We may decide to collaborate with pharmaceutical or biotechnology companies in connection with the development or commercialization of our potential drug candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive collaboration agreement will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar disease indications on which to collaborate, and whether such alternative collaboration project could be more attractive than one with us for our product candidate.

There are a limited number of large pharmaceutical companies with whom we could potentially collaborate, and collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on a timely basis, on acceptable terms or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

We may not be successful in our efforts to identify or discover potential drug development candidates.

A key element of our strategy is to identify and test MDPs that play a role in cellular processes underlying our targeted disease indications. A significant portion of the research that we are conducting involves emerging scientific knowledge and drug discovery methods. Our drug discovery efforts may not be successful in identifying MBTs that are useful in treating disease. Our research programs may initially show promise in identifying potential drug development candidates, yet fail to yield candidates for preclinical and clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying appropriate potential drug development candidates; or
- potential drug development candidates may, on further study, be shown not to be effective in humans, or to have unacceptable toxicities, harmful side effects or other characteristics that indicate that they are unlikely to be medicines that will receive marketing approval and achieve market acceptance.

Research programs to identify new product candidates require substantial technical, financial and human resources. We may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other disease indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to timely capitalize on viable commercial products or profitable market opportunities. If we are unable to advance our lead MBT candidate through clinical development or identify other MBTs that are suitable for preclinical and clinical development, we will not be able to obtain product revenues in future periods, which likely would result in significant harm to our financial position and negatively affect our ability to continue our operations.

Our research and development plans will require substantial additional future funding which could impact our operational and financial condition. Without the required additional funds, we will likely cease operations.

It will take several years before we are able to develop potentially marketable products, if at all. Our research and development plans will require substantial additional capital to:

- conduct research, preclinical testing and human studies;
- manufacture any future drug development candidate or product at pilot and commercial scale; and
- establish and develop quality control, regulatory, and administrative capabilities to support these programs.

Our future operating and capital needs will depend on many factors, including:

- the pace of scientific progress in our research programs and the magnitude of these programs;
- the scope and results of preclinical testing and human studies;
- the time and costs involved in obtaining regulatory approvals;
- the time and costs involved in preparing, filing, prosecuting, securing, maintaining and enforcing intellectual property rights;
- competing technological and market developments;
- our ability to establish additional collaborations;
- changes in any future collaborations;
- the cost of manufacturing our drug products; and
- the effectiveness of efforts to commercialize and market our products.

We base our outlook regarding the need for funds on many uncertain variables. Such uncertainties include the success of our research and development initiatives, regulatory approvals, the timing of events outside our direct control such as negotiations with potential strategic partners, and other factors. Any of these uncertain events can significantly change our cash requirements as they determine such one-time events as the receipt or payment of major milestones and other payments.

Additional funds will be required to support our operations, and if we are unable to obtain them on favorable terms, we may be required to cease or reduce further research and development of our drug product programs, sell or abandon some or all of our intellectual property, merge with another entity or cease operations.

Even if we are able to develop our potential drugs, we may not be able to obtain regulatory approval, or if approved, we may not be able to generate significant revenues or successfully commercialize our products, which will adversely affect our financial results and financial condition, and we will have to delay or terminate some or all of our research and development plans, which may force us to cease operations.

All our potential drug candidates will require extensive additional research and development, including preclinical testing and clinical trials, as well as regulatory approvals, before we can market them. We cannot predict if or when any potential drug candidate we intend to develop will be approved for marketing. There are many reasons that we may fail in our efforts to develop our potential drug candidates. These include:

- the possibility that preclinical testing or clinical trials may show that our potential drugs are ineffective and/or cause harmful side effects or toxicities;
- our potential drugs may prove to be too expensive to manufacture or administer to patients;
- our potential drugs may fail to receive necessary regulatory approvals from the FDA or foreign regulatory authorities in a timely manner, or at all;
- even if our potential drugs are approved, we may not be able to produce them in commercial quantities or at reasonable costs;
- even if our potential drugs are approved, they may not achieve commercial acceptance;
- regulatory or governmental authorities may apply restrictions to any of our potential drugs, which could adversely affect their commercial success; and
- the proprietary rights of other parties may prevent us or our potential collaborative partners from marketing our potential drugs.

If we fail to develop our potential drug candidates, our financial results and financial condition will be adversely affected, we will have to delay or terminate some or all of our research and development plans and may be forced to cease operations.

Risks Related to Our Reliance on Third Parties

If we do not maintain the support of qualified scientific collaborators, our revenue, growth and profitability will likely be limited, which would have a material adverse effect on our business.

We will need to maintain our existing relationships with leading scientists and/or establish new relationships with scientific collaborators. We believe that such relationships are pivotal to establishing products using our technologies as a standard of care for various disease indications. There is no assurance that our founders, scientific advisors or research partners will continue to work with us or that we will be able to attract additional research partners. If we are not able to establish scientific relationships to assist in our research and development, we may not be able to successfully develop our potential drug candidates. If this happens, our business will be adversely affected.

We expect to rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing. These third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or preclinical testing.

We currently rely on third parties to conduct some aspects of our research and expect to continue to rely on third parties to conduct additional aspects of our research and preclinical testing, as well as any future clinical trials. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our product research and development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our drug candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines.

We currently rely, and expect to continue to rely, on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our drug candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

We contract with third parties for the manufacture of our peptide materials for research and preclinical testing and expect to continue to do so for any future product candidate advanced to clinical trials and commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our research peptide materials, product candidates or medicines, or that such supply will not be available to us at an acceptable cost, which could delay, prevent or impair our research, development or commercialization efforts.

We do not have manufacturing facilities adequate to produce our research peptide materials or supplies of any future product candidate. We currently rely, and expect to continue to rely, on third-party manufacturers for the manufacture of our peptide materials, our current and any future product candidates for preclinical and clinical testing, and for commercial supply of any of these product candidates for which we or future collaborators obtain marketing approval. We do not have long term supply agreements with any third-party manufacturers, and we purchase our research peptides on a purchase order basis.

We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for producing the peptide materials or product candidates according to the detailed specifications;
- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- reliance on the third party for regulatory compliance, quality assurance, and safety and pharmacovigilance reporting.

Third-party manufacturers may not be able to comply with current good manufacturing practices, regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in us being subject to sanctions, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or medicines, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our medicines and harm our business and results of operations.

Any drug candidate that we may develop may compete with other drug candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Our current and anticipated future dependence upon others for the manufacture of our investigational materials or future product candidates or medicines may adversely affect our future profit margins and our ability to commercialize any medicines that receive marketing approval on a timely and competitive basis.

Risks Related to Product Development and Regulatory Approval

We may not be able to develop drug candidates, market or generate sales of our products to the extent anticipated. Our business may fail, and investors could lose all of their investment in our Company.

Assuming that we are successful in developing our potential drug candidates and receiving regulatory clearances to market our potential products, our ability to successfully penetrate the market and generate sales of those products may be limited by a number of factors, including the following:

- if our competitors receive regulatory approvals for and begin marketing similar products in the United States, the European Union ("EU"), Japan and other territories before we do, greater awareness of their products as compared to ours will cause our competitive position to suffer;

- information from our competitors or the academic community indicating that current products or new products are more effective or offer compelling other benefits than our future products could impede our market penetration or decrease our future market share; and

- the pricing and reimbursement environment for our future products, as well as pricing and reimbursement decisions by our competitors and by payers, may have an effect on our revenues.

If any of these occur, our business could be adversely affected.

Interim and preliminary or topline data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim topline or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary or topline data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between interim or preliminary or topline data and final data could significantly harm our reputation and business prospects.

Any product candidate we are able to develop and commercialize would compete in the marketplace with existing therapies and new therapies that may become available in the future. These competitive therapies may be more effective, less costly, more easily administered or offer other advantages over any product we seek to market.

Although there are no currently approved therapies for the treatment of NAFLD and NASH, there are numerous therapies in development, including those in clinical trials that are more advanced than ours. Additionally, there are numerous therapies currently marketed to treat diabetes, cancer, Alzheimer's disease and other diseases for which our potential product candidates may be indicated. For example, if we develop an approved treatment for T2D, it would compete with several classes of drugs for T2D that are approved to improve glucose control. These include the insulin sensitizers pioglitazone (Actos) and rosiglitazone (Avandia), which are administered as oral once daily pills, and metformin, which is sometimes called an insulin sensitizer and is available as a generic once daily formulation. If we develop an approved treatment for Alzheimer's disease, it would compete with approved therapies such as donepezil (Aricept), galantamine (Razadyne), memantine (Namenda), rivastigmine (Exelon) and tacrine (Cognex). These therapies are varied in their design, therapeutic application and mechanism of action and may provide significant competition for any of our product candidates for which we obtain market approval. New products may also become available that provide efficacy, safety, convenience and other benefits that are not provided by currently marketed therapies. As a result, they may provide significant competition for any of our product candidates for which we obtain market approval. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more conveniently administered or stored or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers' or other third-party payers' reimbursement polices seeking to encourage the use of existing products which are generic or are otherwise less expensive to provide.

We expect to expand our drug development and regulatory capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the scope of our operations, particularly in the areas of drug development and commercialization and regulatory affairs. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. We expect that if our drug candidates continue to progress into and in development, we may require significant additional investment in personnel, management systems and resources, particularly in the build out of our clinical and commercial capabilities. Over the next several years, we may experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and sales and marketing. Due to our limited financial resources and our limited operating history, we may not be able to effectively manage the expected expansion of our operations. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

The use of any of our products in clinical trials may expose us to liability claims, which may cost us significant amounts of money to defend against or pay out, causing our business to suffer.

The nature of our business exposes us to potential liability risks inherent in the testing, manufacturing and marketing of our products. Our leading product candidate, CB4211, is currently in clinical trials, and if any of our drug candidates enter into clinical trials, or if any of our drug candidates become marketed products, they could potentially harm people or allegedly harm people, possibly subjecting us to costly and damaging product liability claims. Some of the patients who participate in clinical trials are already ill when they enter a trial or may intentionally or unintentionally fail to meet the exclusion criteria. The waivers we obtain may not be enforceable and may not protect us from liability or the costs of product liability litigation. Although we obtained product liability insurance, which we believe is adequate, we are subject to the risk that our insurance will not be sufficient to cover claims. We anticipate that we will need to increase our insurance coverage if we successfully commercialize any product candidate. The insurance costs along with the defense or payment of liabilities above the amount of coverage could cost us significant amounts of money and management distraction from other elements of the business, decrease demand for any product candidates that we may develop, injure our reputation and attract significant negative media attention, and lead to the withdrawal of clinical trial participants, causing our business to suffer. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Compliance with laws and regulations pertaining to the privacy and security of health information may be time consuming, difficult and costly, particularly in light of increased focus on privacy issues in countries around the world, including the United States and the EU.

We are subject to various domestic and international privacy and security regulations. The confidentiality, collection, use and disclosure of personal data, including clinical trial patient-specific information, are subject to governmental regulation generally in the country that the personal data were collected or used. In the United States, we are subject, or expect to be subject, to various state and federal privacy and data security regulations, including but not limited to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009. HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common health care transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In the EU, personal data includes any information that relates to an identified or identifiable natural person with health information carrying additional obligations, including obtaining the explicit consent from the individual for collection, use or disclosure of the information. In addition, the protection of and cross-border transfers of such data out of the EU has become more stringent with the EU's General Data Protection Regulation which came into effect in May 2018. Furthermore, the legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues. The United States and the EU and its member states continue to issue new privacy and data protection rules and regulations that relate to personal data and health information. Compliance with these laws may be time consuming, difficult and costly. If we fail to comply with applicable laws, regulations or duties relating to the use, privacy or security of personal data, we could be subject to the imposition of significant civil and criminal penalties, be forced to alter our business practices and suffer reputational harm.

Any product candidate for which we obtain marketing approval will be subject to extensive post-marketing regulatory requirements and could be subject to post-marketing restrictions or 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 product candidates, when and if any of them are approved.

Our product candidates and the activities associated with their development and potential commercialization, including their testing, manufacturing, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other U.S. and international regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, including current cGMPs, quality control, quality assurance and corresponding maintenance of records and documents, including periodic inspections by the FDA and other regulatory authorities and requirements regarding the distribution of samples to providers and recordkeeping.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of any approved product. The FDA closely regulates the post-approval marketing and promotion of drugs and biologics to ensure drugs and biologics are marketed only for the approved disease indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products. If we promote our product candidates in a manner inconsistent with FDA-approved labeling or otherwise not in compliance with FDA regulations, we may be subject to enforcement action. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws and similar laws in international jurisdictions.

In addition, later discovery of previously unknown adverse events or other problems with our product candidates, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such product candidates, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of any approved product from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of product candidates;
- restrictions on product distribution or use;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our product candidates;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance with European requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the EU's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

The patent positions of biopharmaceutical products are complex and uncertain, and we may not be able to protect our patented or other intellectual property. If we cannot protect this property, we may be prevented from using it, or our competitors may use it, and our business could suffer significant harm. Also, the time and money we spend on acquiring and enforcing patents and other intellectual property will reduce the time and money we have available for our research and development, possibly resulting in a slow down or cessation of our research and development.

We own or exclusively license patents and patent applications related to our MDPs and potential MBTs and we anticipate continuing to develop our intellectual property portfolio. However, neither patents nor patent applications ensure the protection of our intellectual property for a number of reasons, including the following:

- The United States Supreme Court rendered a decision in Molecular Pathology vs. Myriad Genetics, Inc., 133 S.Ct. 2107 (2013) ("Myriad"), in which the court held that naturally occurring DNA segments are products of nature and not patentable as compositions of matter. On March 4, 2014, the U.S. Patent and Trademark Office ("USPTO") issued guidelines for examination of such claims that, among other things, extended the Myriad decision to any natural product. Since MDPs are natural products isolated from cells, the USPTO guidelines may affect allowability of some of our patent claims (pertaining to natural MDP sequences) that are filed in the USPTO but are not yet issued. Further, while the USPTO guidelines are not binding on the courts, it is likely that as the law of subject matter eligibility continues to develop, Myriad will be extended to natural products other than DNA. Thus, our issued U.S. patent claims directed to MDPs as compositions of matter may be vulnerable to challenge by competitors who seek to have our claims rendered invalid. While Myriad and the USPTO guidelines described above will affect our patents only in the United States, there is no certainty that similar laws or regulations will not be adopted in other jurisdictions.

- Competitors may interfere with our patenting process in a variety of ways. Competitors may claim that they invented the claimed invention prior to us. Competitors may also claim that we are infringing their patents and restrict our freedom to operate. Competitors may also contest our patents and patent applications, if issued, by showing in various patent offices that, among other reasons, the patented subject matter was not original, was not novel or was obvious. In litigation, a competitor could claim that our patents and patent applications are not valid or enforceable for a number of reasons. If a court agrees, we would lose some or all of our patent protection.

- As a company, we have no meaningful experience with competitors interfering with our patents or patent applications. In order to enforce our intellectual property, we may need to file a lawsuit against a competitor. Enforcing our intellectual property in a lawsuit can take significant time and money. We may not have the resources to enforce our intellectual property if a third party infringes an issued patent claim. Infringement lawsuits may require significant time and money resources. If we do not have such resources, the licensor is not obligated to help us enforce our patent rights. If the licensor does take action by filing a lawsuit claiming infringement, we will not be able to participate in the suit and therefore will not have control over the proceedings or the outcome of the suit.

- Because of the time, money and effort involved in obtaining and enforcing patents, our management may spend less time and resources on developing potential drug candidates than they otherwise would, which could increase our operating expenses and delay product programs.

- Our licensed patent applications directed to the composition and methods of using MOTS-c, an MDP, and SHLP-6, which we consider as a research peptide for the potential treatment of cancer, have not yet been issued. There can be no assurance that these or our other licensed patent applications will result in the issuance of patents, and we cannot predict the breadth of claims that may be allowed in our currently pending patent applications or in patent applications we may file or license from others in the future.

- Issuance of a patent may not provide much practical protection. If we receive a patent of narrow scope, then it may be easy for competitors to design products that do not infringe our patent(s).

- We have limited ability to expand coverage of our licensed patent related to SHLP-2 and our licensed patent application related to SHLP-6 outside of the United States. The lack of patent protection in international jurisdictions may inhibit our ability to advance MBT drug candidates in these markets.

- If a court decides that the method of manufacture or use of any of our drug candidates infringes on a third-party patent, we may have to pay substantial damages for infringement.

- A court may prohibit us from making, selling or licensing a potential drug candidate unless the patent holder grants a license. A patent holder is not required to grant a license. If a license is available, we may have to pay substantial royalties or grant cross licenses to our patents, and the license terms may be unacceptable.

- Redesigning our potential drug candidates so that they do not infringe on other patents may not be possible or could require substantial funds and time.

It is also unclear whether our trade secrets are adequately protected. While we use reasonable efforts to protect our trade secrets, our employees or consultants may unintentionally or willfully disclose our information to competitors. Enforcing a claim that someone illegally obtained and is using our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Our competitors may independently develop equivalent knowledge, methods and know-how. We may also support and collaborate in research conducted by government organizations, hospitals, universities or other educational institutions. These research partners may be unable or unwilling to grant us exclusive rights to technology or products derived from these collaborations prior to entering into the relationship.

If we do not obtain required intellectual property rights, we could encounter delays in our drug development efforts while we attempt to design around other patents or even be prohibited from developing, manufacturing or selling potential drug candidates requiring these rights or licenses. There is also a risk that disputes may arise as to the rights to technology or potential drug candidates developed in collaboration with other parties.

General Risk Factors

If we fail to establish and maintain proper and effective internal control over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our common stock.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures and that we furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment needs 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 that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. However, for as long as we are not an accelerated filer or large accelerated filer, we intend to take advantage of the exemption permitting us not to comply with the independent registered public accounting firm attestation requirement.

Our compliance with Section 404 will require us to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our consolidated financial statements. In addition, if we are not able to continue to meet these requirements, we may not be able to remain listed on The Nasdaq Capital Market ("Nasdaq").

As we continue to grow, we expect to hire additional personnel and may utilize external temporary resources to implement, document and modify policies and procedures to maintain effective internal controls. However, it is possible that we may identify deficiencies and weaknesses in our internal controls. If material weaknesses or deficiencies in our internal controls exist and go undetected or unremediated, our consolidated financial statements could contain material misstatements that, when discovered in the future, could cause us to fail to meet our future reporting obligations and cause the price of our common stock to decline.

Significant disruptions of information technology systems or security breaches could adversely affect our business.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, among other things, trade secrets or other 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 also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party vendors who may or could have access to our confidential information. Attacks on information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and they are being conducted by increasingly sophisticated and organized groups and individuals with a wide range of motives and expertise. The size and complexity of our information technology systems, and those of third-party vendors with whom we contract, and the large amounts of confidential information stored on those systems, make such systems vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third-party vendors, and/or business partners, or from cyber-attacks by malicious third parties. Cyber-attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information.

Significant disruptions of our information technology systems, or those of our third-party vendors, or security breaches could adversely affect our business operations and/or result in the loss, misappropriation and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information, including, among other things, trade secrets or other intellectual property, proprietary business information and personal information, and could result in financial, legal, business and reputational harm to us.

Any failure or perceived failure by us or any third-party collaborators, service providers, contractors or consultants to comply with our privacy, confidentiality, data security or similar obligations to third parties, or any data security incidents or other security breaches that result in the unauthorized access, release or transfer of sensitive information, including personally identifiable information, may result in governmental investigations, enforcement actions, regulatory fines, litigation or public statements against us, could cause third parties to lose trust in us or could result in claims by third parties asserting that we have breached our privacy, confidentiality, data security or similar obligations, any of which could have a material adverse effect on our reputation, business, financial condition or results of operations. Moreover, data security incidents and other security breaches can be difficult to detect, and any delay in identifying them may lead to increased harm. While we have implemented data security measures intended to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or data security incidents.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. If any of the analysts who may cover us change their recommendation regarding our stock adversely, or provide more favorable relative recommendations about our competitors, our stock price would likely decline. If any analysts who may cover us were to cease coverage of our Company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

The market for our common stock has been characterized by significant price volatility when compared to more established issuers, and we expect that it will continue to be so for the foreseeable future. The market price of our common stock is likely to be volatile for a number of reasons. First, our common stock is likely to be sporadically and/or thinly traded. As a consequence of this lack of liquidity, the trading of relatively small quantities of common stock by our stockholders may disproportionately influence the price of the common stock in either direction. The price of the common stock could, for example, decline precipitously if even a relatively small number of shares are sold on the market without commensurate demand, as compared to a market for shares of an established issuer which could better absorb those sales without adverse impact on its share price. Second, we are a speculative investment due to our lack of profits to date and substantial uncertainty regarding our ability to develop and commercialize a drug product from our new or existing technologies. As a consequence of this enhanced risk, more risk-adverse investors may, under the fear of losing all or most of their investment in the event of negative news or lack of progress, be more inclined to sell their shares on the market more quickly and at greater discounts than would be the case with the shares of an established issuer. We cannot make any predictions or projections as to what the prevailing market price for our common stock will be at any time or as to what effect the sale of common stock or the availability of common stock for sale at any time will have on the prevailing market price.

Our management owns, and could acquire, a significant percentage of our outstanding common stock. If the ownership of our common stock continues to be highly concentrated in management, it may prevent other stockholders from influencing significant corporate decisions.

As of December 31, 2020, our executive officers and directors own, as a group, approximately 22% of the outstanding shares of our common stock. Additionally, our executive officers and directors own, as a group, options and warrants exercisable for approximately 10% of our outstanding common stock, assuming exercise of such options and warrants. As a result, our management could exert significant influence over matters requiring stockholder approval, including the election of our board of directors, the approval of mergers and other extraordinary transactions, as well as the terms of any of these transactions. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which could in turn have an adverse effect on the fair market value of our Company and our common stock. These actions may be taken even if they are opposed by our other stockholders.

The requirements of being a public company may strain our resources, divert management's attention and require us to disclose information that is helpful to competitors, make us more attractive to potential litigants and make it more difficult to attract and retain qualified personnel.

As a public company, we are subject to the reporting requirements of the Securities Act of 1933, as amended, the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, and applicable Canadian securities rules and regulations. Despite recent reforms made possible by the JOBS Act, compliance with these rules and regulations creates significant legal and financial compliance costs and makes some activities difficult, time-consuming or costly. The Exchange Act and applicable Canadian provincial securities legislation require, among other things, that we file annual, quarterly and current reports with respect to our business and operating results.

Additionally, the Sarbanes-Oxley Act and the related rules and regulations of the SEC and the Nasdaq Capital Market require us to implement particular corporate governance practices and adhere to a variety of reporting requirements and complex accounting rules. Among other things, we are subject to rules regarding the independence of the members of our board of directors and committees of the board and their experience in finance and accounting matters, and certain of our executive officers are required to provide certifications in connection with our quarterly and annual reports filed with the SEC. The perceived personal risk associated with these rules may deter qualified individuals from accepting these positions. Accordingly, we may be unable to attract and retain qualified officers and directors. If we are unable to attract and retain qualified officers and directors, our business and our ability to maintain the listing of our shares of common stock on the Nasdaq or another stock exchange could be adversely affected.

Changes in U.S. federal income and other tax laws could adversely affect us.

New U.S. legislation or regulations which could affect our tax burden could be enacted by the U.S. government. We cannot predict the timing or extent of such tax-related developments which could have a negative impact on our financial results. Additionally, we use our best judgment in attempting to quantify and reserve for these tax obligations. However, a challenge by a taxing authority, our ability to utilize tax benefits such as carryforwards or tax credits, or a deviation from other tax-related assumptions could have a material adverse effect on our business, results of operations, or financial condition.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as a global financial crisis, could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruptions. Any of the foregoing could harm our business, and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

We or the third parties upon whom we depend may be adversely affected by natural disasters, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.

Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We are a party to a lease agreement for laboratory space leased on a month-to month basis that is part of a shared facility in Menlo Park, California. In September 2020, we renewed our lease for office space in Fairfield, New Jersey for an additional year at the same annual cost of $13,080 per annum.

Rent expense amounted to $403,449 and $350,979 for the years ended December 31, 2020 and 2019, respectively.

Item 3. Legal Proceedings

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business. We are not currently a party to any material legal proceedings, and to our knowledge none is threatened. There can be no assurance that future legal proceedings arising in the ordinary course of business or otherwise will not have a material adverse effect on our financial position, results of operations or cash flows.

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 for our Common Stock

Our common stock has been trading on the Nasdaq Capital Market under the symbol "CWBR" since December 15, 2017.

Holders of Common Stock

As of March 25, 2021, there were 61,788,325, shares of our common stock outstanding held by approximately 44 holders of record and approximately 8,319 beneficial shareholders.

Dividends

We have not declared or paid a cash dividend on our capital stock and do not intend to pay cash dividends for the foreseeable future. All dividends are subject to the approval of our board of directors. Any future determinations to pay dividends on our capital stock would depend on our results of operations, our financial condition and liquidity requirements, restrictions that may be imposed by applicable laws or our contracts, and any other factors that our board of directors in its sole discretion may consider relevant in declaring a dividend.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Securities Authorized for Issuance under Equity Compensation Plans

See Item 12 for Equity Compensation Plan Information.

Recent Sales of Unregistered Securities

During the year ended December 31, 2020, we completed a private offering (the "Private Offering") with certain promissory note holders converting outstanding amounts due under our 8% Unsecured Promissory Notes (the "Notes") due in 2021 and 2022. We converted Notes totaling an aggregate of $3,847,018 in principal and interest and issued 3,154,115 units at a price of $1.22 per unit. Each unit consists of one share of the Company's common stock and one warrant to purchase 0.75 of one share of the Company's common stock at an exercise price of $1.44 per share. Each warrant can be exercised at any time on or after June 18, 2021 and on or prior to June 18, 2026.

Item 6. Selected Financial Data

Not applicable.

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

We are a clinical stage biotechnology company and a leader in the research and development of mitochondria based therapeutics (MBTs), an emerging class of drugs with the potential to treat a wide range of chronic and age-related diseases, including non-alcoholic steatohepatitis (NASH), obesity, fibrotic diseases including IPF, acute respiratory distress syndrome (ARDS) including COVID-19 associated ARDS, cancer, type 2 diabetes mellitus (T2D), and cardiovascular and neurodegenerative diseases. Our portfolio of programs has substantially expanded from two to five programs in the last year. This expanded pipeline greatly strengthens our belief that there are multiple therapeutic peptides that can be realized from the mitochondrial genome.

MBTs originate from almost two decades of research by our founders, resulting in their discovery of a novel group of mitochondrial-derived peptides (MDPs) encoded within the mitochondrial genome. Some of these naturally occurring MDPs and their analogs have demonstrated a range of biological activity and therapeutic potential in research models across multiple chronic and age-related diseases.

We are focused on building our organization, enhancing our scientific and management teams and their capabilities, planning and strategy, raising capital and the research and development of our MDPs. Our research efforts have focused on discovering and evaluating our MDPs for potential development as MBT drug candidates.

Our efforts have resulted in the identification of more than 100 previously unidentified peptides encoded within the mitochondrial genome and generated over 1,000 analogs. Many of these MDPs and their analogs have demonstrated various degrees of biological activity in cell based and/or animal models relevant to a wide range of diseases, such as NASH, obesity, fibrotic diseases, ARDS, cancer, and other diseases.

Clinical Program: Our first clinical candidate, CB4211, is a potential treatment for NASH and obesity. It is a novel peptide initially developed from a MOTS-c MDP. In July 2018, we initiated a Phase 1a/1b clinical study of CB4211. In November 2019, the double-blind, placebo-controlled Phase 1a stage was completed and the blinded safety and tolerability data supported advancement to the Phase 1b stage of the study. The study was designed to initially assess the safety, tolerability and pharmacokinetics of CB4211 following single and multiple-ascending doses in healthy subjects. In November 2019, we initiated recruitment for the Phase 1b stage which is designed to assess the safety, tolerability and activity of CB4211 in obese subjects with non-alcoholic fatty liver disease (NAFLD). Assessments will include changes in liver fat assessed by MRI-PDFF, body weight and biomarkers relevant to NASH and obesity. On March 30, 2020, we announced a delay in the completion of our Phase 1b study due to the COVID-19 pandemic. The delay was a result of a pause by some of our clinical research organization partners in all of their activities related to the study in response to COVID-19. On July 7, 2020, we announced the resumption of our Phase 1b study. In March 2021, we completed the enrollment for the Phase 1b clinical trial. While topline data is expected at the end of the second quarter of 2021, it is dependent upon a number of factors such as the last patient visit, and therefore, we cannot predict with certainty when such data will be available. Based on positive clinical results and additional funding from potential partnerships and general fundraising, we plan to initiate preparations for a Phase 2 study of CB4211 in 2021 and initiate a Phase 2 study in 2022.

Preclinical Programs: Our preclinical pipeline has substantially expanded from two to four programs in the last year, including one for IPF and other fibrotic diseases, one for COVID-19 associated acute respiratory distress syndrome and two for cancer. Our research efforts have further identified and focused on certain MDPs and their analogs that have demonstrated therapeutic potential for treating indications related to those diseases in preclinical models.

- ***CB5138 Analogs for IPF and other Fibrotic Diseases:*** Our discovery efforts have identified CB5138 Analogs, a family of novel peptides with potential for use as treatments for fibrotic diseases. In co-cultures of human lung cells, CB5138-1 decreased the expression of key fibrosis biomarkers, including alpha smooth muscle actin (αSMA), and collagen types I and III. CB5138-1 also decreased the transformation of healthy lung cells into fibrotic cells after induction by TGF-beta1, resulting in reduced production of the fibrotic components αSMA and pro-collagen I alpha 1. In vivo, CB5138-1 decreased lung fibrosis and inflammation in both the prophylactic mouse model of IPF, initiating treatment with the peptide immediately after fibrosis induction by bleomycin, and in the therapeutic mouse model of IPF, starting peptide treatment one week after induction. In addition, using the more exacting therapeutic model of IPF, two new analogs of CB5138 (CB5138-2 and CB5138-3) significantly reduced lung fibrosis assessed by the Ashcroft Score, reduced inflammation, and decreased fibrosis-related changes in lung weight, collagen deposition in lung tissue, and collagen secretion into lung fluid. In addition, we have demonstrated that a CB5138 Analog has enhanced effects when combined with nintedanib, the leading treatment for IPF, suggesting potential utility for combination therapy in IPF. In the first quarter of 2021, we identified CB5138-3 as the lead clinical candidate in this program and our goal is to initiate IND-enabling activities with the potential to file an IND in 2022.

- ***CB5064 Analogs for ARDS, including COVID-19 Associated ARDS:*** Our internal discovery efforts have identified CB5064 Analogs, a family of peptides that are agonists of the apelin receptor with potential for use as therapeutics for COVID-19 associated ARDS and ARDS in general. In May 2020, we initiated testing of CB5064 Analogs in preclinical models of ARDS. In the preclinical studies, acute lung injury was induced in mice by administration of lipopolysaccharide (LPS), a bacterial toxin that produces similar symptoms to other causes of ARDS, including fluid accumulation and cytokine secretion. A single dose of CB5064 Analog was administered one hour prior to the LPS exposure and effects on lung weight and levels of pro-inflammatory cytokines were measured at 4 hours after LPS exposure. Treatment with CB5064 Analogs reduced fluid accumulation in the lungs and a corresponding broad reduction in levels of key pro-inflammatory cytokines secreted into the lung fluid, when compared to treatment with a placebo control. We previously demonstrated the beneficial effects of this novel family of peptides on glucose tolerance, insulin sensitivity and weight loss in an obese mouse model of T2D, as presented at the American Diabetes Association in 2019. In January 2021, we signed a Non-Clinical Evaluation Agreement (NCEA) with the National Institute of Allergy and Infectious Diseases (NIAID) initiating a collaboration to evaluate the potential of CB5064 Analogs for the treatment of COVID-19 associated ARDS. In parallel with the work being conducted by NIAID, we are currently performing the required studies in this program to select a candidate. Based on successful outcomes of those studies and additional funding, we will nominate a clinical candidate followed by initiation of pre-IND work in 2021, with the longer-term goal of initiating a Phase 1 study.

- ***CB5046 Analogs for Cancer and Other Disease Indications:*** Our internal discovery efforts have identified CB5046 Analogs, a family of novel potent and selective peptide inhibitors of CXCR4, a key chemokine receptor involved in tumor growth, metastasis and avoidance of immune surveillance that is overexpressed in 75% of human tumors. CXCR4 is also involved in localization of healthy stem cells and in certain genetic diseases. We have demonstrated positive effects of one of the CB5046 Analogs when administered in combination with chemotherapy in an animal model of aggressive melanoma. We are screening multiple peptide analogs for in vitro activity and plan to explore the potential for use initially in stem cell mobilization and hematologic cancers.

- ***MBT3 Analogs for Cancer Immunotherapy:*** Our discovery efforts identified a novel peptide family, MBT3 Analogs. We have demonstrated the enhanced killing of cancer cells by human immune cells in the presence of an MBT3 Analog, and plan to further explore the therapeutic potential of this analog family for treatment of cancer, subject to resource availability and the requirements of our more-advanced programs.

We have financed our operations primarily with proceeds from sales of our equity securities, including our initial public offering, private placements of our securities, a debt offering, public sales of our securities and the exercise of outstanding warrants and stock options. Since our inception through December 31, 2020, our operations have been funded with an aggregate of approximately $76.5 million from the sale and issuance of equity instruments and debt.

Since inception, we have incurred significant operating losses. Our net losses were $16.3 million and $13.0 million for the years ended December 31, 2020 and 2019, respectively. We incurred $5.2 million and $3.2 million in non-cash expenses during the years ended December 31, 2020 and 2019, respectively. Our net losses excluding non-cash expenses were $11.1 million and $9.9 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $69.3 million. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and from year to year. Although we anticipate incurring increasing expenses as we advance CB4211 through the clinic and as we conduct preclinical development of our other research peptides, the extent of that increase is uncertain at this time and subject to change due to the ongoing COVID-19 pandemic and other factors.

Impacts of the COVID-19 Pandemic

The extent of the impact of COVID-19 on our operational and financial performance will depend on certain developments, including the duration of the outbreak, impact on our preclinical and clinical studies including patient enrollment and retention, employee or industry events, and effect on our suppliers, service providers and manufacturers, all of which are uncertain and cannot be predicted. The COVID-19 pandemic and its adverse effects are prevalent in the locations where we, our CROs, suppliers or third-party business partners conduct business and, as a result, we may experience more pronounced disruptions in our operations, liquidity, supply chain, facilities, and clinical trials. With respect to our clinical trials, we have experienced delays due to our clinical sites closing down during the pandemic, we have experienced delays in enrollment due to those closures and weather-related events in the state where our clinical sites are located. We may in the future experience more significant delays in enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis that could materially adversely impact our business, results of operations and overall financial performance in future periods. Specifically, we may experience impact from restrictions on travel and in-person meetings, delays in site activations and enrollment of clinical trials, prioritization of hospital resources toward pandemic effort, delays in review by the FDA and comparable foreign regulatory agencies, and disruptions in our supply chain for our product candidates. As of the filing date of this Form 10-K, the extent to which the COVID-19 pandemic may impact our financial condition, results of operations or guidance is uncertain. The effect of the COVID-19 pandemic will not be fully reflected in our results of operations and overall financial performance until future periods. See the section titled “Risk Factors” for further discussion of the possible impact of the COVID-19 pandemic on our business.

Financial Operations Review

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the near future. In the future, we will seek to generate revenue from product sales, either directly or under any future licensing, development or similar relationship with a strategic partner.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our drug discovery efforts, and the development of our product candidates, which include:

- employee-related expenses including salaries, benefits and stock-based compensation expense;
- expenses incurred under agreements with third parties, including contract research organizations (CROs) that conduct research and development and preclinical activities on our behalf and the cost of consultants;
- the cost of laboratory equipment, supplies and manufacturing MBT test materials; and
- depreciation and other personnel-related costs associated with research and product development.

We record all research and development expenses as incurred. We expect our research and development expenses to increase in the year ending December 31, 2021 compared to the year ended December 31, 2020, as we incur additional costs related to our clinical activities and for discovery, evaluation and optimization of other MDPs as potential MBT drug candidates.

Our Research Programs

Our research and development programs include activities in support of the clinical development of our lead MBT candidate program, CB4211, as well as the operation of our platform technology related to the discovery and development of new MBTs, evaluation of newly discovered MDPs, design of novel improved analogs, evaluation of their therapeutic potential and optimization of their characteristics as potential MBT drug development candidates. Depending on factors of capability, cost, efficiency and intellectual property rights, we conduct our research programs at our laboratory facility, or externally, pursuant to contractual arrangements with CROs or under collaborative arrangements with academic institutions.

The success of our research programs and the timing of those programs and the possible development of research peptides into drug candidates is highly uncertain. As such, at this time, we cannot reasonably estimate or know the nature, timing or estimated costs of the efforts that will be necessary to complete research and development of a commercial drug. We are also unable to predict when, if ever, we will receive material net cash inflows from our operations. This is due to the numerous risks and uncertainties associated with developing medicines, including the uncertainty of:

- developing appropriate manufacturing processes and formulations;
- establishing an appropriate safety profile with toxicology studies;
- obtaining appropriate regulatory approval for conducting clinical trials;
- successfully designing, enrolling and completing clinical trials;
- receiving marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and enforcing patent and trade secret protection for our product candidates;
- launching commercial sales of the products, if and when approved, whether alone or in collaboration with others; and
- maintaining an acceptable safety profile of the products following approval.

A change in the outcome of any of these variables with respect to the development of any of our product candidates would significantly change the costs and timing associated with the development of that product candidate.

Research and development activities are central to our business model. Most of our potential MBT drug candidates are in early stages of investigational research. Candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect research and development costs to increase for the foreseeable future as our product candidate development programs progress. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control may impact our clinical development programs and plans.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in executive, finance and administrative functions. Other significant costs include legal fees relating to patent and corporate matters and fees for accounting and consulting services and directors' and officers' insurance. We anticipate that our general and administrative expenses will increase in the year ending December 31, 2021 as we plan to expand our business.

Results of Operations

The following tables set forth our results of operations for the periods presented. The year-to-year comparison of financial results is not necessarily indicative of financial results to be achieved in future periods.

	For The Years Ended December 31,		Change	
	2020	2019	$	%
Operating expenses:				
Research and development	$ 6,937,610	$ 6,631,928	$ 305,682	5%
General and administrative	6,261,905	5,951,106	310,799	5%
Total operating expenses	$ 13,199,515	$ 12,583,034	$ 616,481	5%

Comparison of Fiscal Years Ended December 31, 2020 and 2019

Operating Expenses

Research and development expenses were $6.9 million in the year ended December 31, 2020 compared to $6.6 million in the prior year, a $0.3 million increase, or 5%. The increase in research and development expenses in the year ended December 31, 2020, was primarily due to an increase in clinical costs of $0.9 million related to the timing of those expenses. This increase was partially offset by a decrease of $0.3 million in stock-based compensation as prior year grants became fully expensed during the current year period and a $0.2 million decrease in lab supply purchases related to the slow down experienced during the current year period from the COVID-19 pandemic.

General and administrative expenses were $6.3 million in the year ended December 31, 2020 compared to $6.0 million in the prior year, a $0.3 million increase, or 5%. The increase in general and administrative expenses was due to a $0.2 million increase in insurance costs related to higher D&O premiums and $0.1 million in legal fees related to an increase in compliance related matters during the current year period.

Liquidity and Capital Resources

As of December 31, 2020, we had $21.0 million in cash, cash equivalents and investments. As of December 31, 2019, we had $12.6 million in cash and cash equivalents. We maintain our cash in a checking and a savings account on deposit with a banking institution in the United States. Our cash equivalent balance as of December 31, 2020 and 2019 included $0 and $9.5 million, respectively, of U.S. Treasury Bills that had maturity dates of less than three months at the date of purchase. As of December 31, 2020, we had working capital and stockholders' equity of $18.4 million and $18.5 million, respectively, and incurred a net loss of $16.3 million for the year ended December 31, 2020. As of December 31, 2019, we had working capital and stockholders' equity of $10.9 million and $8.1 million, respectively, and incurred a net loss of $13.0 million.

On May 27, 2020, we entered into an At-the-Market Offering Sales Agreement ("ATM") with Virtu Americas, LLC, as sales agent, pursuant to which we may sell shares of common stock with an aggregate offering price of up to $20,000,000. As of December 31, 2020, we had sold 2,350,067 shares of our common stock under the ATM program for proceeds of $4,308,352, net of commissions and professional fees of $214,456.

In August 2020, we completed an underwritten public offering of our securities (the "Public Offering") pursuant to which we sold 12,300,000 shares of our common stock and warrants to purchase 10,608,750 shares of common stock for proceeds of $13,655,531, net of commissions and professional fees of $1,368,919. The warrants issued in the Public Offering were immediately exercisable and have a term of five years and a per share exercise price of $1.44.

As reflected in the financial statements, we had an accumulated deficit as of December 31, 2020 and 2019, as well as recurring losses and negative cash flows from operating activities from inception. These factors raise substantial doubt about our ability to continue as a going concern for at least one year from the issuance of these financial statements. However, based on current budget assumptions, projected cash burn, the cash and investments on hand as of December 31, 2020 and funding of approximately $1 million received from equity exercises subsequent to December 31, 2020, we believe that we have sufficient capital to meet our operating expenses and obligations for the next twelve months from the date of this filing. However, if unanticipated difficulties or circumstances arise, we may require additional capital sooner to support our operations. If we are unable to raise additional capital whenever necessary, we may be forced to decelerate or curtail our research and development activities and/or other operations until such time as additional capital becomes available. Such limitation of our activities would allow us to slow our rate of spending and extend our use of cash until additional capital is raised. There can be no assurance that such a plan would be successful. There is no assurance that additional financing will be available when needed or that we will be able to obtain such financing on reasonable terms.

Cash Flows from Operating Activities

Net cash used in operating activities for the years ended December 31, 2020 and 2019 was $9.8 million and $10.1 million, respectively. Cash used in operations for the year ended December 31, 2020 was primarily due to our net loss of $16.3 million, which was partially offset by non-cash items of stock based-compensation, depreciation and amortization of the debt discount totaling $5.2 million. Cash used in operations for the year ended December 31, 2019 was primarily due to our net loss of $13.0 million, which was partially offset by non-cash items of stock based-compensation, depreciation and amortization of the debt discount totaling $3.2 million.

Cash Flows from Investing Activities

Net cash used in investing activities for the year ended December 31, 2020 was $18.2 million and net cash provided by investing activities for the year ended December 31, 2019 was $16.3 million. The cash used in investing activities was due to the timing of the purchases of our investments in certificates of deposit and treasury bills as compared to the timing of the maturities of those investments. The cash provided by investing activities was due to the timing of the purchases of our investments in certificates of deposit and treasury bills as compared to the timing of the maturities of those investments and the purchases of property and equipment we made during year ended December 31, 2019.

Cash Flows from Financing Activities

Net cash provided by financing activities for the years ended December 31, 2020 and 2019 was $18.3 million and $0.6 million, respectively. Cash provided by financing activities in the year ended December 31, 2020 was due to net proceeds of $13,655,531 and $4,308,352received from our underwritten public and At-the-Market offering, respectively, and the exercise of stock options and warrants. Cash provided by financing activities in the year ended December 31, 2019 was due to proceeds from the exercise of warrants and stock options totaling $0.6 million.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Operating Leases

We are a party to a lease agreement for laboratory space leased on a month-to month basis that is part of a shared facility in Menlo Park, California. In September 2020, we renewed our lease for office space in Fairfield, New Jersey for an additional year at the same annual cost of $13,080 per annum.

Rent expense amounted to $403,449 and $350,979 for the years ended December 31, 2020 and 2019, respectively.

Recent Accounting Pronouncements

See Note 3 “Summary of Significant Account Policies – Recent Accounting Pronouncements” to our Financial Statements for the year ended December 31, 2020, for a summary of the relevant recent accounting pronouncements.

Other recent accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Company’s financial statements upon adoption.

Critical Accounting Estimates

Our management’s discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP). U.S. GAAP requires us to make certain estimates and judgments that can affect the reported amounts of assets and liabilities as of the dates of the financial statements, the disclosure of contingencies as of the dates of the financial statements, and the reported amounts of revenue and expenses during the periods presented. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. If actual results or events differ materially from those contemplated by us in making these estimates, our reported financial condition and results of operations for future periods could be materially affected. See “Risk Factors” for certain matters that may affect our future financial condition or results of operations. An accounting policy is deemed to be critical if it requires an accounting estimate to be made based on assumptions about matters that are uncertain at the time the estimate is made, if different estimates reasonably could have been used, or if the changes in estimate that are reasonably likely to occur could materially impact the financial statements. Our management has discussed the development, selection and disclosure of these estimates with the audit committee of our board of directors.

The following critical accounting estimates reflect significant judgments and estimates used in the preparation of our financial statements:

- Fair value of financial instruments
- Share-based payments
- Valuation of deferred tax assets

Fair Value of Financial Instruments

We measure the fair value of financial assets and liabilities based on the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. We utilize three levels of inputs that may be used to measure fair value:

- Level 1 – quoted prices in active markets for identical assets or liabilities
- Level 2 – quoted prices for similar assets and liabilities in active markets or inputs that are observable
- Level 3 – inputs that are unobservable (for example, cash flow modeling inputs based on assumptions)

The carrying amounts of cash, accounts payable, accrued liabilities and debt approximate fair value due to the short-term nature of these instruments.

Share-based Payments

We account for share-based payments using the fair value method. For employees and directors, the fair value of the award is measured on the grant date. For non-employees, fair value is generally measured based on the fair value of the services provided or the fair value of the common stock on the measurement date, whichever is more readily determinable. We have historically granted stock options at exercise prices no less than the fair market value as determined by the board of directors, with input from management.

See Note 3 “Summary of Significant Account Policies – Share-Based Payment” to our Financial Statements for the years ended December 31, 2020 and 2019 regarding the specific assumptions used with respect to stock-based compensation for the periods presented.

Valuation of Deferred Tax Assets

We recognize deferred tax assets and liabilities for the expected future tax consequences of items that have been included or excluded in the financial statements or tax returns. Deferred tax assets and liabilities are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts (“temporary differences”) at enacted tax rates in effect for the years in which the temporary differences are expected to reverse.

The benefit of tax positions taken or expected to be taken in income tax returns are recognized in the financial statements if such positions are more likely than not of being sustained. We have evaluated and concluded that there were no material uncertain tax positions requiring recognition in the Company’s financial statements as of December 31, 2020 and 2019. The Company does not expect any significant changes in the unrecognized tax benefits within twelve months of the reporting date.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

Item 8. Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
CohBar, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of CohBar, Inc. (the "Company") as of December 31, 2020 and 2019, the related statements of operations, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, 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 audits 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 Matters

Critical Audit Matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2014

New York, NY
March 30, 2021

CohBar, Inc.
Balance Sheets

	As of	
	December 31, 2020	**December 31, 2019**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,894,575	$ 12,563,853
Investments	18,120,266	-
Prepaid expenses and other current assets	413,692	361,311
Total current assets	21,428,533	12,925,164
Property and equipment, net	394,004	523,677
Intangible assets, net	18,075	19,154
Other assets	67,403	64,242
Total assets	$ 21,908,015	$ 13,532,237
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 727,599	$ 444,776
Accrued liabilities	1,141,741	916,692
Accrued payroll and other compensation	853,335	677,755
Note payable, net of debt discount and offering costs of $15,656 and $0 as of December 31, 2020 and 2019, respectively	349,344	-
Total current liabilities	3,072,019	2,039,223
Notes payable, net of debt discount and offering costs of $26,159 and $546,312 as of December 31, 2020 and 2019, respectively	348,841	3,356,188
Total liabilities	3,420,860	5,395,411
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, Authorized 5,000,000 shares; No shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	-	-
Common stock, $0.001 par value, Authorized 180,000,000 shares; Issued and outstanding 61,117,524 shares as of December 31, 2020 and 43,069,418 as of December 31, 2019	61,118	43,069
Additional paid-in capital	87,684,323	61,087,082
Accumulated deficit	(69,258,286)	(52,993,325)
Total stockholders' equity	18,487,155	8,136,826
Total liabilities and stockholders' equity	$ 21,908,015	$ 13,532,237

The accompanying notes are an integral part of these financial statements

CohBar, Inc.
Condensed Statements of Operations

	For The Years Ended December 31,	
	2020	**2019**
Revenues	$ -	$ -
Operating expenses:		
Research and development	6,937,610	6,631,928
General and administrative	6,261,905	5,951,106
Total operating expenses	13,199,515	12,583,034
Operating loss	(13,199,515)	(12,583,034)
Other income (expense):		
Interest income	41,149	290,313
Interest expense	(311,410)	(312,200)
Equity modification expense	(2,290,688)	-
Amortization of debt discount and offering costs	(504,497)	(439,851)
Total other expense	(3,065,446)	(461,738)
Net loss	$ (16,264,961)	$ (13,044,772)
Basic and diluted net loss per share	$ (0.33)	$ (0.30)
Weighted average common shares outstanding - basic and diluted	48,814,353	42,816,616

The accompanying notes are an integral part of these financial statements

CohBar, Inc.
Statements of Changes in Stockholders' Equity
For the Years Ended December 31, 2020 and 2019

	Common Stock			Accumulated	Total Stockholders'
	Number	Amount	APIC	Deficit	Equity
Balance, December 31, 2018	**42,578,208**	**$ 42,578**	**$ 57,868,593**	**$ (39,948,553)**	**$ 17,962,618**
Stock based compensation	-	-	2,609,370	-	2,609,370
Exercise of employee stock options	441,210	441	551,669	-	552,110
Exercise of warrants	50,000	50	57,450	-	57,500
Net loss	-	-	-	(13,044,772)	(13,044,772)
Balance, December 31, 2019	**43,069,418**	**$ 43,069**	**$ 61,087,082**	**$ (52,993,325)**	**$ 8,136,826**
Stock based compensation	-	-	2,216,316	-	2,216,316
Equity modification expense	-	-	2,290,688	-	2,290,688
Exercise of employee stock options	223,924	224	252,161	-	252,385
Exercise of warrants	20,000	20	44,980	-	45,000
Sale of common stock in ATM, net	2,350,067	2,350	4,306,002	-	4,308,352
Sale of common stock in CMPO, net	12,300,000	12,300	13,643,231	-	13,655,531
Issuance of equity to convert debt	3,154,115	3,155	3,843,863	-	3,847,018
Net loss	-	-	-	(16,264,961)	(16,264,961)
Balance, December 31, 2020	**61,117,524**	**61,118**	**87,684,323**	**(69,258,286)**	**18,487,155**

The accompanying notes are an integral part of these financial statements

CohBar, Inc.
Statements of Cash Flows

	For The Years Ended December 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (16,264,961)	$ (13,044,772)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	156,664	147,687
Stock-based compensation	2,216,316	2,609,370
Equity modification expense	2,290,688	-
Amortization of debt discount	463,781	420,341
Amortization of debt issuance costs	40,716	19,510
Discount on investments	2,734	(34,574)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(52,381)	(100,681)
Accounts payable	282,823	(697,959)
Accrued liabilities	909,567	564,879
Accrued payroll and other compensation	175,580	10,094
Net cash used in operating activities	(9,778,473)	(10,106,105)
Cash flows from investing activities:		
Purchases of property and equipment	(25,912)	(149,545)
Payment for security deposit	(3,161)	(7,449)
Purchases of investments	(25,417,000)	(40,348,000)
Proceeds from redemptions of investments	7,294,000	56,843,000
Net cash (used in) provided by investing activities	(18,152,073)	16,338,006
Cash flows from financing activities:		
Proceeds from public offering, net	13,655,531	-
Proceeds from the At-the-Market Offering, net	4,308,352	-
Proceeds from exercise of warrants	45,000	57,500
Proceeds from exercise of employee stock options	252,385	552,110
Net cash provided by financing activities	18,261,268	609,610
Net (decrease) increase in cash and cash equivalents	(9,669,278)	6,841,511
Cash and cash equivalents at beginning of period	12,563,853	5,722,342
Cash and cash equivalents at end of period	$ 2,894,575	$ 12,563,853
Non-cash financing activities:		
Conversion of Promissory Notes to Common Stock	$ 3,847,018	$ -
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ 1,300	$ 1,300

The accompanying notes are an integral part of these financial statements

Note 1 - Business Organization and Nature of Operations

CohBar, Inc. ("CohBar," "its" or the "Company") is a clinical stage biotechnology company focused on the research and development of mitochondria based therapeutics ("MBTs"), an emerging class of drugs for the treatment of chronic and age-related diseases including nonalcoholic steatohepatitis ("NASH"), obesity, cancer, fibrotic diseases such as idiopathic pulmonary fibrosis, acute respiratory distress syndrome ('ARDS') including COVID-19 associated ARDS, type 2 diabetes mellitus and cardiovascular and neurodegenerative diseases.

The Company's primary activities include the research and development of its MBT pipeline, securing intellectual property protection for its discoveries and assets, managing collaborations and clinical trials with contract research organizations ("CROs") and raising capital to fund the Company's operations. To date, the Company has not generated any revenues from operations and does not expect to generate any revenues in the near future. The Company has financed its operations primarily with proceeds from sales of its equity securities, private placements, the exercise of outstanding warrants and stock options and the issuance of debt instruments.

The Company is monitoring the COVID-19 pandemic, which continues to rapidly evolve, and has taken steps to mitigate the potential impacts on its business. The extent to which the pandemic may impact the Company's business, preclinical studies and its clinical trial will depend on future developments, which are highly uncertain and cannot be predicted with confidence. The Company has modified its business practices by restricting nonessential travel, implementing a partial work from home policy for its employees and instituting new safety protocols for its lab to enable essential on-site work to continue. The Company expects to continue to take actions that are in the best interests of its employees and business partners. Due to the uncertainty surrounding the pandemic, the Company's visibility into the duration of these actions is limited.

Note 2 – Liquidity and Management's Plans

As of December 31, 2020, the Company had a cash and cash equivalents balance of $2,894,575 and working capital and stockholders' equity of $18,356,514 and $18,487,155, respectively. During the year ended December 31, 2020, the Company incurred a net loss of $16,264,961. As reflected in the financial statements, the Company had an accumulated deficit as of December 31, 2020 and 2019, as well as recurring losses and negative cash flows from operating activities from inception. These factors raise substantial doubt about the Company's ability to continue as a going concern for at least one year from the issuance of these financial statements. However, based on current budget assumptions, projected cash burn, the cash and investments on hand as of December 31, 2020 and funding of approximately $1 million received from equity exercises subsequent to December 31, 2020, the Company believes that it has sufficient capital to meet its operating expenses and obligations for the next twelve months from the date of this filing. However, if unanticipated difficulties or circumstances arise, the Company may require additional capital sooner to support its operations. If the Company is unable to raise additional capital whenever necessary, it may be forced to decelerate or curtail its research and development activities and/or other operations until such time as additional capital becomes available. Such limitation of the Company's activities would allow it to slow its rate of spending and extend its use of cash until additional capital is raised. There can be no assurance that such a plan would be successful. There is no assurance that additional financing will be available when needed or that the Company will be able to obtain such financing on reasonable terms.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

BASIS OF PRESENTATION

All amounts are presented in U.S. Dollars.

USE OF ESTIMATES

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at dates of the financial statements and the reported amounts of revenue and expenses during the periods. Actual results could differ from these estimates. The Company's significant estimates and assumptions include the fair value of financial instruments, stock-based compensation and the valuation allowance relating to the Company's deferred tax assets.

CONCENTRATIONS OF CREDIT RISK

The Company maintains deposits in a financial institution which is insured by the Federal Deposit Insurance Corporation ("FDIC"). At various times, the Company has deposits in this financial institution in excess of the amount insured by the FDIC. The Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risk.

INVESTMENTS

Investments as of December 2020 and 2019 consist of U.S. Treasury Bills, which are classified as held-to-maturity, and Certificates of Deposit totaling $18,120,266 and $0, respectively. The Company determines the appropriate balance sheet classification of its investments at the time of purchase and evaluates the classification at each balance sheet date. All of the Company's U.S. Treasury Bills mature within the subsequent twelve months from the date of purchase. Unrealized gains and losses were *de minimus*. As of December 31, 2020, the carrying value of the Company's U.S. Treasury Bills approximates their fair value due to their short-term maturities.

CAPITALIZATION OF PATENT COSTS

The Company capitalizes the costs of its patents which consists of legal and filing fees related to the prosecution of patent filings. The patents will be amortized using the straight-line method over the estimated remaining lives of the patents which is 20 years from the initial filing of the patent.

CASH EQUIVALENTS

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. As of December 31, 2020, the Company did not have any cash equivalents. As of December 31, 2019, the Company invested $9,505,777 in Treasury Bills that are considered cash equivalents due to their maturity date being less than three months from the date of purchase.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

PROPERTY AND EQUIPMENT, NET

Property and equipment are stated at cost less accumulated depreciation. Depreciation of computer and lab equipment is computed by use of the straight-line method based on the estimated useful lives of the assets, which range from three to five years. Expenditures for maintenance and repairs that do not improve or extend the expected lives of the assets are expensed to operations, while expenditures for major upgrades to existing items are capitalized. Upon retirement or other disposition of these assets, the costs and accumulated depreciation are removed from the accounts and resulting gains or losses are reflected in the results of operations.

FAIR VALUE OF FINANCIAL INSTRUMENTS

The Company measures the fair value of financial assets and liabilities based on the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company utilizes three levels of inputs that may be used to measure fair value:

Level 1 - quoted prices in active markets for identical assets or liabilities
Level 2 - quoted prices for similar assets and liabilities in active markets or inputs that are observable
Level 3 - inputs that are unobservable (for example, cash flow modeling inputs based on assumptions)

The carrying amounts of cash, investments and accounts payable approximate fair value due to the short-term nature of these instruments. The amount of debt included in the accompanying balance sheets approximates its fair value because the interest rate of the notes approximates the current market interest rate.

COMMON STOCK PURCHASE WARRANTS

The Company classifies as equity any contracts that (i) require physical settlement or net-share settlement or (ii) provides the Company with a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement) providing that such contracts are indexed to the Company's own stock. The Company classifies as assets or liabilities any contracts that (i) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside the Company's control), or (ii) gives the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement). The Company assesses classification of its common stock purchase warrants and other free-standing derivatives at each reporting date to determine whether a change in classification between assets, liabilities and equity is required. The Company's free-standing derivatives consist of warrants to purchase common stock that were issued in connection with its notes payable and private offering. The Company evaluated these warrants to assess their proper classification using the applicable criteria enumerated under U.S. GAAP and determined that the common stock purchase warrants meet the criteria for equity classification in the accompanying balance sheets as of December 31, 2020 and 2019.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

INCOME TAXES

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of items that have been included or excluded in the financial statements or tax returns. Deferred tax assets and liabilities are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts ("temporary differences") at enacted tax rates in effect for the years in which the temporary differences are expected to reverse.

The benefit of tax positions taken or expected to be taken in income tax returns are recognized in the financial statements if such positions are more likely than not of being sustained. Management has evaluated and concluded that there were no material uncertain tax positions requiring recognition in the Company's financial statements as of December 31, 2020 and 2019. The Company does not expect any significant changes in the unrecognized tax benefits within twelve months of the reporting date.

The Company classifies interest expense and any related penalties related to income tax uncertainties as a component of income tax expense. No interest or penalties have been recognized during the years ended December 31, 2020 and 2019.

RESEARCH AND DEVELOPMENT EXPENSES

The Company expenses all research and development expenses as incurred. These costs include payroll, employee benefits, supplies, contracted for lab services, depreciation and other personnel-related costs associated with product development.

SHARE-BASED PAYMENT

The Company accounts for share-based payments using the fair value method. For employees and directors, the fair value of the award is measured, as discussed below, on the grant date. For non-employees, fair value is generally valued based on the fair value of the services provided or the fair value of the equity instruments on the measurement date, whichever is more readily determinable. The Company has granted stock options at exercise prices equal to the closing price of the Company's common stock as reported by Nasdaq, with input from management on the date of grant. Upon exercise of an option or warrant, the Company issues new shares of common stock out of its authorized shares.

The weighted-average fair value of options and warrants has been estimated on the grant date or measurement date using the Black-Scholes pricing model. The fair value of each instrument is estimated on the grant date or measurement date utilizing certain assumptions for a risk-free interest rate, volatility and expected remaining lives of the awards. The risk-free interest rate used is the United States Treasury rate for the day of the grant having a term equal to the life of the equity instrument. Beginning with the first quarter of the year ending 2019, the fair value of stock-based payment awards issued was estimated using a volatility derived from the Company's share price. Prior to the first quarter of the year ending 2019, the Company had a limited history of being publicly traded and estimated the fair value of stock-based payment awards using a volatility derived from an index of comparable entities. The assumptions used in calculating the fair value of share-based payment awards represent management's best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and the Company uses different assumptions, the Company's stock-based compensation expense could be materially different in the future.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

The weighted-average Black-Scholes assumptions are as follows:

	For the Years Ended December 31,	
	2020	2019
Expected life	6 years	6 years
Risk free interest rate	0.85%	2.18%
Expected volatility	97%	77%
Expected dividend yield	0%	0%

As of December 31, 2020, total unrecognized stock compensation expense was $2,538,211, which will be recognized as those options vest over a period of approximately four years. The amount of future stock option compensation expense could be affected by any future option grants or by any option holders leaving the Company before their grants are fully vested.

NET LOSS PER SHARE OF COMMON STOCK

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net earnings per share reflects the potential dilution that could occur if securities or other instruments to issue common stock were exercised or converted into common stock. Potentially dilutive securities are excluded from the computation of diluted net loss per share as their inclusion would be anti-dilutive and consist of the following:

	As of December 31,	
	2020	2019
Options	7,469,891	7,632,358
Warrants	19,372,818	4,907,223
Totals	26,842,709	12,539,581

RECENT ACCOUNTING PRONOUNCEMENTS

In August 2020, the FASB issued ASU 2020-06, ASC Subtopic 470-20 "*Debt—Debt with Conversion and Other Options*" and ASC subtopic 815-40 "*Hedging—Contracts in Entity's Own Equity*". The standard reduced the number of accounting models for convertible debt instruments and convertible preferred stock. Convertible instruments that continue to be subject to separation models are (1) those with embedded conversion features that are not clearly and closely related to the host contract, that meet the definition of a derivative, and that do not qualify for a scope exception from derivative accounting; and (2) convertible debt instruments issued with substantial premiums for which the premiums are recorded as paid-in capital. The amendments in this update are effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company is currently assessing the impact of the adoption of this standard on its consolidated financial statements.

NOTE 4 - PROPERTY AND EQUIPMENT

Property and equipment consist of the following:

	As of December 31,	
	2020	2019
Lab equipment	$ 860,433	$ 839,802
Computer and equipment	65,665	60,384
Total property and equipment	$ 926,098	$ 900,186
Less: accumulated depreciation	(532,094)	(376,509)
Total property and equipment, net	$ 394,004	$ 523,677

Depreciation expense related to property and equipment for the years ended December 31, 2020 and 2019 was $155,585 and $147,441, respectively. During the year ended December 31, 2019, the Company wrote off fully depreciated assets and adjusted the carrying value of the assets and accumulated depreciation by $833, respectively.

NOTE 5 – INTANGIBLE ASSETS

Intangible assets consist of the following:

	As of December 31,	
	2020	2019
Intangible assets: patents	$ 21,604	$ 21,604
Less: amortization	(3,529)	(2,450)
Total intangible assets, net	$ 18,075	$ 19,154

Amortization expense for each of the years ended December 31, 2020 and 2019 was $1,079.

The Company will recognize intangible amortization expense of $1,079 in each of the next five years. Thereafter, amortization expense will total $12,680.

NOTE 6 – ACCRUED LIABILITIES

Accrued liabilities consist of the following:

	As of December 31,	
	2020	2019
Lab services & supplies	$ 917,194	$ 131,176
Professional fees	44,171	61,662
Interest	162,731	544,199
Other	17,645	179,655
Total accrued liabilities	$ 1,141,741	$ 916,692

NOTE 7 - NOTES PAYABLE

During the year ended December 31, 2020, the Company completed a private offering (the "Private Offering") with certain promissory note holders converting outstanding amounts due under its 8% Unsecured Promissory Notes (the "Notes") due in 2021 and 2022. The Company converted the Notes in the Private Offering totaling an aggregate of $3,847,018 in principal and interest and issued 3,154,115 units at a price of $1.22 per unit. Two officers of the Company participated in the private offering converting an aggregate of approximately $131,000 into 107,000 units. Each unit consists of one share of the Company's common stock and one warrant to purchase 0.75 of one share of the Company's common stock at an exercise price of $1.44 per share. Each warrant can be exercised at any time on or after June 18, 2021 and on or prior to June 18, 2026. As of December 31, 2020, the aggregate principal balance of the promissory notes totaling $740,000 remains outstanding. Of such amount, $365,000 in aggregate principal amount is due and payable 2021 and $375,000 in aggregate principal amount is due and payable in 2022.

NOTE 8 - COMMITMENTS AND CONTINGENCIES

LITIGATIONS, CLAIMS AND ASSESSMENTS

The Company may from time to time be a party to litigation and subject to claims incident to the ordinary course of business. As the Company grows and gains prominence in the marketplace it may become a party to an increasing number of litigation matters and claims. The outcome of litigation and claims cannot be predicted with certainty, and the resolution of these matters could materially affect the Company's future results of operations, cash flows or financial position. The Company is not currently a party to any legal proceedings.

LICENSING AGREEMENTS

The Company is a party to an Exclusive License Agreement (the "2011 Exclusive Agreement") with the Regents of the University of California ("the Regents" or "Licensors") which remains in effect for the life of the last-to-expire patent or last to be abandoned patent application, whichever is later. The Company agreed to pay the Licensors specified development milestone payments aggregating up to $765,000 for the first product sold under the license. Milestone payments for additional products developed and sold under the license are reduced by 50%. The Company is also required to pay annual maintenance fees to the Licensors. Aggregate maintenance fees for the first five years following execution of the agreement were $80,000. Thereafter, the Company is required to pay maintenance fees of $50,000 annually until the first sale of a licensed product. In addition, for the duration of the 2011 Exclusive Agreement, the Company is required to pay the Licensors royalties equal to 2% of its worldwide net sales of drugs, therapies or other products developed from claims covered by the licensed patents, subject to a minimum royalty payment of $75,000 annually, beginning after the first commercial sale of a licensed product. The Company is required to pay royalties ranging from 8% of worldwide sublicense sales of covered products (if the sublicense is entered after commencement of Phase II clinical trials) to 12% of worldwide sublicense sales (if the sublicense is entered prior to commencement of Phase I clinical trials). The agreement also requires the Company to meet certain diligence and development milestones, including filing of an Investigational New Drug ("IND") Application for a product covered by the agreement on or before the seventh anniversary of the agreement date. In October 2020, the Regents accepted the Company's payment for an additional year of license maintenance. Through December 31, 2020, no royalties have been incurred under the agreement. All maintenance fees due and payable have been paid.

NOTE 8 - COMMITMENTS AND CONTINGENCIES (CONTINUED)

The Company is also a party to an Exclusive License Agreement (the "2013 Exclusive Agreement") with the Regents whereby the Regents granted to the Company an exclusive license for the use of certain other patents. The 2013 Exclusive Agreement remains in effect for the life of the last-to-expire patent or last to be abandoned patent application, whichever is later. The Company paid the Regents an initial license issue fee of $10,000 for these other patents, which was charged to General and Administrative expense, as incurred. The Company is also required to pay annual maintenance fees to the Licensors. Aggregate maintenance fees for the first three years following execution of the agreement were $7,500. Thereafter, the Company is required to pay maintenance fees of $5,000 annually until the first sale of a licensed product. The Company agreed to pay the Regents specified development milestone payments aggregating up to $765,000 for the first product sold under the 2013 Exclusive Agreement. Milestone payments for additional products developed and sold under the 2013 Exclusive Agreement are reduced by 50%. In addition, for the duration of the 2013 Exclusive Agreement, the Company is required to pay the Regents royalties equal to 2% of the Company's worldwide net sales of drugs, therapies or other products developed from claims covered by the licensed patent, subject to a minimum royalty payment of $75,000 annually, beginning after the first commercial sale of a licensed product. The Company is required to pay the Regents royalties ranging from 8% of worldwide sublicense sales of covered products (if the sublicense is entered after commencement of Phase II clinical trials) to 12% of worldwide sublicense sales (if the sublicense is entered prior to commencement of Phase I clinical trials). The agreement also requires the Company to meet certain diligence and development milestones, including filing of an IND Application for a product covered by the agreement on or before the seventh anniversary of the agreement date. Through December 31, 2020, no royalties have been incurred under the agreement. All maintenance fees due and payable have been paid.

OPERATING LEASES

The Company is a party to a lease agreement for laboratory space leased on a month-to-month basis that is part of a shared facility in Menlo Park, California. In September 2020, the Company renewed its lease for office space in Fairfield, New Jersey for an additional year at the same annual cost of $13,080 per annum.

Rent expense amounted to $403,449 and $350,979 for the years ended December 31, 2020 and 2019, respectively.

NOTE 9 - INCOME TAXES

The tax effects of temporary differences that give rise to deferred tax assets are as follows:

	As of December 31,	
	2020	**2019**
Current:		
Accrued expenses	$ 464,042	$ 223,712
Stock compensation	869,815	838,753
Net operating loss carryforward	16,165,927	11,978,595
Research and development credit carry forward	548,983	367,261
Total deferred tax assets	18,048,767	13,408,321
Valuation allowance	(18,048,767)	(13,408,321)
Deferred tax asset, net of valuation allowance	$ -	$ -

NOTE 9 - INCOME TAXES (CONTINUED)

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

	For the Years Ended December 31,	
	2020	2019
U.S. statutory federal rate	(21.0)%	(21.0)%
State income taxes, net of federal tax	(7.0)%	(7.0)%
Federal tax rate change	-%	-%
Permanent differences	0.4%	3.0%
Prior year true-ups	(0.4)%	0.3%
R&D tax credit	(0.5)%	(0.7)%
Change in valuation allowance	28.5%	25.4%
Income tax provision (benefit)	-%	-%

The income tax provision consists of the following:

	For the Years Ended December 31,	
	2020	2019
Federal		
Current	$ -	$ -
Deferred	(3,482,375)	(2,378,218)
State and local		
Current	-	-
Deferred	(1,158,072)	(790,882)
Change in valuation allowance	4,640,447	3,169,100
Income tax provision (benefit)	$ -	$ -

The Company assesses the likelihood that deferred tax assets will be realized. To the extent that realization is not more-likely-than-not, a valuation allowance is established. Based upon the Company's losses since inception, management believes that it is more-likely-than-not that future benefits of deferred tax assets will not be realized. Therefore, the Company established a full valuation allowance as of December 31, 2020 and 2019. As of December 31, 2020 and 2019, the change in valuation allowance was $4,640,447 and $3,169,100, respectively.

The Company files income tax returns in the U.S. federal jurisdiction and various state jurisdictions, principally California and New Jersey. The Company is subject to examination by the various taxing authorities. The Company's federal and state income tax returns for tax years beginning in 2015 remain subject to examination.

At December 31, 2020 and 2019, the Company had approximately $58,000,000 and $43,000,000, respectively, of federal and state net operating loss carryovers that may be available to offset future taxable income. The Company's 2017 and prior federal and state net operating loss carry forwards, if not utilized, will begin to expire from 2029 to 2037. Beginning with 2018, and for subsequent years, the Company's NOLs will have indefinite lives for federal tax purposes. In addition, net operating losses arising from prior years are also subject to examination at the time they are utilized in future years. In accordance with Section 382 of the Internal Revenue Code, the usage of the Company's net operating loss carryforward could be limited in the event of a change in ownership. At this time, the Company has not completed a full study to assess whether an ownership change under Section 382 of the Code occurred due to the costs and complexities associated with such a study.

At December 31, 2020 and 2019, the Company had approximately $549,000 and $367,000, respectively, in gross R&D tax credits. These R&D tax credits will begin to expire from 2033 to 2040, respectively.

NOTE 10 - STOCKHOLDERS' EQUITY

AUTHORIZED CAPITAL

The Company has authorized the issuance and sale of up to 185,000,000 shares of stock, consisting of 180,000,000 shares of common stock having a par value of $0.001 and 5,000,000 shares of Preferred Stock having a par value of $0.001 per share. As of December 31, 2020 and 2019, there were no shares of Preferred Stock outstanding and there were no declared but unpaid dividends or undeclared dividend arrearages on any shares of the Company's capital stock.

AT-THE-MARKET OFFERING

During the year ended December 31, 2020, the Company entered into an At-the-Market Offering Sales Agreement ("ATM") with Virtu Americas, LLC as sales agent. During the year ended December 31, 2020, the Company sold 2,350,067 shares of its common stock under the ATM program for proceeds of $4,308,352, net of commissions and professional fees of $214,456.

UNDERWRITTEN PUBLIC OFFERING

During the year ended December 31, 2020, the Company completed an underwritten public offering of the Company's securities (the "Public Offering") pursuant to which the Company sold 12,300,000 shares of its common stock and warrants to purchase 10,608,750 shares of common stock for proceeds of $13,655,531, net of commissions and professional fees of $1,368,919. The warrants issued in the Public Offering were immediately exercisable and have a term of five years and a per share exercise price of $1.44.

STOCK OPTIONS

The Company has an incentive stock plan, the Amended and Restated 2011 Equity Incentive Plan (the "2011 Plan"), and has granted stock options to employees, non-employee directors and consultants from the 2011 Plan. Options granted under the 2011 Plan may be Incentive Stock Options or Non-statutory Stock Options, as determined by the Administrator at the time of grant. During the year ended December 31, 2020, the Company's stockholders approved an amendment to the 2011 Plan to increase the number of shares authorized for issuance under the 2011 Plan to a total of 14,000,000. As of December 31, 2020, there were 5,129,109 shares remaining available for issuance under the 2011 Plan.

During the year ended December 31, 2020, the Company granted stock options to employees to purchase 275,000 shares of the Company's common stock at exercise prices that ranged between $1.55 to $2.56 per share. The options have terms of ten years. The stock options have an aggregate grant date fair value of $486,273.

During the year ended December 31, 2020, stock options to purchase 223,924 shares of common stock were exercised for cash proceeds of $252,385.

During the year ended December 31, 2020, stock options to purchase 213,543 shares of common stock were cancelled and returned to the option pool for future issuance.

During the year ended December 31, 2019, the Company granted stock options to employees to purchase 2,279,000 shares of the Company's common stock at exercise prices that ranged between $1.43 to $3.15 per share. The options have terms of ten years. The stock options have an aggregate grant date fair value of $3,471,351.

NOTE 10 - STOCKHOLDERS' EQUITY (CONTINUED)

During the year ended December 31, 2019, 441,210 stock options were exercised for cash proceeds of $552,110 and the Company cancelled 193,714 stock options.

The Company recorded stock-based compensation as follows:

	For the Years Ended December 31,	
	2020	2019
Research and development	$ 604,107	$ 915,075
General and administrative	1,612,209	1,694,295
Total	$ 2,216,316	$ 2,609,370

The following table represents stock option activity for the years ended December 31, 2020 and 2019:

	Stock Options		Weighted Average Exercise Price		Fair Value	Contractual	Aggregate
	Outstanding	Exercisable	Outstanding	Exercisable	Vested	Life (Years)	Intrinsic Value
Balance – January 1, 2019	5,488,282	4,384,294	$ 2.10	$ 1.32	$ 1.32	5.80	$ -
Granted	2,779,000	-	-	-	-	-	-
Exercised	(441,210)	-	-	-	-	-	-
Cancelled	(193,714)	-	-	-	-	-	-
Balance – December 31, 2019	7,632,358	4,542,144	$ 2.21	$ 1.57	$ 1.57	6.44	$ -
Granted	275,000	-	-	-	-	-	-
Exercised	(223,924)	-	-	-	-	-	-
Cancelled	(213,543)	-	-	-	-	-	-
Balance – December 31, 2020	7,469,891	5,390,431	$ 2.06	$ 1.68	$ 1.68	6.27	$ 1,634,719

The following table summarizes information on stock options outstanding and exercisable as of December 31, 2020:

Grant Price		Weighted Average	Total	Number	Weighted Average Remaining
From	To	Exercise Price	Outstanding	Exercisable	Contractual Term
$ 0.26	$ 2.02	$ 0.89	3,119,974	2,935,807	3.48 years
$ 2.10	$ 4.60	$ 2.42	3,756,917	1,914,915	7.76 years
$ 5.30	$ 8.86	$ 6.25	593,000	539,709	7.34 years
		Totals	**7,469,891**	**5,390,431**	

WARRANTS

During the year ended December 31, 2020, the Company issued warrants to purchase 10,608,750 shares of the Company's common stock as part of the Public Offering (see Note 8 – Underwritten Public Offering) and to the note holders that extended the due date of their unsecured promissory notes (see Note 10 – Amendments to Notes and Warrants) and warrants to purchase 2,365,595 shares of the Company's common stock as part of the Private Offering that converted outstanding amounts due under the Company's 8% Unsecured Promissory Notes due 2021 (see Note 7 - Notes Payable).

NOTE 10 - STOCKHOLDERS' EQUITY (CONTINUED)

During the year ended December 31, 2020, the Company entered into amendments (the "Amendments") with certain holders of the Company's 8% Unsecured Promissory Notes (the "2018 Notes") and Nontransferable Common Stock Purchase Warrants (the "2018 Warrants"). Pursuant to the Amendments, the maturity date of the applicable 2018 Notes was extended from March 29, 2021 to June 30, 2021 and the expiration date of the applicable 2018 Warrants was extended from March 29, 2021 to March 29, 2022. The terms of the applicable 2018 Notes were also amended to grant the holders of such 2018 Notes a right to participate in a future private offering of the Company's securities upon terms substantially similar to those offered to investors in a future primary offering of the Company's securities and to grant resale registration rights in connection therewith. The Company recognized $209,810 of non-cash costs in Other Expenses in the accompanying statements of operations relating to the 2018 Warrants extension.

The Company subsequently entered into a second amendment to the 2018 Notes with certain holders whereby the maturity date of the applicable 2018 Notes was extended from June 30, 2021 to June 30, 2022 and the expiration date of the applicable 2018 Warrants was extended from March 29, 2022 to March 29, 2026. The exercise price of the 2018 Warrants was adjusted from $5.30 per share to $2.00 per share. The terms of the applicable 2018 Notes were also amended to require that the holders of such 2018 Notes participate in a future private offering of the Company's securities upon terms substantially similar to those offered to investors in a future primary offering of the Company's securities (see Note 7 – Notes Payable). The Company also granted an additional warrant to purchase 0.5 of one share of its common stock, or 1,511,250 shares of common stock in total, per dollar of each participating 2018 Note holder's principal amount of the 2018 Notes with an exercise price of $2.00 per share and an expiration date of March 29, 2026 (the "New Warrants"). The New Warrants will be exercisable beginning on the six-month anniversary of the date of issuance, and the Company granted to the participating 2018 Note holders certain registration rights with respect to its securities issued in the Private Offering and the shares of common stock underlying the New Warrants. The Company recognized $489,645 of non-cash costs in Other Expenses in the accompanying statements of operations related to this second amendment.

Also, during the year ended December 31, 2020, the Company entered into amendments with certain holders of the Company's Common Stock Purchase Warrants (the "2017 Warrants") pursuant to which the expiration date of the applicable 2017 Warrants was extended from June 30, 2020 to September 30, 2021. The Company recognized $1,591,233 of non-cash costs in Other Expenses in the accompanying statements of operations relating to the 2017 Warrants extension.

The Company determined the proper classification of the loan modification based on ASC 470-50, Debt Modifications and Extinguishments. Because the change in present value of cash flows of the modified debt is less than 10% when compared to the present value of the cash flows of the original debt, no change is required to be made to the debt in the accompanying condensed financial statements.

During the year ended December 31, 2020, warrants to purchase 20,000 shares of common stock were exercised for cash proceeds of $45,000.

During the year ended December 31, 2019, warrants to purchase 50,000 shares of the Company's common stock were exercised for cash proceeds of $57,500.

During the year ended December 31, 2019, warrants to purchase 6,982 shares of the Company's common stock expired and were cancelled.

NOTE 10 - STOCKHOLDERS' EQUITY (CONTINUED)

The following table represents warrant activity for the years ended December 31, 2020 and 2019:

	Warrants		Weighted Average Exercise Price		Fair Value	Contractual	Aggregate
	Outstanding	Exercisable	Outstanding	Exercisable	Vested	Life (Years)	Intrinsic Value
Balance – January 1, 2019	4,964,205	4,964,205	$ 2.39	$ 2.39	$ 1.14	2.27	$ -
Granted	-	-	-	-	-	-	-
Exercised	(50,000)	-	-	-	-	-	-
Cancelled	(6,982)	-	-	-	-	-	-
Balance – December 31, 2019	4,907,223	4,907,223	$ 2.40	$ 2.40	$ 1.11	1.55	$ 833,793
Granted	14,485,595	-	-	-	-	-	-
Exercised	(20,000)	-	-	-	-	-	-
Cancelled	-	-	-	-	-	-	-
Balance – December 31, 2020	19,372,818	15,495,973	$ 1.62	$ 1.61	$ 0.81	4.07	$ 866,300

NOTE 11 – NON-CASH EXPENSES

The following table details the Company's non-cash expenses included in the accompanying statements of operations:

	For the Years Ended December 31,	
	2020	2019
Operating expenses:		
Stock-based compensation	$ 2,216,316	$ 2,609,370
Depreciation & amortization	156,664	148,520
Subtotal	$ 2,372,980	$ 2,757,890
Other expense:		
Amortization of debt discount	504,498	420,341
Equity modification	2,290,688	-
Subtotal	$ 2,795,186	$ 420,341
Total non-cash expenses	$ 5,168,166	$ 3,178,231

NOTE 12 - SUBSEQUENT EVENTS

Management has evaluated subsequent events to determine if events or transactions occurring through the date on which the financial statements were issued require adjustment or disclosure in the Company's financial statements.

Subsequent to December 31, 2020, a total of 623,901 stock options were exercised for cash proceeds of $958,847.

Subsequent to December 31, 2020, a total of 46,900 warrants were exercised for cash proceeds of $67,536.

Subsequent to December 31, 2020, the Company granted warrants to purchase a total of 60,000 shares of the Company's common stock with an exercise price of $1.38 per share. The warrants have terms that range from two to three years with vesting over a one-year period.

Subsequent to December 31, 2020, the company repaid two promissory notes totaling approximately $105,000 in principal and interest.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

An evaluation was conducted under the supervision and with the participation of our management, including Steven Engle, our Chief Executive Officer, and Jeff Biunno, our Chief Financial Officer (collectively, the "Certifying Officers"), of the effectiveness of our disclosure controls and procedures as of December 31, 2020, as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 (the "Exchange Act"). Based on that evaluation, our management concluded that, during the year ended December 31, 2020, our disclosure controls and procedures was effective.

Management's Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Rule 13a-15(f) and 15(d)-15(f) under the Exchange Act. This rule defines internal control over financial reporting as a process designed by, or under the supervision of, Certifying Officers, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

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

Management's Assessment

Our management, including our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our internal control over financial reporting based on the criteria established in Internal Control - Integrated Framework (2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Chief Executive Officer and Chief Financial Officer have concluded that as of December 31, 2020, our internal control over financial reporting was effective.

We have limited capital resources and have given priority in the use of those resources to our research and development efforts. If we are unable to maintain effective internal control over financial reporting, we may not be able to report our financial results accurately, prevent fraud or file our periodic reports in a timely manner. We continue to evaluate the effectiveness of our internal controls and procedures on an on-going basis. As our operations continue to grow and become more complex, we intend to hire additional personnel in financial reporting and other areas.

Auditor Attestation

This Annual Report on Form 10-K does not include an attestation of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to applicable rules of the Securities and Exchange Commission.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K, or will be included in an amendment to this Annual Report on Form 10-K.

Item 11. Executive Compensation

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K, or will be included in an amendment to this Annual Report on Form 10-K.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Equity Compensation Plan Information

The following table provides information about our equity compensation plan as of December 31, 2020.

Plan Category	Number of securities to be issued upon exercise of options warrants and rights	Weighted-average exercise price of outstanding options warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by stockholders	7,469,891	$ 2.07	5,629,109(2)
Equity compensation plans not approved by stockholders	942,671(1)	$ 0.51	-
Total	8,412,562	$ 0.53	5,629,109

(1) Consists of warrants issued to our former Chief Operating Officer pursuant to an employment agreement, and warrants issued to two consultants pursuant to consulting agreements, and warrants issued to the Alzheimers Drug Discovery Foundation for the 2013 grant.

(2) Consists of securities for two equity compensation plans approved by the Company's stockholders, (i) an incentive stock plan, the Amended and Restated 2011 Equity Incentive Plan, as amended (the "2011 Plan"), which the Company has granted stock options to employees, non-employee directors and consultants; and (ii) an Employee Stock Purchase Plan which allows employees of the Company to purchase shares through payroll deductions during set offering periods.

Beneficial Ownership

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K, or will be included in an amendment to this Annual Report on Form 10-K.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K, or will be included in an amendment to this Annual Report on Form 10-K.

Item 14. Principal Accounting Fees and Services

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K, or will be included in an amendment to this Annual Report on Form 10-K.

PART IV

Item 15. Exhibits, Financial Statement Schedules

The financial statements, together with the report thereon of Marcum LLP, are included on the pages indicated below:

Financial Statements and Schedules

Financial statement schedules have been omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

Exhibits

The following exhibits are filed herewith and this list is intended to constitute the exhibit index.

Exhibit No	Description
3.1	Third Amended and Restated Articles of Incorporation - Incorporated by reference to Exhibit 3.1 of our Current Report on Form 8-K, as filed with the Commission on January 8, 2015.
3.2	Certificate of Amendment of Third Amended and Restated Certificate of Incorporation – Incorporated by reference to Exhibit 3.1 of our Current Report on Form 8-K, as filed with the Commission on June 18, 2020.
3.3	Amended and Restated Bylaws - Incorporated by reference to Exhibit 3.2 of our Current Report on Form 8-K, as filed with the Commission on January 8, 2015.
4.1	Description of the Registrant's Securities.
4.2	Common Stock Purchase Warrant, dated April 11, 2014, issued to Jon Stern - Incorporated by reference to Exhibit 10.7 to our Registration Statement on Form S-1 (File No. 333-200033), as filed with the Commission on November 10, 2014.
4.3	Form of Common Stock Purchase Warrants issued July 2017 - Incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K, as filed with the Commission on July 18, 2017.
4.4	Form of Nontransferable Common Stock Purchase Warrants issued March and April 2018 – Incorporated by reference to Exhibit 4.2 to our Current Report on Form 8-K, as filed with the Commission on May 4, 2018.
4.5	Form of 8% Unsecured Promissory Note Due 2021 issued March and April 2018 - Incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K, as filed with the Commission on May 4, 2018.
4.6	Form of Amendment to 8% Unsecured Promissory Note and Nontransferable Common Stock Purchase Warrant – Incorporated by reference to Exhibit 10.26 to our Annual Report on Form 10-K filed with the Commission on March 12, 2020.
4.7	Form of Amendment to Common Stock Purchase Warrant – Incorporated by reference to Exhibit 10.27 to our Annual Report on Form 10-K, as filed with the Commission on March 12, 2020.
4.8	Form of Second Amendment to 8% Unsecured Promissory Note and Nontransferable Common Stock Purchase Warrant – Incorporated by reference to Exhibit 10.2 of our Quarterly Report on Form 10-Q, as filed with the Commission on August 13, 2020.
4.9	Form of Nontransferable Common Stock Purchase Warrant – Incorporated by reference to Exhibit 10.3 of our Quarterly Report on Form 10-Q, as filed with the Commission on August 13, 2020.
4.10	Form of Common Stock Purchase Warrant issued August 2020 – Incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K, as filed with the Commission on August 26, 2020.
4.11	Form of Common Stock Purchase Warrant issued December 2020 – Incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K, as filed with the Commission on December 22, 2020.
10.1*	Amended and Restated 2011 Equity Incentive Plan - Incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, as filed with the Commission on January 8, 2015.
10.2*	First Amendment to Amended and Restated 2011 Equity Incentive Plan - Incorporated by reference to Exhibit 10.1 of our Quarterly Report on Form 10-Q, as filed with the Commission on August 24, 2017.
10.3*	Second Amendment to Amended and Restated 2011 Equity Incentive Plan – Incorporated by reference to Exhibit 99.4 to our Registration Statement on Form S-8 (File No. 333-226434), as filed with the Commission on July 30, 2018.
10.4*	Third Amendment to Amended and Restated 2011 Equity Incentive Plan – Incorporated by reference to Exhibit 99.5 to our Registration Statement on Form S-8 (File No. 333-239387), as filed with the Commission on June 23, 2020.
10.5*	Form of Option Agreement under the 2011 Equity Incentive Plan - Incorporated by reference to Exhibit 10.2 to our Registration Statement on Form S-1 (File No. 333-200033), as filed with the Commission on November 10, 2014.
10.6	Exclusive License Agreement, dated August 6, 2013, between CohBar, Inc. and the Regents of the University of California - Incorporated by reference to Exhibit 10.4 to our Registration Statement on Form S-1 (File No. 333-200033), as filed with the Commission on November 10, 2014.
10.7	Exclusive License Agreement, dated November 3, 2011, between and among CohBar, Inc. and the Regents of the University of California, and Albert Einstein College of Medicine of Yeshiva University - Incorporated by reference to Exhibit 10.5 to our Registration Statement on Form S-1 (File No. 333-200033), as filed with the Commission on November 10, 2014.
10.8*	Form of Indemnification Agreement - Incorporated by reference to Exhibit 10.6 to our Registration Statement on Form S-1 (File No. 333-200033), as filed with the Commission on November 10, 2014.

10.9*	Executive Employment Agreement, dated November 27, 2013, between CohBar, Inc. and Jeffrey F. Biunno - Incorporated by reference to Exhibit 10.12 to our Registration Statement on Form S-1 (File No. 333-200033), as filed with the Commission on November 10, 2014.
10.10*	Amendment, dated as of July 11, 2016, to Executive Employment Agreement, dated as of November 27, 2013, between CohBar, Inc. and Jeffrey F. Biunno. Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, as filed with the Commission on November 14, 2016.
10.11*	Executive Employment Agreement, dated November 17, 2014, between CohBar, Inc. and Kenneth Cundy - Incorporated by reference to Exhibit 10.13 to the Amendment No. 2 of our Registration Statement on Form S-1 (File No. 333-200033), as filed with the Commission on November 28, 2014.
10.12*	Consulting Agreement, dated November 10, 2011, by and between the Company and Nir Barzilai, as extended by an extension agreement dated November 1, 2014 - Incorporated by reference to Exhibit 10.13 to our Registration Statement on Form S-1 (File No. 333-200033), as filed with the Commission on November 10, 2014.
10.13*	Consulting Agreement, dated September 29, 2014, by and between the Company and Pinchas Cohen - Incorporated by reference to Exhibit 10.14 to our Registration Statement on Form S-1 (File No. 333-200033), as filed with the Commission on November 10, 2014.
10.14*	Executive Employment Agreement dated May 6, 2019, by and between CohBar, Inc. and Steven Engle - Incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, as filed with the Commission on May 8, 2019.
10.15*	Amendment, dated as of June 4, 2019, to Executive Employment Agreement, dated as of November 27, 2013, between CohBar, Inc. and Jeffrey F. Biunno. Incorporated by reference to Exhibit 10.3 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, as filed with the Commission on August 9, 2019.
10.16*	Employee Stock Purchase Plan. – Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K, as filed with the Commission on June 21, 2019.
10.17	At-the-Market Sales Agreement, dated May 27, 2020, between CohBar, Inc. and Virtu Americas LLC – Incorporated by reference to Exhibit 1.1 to our Current Report on Form 8-K, as filed with the Commission on May 27, 2020.
10.18	Form of Subscription Agreement – Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K, as filed with the Commission on December 22, 2020.
23.1	Consent of independent registered public accounting firm.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Indicates management contract, compensatory agreement or arrangement, in which our directors or executive officers may participate.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

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

Date: March 30, 2021

COHBAR, INC.

By: /s/ Jeffrey F. Biunno
Jeffrey F. Biunno
Chief Financial Officer
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Jeffrey F. Biunno and Steven Engle, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his true and lawful attorney-in-fact and agent to act in his name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this report, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

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/ Steven Engle **Steven Engle**	Chief Executive Officer and Director *(Principal Executive Officer)*	March 30, 2021
/s/ Jeffrey F. Biunno **Jeffrey F. Biunno**	Chief Financial Officer, Treasurer and Secretary *(Principal Financial and Accounting Officer)*	March 30, 2021
/s/ Albion J. Fitzgerald **Albion J. Fitzgerald**	Chairman of the Board of Directors	March 30, 2021
/s/ Nir Barzilai **Nir Barzilai**	Director	March 30, 2021
/s/ Pinchas Cohen **Pinchas Cohen**	Director	March 30, 2021
/s/ Phyllis Gardner **Phyllis Gardner**	Director	March 30, 2021
/s/ David Greenwood **David Greenwood**	Director	March 30, 2021
/s/ Misha Petkevich **Misha Petkevich**	Director	March 30, 2021
/s/ Jon L. Stern **Jon L. Stern**	Director	March 30, 2021

Exhibit 4.1

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2020, CohBar, Inc. (the "***Company***," "***we***" or "***our***") had one class of securities registered under Section 12 of the Securities Exchange Act of 1934: our common stock. The following is a summary of our Common Stock and certain provisions of our Third Amended and Restated Certificate of Incorporation ("Certificate ***of Incorporation***") and Amended and Restated Bylaws ("***Bylaws***"). This summary does not purport to be complete and is qualified in its entirety by the provisions of our Certificate of Incorporation and our Bylaws, which are included as exhibits to our most recent Annual Report on Form 10-K, and to the applicable provisions of the Delaware General Corporation Law.

Our authorized capital stock consists of 180,000,000 shares of common stock, par value $0.001 per share, and 5,000,000 shares of preferred stock, par value $0.001 per share. Currently, we have no other authorized class of stock.

Dividend Rights

Subject to any preferences that may be applicable to any then outstanding shares of preferred stock, holders of our common stock are entitled to receive dividends of cash, property or shares of our capital stock that we pay or distribute out of funds legally available if our board of directors, in its discretion, determines to issue dividends and only then at the times and in the amounts that our board of directors may determine.

Voting Rights

Each holder of our common stock is entitled to one vote for each share of common stock held by such holder on all matters on which stockholders generally are entitled to vote, provided that holders of common stock are not entitled to vote on amendments to our Certificate of Incorporation related solely to the terms of one or more outstanding series of preferred stock if the holders of such series are entitled to vote thereon, unless required by law. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, subject to the preferences that may be applicable to any then outstanding shares of preferred stock, holders of a majority of the voting shares are able to elect all of the directors.

Liquidation

In the event of our dissolution or liquidation, whether voluntary or involuntary, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and subject to any preferential or other rights of any then outstanding shares of preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate in the future.

Authorized but Unissued Shares

The authorized but unissued shares of common stock and preferred stock are available for future issuance without stockholder approval, subject to any limitations imposed by the listing standards of the Nasdaq Capital Market, or any other exchange or quotation service on which our stock may be traded. These additional shares may be used for a variety of corporate finance transactions, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could make more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Transfer Agent and Registrar

The main transfer agent and registrar for our common stock is AST Trust Company (Canada) in Vancouver, British Columbia, and the co-transfer agent and co-registrar for our common stock is American Stock Transfer & Trust Company, LLC in New York, New York.

Stock Exchange Listing

Our common stock is traded on the Nasdaq Capital Market under the symbol "CWBR."

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

Delaware Anti-Takeover Law

We are subject to Section 203 of the Delaware General Corporation Law. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (i) shares owned by persons who are directors and also officers and (ii) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with, or controlling, or controlled by, the entity or person. The term "owner" is broadly defined to include any person that, individually, with or through that person's affiliates or associates, among other things, beneficially owns the stock, or has the right to acquire the stock, whether or not the right is immediately exercisable, under any agreement or understanding or upon the exercise of warrants or options or otherwise or has the right to vote the stock under any agreement or understanding, or has an agreement or understanding with the beneficial owner of the stock for the purpose of acquiring, holding, voting or disposing of the stock.

The restrictions in Section 203 do not apply to corporations that have elected, in the manner provided in Section 203, not to be subject to Section 203 of the Delaware General Corporation Law or, with certain exceptions, which do not have a class of voting stock that is listed on a national securities exchange or held of record by more than 2,000 stockholders. Our Certificate of Incorporation and Bylaws do not opt out of Section 203.

Section 203 could delay or prohibit mergers or other takeover or change in control attempts with respect to us and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

Certificate of Incorporation and Bylaws

Provisions of our Certificate of Incorporation and Bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Among other things, our Certificate of Incorporation and Bylaws:

- permit our board of directors to issue up to 5,000,000 shares of preferred stock, without further action by the stockholders, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in control;
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose); and
- set forth an advance notice procedure with regard to the nomination, other than by or at the direction of our board of directors, of candidates for election as directors and with regard to business to be brought before a meeting of stockholders.

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of CohBar, Inc. on Form S-8 (File No. 333-239387), Form S-8 (File No. 333-251912), Form S-3 (File No. 333-248279), and Form S-3 (File No. 333-252331) of our report dated March 30, 2021, with respect to our audits of the financial statements of CohBar, Inc. as of December 31, 2020 and 2019 and for the years ended December 31, 2020 and 2019, which report is included in this Annual Report on Form 10-K of CohBar, Inc. for the year ended December 31, 2020.

/s/ Marcum LLP

Marcum LLP
New York, NY
March 30, 2021

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Steven Engle, certify that:

1. I have reviewed this Annual Report on Form 10-K of CohBar, Inc.;

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

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

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

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with general accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

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

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 30, 2021
Date

By: /s/ Steven Engle
Steven Engle
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jeffrey F. Biunno, certify that:

1. I have reviewed this Annual Report on Form 10-K of CohBar, Inc.;

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

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

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

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with general accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

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

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 30, 2021
Date

By: /s/ Jeffrey F. Biunno
Jeffrey F. Biunno
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(Subsection (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code), the undersigned officers of CohBar, Inc., a Delaware corporation (the "Company"), do hereby certify that:

1. To our knowledge, the Annual Report on Form 10-K for the year ended December 31, 2020 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Act of 1934; and

2. The information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 30, 2021
Date

By: /s/ Steven Engle
Steven Engle
Chief Executive Officer
(Principal Executive Officer)

March 30, 2021
Date

By: /s/ Jeffrey F. Biunno
Jeffrey F. Biunno
Chief Financial Officer
(Principal Financial and Accounting Officer)