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

FORM 10-K

(Mark One)
☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2022

OR

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

For the transition period from: _____ to _____

Commission File Number: **001-38105**

180 LIFE SCIENCES CORP.
(Exact name of registrant as specified in its charter)

Delaware	**90-1890354**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
3000 El Camino Real, Bldg. 4, Suite 200 Palo Alto, CA	**94306**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **(650) 507-0669**

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	ATNF	The NASDAQ Stock Market LLC (NASDAQ Capital Market)
Warrants to purchase shares of Common Stock	ATNFW	The NASDAQ Stock Market LLC (NASDAQ Capital Market)

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post 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" and "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter was $25,377,272. For purposes of calculating the aggregate market value of shares held by non-affiliates, we have assumed that all outstanding shares are held by non-affiliates, except for shares held by each of our executive officers, directors and 5% or greater stockholders. In the case of 5% or greater stockholders, we have not deemed such stockholders to be affiliates unless there are facts and circumstances which would indicate that such stockholders exercise any control over our company, or unless they hold 10% or more of our outstanding common stock. These assumptions should not be deemed to constitute an admission that all executive officers, directors and 5% or greater stockholders are, in fact, affiliates of our company, or that there are not other persons who may be deemed to be affiliates of our company. Further information concerning shareholdings of our officers, directors and principal stockholders is incorporated by reference in Part III, Item 12 of this Annual Report on Form 10-K.

As of March 31, 2023, there were 3,746,906 shares of common stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2023 annual meeting of shareholders (the "2023 Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2023 Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

Auditor Firm Id: 688 Auditor Name: Marcum, LLP Auditor Location: San Francisco, CA

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GLOSSARY

The following are abbreviations and definitions of certain terms used in this Report, which are commonly used in the pharmaceutical and biotechnology industry:

"ACA" means the Patient Protection and Affordable Care Act, often shortened to the Affordable Care Act, nicknamed Obamacare, which is a U.S. federal statute which provides numerous rights and protections that make health coverage fairer and easier to understand, along with subsidies (through "premium tax credits" and "cost-sharing reductions") to make it more affordable. The law also expands the Medicaid program to cover more people with low incomes.

"Analgesics" are a class of medications designed specifically to relieve pain.

"ANDA" means an abbreviated new drug application which contains data which is submitted to the FDA for the review and potential approval of a generic drug product.

"Anti-TNF" is a pharmaceutical drug that suppresses the physiologic response to TNF.

"BLA" means the FDA's Biologics License Application, which is the vehicle in the United States through which biologic sponsors formally propose that the FDA approve a new biologic for sale and marketing.

"BPCIA" means the Biologics Price Competition and Innovation Act.

"Cannabinoids" mean compounds found in *cannabis sativa L*., and when used throughout this prospectus, refer to compounds found in the hemp plant which do not contain THC.

"CBD" or cannabidiol is an active ingredient in cannabis derived from the hemp plant. CBD is a non-psychoactive oxidative degradation product of THC.

"CBG" or cannabigerol is one of the compounds found in the cannabis plant.

"CCMO" means De Centrale Commissie Mensgebonden Onderzoek (CCMO), or the Central Committee on Research Involving Human Subjects, the organizational responsible for reviewing and regulating medical research involving human subjects in The Netherlands.

"CHMP" means the Committee for Medicinal Products for Human Use, formerly known as Committee for Proprietary Medicinal Products, which is the European Medicines Agency's committee responsible for elaborating the agency's opinions on all issues regarding medicinal products for human use.

"CMS" means the Centers for Medicare & Medicaid Services, which is a federal agency within the HHS that administers the Medicare program and works in partnership with state governments to administer Medicaid.

"Corticosteroids" are a class of drug that lowers inflammation in the body.

"CRO" means a contract research organization which is a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

"CSA" means the Controlled Substances Act, the statute establishing federal U.S. drug policy under which the manufacture, importation, possession, use, and distribution of certain substances is regulated.

"CTA" means a Clinical Trial Application, which is a submission to the competent National Regulatory Authority(ies) for obtaining authorization to conduct a clinical trial in a specific country. It is an application with necessary information on investigational medicinal products. The purpose of a CTA is to provide all the important details about the clinical trial to the health authorities in order to obtain the product approval.

"DEA" means the Drug Enforcement Administration, a United States federal law enforcement agency under the United States Department of Justice, tasked with combating drug trafficking and distribution within the United States.

"EMA" means the European Medicines Agency, an agency of the EU in charge of the evaluation and supervision of medicinal products.

"EU" means the European Union.

"FDC Act" means the Federal Food, Drug and Cosmetic Act, which is a set of U.S. laws passed by Congress in 1938 giving authority to the FDA to oversee the safety of food, drugs, medical devices, and cosmetics.

"FDA" means U.S. The Food and Drug Administration, which is a federal agency of the United States Department of Health and Human Services. The FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of U.S. food supply, cosmetics, and products that emit radiation.

"FS" means Frozen Shoulder, a condition characterized by stiffness and pain in an individual's shoulder joint.

"GCP" means good clinical practice, which is an international quality standard, which governments can then transpose into regulations for clinical trials involving human subjects. GCP follows the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), and enforces tight guidelines on ethical aspects of clinical research.

"GLP" means good laboratory practice, which is a quality system concerned with the organization process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.

"GMP" means good manufacturing practice regulations promulgated by the FDA under the authority of the FDC Act. These regulations, which have the force of law, require that manufacturers, processors, and packagers of drugs, medical devices, some food, and blood take proactive steps to ensure that their products are safe, pure, and effective.

"HHS", the U.S. Department of Health and Human Services also known as the Health Department, is a cabinet-level department of the U.S. federal government with the goal of protecting the health of all Americans and providing essential human services.

"HIPAA" means the Health Insurance Portability and Accountability Act of 1996, which has the goal of making it easier for people to keep health insurance, protect the confidentiality and security of healthcare information and help the healthcare industry control administrative costs.

"HMGB1" means High Mobility Group Box 1, a protein that, in humans, is encoded by the HMGB1 gene. Activated macrophages and monocytes secrete HMGB1 as a cytokine mediator of inflammation.

"IBD" means inflammatory bowel disease, an umbrella term used to describe disorders that involve chronic inflammation of the digestive tract.

"IND" means investigational new drug application. Before a clinical trial can be started, the research must be approved. An investigational new drug or IND application or request must be filed with the FDA when researchers want to study a drug in humans. The IND application must contain certain information, such as: results from studies so that the FDA can decide whether the treatment is safe for testing in people; how the drug is made, who makes it, what's in it, how stable it is, and more; detailed outlines for the planned clinical studies, called study protocols, are reviewed to see if people might be exposed to needless risks; and details about the clinical trial team to see if they have the knowledge and skill to run clinical trials.

"Individually identifiable health information" is defined by HIPPA to mean information that is a subset of health information, including demographic information collected from an individual, and: (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (a) that identifies the individual; or (b) with respect to which there is reasonable basis to believe the information can be used to identify the individual.

"IRB" means an Institutional Review Board, which is a group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. This group review serves an important role in the protection of the rights and welfare of human research subjects.

"Medicaid" is a federal and state health insurance program in the U.S. that helps with medical costs for some people with limited income and resources. Medicaid also offers benefits not normally covered by Medicare, including nursing home care and personal care services.

"Medicare" is a national health insurance program in the U.S. It primarily provides health insurance for Americans aged 65 and older, but also for some younger people with disability status as determined by the Social Security Administration, as well as people with end stage renal disease and amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease).

"MHRA" means The Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health and Social Care in the United Kingdom which is responsible for ensuring that medicines and medical devices work and are acceptably safe.

"MRP" means a Mutual Recognition Procedure, a market authorization which is granted in one EU member state and is recognized in other EU member states.

"NDA" means the FDA's New Drug Application, which is the vehicle in the United States through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing.

"NIHR" means The National Institute for Health Research is a United Kingdom government agency which funds research into health and care, and is the largest national clinical research funder in Europe.

"Orphan Drug Designation" means a pharmaceutical agent developed to treat medical conditions which, because they are so rare, would not be profitable to produce without government assistance.

"Phase 1" trials are typically where the drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and elimination. In the case of some drug candidates for severe or life-threatening diseases, such as cancer, especially when the drug candidate may be inherently too toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

"Phase 2" trials are generally when clinical trials are initiated in a limited patient population intended to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the drug candidate for specific targeted diseases and to determine dosage tolerance and optimal dosage. Phase 2 trials are sometimes further divided into: Phase 2a and Phase 2b trials — Phase 2a is focused specifically on dosing requirements. A small number of patients are administered the drug in different quantities to evaluate whether there is a dose-response relationship, which is an increase in response that correlates with increasing increments of dose. In addition, the optimal frequency of dose is also explored; and Phase 2b trials are designed specifically to rigorously test the efficacy of the drug in terms of how successful it is in treating, preventing or diagnosing a disease.

"Phase 3" trials are when clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk-benefit ratio of the drug candidate and provide an adequate basis for regulatory approval and product labeling.

"Phase 4" trials are studies required to be conducted as a condition of approval in order to gather additional information on the drug's effect in various populations and any side effects associated with long-term use.

"Physiotherapy" is treatment to restore, maintain, and make the most of a patient's mobility, function, and well-being.

"POCD" means post-operative cognitive dysfunction/delirium.

"RA" means rheumatoid arthritis.

"REMS" means a risk evaluation and mitigation strategy which is a drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

"SCA" means Synthetic Cannabidiol Analogs, which are synthetic pharmaceutical grade molecules close or distant analogs of non-psychoactive cannabinoids such as CBD for the treatment of inflammatory diseases and pain.

"Sponsor" means the applicant or drug sponsor, which is the person or entity who assumes responsibility for the marketing of a new drug, including responsibility for compliance with applicable provisions of the FSC Act and related regulations. *Note that as used herein the term "Sponsor" may also refer to the Sponsor of our IPO, KBL IV Sponsor LLC, depending on the context in which such term is used.*

"THC" means tetrahydrocannabinol, which is the principal psychoactive constituent of cannabis.

"TNF" means tumor necrosis factor, which is part of the body's response to inflammation.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

This Annual Report on Form 10-K (this "Report") contains forward-looking statements under federal securities laws, including within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward-looking statements by the following words: "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "should," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. Forward-looking statements are not a guarantee of future performance or results and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. Forward-looking statements are based on information available at the time the statements are made and involve known and unknown risks, uncertainties and other factors that may cause our results, levels of activity, performance or achievements to be materially different from the information expressed or implied by the forward-looking statements in this Report, including those described under the heading "Risk Factors" contained in Item 1A of this Report. Forward-looking statements include, but are not limited to, statements about:

- Expectations for the clinical and preclinical development, manufacturing, regulatory approval, and commercialization of our product candidates;
- the uncertainties associated with the clinical development and regulatory approval of the Company's drug candidates, including potential delays in the enrollment and completion of clinical trials, issues raised by the U.S. Food and Drug Administration (FDA) and the U.K. Medicines and Healthcare products Regulatory Agency (MHRA);
- regulatory developments in the United States and foreign countries;
- our success in retaining or recruiting, or changes required in, our officers, key employees or directors;
- current negative operating cash flows and our potential ability to obtain additional financing to advance our business and the terms of any further financing, which may be highly dilutive and may include onerous terms;
- the continued impact of the COVID-19 pandemic on our business operations and our research and development initiatives;
- the accuracy of our estimates regarding expenses, future revenues and capital requirements;
- the Company's reliance on third parties to conduct its clinical trials, enroll patients, and manufacture its preclinical and clinical drug supplies;
- the ability to come to mutually agreeable terms with such third parties and partners, and the terms of such agreements;
- estimates of patient populations for the Company's planned products;
- unexpected adverse side effects or inadequate therapeutic efficacy of drug candidates that could limit approval and/or commercialization, or that could result in recalls or product liability claims;
- the Company's ability to fully comply with numerous federal, state and local laws and regulatory requirements, as well as rules and regulations outside the United States, that apply to its product development activities;
- challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success;
- the ability of the Company to execute its plans to develop and market new drug products and the timing and costs of these development programs;
- high inflation, increasing interest rates and economic downturns, including potential recessions, as well as macroeconomic, geopolitical, health and industry trends, pandemics, acts of war (including the ongoing Ukraine/Russian conflict) and other large-scale crises;
- estimates of the sufficiency of our existing capital resources combined with future anticipated cash flows to finance our operating requirements;
- our ability to maintain the listing of our common stock and warrants on NASDAQ; and
- other risks and uncertainties, including those listed under "Risk Factors", below.

Any forward-looking statements in this Report reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. All forward-looking statements included herein speak only as of the date of the filing of this Report. All subsequent written and oral forward-looking statements attributable to the Company, or persons acting on its behalf, are expressly qualified in their entirety by the cautionary statements above. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

PART I

ITEM 1. BUSINESS.

INTRODUCTION

General

The information included in this Annual Report on Form 10-K should be read in conjunction with the consolidated financial statements and related notes included at the end of this report.

Please see the "Glossary" above for a list of biotechnology industry abbreviations and definitions used throughout this Report.

Our logo and some of our trademarks and tradenames are used in this Report. This Report also includes trademarks, tradenames and service marks that are the property of others. Solely for convenience, trademarks, tradenames and service marks referred to in this Report may appear without the ®, ™ and SM symbols. References to our trademarks, tradenames and service marks are not intended to indicate in any way that we will not assert to the fullest extent under applicable law our rights or the rights of the applicable licensors if any, nor that respective owners to other intellectual property rights will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend the use or display of other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

The market data and certain other statistical information used throughout this Report are based on independent industry publications, reports by market research firms or other independent sources that we believe to be reliable sources; however, we have not commissioned any of the market or survey data that is presented in this Report. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We are responsible for all of the disclosures contained in this Report, and we believe these industry publications and third-party research, surveys and studies are reliable. While we are not aware of any misstatements regarding any third-party information presented in this Report, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed under the section entitled "Risk Factors" of this Report. These and other factors could cause our future performance to differ materially from our assumptions and estimates. Some market and other data included herein, as well as the data of competitors as they relate to 180 Life Sciences Corp., is also based on our good faith estimates.

Our fiscal year ends on December 31. Interim results are presented on a quarterly basis for the quarters ended March 31, June 30, and September 30, the first quarter, second quarter and third quarter, respectively, with the quarter ended December 31st being referenced herein as our fourth quarter. Fiscal 2022 means the year ended December 31, 2022, whereas fiscal 2021 means the year ended December 31, 2021.

Reverse Stock Split

On December 15, 2022, at a Special Meeting of the Stockholders of 180 Life Sciences Corp., the stockholders of the Company approved an amendment to the Company's Second Amended and Restated Certificate of Incorporation, as amended, to effect a reverse stock split of our issued and outstanding shares of our common stock, par value $0.0001 per share, by a ratio of between one-for-four to one-for-twenty, inclusive, with the exact ratio to be set at a whole number to be determined by our Board of Directors or a duly authorized committee thereof in its discretion, at any time after approval of the amendment and prior to December 15, 2023 (the "Stockholder Authority"). On December 15, 2022, the Company's Board of Directors (the "Board"), with the Stockholder Authority, approved an amendment to our Second Amended and Restated Certificate of Incorporation to affect a reverse stock split of our common stock at a ratio of 1-for-20 (the "Reverse Stock Split").

Immediately after the Special Meeting and the approval thereof by the Board, on December 15, 2022, we filed a Certificate of Amendment to our Second Amended and Restated Certificate of Incorporation (the "Certificate of Amendment") with the Secretary of State of the State of Delaware to effect the Reverse Stock Split. A copy of the Certificate of Amendment is attached hereto as Exhibit 3.1 and is incorporated by reference herein.

Pursuant to the Certificate of Amendment, the Reverse Stock Split became effective on December 19, 2022 at 12:01 a.m. Eastern Time (the "Effective Time"). No change was made to the trading symbol for the Company's shares of common stock or public warrants, "ATNF" and "ATNFW", respectively, in connection with the Reverse Stock Split.

The Certificate of Amendment did not reduce the number of authorized shares of our common stock, nor alter the par value of our common stock or modify any voting rights or other terms of our common stock.

No fractional shares were issued in connection with the Reverse Stock Split and stockholders of record who otherwise would be entitled to receive fractional shares, were instead entitled to have their fractional shares rounded up to the nearest whole share.

The effects of the 1-for-20 Reverse Stock Split have been retroactively reflected throughout this Report.

Definition

Unless the context requires otherwise, references to the "Company," "we," "us," "our," "180 Life", "180LS" and "180 Life Sciences Corp." refer specifically to 180 Life Sciences Corp. and its consolidated subsidiaries. References to "KBL" refer to the Company prior to the November 6, 2020 Business Combination (discussed and defined below).

In addition, unless the context otherwise requires and for the purposes of this Report only:

- "CAD" refers to Canadian dollars;
- "Exchange Act" refers to the Securities Exchange Act of 1934, as amended;
- "£" or "GBP" refers to British pounds sterling;
- "SEC" or the "Commission" refers to the United States Securities and Exchange Commission; and
- "Securities Act" refers to the Securities Act of 1933, as amended.

Where You Can Find Other Information

We file annual, quarterly, and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at www.sec.gov and are available for download, free of charge, soon after such reports are filed with or furnished to the SEC, on the "Investors"—"SEC Filings"—"All SEC Filings" page of our website at www.180lifesciences.com. Copies of documents filed by us with the SEC are also available from us without charge, upon oral or written request to our Secretary, who can be contacted at the address and telephone number set forth on the cover page of this Report. Our website address is www.180lifesciences.com. The information on, or that may be accessed through, our website is not incorporated by reference into this Report and should not be considered a part of this Report.

Company Overview

We are a clinical stage biotechnology company headquartered in Palo Alto, California, focused on the development of therapeutics for unmet medical needs in chronic pain, inflammation and fibrosis by employing innovative research, and, where appropriate, combination therapy. Our Company was founded by several world-leading scientists in the biotechnology and pharmaceutical sectors. Our world-renowned scientists Prof. Sir Marc Feldmann, Prof. Lawrence Steinman, Prof. Raphael Mechoulam, recently deceased, Dr. Jonathan Rothbard, and Prof. Jagdeep Nanchahal have significant experience and significant previous success in drug discovery. The scientists are from the University of Oxford ("Oxford"), Stanford University and Hebrew University of Jerusalem (the "Hebrew University"), and the management team has extensive experience in financing and growing early-stage healthcare companies. Prof. Raphael Mechoulam passed away in March 2023, but his research at Hebrew University is being carried on by other scientists as noted later in this document under the "SCAs Platform" section.

We have three different product development platforms that are focused on different diseases or medical conditions, and that target different factors, molecules or proteins, as follows:

- Anti-TNF platform: focusing on fibrosis and anti-tumor necrosis factor ("anti-TNF");
- SCAs platform: focusing on drugs which are synthetic cannabidiol ("CBD") or cannabigerol ("CBG") analogues ("SCAs"); and
- α7nAChR platform: focusing on alpha 7 nicotinic acetylcholine receptor ("α7nAChR").

Our lead product candidate recently completed Phase 2a and Phase 2b proof-of-concept clinical trials in the United Kingdom ("U.K.") and the Netherlands for early-stage Dupuytren's Contracture, a condition that affects the development of fibrous connective tissue in the palm of the hand. Currently, we are planning or conducting clinical trials only for certain indications under the anti-TNF platform, such as a planned Phase 2 trial for post-operative cognitive decline as well as a planned Phase 2 trial for frozen shoulder. The Company was recruiting patients for a feasibility trial for frozen shoulder, for which we have ended such recruitment at nine patients, due to a regulatory request in the UK to end slow recruiting trials. The result of the closure of the trial means that another trial will likely need to be undertaken in the future to recruit additional participants. Of our three product development platforms, only one, the SCAs platform, involves products that are related to cannabidiol (CBD) (and not to cannabis or tetrahydrocannabinol (THC)), and no clinical trials for indications or products under the SCAs platform are currently being conducted in the United States or abroad. We are currently undertaking preclinical research and development activities for the SCA and the α7nAChR platforms.

Business Strategy

Our goal is to capitalize on our research in chronic pain, inflammation and fibrosis by pursuing the following strategies:

- advance our clinical-stage product candidate for early-stage Dupuytren's Contracture from its current late-stage development to seek and obtain approval in the U.K., European Union ("EU") and the United States ("U.S.") for such product candidate, potentially commercialize the product candidate in the U.K., EU and U.S. and identify the optimal commercial pathway in other markets around the world;

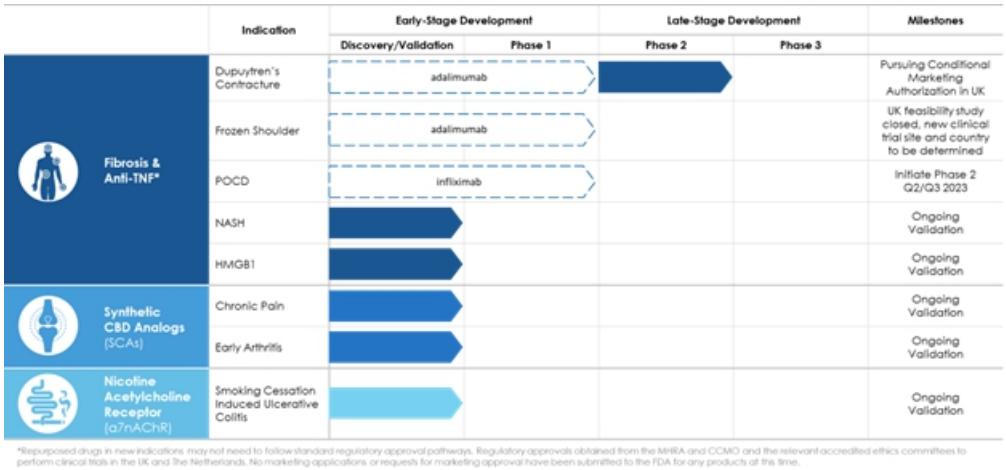
- move our pre-clinical product candidates into clinical trials, seek and obtain approval in the U.K., EU and U.S. for such future product candidates, and potentially commercialize such future product candidates in the U.S., U.K. and EU;

- leverage our proprietary product development platforms to discover, develop and commercialize novel first-in-class products for the treatment of chronic pain, inflammation and fibrosis; and

- strengthen our position in research in chronic pain, inflammation and fibrosis.

Overview of Product Development Platforms

The following chart summarizes the products and indications, including those currently in clinical trial, for our three product development platforms.



"*Regulatory approvals obtained from the MHRA and CCMO and the relevant accredited ethics committees to perform clinical trials in the U.K. and The Netherlands. No marketing applications or requests for marketing approval have been submitted to the FDA for any products at this time."

On December 1, 2021, the Company announced positive top line data for the Phase 2b clinical trial of Dupuytren's Contracture.

On February 22, 2023, the Company announced the closure of recruitment of patients for the feasibility trial for frozen shoulder, for which we have ended such recruitment at nine patients, due to a regulatory request in the UK to end slow recruiting trials. The result of the closure of the trial means that another trial will likely need to be undertaken in the future to recruit additional participants.

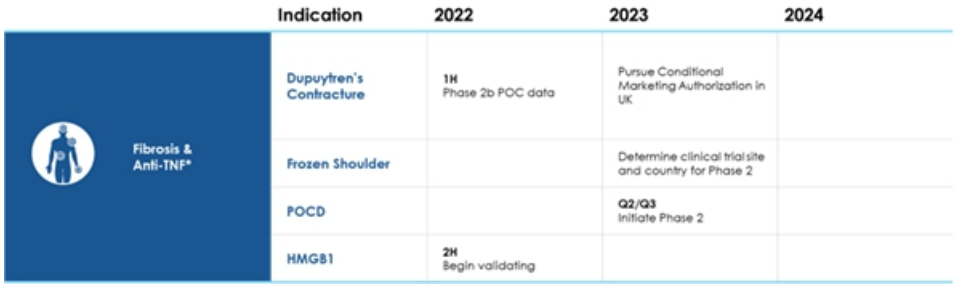
The product development platforms are each described in more detail below.

Fibrosis & Anti-TNF Platform

Our anti-tumor necrosis factor (TNF) platform began at our wholly-owned subsidiary, 180 Therapeutics L.P. ("180 LP"). This platform is focused on studying the molecular mechanism of inflammatory diseases and fibrosis and on the discovery of TNF as a mediator of fibrosis, as well as other immune-driven diseases. This research was first undertaken in the 1980s by our Co-Chairman, Prof. Sir Marc Feldmann, based on analysis of tissue from patients with rheumatoid arthritis ("RA"). We are applying this same approach to the analysis of human disease tissue from patients with active fibrosis, research led by Prof. Jagdeep Nanchahal in Oxford (who is also the Chairman of our Clinical Advisory Board), which has led to the identification of new therapeutic targets and approaches that we are developing. Profs. Nanchahal and Feldmann, in collaboration with other scientists, are leveraging their experience and expertise in developing anti-inflammatories to search for new applications for anti-TNF therapeutics. We are seeking to demonstrate that anti-TNF drugs, such as adalimumab, have a positive effect on new indications such as Dupuytren's Contracture, frozen shoulder and post-operative cognitive dysfunction/delirium ("POCD").

Our first product candidate in clinical development is for the potential treatment of early-stage fibrosis of the hand, Dupuytren's Contracture, for which there is currently no approved treatment in the U.K. or EU. Collagenase from Clostridium histolyticum has been approved in the USA for late-stage Dupuytren's Contracture. The proposed treatment will be administered by a local injection of adalimumab, an anti-TNF antibody, into early-stage disease tissue. The results for the Phase 2a clinical trial for Dupuytren's Contracture, supported by the Wellcome Trust, U.K. Department of Health and the Company, were published in July 2018. The study demonstrated positive tissue response indicative of anti-fibrotic mechanisms, as well as guiding dosing for follow up trials. Having defined the most efficacious dose and preparation and based on these positive proof of concept data, the Company, together with the Wellcome Trust and the U.K. Department of Health, initiated a Phase 2b trial in patients with early-stage Dupuytren's Contracture. The initial plan was to randomize 138 patients in a ratio of 1:1 to receive four injections of adalimumab or placebo at three-month intervals and followed for a total of 18 months from baseline. With additional funding from the Wellcome Trust, the Phase 2b trial completed recruitment of 174 patients in April 2019, having commenced dosing in February 2017. The final patient was enrolled in April 2019. The Phase 2b clinical trial for early-stage Dupuytren's Contracture has been completed. On December 1, 2021, the Company announced top line data from the trial, which indicates that the primary end point of nodule hardness and the secondary end point of nodule size on ultrasound scan were met with statistically significant differences. There were no related severe adverse events. The full results have been submitted for publication in a peer-reviewed journal and will be disclosed upon publication. Through this fibrosis and anti-TNF product development platform, we are also performing research for the development of potential treatments of frozen shoulder, liver and lung fibrosis and POCD.

The following chart summarizes the timing of current and future clinical trials, based on current proposals, under the anti-TNF platform.



We have obtained regulatory approvals from the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) and the Dutch Centrale Commissie Mensgebonden Onderzoek (CCMO), as well as from the relevant accredited ethics committees, in order to perform clinical trials in the U.K. and The Netherlands solely for indications under the anti-TNF platform. No marketing applications or requests for marketing approval have been submitted to, the U.S. Food and Drug Administration ("FDA") for any indications or products under the anti-TNF platform at this time. On March 29, 2022 we submitted a request to FDA for a Type C Meeting to discuss clinical outcome assessment in clinical trials of the anti-TNF platform for early stage Dupuytren's disease. On April 26, 2022, FDA granted the meeting request and agreed to provide written responses in lieu of a meeting. On June 9, 2022, FDA provided the aforementioned written responses in which the agency questioned whether nodule hardness and size would constitute an appropriate end point in such studies. Specifically, FDA stated, "The proposed outcome measures of nodule hardness and nodule size do not appear to be clinical outcome measures that measure how a patient feel, functions, or survives, which would be needed to support a demonstration of efficacy in your future registrational studies."

On February 22, 2023, the Company announced the closure of recruitment of patients for the feasibility trial for frozen shoulder, for which we have ended such recruitment at nine patients, due to a regulatory request in the UK to end slow recruiting trials. The result of the closure of the trial means that another trial will likely need to be undertaken in the future to recruit additional participants.

HMGB1 Program

Our *HMGB1* program was formed with the in-licensing of the technology from the University of Oxford on November 2, 2021. Our HMGB1 program falls under the Fibrosis and Anti-TNF Platform. We have identified HMGB1 as a therapeutic target that acts on multiple endogenous adult stem cells to accelerate the physiological regenerative response to current or future injuries. These findings have broad relevance to the fields of stem cell biology and regenerative medicine and suggest a therapeutic approach to promote tissue repair such as in NASH liver regeneration.

The technology was developed by Prof. Jagdeep Nanchahal's laboratory at the University Oxford prior to licensing. Due to the early stage of development of HMGB1, we are still in the process of assessing milestones and development timelines. The licensing of HMGB1 included the lead development candidate for liver fibrosis. Our HMGB1 program continues to advance slowly. The molecular dynamics for the binding of this molecule are extremely complex and potentially need more extensive research in order to identify a lead candidate.

No regulatory approvals have been sought or obtained from appropriate authorities at this time for any products or indications under the HMGB1 platform.

SCAs Platform

Our SCAs platform began at our wholly-owned subsidiary, CannBioRex Pharmaceuticals Corp. ("CBR Pharma") with the collaborative work of its founders Prof. Mechoulam, deceased, and Prof. Feldmann. This platform focuses on the development of synthetic pharmaceutical grade molecules close or distant analogs of non-psychoactive cannabinoids such as CBD for the treatment of inflammatory diseases and pain. These development efforts are a result of a 20-year collaboration between Prof. Feldmann, who discovered and commercialized anti-TNF therapy for treatment of RA and subsequently a number of inflammatory diseases, which is currently the best-selling drug class in the world, and Prof. Mechoulam, who was a world leading expert in cannabis chemistry who successfully identified THC, CBD and, subsequently, the endocannabinoids. We are working with a research team based at the Kennedy Institute at Oxford, consisting of Prof. Feldmann, Prof. Richard Williams and others, and a research team based at Hebrew University, consisting of Prof. Avi Domb, Prof. Amnon Hoffman and others, to generate new drugs, test them, and optimize their uptake and delivery to disease targets. The aim is to develop novel, orally active analgesic and anti-inflammatory medications based on synthetic compounds to target chronic diseases. We term these synthetic compounds generically as "synthetic CBD analogs" ("SCAs"). Our primary development targets are arthritis and chronic and recurrent pain, while our secondary development targets are diabetes/diabetic neuropathy, fibromyalgia, multiple sclerosis, obesity and fatty liver disease.

No regulatory approvals have been sought or obtained from appropriate authorities at this time for any products or indications under the SCAs platform.

α7nAChR Platform

Our *α7nAChR* platform began at our wholly-owned subsidiary, Katexco, where its founders identified *α7nAChR* as a key receptor for the amyloid proteins associated with diseases like Alzheimer's and Parkinson's Disease. *α7nAChR* is expressed on the surface of both neuronal cells in the brain and on important cells of the immune system. The research conducted by Dr. Jonathan Rothbard and Prof. Steinman has shown that small molecules available as drugs taken by mouth can engage this receptor and potentially reduce inflammatory diseases. Dr. Rothbard and Prof. Steinman have also shown that *α7nAChR* is critical in reducing disease animal models of multiple sclerosis and RA, as well as heart attack and stroke. Our *α7nAChR* product development platform is currently focused on developing *α7nAChR* agonists for the treatment of inflammatory diseases, initially ulcerative colitis induced after cessation of smoking.

No regulatory approvals have been sought or obtained from appropriate authorities at this time for any products or indications under the ***α***7nAChR platform.

Product Candidates

We are attempting to build a broad and diverse pipeline of product candidates in chronic pain, inflammation and fibrosis. Our product candidates are and will be selected for development based on: potential to address unmet medical needs; development feasibility as determined by our preclinical research and development efforts; potential to rapidly achieve proof-of-concept based on easy-to-measure validated regulatory endpoints; and significant commercial potential.

Anti-TNF Platform Dupuytren's Contracture

Overview

Dupuytren's Contracture, also referred to as hand fibrosis, is a progressive, incurable disease characterized by the development of fibrous cords in the palm of the hand, commonly affecting the ring and/or small finger and often multiple joints, leading to contracture and the inability to straighten the affected fingers. Symptoms, when presented to a physician, range from the appearance of nodules in the palm, which can be painless or painful and often disconcerting to the patient, to the loss of the use of the contracted finger. There are currently no approved treatment options for those patients who present with symptomatic, early-stage disease.

Surgery remains the standard treatment for patients with Dupuytren's Contractures but is associated with extended recovery periods and risks of recurrence.

We are developing therapies by repurposing of the anti-TNF therapeutic adalimumab, previously approved and used under the brand name Humira for several autoimmune conditions, for the treatment of early-stage Dupuytren's Contracture. Research at Oxford University has indicated an anti-TNF mechanism can slow or prevent the proliferation of myoblast cells that lead to the formation and growth of the fibrous nodules/cords in the palm and possible finger contracture. We have advanced the development program through Phase 2b clinical trials to evaluate the impact of multiple, intralesional injections on disease progression and functional improvement.

Dupuytren's patients who have advanced disease are primarily treated by orthopedic or plastic surgeons, who rely on invasive interventions when the contracture impacts hand function. Current treatment options include open surgeries (fasciotomies or fasciectomies) and the less invasive procedures of needle aponeurotomy (NA) or collagenase injections. The less invasive procedures are designed to disrupt the integrity of a contracted cord so the fingers can be straightened. Unfortunately, these options are associated with a high rate of recurrence. Dissatisfaction within the medical and Dupuytren patient community with outcomes for later-stage disease and the lack of options to intervene at an early/pre-contracture stage indicate there is an unmet medical need for early-stage intervention.

According to the Dupuytren's Foundation, Dupuytren's Contracture prevalence is estimated to be up to 7% of the U.S. population. Based on the Foundation's estimates, approximately three million patients have contractures that should be treated but only 10% to 20% of those patients are treated. Reasons for the lack of treatment may include the type of available interventions, poor long-term outcomes, and reimbursement hurdles.

In primary interviews in late 2021 with 8 orthopedic/plastic surgeons, conducted by Red Sky Partners (an independent third-party consulting firm) on our behalf and designed to better understand the unmet need for patients with Dupuytren's Contracture, revealed a strong desire among hand surgeons and patients to treat this condition early, before the development of late stage contractures, in a non-invasive manner that will limit further progression, preserve function and prevent or delay invasive surgery. Surgeons' reactions to the rationale for the use of adalimumab to address this unmet need were overall positive and the mechanistic concept of an anti-TNF compound was considered compelling. In the view of the majority of surveyed hand surgeons, the non-invasive, safe product profile would potentially position adalimumab as an important therapeutic option for a much wider range of patients than are typically treated today. Assuming clinical efficacy and safety are supported with published data, we believe that adalimumab would become an attractive alternative to surgery, needle aponeurotomy or collagenase. Further, we believe it has potential use in many early-stage patients who are not treated today.

Based on both primary (feedback from these physician interviews) and secondary research, Red Sky Partners concluded that an initial label focused on patients with a clear contracture where adalimumab would soften nodules and limit progression would be highly differentiated from current therapies and could generate revenues in the range of $300 million to $350 million annually in the U.S. More significantly, the opportunity to offer a safe, non-invasive therapeutic leading to improved function could dramatically expand the treatable population as more patients seek treatment and more physicians are motivated to offer their patients an alternative to waiting to see if their disease progresses, which they cannot do today. This product positioning could generate a revenue opportunity two to three times the initial market opportunity.

Phase 2 Clinical Trials

Our wholly-owned subsidiary, 180 LP, contributed to the funding of a Phase 2a clinical trial for Dupuytren's Contracture along with the Wellcome Trust and the U.K. Department of Health, which using an experimental medicine clinical trial design demonstrated positive tissue response, as well as guiding dosing and tolerability for follow-up trials. The data was published in June 2018.

For the Phase 2a trial, we recruited 28 patients, eight assigned to the 15 milligrams (mg), 12 to the 35 mg and eight to the 40 mg adalimumab cohorts. There was no change in mRNA levels for *ACTA2, COL1A1, COL3A1* and *CDH11*. Levels of α-SMA protein expression in patients treated with 40 mg adalimumab (1.09 ± 0.09 ng per µg of total protein) were significantly lower ($p = 0.006$) compared to placebo treated patients (1.51 ± 0.09 ng/µg). The levels of procollagen type I protein expression were also significantly lower ($p = 0.019$) in the subgroup treated with 40 mg adalimumab (474 ± 84 pg/µg total protein) compared with placebo (817 ± 78 pg/µg). There were two serious adverse events, both considered unrelated to the study drug. In this dose-ranging study, injection of 40 mg of adalimumab in 0.4 ml resulted in down regulation of the myofibroblast phenotype as evidenced by reduction in expression of α-SMA and type I procollagen proteins at 2 weeks.

Having defined the most efficacious dose and preparation and based on these positive proof-of-concept data, the Company, together with the Wellcome Trust and the U.K. Department of Health, initiated a Phase 2b trial in patients with early-stage Dupuytren's Contracture. The initial plan was to randomize 138 patients in a ratio of 1:1 to receive four injections of adalimumab or placebo at three-month intervals and followed for a total of 18 months from baseline. The Phase 2b trial, which was funded by grants from the Wellcome Trust and the U.K. Department of Health, with a contribution from 180 LP to purchase the drug, completed recruitment of 174 patients in April 2019 and commenced dosing in February 2017 in the U.K. and Groningen, The Netherlands.

The Phase 2b clinical trial for early-stage Dupuytren's Contracture has been completed. On December 1, 2021, the Company announced top line data from the trial, which indicates that the primary end point of nodule hardness and the secondary end point of nodule size on ultrasound scan were met with statistically significant differences. There were no related severe adverse events. The full results have been published in the Lancet Rheumatology publication on April 29, 2022.

Other Product Candidates or Indications

In addition to the potential treatment, we are developing for Dupuytren's Contracture described above, we are seeking to repurpose anti-TNF for use as a treatment for other fibrotic conditions such as frozen shoulder. Prof. Feldmann's previous work in the 1980's demonstrated that anti-TNF is an effective anti-inflammatory with many possible uses, and it was subsequently approved for various forms of inflammatory arthritis and inflammatory bowel disease (IBD), as well as other indications. This has since created what is currently the best-selling drug class in the world, anti-TNF therapeutics, which, according to a Research Reports World report published on November 3, 2022, was valued at $42.7 billion in 2022. By using a well-known and extensively used therapeutic, adalimumab, the research and development process may be truncated because of existing product information relating to safety, as the drug has been widely used over the past 20 years in millions of patients.

Frozen Shoulder

Frozen shoulder, also referred to as adhesive capsulitis, is an extremely painful and debilitating condition that affects an individual's everyday activities, including sleep. According to the National Institute of Health, frozen shoulder is most common in people between the ages of 40 and 60. It is estimated that 2 to 5% of the population are affected by frozen shoulder at some point, and it is somewhat more common in women than in men. People with diabetes are particularly likely to develop a frozen shoulder: About 10 to 20% of them get it, but it is not yet known why this happens. In addition, approximately 20% of people suffering from a frozen shoulder will develop the same problem in their other shoulder. According to an article published in Shoulder & Elbow in 2010, it is estimated that up to 30% of patients with diabetes develop frozen shoulder, and the symptoms tend to be more persistent and recalcitrant in this group.

During the pain predominant inflammatory phase, patients are typically treated with analgesics, physiotherapy and corticosteroid injections. Patients with persistent stiffness may be referred to secondary care for capsular release by manipulation under anesthesia, hydrodilatation or surgical arthroscopy. To our knowledge, there is currently no approved targeted therapy, and in conjunction with the National Institute for Health Research (U.K.), we are investigating the feasibility of recruiting patients during the early pain-predominant inflammatory phase of the disease and delivery of a local injection of anti-TNF. The set-up stage for this Phase 2 clinical trial for the local injection of anti-TNF for frozen shoulder started in June 2021. A £250,000 grant has been awarded from NIHR to the University of Oxford to support execution and clinical trial sites are being identified. The Company is providing additional funding to support this trial. The recruitment of men and women across England with early-stage Frozen shoulder for a trial to determine the feasibility of conducting a large randomized controlled trial to assess whether an intra-articular injection of anti-TNF (Adalimumab) can reduce pain and improve function in people with pain predominant early-stage frozen shoulder, which was called the Anti-Freaze-F trial, began in May 2022. The Anti-Freaze-F trial was being run by the University of Oxford and originally sought to recruit 84 participants. Following delays in gaining approvals due to backlogs in the NIHR system due to COVID-19 and consequential staff vacancies, nine participants were recruited for participation in the trial through mid-February 2023. Subsequently, the NIHR's Research Recovery and Reset program identified the trial as slow moving, due to the considerable challenges we faced to open recruitment sites and enroll sufficient participants during COVID-19. Therefore, the NIHR asked the chief investigators to close the trial for further recruitment. The participants enrolled to date will receive their injections and follow up according to the established protocol. The Company had previously requested a no-cost extension, which was denied. The result of the closure of the trial means that another trial will likely need to be undertaken at a future time to recruit additional participants.

Human Liver Fibrosis

Fibrosis of the liver is characterized by long-term damage to the organ caused by the replacement of normal liver tissue with scar tissue. The condition is most commonly caused by non-alcoholic fatty liver disease ("NAFLD"), which encompasses non-alcoholic fatty liver ("NFL") and non-alcoholic steatohepatitis ("NASH"). NAFLD affects approximately 30% of the U.S. population, according to an article published in Nature Reviews Gastroenterology & Hepatology in 2016. Approximately 2% of patients with NFL and approximately 15% to 20% of patients with NASH progress to cirrhosis, fibrosis of the liver with major health issues.

To our knowledge, there is no current approved treatment for individuals with NASH. We therefore believe that there is a large potential market for the creation of an effective preventative treatment. According to Allied Market Research, the market for treating liver fibrosis was approximately $13 billion in 2018 and is projected to rise to approximately $20 billion in 2022, rising at a compounded annual growth rate (CAGR) of over 11% per year. We initiated preclinical studies for NASH based on human liver samples during the second quarter of 2020.

Post-operative Cognitive Decline (POCD)

POCD is a common neuropsychiatric syndrome, defined as disturbance of attention, awareness and cognition, which develops over a short period of time and tends to fluctuate during the course of the day. Patients with hip fracture are at particularly high risk of developing POCD. The U.K.'s national audit data for 2018 showed that 25% of all patients with hip fracture suffered from delirium. POCD is associated with poor functional outcomes, reduced quality of life and longer hospital stays. People with hip fracture who developed delirium are twice as likely to die as inpatients, and nearly four times more likely to need placement in a nursing home. POCD has also been closely associated with long-term cognitive impairment.

Hip fractures are one of the main challenges facing elderly patients and healthcare systems. According to an article published in The Lancet Public Health in 2017, hip fractures are associated with an average loss of 2.7% of the healthy life expectancy in the middle-aged and older population in the U.S. and Europe. People suffering hip fracture have a mean age of 83 years, are frail, and two-thirds are women. They suffer a 30-day mortality of 7% and experience a persistent reduction in their health-related quality-of-life similar to that of a diagnosis of Parkinson's disease or multiple sclerosis. According to various studies, POCD is developed in 13-40% of patients following cardiac surgery. With 500,000 open heart surgeries and 450,000 hip surgeries in the USA each year, in advanced age patients, a beneficial therapy to treat POCD would be a significant benefit to these patients. We plan to initiate a Phase 2 study using anti-TNF for POCD and start patient recruitment during the second or third quarter of 2023. An issued patent to protect this potential use has been licensed from The Kennedy Trust for Rheumatology Research.

SCAs Platform

Overview

Cannabinoids are a class of compounds derived from cannabis plants. The two major cannabinoids contained in cannabis are CBD and THC. Although one cannabinoid, THC, is known to cause psychoactive effects associated with the use of herbal cannabis, no other cannabinoid is known to share these properties. In recent decades, there have been major scientific advances that have led to the discovery of new plant-derived cannabinoids and the endocannabinoid system. There are at least two types of cannabinoid receptors in the human endocannabinoid system, cannabinoid receptor 1 ("CB1") and cannabinoid receptor 2 ("CB2"). CB1 receptors are considered to be among the most widely expressed G protein-coupled receptors in the brain and are particularly abundant in areas of the brain concerned with movement and postural control, pain and sensory perception, memory, cognition, emotion, and autonomic and endocrine function. CB1 receptors are also found in peripheral tissues including peripheral nerves and non-neuronal tissues such as muscle, liver tissues and fat. CB2 receptors are expressed primarily in tissues in the immune system and are believed to mediate the immunological effects of cannabinoids. CBD does not interact with CB1 receptors and is only a weak agonist of CB2 receptors. CBD interacts with other important neurotransmitter and neuromodulatory systems in the human body, including transient receptor potential channels, adenosine uptake and serotonin receptors. The far-reaching and diverse pharmacology of the numerous cannabinoids provides significant potential for development of cannabinoid therapeutics across many indications and disease areas, but also adds to the complexity of the research.

For the SCA program, we have agreements in place with Hebrew University and Oxford, pursuant to which we intend to conduct research to develop and characterize novel SCAs for the treatment of certain target indications, and to perform early-phase clinical trials. Through the Research Agreements with Hebrew University and Oxford, we established research facilities at the Hebrew University and Oxford, in which the development and testing of new cannabinoids designed and synthesized at the Hebrew University will be facilitated. The labs at the Hebrew University will synthesize the chemical compounds and perform preliminary efficacy and safety studies.

Once these initial studies are completed at the Hebrew University, the chemical compounds are sent to Prof. Richard Williams at Oxford, where further evaluation is carried out to identify candidates which have the best potential for clinical efficacy and commercial development. Subsequently, we will support the clinical development of the lead compound(s), culminating in Phase 2 clinical trials to establish clinical utility in chronic pain and inflammatory indications.

The focus of the research is the development of safe and well-tolerated compounds with analgesic and immunomodulatory activity and with the capacity to synergize with current therapies, which target downstream inflammatory processes. After conducting initial research and development, we selected the most promising of the chemical derivatives to move into Phase 1/2 clinical trials, pending successful toxicity studies. In addition, we have identified two lead solid dosage oral formulations of CBD from animal studies, and preparations are underway to facilitate pharmacokinetic analysis in healthy human volunteers.

Product Candidates or Indications

We believe that there are unmet needs for orally available, relatively safe anti-inflammatory drugs, especially those with analgesic properties. We believe that SCAs have the potential to fulfill these needs and we have started to develop novel, orally available and patentable drug candidates to treat certain diseases or conditions such as arthritis, multiple sclerosis, diabetes, psoriasis, obesity and fatty liver, and various painful conditions. Our work on SCAs is currently in the preclinical development stage.

Because medical cannabis is a complex mixture of compounds from plants, providing a consistent level of the active compound of interest or controlling the level of the other natural compounds is difficult. Accordingly, we are working on orally available SCAs, not derived from plants, to address the deleterious issues of medical cannabis described above. If successful, these SCAs could become approved drug products that offer a robustly consistent and safe dosage that allows patient intake to be carefully controlled.

We believe that the development and clinical study of SCAs will reveal that SCAs have several key advantages over medical cannabis, including:

- use of a pure compound (>99.5%) rather than a mixture of compounds;
- ability to test and control dosing, which in turn controls efficacy and side effect levels;
- creation of a reproducible product; and
- ability to engineer novel synthetic analogs to control binding preferences to select receptors, control agonist or antagonist effects of receptor binding (pharmacokinetics and dynamics), modify half-life of the drug in the body, and create pro-drug forms that are only activated in specified tissues, thereby potentially reducing off target side effects.

In addition to the above advantages, testing SCAs in scientific, double-blind clinical trials would help to allay physicians' concerns regarding the therapeutic use of marijuana-based compounds. This change could increase the number of patients that have access to these drug therapies. If clinical trials are successful, there are a number of potential markets and indications for SCAs which we could target, which include individuals suffering from chronic and recurrent pain, diabetes, osteoarthritis, obesity and fatty liver disease.

α7nAChR Platform

Overview

Two of our lead scientists, Prof. Steinman and Dr. Rothbard, previously identified a key receptor for the amyloid proteins associated with diseases like Alzheimer's and Parkinson's disease, called α7nAChR. The α7nAChR is expressed on the surface of both neuronal cells in the brain and on cells of the immune system. The research conducted by Dr. Rothbard and Prof. Steinman has shown that small molecules available as drugs taken by mouth can engage this receptor and potently reduce inflammatory diseases. Dr. Rothbard and Prof. Steinman have shown that this receptor is critical in reducing disease in animal models of multiple sclerosis and RA, as well as heart attack and stroke.

Our efforts to understand the role of the high concentration of small heat shock proteins ("sHsp") found in the lesions in the brains of patients with multiple sclerosis led us to realize that the protein was (i) immune suppressive and (ii) therapeutic in animal 2 models of multiple sclerosis, cardiac and retinal ischemia, and stroke. A significant realization was that amyloid fibrils composed of proteins or small peptides exhibited biological responses equivalent to the sHsps. The fibrils and the sHsps specifically bound and activated macrophages ("MΦ") and regulatory B cells. Crosslinking and precipitation experiments demonstrated that both species bound nAChR and signaled through Jak2/Stat3. We realized that nicotine treatment of experimental autoimmune encephalomyelitis ("EAE") induces an identical pattern of immune suppression as our treatments and exhibits pre-clinical efficacy that is comparable with many of the drugs that are approved for multiple sclerosis (MS) when they were tested in EAE models. Collectively, these observations have informed our strategy to develop an orally available, small molecule agonist of α7nAChR for inflammation and autoimmune diseases.

The α7 subunit of α7nAChR is an integral part of an endogenous immune suppressive pathway, in which activation of the vagus nerve stimulates acetylcholine secretion, which in turn binds α7nAChR on MΦs and regulatory B lymphocytes. Activation of the MΦs initiates an immunosuppressive cascade of events that lead to reduction of pro-inflammatory cytokines, suppression of B and T cell activation and control of inflammation.

In autoimmune diseases like RA, where there is intense inflammation destroying joints, and in multiple sclerosis, where the brain is under attack with damage to vital neurologic circuits, the body's immune system turns against its own tissues. Other diseases ranging from atherosclerosis to gout, also reveal manifestations of an unwanted autoimmune attack.

Activation of the α7nAChR results in a signaling cascade involving Jak2 and Stat3 leading to the conversion of the macrophages to an immune suppressive phenotype and the production of IL-10. IL-10 is known to reduce inflammatory cytokines, most prominently TNF, IL-1, and IL-6. Consequently, α7nAChR agonists should complement anti-TNF therapy, which opens up the possibility of developing a new class of orally available medicines which are anti-inflammatory but much safer than existing medications such as NSAIDS, Cox2 inhibitors, methotrexate, and Janus kinase (JAK) inhibitors. This is because α7nAChR agonists are activating an endogenous regulatory pathway, rather than blocking important pathways needed for diverse processes. The market opportunity arises from the complex and expensive effort by several large and small biotechnology companies in the development of a spectrum of orally available partial agonists specific for α7nAChR. The compounds underwent extensive preclinical assessment and were used in 18 studies comprising 2,670 subjects.

The drugs universally were shown to be safe, but ineffective in trials for neurologic and psychiatric diseases, namely Alzheimer's disease and schizophrenia. In randomized, placebo-controlled clinical trials for cognitive impairment in Alzheimer's disease and schizophrenia, the compounds failed to meet their primary endpoint.

We plan to use these previous studies as a foundation to potentially develop a patentable α7nAChR analog within this family to use as an immune suppressive to treat a range of inflammatory and autoimmune indications including RA, inflammatory bowel disease (IBD), relapsing and progressive forms of multiple sclerosis, atherosclerosis, gout and osteoarthritis. Our scientists have found that the α7 receptor on macrophages and regulatory B lymphocytes are different from the target of the drugs developed so far.

Product Candidates or Indications

We intend to identify, characterize, synthesize, and patent an orally available small molecular weight agonist of α7nAChR by screening non-patented analogs of large numbers of known agonists defined by pharmaceutical companies. We intend to outsource this work to Evotec GMBH, an integrated early discovery organization, and one which we have worked with in the past, specializing in ion channels and transporters, offering clients specialized technologies and scientific expertise to move from target to lead compounds.

Following a safety and efficacy assessment program, we intend to select candidates for pre-clinical development as a prelude to the potential initiation of clinical studies, which could potentially be followed by an Investigational New Drug Application ("IND") to the FDA. Our first intended target indication for its α7nAChR development platform is smoking cessation induced ulcerative colitis.

Outsourcing and Manufacturing

We are currently outsourcing our clinical trials, which are conducted at Oxford University, Edinburgh, U.K. and Groningen, The Netherlands and only involve certain indications under the anti-TNF platform. We expect to continue to outsource our clinical trials and conduct them at (1) in the case of the anti-TNF platform, Oxford University and Groningen, The Netherlands, (2) in the case of the SCAs platform, Hebrew University and Oxford University, and (3) in the case of the α7nAChR platform, to be determined.

We also expect to outsource all of our manufacturing activities, including those activities at the research or clinical stage, with SCAs to be produced at Hebrew University and α7nAChR to be produced by Evotec GMBH and the anti-TNF platform utilizing off-the-shelf adalimumab. In addition, we expect our products to be good manufacturing practice (GMP) grade and produced by accredited contract research organizations (CROs).

Material Agreements

We have entered into material research and licensing agreements (the "Research Agreements") with various universities and parties in order to conduct research to develop potential product candidates. We have also entered into other material consulting and advisory services agreements with various scientists (the "Consulting Agreements") to assist with such research.

Overview of Research Agreements

The Research Agreements include agreements with the Hebrew University and Oxford. For the anti-TNF platform, the Research Agreements with Oxford allow the Company to contribute financially to sponsor the research being conducted for the anti-TNF platform. In return, the Company will receive an exclusive option to license any intellectual property arising from the Research Agreements. There are also license agreements in place whereby we have exclusively licensed certain intellectual property from Oxford.

For the SCA program, we have agreements in place with Hebrew University and Oxford, pursuant to which we intend to conduct research to develop and characterize novel SCAs for the treatment of certain target indications, and to perform early-phase clinical trials. Through the Research Agreements with Hebrew University and Oxford, we established research facilities at the Hebrew University and Oxford, in which the development and testing of new cannabinoids designed and synthesized at the Hebrew University will be facilitated.

The Research Agreements are each described below.

Research Agreements with the Hebrew University

On May 13, 2018, our wholly-owned subsidiary CBR Pharma entered into a research and license agreement (the "2018 Hebrew Agreement") with Yissum Research Development Company of the Hebrew University of Jerusalem, Ltd. ("Yissum"), pursuant to which Yissum granted CBR Pharma a worldwide exclusive license (the "2018 Hebrew License") to develop and commercialize certain patents (the "2018 Hebrew Licensed Patents"), know-how and research results (collectively, the "2018 Hebrew Licensed Technology"), in order to develop, manufacture, market, distribute or sell products, all within the use of the 2018 Hebrew Licensed Technology for the treatment of any and all veterinary and human medical conditions, including obesity, pain, inflammation and arthritis (the "2018 Field").

Pursuant to the 2018 Hebrew Agreement, notwithstanding the grant of the 2018 Hebrew License, Yissum, on behalf of Hebrew University, will retain the right to (i) make, use and practice the 2018 Hebrew Licensed Technology for Hebrew University's own research and educational purposes; (ii) license or otherwise convey to other academic and not-for-profit research organizations the 2018 Hebrew Licensed Technology for use in non-commercial research; and (iii) license or otherwise convey the 2018 Hebrew Licensed Technology to any third party for research or commercial applications outside the 2018 Field.

The 2018 Hebrew Agreement further provides that CBR Pharma is entitled to grant one or more sublicenses to the 2018 Hebrew Licensed Technology for exploitation in the 2018 Field.

All right, title and interest in and to the 2018 Hebrew Licensed Technology vest solely in Yissum, and CBR Pharma will hold and make use of the rights granted pursuant to the 2018 Hebrew License solely in accordance with the terms of the 2018 Hebrew Agreement.

As consideration for the 2018 Hebrew License, CBR Pharma paid Yissum a license fee of $75,000 and agreed to continue to pay an annual license maintenance fee (the "License Maintenance Fee") of $50,000, beginning on May 1, 2019 and thereafter on the first day of May each year. The License Maintenance Fee is non-refundable but may be credited each year against royalties on account of net sales of products made from May 1 to April 30 of each year.

Yissum has also agreed to undertake research and to synthesize chemical compounds that will be used by CBR Pharma, through additional research at both Oxford and Hebrew University, to develop orally active analgesic and anti-inflammatory medications. Compounds will be shipped from Hebrew University to Oxford for use in pre-clinical studies to establish efficacy in pain and inflammation.

Upon the achievement of certain milestones in respect of the chemical compounds derived from the 2018 Hebrew Licensed Technology, CBR Pharma is obligated to make certain payments to Yissum, including but not limited to the following:

Milestone	**Milestone Fee**
Submission of the first IND testing for the FDA	$ 75,000
Commencement of one Phase 1/2 trial with the FDA	$ 100,000
Commencement of one Phase 3 trial with the FDA	$ 150,000
For each product market authorization/clearance (maximum of $500,000)	$ 100,000 (maximum of $500,000)
For every $250 million in accumulated sales of the product until $1 billion in sales is achieved	$ 250,000

CBR Pharma will pay Yissum royalties equal to (i) 3% of the net sales for the first annual $500 million of net sales, and (ii) 5% of the net sales after the net sales are at or in excess of $500 million.

In the event of a sale by CBR Pharma stockholders of their common shares or the transfer or assignment of the 2018 Hebrew Agreement, CBR Pharma is obligated to pay Yissum a fee of 5% of the consideration received by CBR Pharma pursuant to such corporate transaction. In the event of an initial public offering, or a go-public event, CBR Pharma was obligated to issue registered common shares to Yissum equal to 5% of the issued and outstanding common shares, on a fully-diluted basis, concurrently with the closing of such transaction. The Business Combination that was consummated on November 6, 2020, was considered a go-public event, pursuant to which the Company issued 12,028 of its common shares to Yissum prior to the closing of the Business Combination. See Note 11 - Commitments and Contingencies and Note 12 – Stockholders' Equity of the financial statements for the fiscal period ended December 31, 2022 included herein for more information on the shares issued to Yissum as per the research and license agreement.

CBR Pharma has also agreed to reimburse Yissum (to a maximum of $30,000) for costs incurred for patent expenses.

Yissum and CBR Pharma also agreed to establish a research program for which CBR Pharma funded a $400,000 budget for the 12-month period ended May 2019, which is in the process of being extended by an amendment.

The 2018 Hebrew Agreement will terminate upon the occurrence of the later of the following: (i) the expiration of the last of the 2018 Hebrew Licensed Patents; (ii) the expiration of the last exclusivity on any product granted by any regulatory or government body; (iii) the expiration of a continuous period of twenty years during which there was no commercial sale of any product in any country; or (iv) if we elect to obtain an exclusive license to the know-how under the terms of the 2018 Hebrew Agreement, the expiration of such exclusive license.

On November 11, 2019, CBR Pharma entered into an additional research and license agreement (the "2019 Hebrew Agreement") with Yissum, pursuant to which Yissum granted CBR Pharma a worldwide sole and exclusive license (the "2019 Hebrew License") to develop and commercialize certain patents (the "2019 Hebrew Licensed Patents"), know-how and research results (collectively, the "2019 Hebrew Licensed Technology," and together with the 2018 Hebrew Licensed Technology, the "Hebrew Licensed Technology"), in order to develop, manufacture, market, distribute, sell, repair and refurbish products, all within the use of the 2019 Hebrew Licensed Technology for (i) Cannabinoid phenolate metal salts, including mono, di and trivalent metals such as Li, Na, K, Ca, Mg, Zn, Fe and Al and their mixtures with native or synthetic cannabinoids, their pharmaceutical formulations, including for oral and topical administration; and (ii) pharmaceutical formulations, for the administration of cannabinoid chemical derivatives, including any and all veterinary and human medical conditions, including obesity, pain, inflammation and arthritis (the "2019 Field").

Pursuant to the 2019 Hebrew Agreement, notwithstanding the grant of the 2019 Hebrew License, Yissum, on behalf of Hebrew University, will retain the right to (i) make, use and practice the 2019 Hebrew Licensed Technology for Hebrew University's own research and educational purposes, but not for commercial purposes, and subject to the maintenance of confidentiality for any know-how or unpublished patent information contained in the 2019 Hebrew Licensed Technology; (ii) license or otherwise convey to other academic and not-for-profit research organizations the 2019 Hebrew Licensed Technology for use in non-commercial research and subject to the maintenance of confidentiality for any know-how or unpublished patent information contained in the 2019 Hebrew Licensed Technology; and (iii) license or otherwise convey the 2019 Hebrew Licensed Technology to any third party for research or commercial applications outside the 2019 Field, subject to the maintenance of confidentiality for any know-how or unpublished patent information contained in the 2019 Hebrew Licensed Technology.

The 2019 Hebrew Agreement further provides that CBR Pharma is entitled to grant one or more sublicenses to the 2019 Hebrew Licensed Technology for exploitation in the 2019 Field.

All right, title and interest in and to the 2019 Hebrew Licensed Technology vests solely in Yissum, and CBR Pharma will hold and make use of the rights granted pursuant to the 2019 Hebrew License solely in accordance with the terms of the 2019 Hebrew Agreement.

The 2019 Hebrew Licensed Technology will terminate upon the occurrence of the later of the following: (i) the expiration of the last of the 2019 Hebrew Licensed Patents; (ii) the expiration of the last exclusivity on any product granted by any regulatory or government body; (iii) the expiration of a continuous period of twenty years plus any applicable patent extension period, during which there was no commercial sale of any product in any country; or (iv) if we elect to obtain an exclusive license to the know-how under the terms of the 2019 Hebrew Agreement, the expiration of such exclusive license.

On January 1, 2020, CBR Pharma and Yissum entered into the first amendment to the 2018 Hebrew Agreement, which provided for additional research to be done at Yissum on new derivatives of certain molecules. Pursuant to the terms of the First Amendment, the Company will pay Yissum $200,000 per year plus 35% additional for University overhead for the additional research performed by each professor over an 18-month period, starting May 1, 2019. The additional research ended in April 2021 and further preclinical work is expected to be undertaken following research and development of a potentially successful drug delivery method, which is in its late stage development.

Research Agreements with the University of Oxford

On November 1, 2013, our wholly-owned subsidiary 180 LP entered into an agreement (the "First Oxford Agreement") with Oxford, pursuant to which 180 LP will sponsor Oxford's research and development of repurposing anti-TNF for Dupuytren's Contracture.

Pursuant to the First Oxford Agreement, each payment is to be made to ISIS Innovation (now Oxford University Innovation) at different milestones of the project, outlined below:

Milestone		Milestone Fee
Minimum investment completed	£	10,000
Initiation of Phase 2 trial for a licensed product	£	10,000
Initiation of Phase 3 trial for a licensed product	£	10,000
Registerable Phase 3 trial primary endpoint achieved for a licensed product	£	20,000
Any issued U.S. patent of the licensed intellectual property rights	£	5,000
Approval by FDA of a New Drug Application ("NDA") filed by 180 LP or one of its sub-licensees for a licensed product	£	30,000
Approval by EMA of an MAA filed by 180 LP or one of its sub-licensees for a licensed product	£	30,000
First commercial sale of a licensed product by 180 LP or any sub-licensee in the U.S.	£	50,000
First commercial sale of a licensed product by 180 LP or any sub-licensee in the EU	£	50,000

ISIS Innovation is also eligible for royalty payments equal to 0.5% of net sales in any country where there is a valid claim, 0.25% of net sales in other countries and a fee income royalty rate of 7.5% on all up-front, milestone and other one-off payments under or in connection with all sub-licenses and other contracts granted by 180 LP with respect to the licensed technology. The First Oxford Agreement is effective, unless earlier terminated, for so long as the specified patent application remains in effect as an issued patent, pending patent application or supplementary protection certificate or for a term of 20 years, whichever is longer.

On August 15, 2018, CannBioRex Pharma Limited, a company incorporated under the laws of England and Wales ("CannU.K.") and a wholly-owned subsidiary of our wholly-owned subsidiary CBR Pharma, entered into the Research Agreement (the "Second Oxford Agreement") with Oxford, pursuant to which CBR Pharma (through CannU.K.) has sponsored Oxford's research and development of SCAs developed from the Hebrew Licensed Technology. At Oxford, the SCAs generated in the Hebrew University are being tested for analgesic and anti-inflammatory effects in established pre-clinical models.

Pursuant to the Second Oxford Agreement, Oxford undertook a research project (the "Research Project") based around the clinical development of SCAs that are known to exhibit both anti-inflammatory and immunomodulatory properties. The aim of the Research Project was to develop and characterize chemical compounds that are synthesized at Hebrew University to create treatments for chronic pain, RA and other chronic inflammatory conditions, and to eventually obtain regulatory approval to initiate early-phase clinical trials by mid to late 2022 or as soon as possible thereafter. The Second Oxford Agreement had an initial term of one year beginning on March 22, 2019, but was extended by amendment to March 31, 2020, or any later date agreed to by the parties, unless terminated earlier. The Second Oxford Agreement was not extended any further after March 31, 2020, and CannU.K.'s relationship with Oxford continued with additional agreements with Oxford, as described below.

CannU.K., as the sponsor of the Research Project, made the following payments to Oxford pursuant to the Second Oxford Agreement:

Milestone		Milestone Fee
Signature of the Oxford Agreement	£	166,800
6 months post start of the Research Project	£	166,800
9 months post start of the Research Project	£	166,800
12 months post start of the Research Project, after report	£	55,600

On September 18, 2020, CannU.K. entered into another research agreement with Oxford (the "Third Oxford Agreement"), pursuant to which CannU.K. sponsors work led by Prof. Nanchahal at the University of Oxford to investigate the mechanisms underlying fibrosis. In connection with the agreement, CannU.K. initially provided $100,000 and then at 6-month intervals further funding to support the salary of Dr. Lynn Williams and consumables.

CannU.K., as the sponsor, agreed to make the following payments to Oxford pursuant to the Third Oxford Agreement:

Milestone		Amount Due (excluding VAT)
30 days post signing of the Third Oxford Agreement	£	80,000
6 months post signing of the Third Oxford Agreement	£	178,867
12 months post signing of the Third Oxford Agreement	£	178,867
24 months post signing of the Third Oxford Agreement	£	178,867
36 months post signing of the Third Oxford Agreement	£	178,867

On September 21, 2020, CannU.K. entered into another research agreement with Oxford (the "Fourth Oxford Agreement"), pursuant to which CannU.K. agreed to sponsor work at the University of Oxford to develop and characterize novel cannabinoid derived new chemical entities (NCEs) for the treatment of inflammatory diseases towards initiation of early phase clinical trials in patients within a period of 3 years.

CannU.K., as the sponsor, agreed to make the following payments to Oxford pursuant to the Fourth Oxford Agreement:

Milestone		Amount Due (excluding VAT)
30 days post signing of the Fourth Oxford Agreement	£	101,778
6 months post signing of the Fourth Oxford Agreement	£	101,778
12 months post signing of the Fourth Oxford Agreement	£	101,778
18 months post signing of the Fourth Oxford Agreement	£	101,778
24 months post signing of the Fourth Oxford Agreement	£	101,778

On March 22, 2022, CannU.K. entered into an amendment to the Fourth Oxford Agreement, to extend the research period to December 31, 2023, at no additional cost to CannU.K.

On May 24, 2021, CannU.K. entered into another research agreement with Oxford (the "Fifth Oxford Agreement"), pursuant to which CannU.K. will sponsor work at the University of Oxford to conduct a multi-center, randomized, double blind, parallel group, feasibility study of anti-TNF injection for the treatment of adults with frozen shoulder during the pain-predominant phase.

CannU.K., as the sponsor, agreed to make the following payments to Oxford pursuant to the Fifth Oxford Agreement:

Milestone		Amount Due (excluding VAT)
Upon signing of the Fifth Oxford Agreement	£	70,546
6 months post signing of the Fifth Oxford Agreement	£	70,546
12 months post signing of the Fifth Oxford Agreement	£	70,546
24 months post signing of the Fifth Oxford Agreement	£	70,546

Oxford License Agreement

On November 3, 2021, we entered into an exclusive license agreement with Oxford University Innovation Limited ("Oxford License Agreement"), pursuant to which we were granted the rights to certain patents related to the HMGB1 molecule for liver regeneration.

Pursuant to the Oxford License Agreement, the Company agreed to the following payment terms:

Payment		Amount Due
Past patent costs	£	49,207
License fee	£	10,000
Annual maintenance fee	£	3,000

Milestone		Amount Due
Submission of IND	£	25,000
1st Subject dosed in Phase I studies for each product, each indication	£	25,000
1st Subject dosed in Phase II studies for each product, each indication	£	100,000
1st Subject dosed in Phase III studies for each product, each indication	£	50,000
Submission of New Drug Application for each product for each indication	£	50,000
Issued US patent, per patent	£	5,000
Receipt of Regulatory Approval in the US for each product for each indication	£	1,250,000
Receipt of Regulatory Approval in the EU or U.K. for each product for each indication	£	550,000
Receipt of Regulatory Approval in the Japan for each product for each indication	£	150,000
Aggregate Net Sales Exceed $5Bn	£	10,000,000
Aggregate Net Sales Exceed $10Bn	£	50,000,000

Net Sales (US$)	Royalty Rate
< $250M	1.00%
$250M - $1B	2.00%
$1B - $10B	3.00%
> $10B	3.50%

Stanford License Agreement

On May 8, 2018, Katexco Pharmaceuticals Corp, a wholly-owned subsidiary of our wholly-owned subsidiary Katexco, entered into an option agreement (the "Stanford Option") with the Board of Trustees of the Leland Stanford Junior University ("Stanford"), pursuant to which Stanford granted Katexco an option to acquire an exclusive license for the development and commercialization of certain inventions. In consideration for the Stanford Option, Katexco paid Stanford $10,000 (the "Option Payment"), creditable against the license issue fee agreement.

On July 25, 2018 (the "Stanford Effective Date"), Katexco exercised the Stanford Option, and entered into an exclusive license agreement (the "Stanford License Agreement") with Stanford, pursuant to which Katexco was granted the rights to certain U.S. patents related to (i) alpha B-crystallin as a therapy for autoimmune demyelination and (ii) peptides as short as six amino acids that form amyloid fibrils that activate B-1 cells and macrophages and are anti-inflammatory and therapeutic in autoimmune and neurodegenerative diseases (the "Stanford Licensed Patents"). Through the Stanford License Agreement, Katexco established research facilities at Stanford. We will support the clinical development of the lead compound(s), culminating in Phase 1 and Phase 2 clinical trials to establish potential clinical utility in ulcerative colitis indications.

Under the Stanford License Agreement, no rights of Stanford, including intellectual property rights, are granted to Katexco other than those rights granted under the Stanford Licensed Patents.

As consideration for the grant of the Stanford Licensed Patents, Katexco paid Stanford an initial fee of $50,000, inclusive of the Option Payment. The Company also issued 5,574 common shares to Stanford and provided a letter stating the value of such shares. A portion of the shares issued to Stanford were later distributed to five individuals, including our Chief Scientific Officer and co-chairman.

Beginning upon the first anniversary of the Stanford Effective Date and each anniversary thereafter, Katexco will pay Stanford an annual license maintenance fee of $20,000 on the first and second anniversaries and $40,000 on each subsequent anniversary. Furthermore, Katexco is obligated to make the following payments, including (i) $100,000 upon initiation of Phase 2 trial, (ii) $500,000 upon the first FDA approval of a product (the "Licensed Product") resulting from the Stanford Licensed Patents, and (iii) $250,000 upon each new Licensed Product thereafter. Royalties, calculated at 2.5% of net sales (calculated as gross revenue received by Katexco or its sublicensees, their distributors or designees, from the sale, transfer or other disposition of products based on the Stanford Licensed Patents minus 5%), will be payable to Stanford. In addition, Katexco has reimbursed Stanford $51,385 to offset the Stanford Licensed Patent's patenting expenses and will reimburse Stanford for all Stanford Licensed Patent's patenting expenses, including any interference and or re-examination matters, incurred by Stanford after March 3, 2018.

We can terminate the Stanford License Agreement without cause by providing a 30-day notice. In the case of a change of control, upon the assignment of the Stanford License Agreement, Katexco is obligated to pay Stanford a $200,000 change of control fee. The Stanford License Agreement also provides Stanford with the right to purchase for cash up to either (i) 10% or (ii) the percentage necessary for Stanford to maintain its pro rata ownership interest in Katexco, of Katexco's equity securities issued in a private offering. The shares issued to Stanford in connection with the Stanford License Agreement, gave Stanford and the five individuals who received a portion of the shares a total ownership of 2.11% in Katexco's stock, prior to the July 2019, corporate restructuring completed between 180 and each of 180 LP, Katexco and CBR Pharma, pursuant to which 180 LP, Katexco and CBR Pharma became wholly-owned subsidiaries of 180LS (the "Reorganization") under the *Business Corporations Act* (British Columbia).

The Evotec Agreement

On June 7, 2018, our wholly-owned subsidiary Katexco entered into the Evotec Agreement with Evotec, a leading CRO, pursuant to which Evotec was retained to perform certain research services. Pursuant to the Evotec Agreement, the goal of the joint project (the "Evotec Project") is to identify small molecules that pharmacologically stimulate the human ChrFam7a receptor and function. The Evotec Project is being conducted in two phases over a 24-month period where resources are allocated by the steering committee, which is controlled equally by the parties to the Evotec Agreement, on a quarterly basis.

Subject to certain exemptions described in the Evotec Agreement, Katexco owns all intellectual property rights, conceived, invented, discovered or made by Evotec during the performance of its services, other than intellectual property rights owned or controlled by Evotec relating to its already existing technology and components to be used in the services to be provided under the Evotec Agreement.

The Evotec Agreement is subject to a minimum payment of $4,937,500 and a maximum payment of $5,350,250 to Evotec. This program was paused in mid-2019 and the Company expects to re-engage with Evotec in 2023. As of December 31, 2022, the Company has made payments to Evotec in the amount of approximately $1.1 million.

The Petcanna Agreement

On August 20, 2018, we entered into a sublicense agreement with Petcanna Pharma Corp. ("Petcanna"), a private company which was founded by Prof. Sir Marc Feldmann (our Co-Executive Chairman), and Yissum (the "Petcanna Agreement").

Under the Petcanna Agreement, we granted Petcanna an exclusive, worldwide, non-transferable, non-sublicensable sublicense to make commercial use of certain patents related to cyclohexenyl compounds and listed in the Petcanna Agreement (the "Petcanna IP") in order to develop, manufacture, market, distribute or sell products that incorporate the Petcanna IP in products that are intended for the treatment of veterinary medical conditions, initially osteoarthritis.

As consideration for the sublicense, Petcanna agreed to issue to us approximately 9,000,000 of Petcanna's common shares in the fourth quarter of 2018. As of the date of this filing, Petcanna has not issued shares to any shareholder and has not commenced operations. We intend to retain 85% of such shares and transfer 15% of such shares to Yissum. In the event that Yissum does not accept such shares, we will have an obligation to pay Yissum 15% of the-then current fair market value of such shares. Petcanna will also pay a 1% royalty to us on Petcanna's net sales of products that incorporate the Petcanna IP.

All right, title and interest in and to the Petcanna IP, including any improvements to the Petcanna IP, will vest solely in our company.

Unless the parties to the Petcanna Agreement agree otherwise in writing, the Petcanna Agreement will terminate on the occurrence of the later of: (i) the date of expiration of the last of the Petcanna IP, (ii) the date of the final expiration of exclusivity on any Product granted by any regulatory or government body, and (iii) the expiration of a continuous period of twenty (20) years during which there was no First Commercial Sale of any product. The terms "Product" and "First Commercial Sale" apply as they are defined in the Petcanna Agreement. Our ability to grant this sublicense to Petcanna is contingent upon (i) Yissum having the necessary rights to the Hebrew Patent Applications assigned to it from all applicable parties, (ii) Yissum being able to grant a license to us per the terms of the Hebrew Agreement, and (iii) the Hebrew Patent Applications and any related resulting patents being valid and maintained in good standing for the respective terms of the Hebrew Licensing Agreement and the Petcanna Agreement.

Kennedy License Agreement

On September 27, 2019, our wholly-owned subsidiary 180 LP entered into an exclusive license agreement (the "Kennedy License Agreement") with the Kennedy Trust For Rheumatology Research ("Kennedy"), pursuant to which Kennedy granted to 180 LP an exclusive license in the U.S., Japan and member countries of the EU (including the United Kingdom), to certain licensed patents (the "Kennedy Licensed Patents"), including the right to grant sublicenses, and the right to research, develop, sell or manufacture any pharmaceutical product (i) whose research, development, manufacture, use, importation or sale would infringe on the Kennedy Licensed Patents absent the license granted under the Kennedy License Agreement or (ii) containing an antibody that is a fragment of or derived from an antibody whose research, development, manufacture, use, importation or sale would infringe on the Kennedy Licensed Patents absent the license granted under the Kennedy License Agreement, for all human uses, including the diagnosis, prophylaxis and treatment of diseases and conditions.

Under the Kennedy License Agreement, Kennedy reserves the perpetual, irrevocable, non-exclusive, royalty-free, sublicensable, worldwide right for the Kennedy Licensed Patents and its affiliates, employees, students and other researchers to carry out any acts which would otherwise infringe on the Kennedy Licensed Patents for the purposes of teaching and carrying out research and development, including the right to accept external sponsorship for such research and development and the right to grant sub-licenses for the same purposes.

As consideration for the grant of the Kennedy Licensed Patents, 180 LP paid Kennedy an upfront fee of £60,000, and will also pay Kennedy royalties equal to (i) 1% of the net sales for the first annual $1 billion of net sales, and (ii) 2% of the net sales after the net sales are at or in excess of $1 billion, as well as 25% of all sublicense revenue, provided that the amount of such percentage of sublicense revenue based on amounts which constitute royalties shall not be less than 1% on the first cumulative $1 billion of net sales of the products sold by such sublicenses or their affiliates, and 2% on that portion of the cumulative net sales of the products sold by such sublicenses or their affiliates in excess of $1 billion.

The term of the royalties paid to Kennedy will expire on the later of (i) the last valid claim of a patent included in the Kennedy Licensed Patents which covers or claims the exploitation of a product in the applicable country; (ii) the expiration of regulatory exclusivity for the product in the country; or (iii) 10 years from first commercial sale of the product in the country.

We may terminate the Kennedy License Agreement without cause by providing 90-days' notice.

Kinexum Agreement

On January 13, 2023, we entered into a contract with Kinexum in the ordinary course of business (the "MSA"). Pursuant to the MSA, Kinexum will provide assistance to the Company in connection with the Conditional Marketing Authorisation (CMA) and Marketing Approval Application (MAA) which the Company expects to submit to the MHRA in connection with the Company's planned use of adalimumab to treat progressive early-stage Dupuytren's disease. Including the costs associated with the Kinexum contract, the Company anticipates that it will spend approximately $900,000 to $1,000,000, cumulative in the three quarters ending September 30, 2023 for activities associated with the MHRA filing and other regulatory preparation.

Consulting Agreements

The Consulting Agreements are each described below.

Prof. Jagdeep Nanchahal Consulting Agreement

On February 25, 2021, we (and CannBioRex Pharma Limited, which was added as a party to the agreement later), entered into a Consultancy Agreement dated February 22, 2021, and effective December 1, 2020, with Prof. Jagdeep Nanchahal (as amended, the "Consulting Agreement"). Prof. Nanchahal has been providing services to the Company and/or its subsidiaries since 2014 and is currently a greater than 5% stockholder of the Company and the Chairman of our Clinical Advisory Board.

On March 31, 2021, we entered into a First Amendment to Consultancy Agreement with Prof. Jagdeep Nanchahal, which amended the Consultancy Agreement entered into with Prof. Nanchahal on February 25, 2021, to include CannBioRex Pharma Limited, a corporation incorporated and registered in England and Wales ("CannBioRex"), and an indirect wholly-owned subsidiary of the Company, as a party thereto, and to update the prior Consultancy Agreement to provide for cash payments due to Prof. Nanchahal to be paid by CannBioRex, for tax purposes, provide for CannBioRex to be party to certain other provisions of the agreement and to provide for the timing of certain cash bonuses due under the terms of the agreement.

Prof. Nanchahal is a surgeon scientist focusing on defining the molecular mechanisms of common diseases and translating his findings through to early phase clinical trials. He undertook his PhD, funded by the U.K. Medical Research Council, whilst a medical student in London and led a lab group funded by external grants throughout his surgical training. After completing fellowships in microsurgery and hand surgery in the USA and Australia, he was appointed as a senior lecturer at Imperial College. His research is focused on promoting tissue regeneration by targeting endogenous stem cells and reducing fibrosis. In 2013 his group identified anti-tumor necrosis factor (TNF) as therapeutic target for Dupuytren's Contracture, a common fibrotic condition of the hand. He is currently leading a Phase 2b clinical trial funded by the Wellcome Trust and Department of Health to assess the efficacy of local administration of anti-TNF in patients with early-stage Dupuytren's Contracture and a clinical trial for patients with early-stage frozen shoulder. He is a proponent of evidence-based medicine and was the only plastic surgery member of the NICE Guidance Development Groups on complex and non-complex fractures. He was a member of the group that wrote the Standards for the Management of Open Fractures published in 2020. This is an open-source publication to facilitate the care of patients with these severe injuries.

Pursuant to the Consulting Agreement, Prof. Nanchahal agreed, during the term of the agreement, to serve as a consultant to the Company and provide such services as the Chief Executive Officer and/or the board of directors of the Company shall request from time to time, including but not be limited to: (1) conducting clinical trials in the fields of Dupuytren's Contracture, frozen shoulder and post-operative delirium/cognitive decline; and (2) conducting laboratory research in other fibrotic disorders, including fibrosis of the liver and lung (collectively, the "Services").

In consideration for providing the Services, the Company (through CannBioRex Pharma Limited) agreed to pay Prof. Nanchahal 15,000 British Pounds (GBP) per month (approximately $20,800) during the term of the agreement, increasing to GBP 23,000 (approximately $32,000) on the date (a) of publication of the data from the phase 2b clinical trial for Dupuytren's Contracture (RIDD) and (b) the date that the Company has successfully raised over $15 million in capital. The fee will increase annually thereafter to reflect progression in other clinical trials and laboratory research as approved by the board of directors. The Company also agreed to pay Prof. Nanchahal a bonus ("Bonus 1") in the sum of GBP 100,000 upon submission of the Dupuytren's Contracture clinical trial data for publication in a peer-reviewed journal, which submission occurred in December 2021, and which bonus was paid in December 2021. In addition, for prior work performed, including completion of the recruitment to the RIDD (Dupuytren's) trial, the Company agreed to pay Prof. Nanchahal GBP 434,673 (approximately $605,000) ("Bonus 2"). At the election of Prof. Nanchahal, Bonus 2 shall be paid at least 50% (fifty percent) or more, as Prof. Nanchahal elects, in shares of the Company's common stock, at a share price of $60.00 per share, or the share price on the date of the grant, whichever is lower, with the remainder paid in GBP. Bonus 2 shall be deemed earned and payable upon the Company raising a minimum of $15 million in additional funding, through the sale of debt or equity, after December 1, 2020 (the "Vesting Date") and shall not be accrued, due or payable prior to such Vesting Date. Bonus 2 shall be payable by the Company within 30 calendar days of the Vesting Date. Finally, Prof. Nanchahal shall receive another one-time bonus ("Bonus 3") of GBP 5,000 (approximately $7,000) on enrollment of the first patient to the phase 2 frozen shoulder trial, and another one-time bonus ("Bonus 4") of GBP 5,000 (approximately $7,000) for enrollment of the first patient to the phase 2 delirium/POCD trial. On March 30, 2021, the Company issued Prof. Nanchahal 5,035 shares of Company common stock in lieu of GBP 217,337 and on April 15, 2021, the Company issued Prof. Nanchahal 1,886 shares of Company common stock in lieu of GBP 82,588. The Company also waived the requirement for the Company having to raise $15 million in order for Prof. Nanchahal to agree to receive an aggregate of GBP 300,000 via the issuance of shares. Prof. Nanchahal agreed that the remaining GBP 134,673 that is due pursuant to Bonus 2 shall be paid after the Company has raised a minimum of $15 million in additional funding. On August 23, 2021, at the request of Prof. Nanchahal, the Company agreed to issue Prof. Nanchahal 3,077 shares of common stock in consideration for the remaining 31% (or 134,749 GBP, or $184,606) of Bonus 2, based on a $60.00 per share price. The shares were issued under the Company's 2020 Omnibus Incentive Plan, which has been approved by stockholders.

Effective on April 27, 2022, we and CannBioRex entered into a Second Amendment to Consulting Agreement with Prof. Jagdeep Nanchahal (the "Second Nanchahal Amendment"). Pursuant to the Second Nanchahal Amendment, Prof. Nanchahal agreed that upon acceptance of the data for the phase 2b clinical trial for Dupuytren's disease for publication (which occurred March 1, 2022, subject to editing and final approvals), his monthly fee was increased to £23,000, provided that £4,000 of such increase shall be accrued and £19,000 per month of such fees shall be payable per the payroll practices of the Company in cash by the Company starting effective March 1, 2022, and until the earlier of (a) November 1, 2022 or (b) such time as the Board of Directors determines that the Company has sufficient cash on hand to pay such Accrued Amounts, which the Company expects will not be until it has raised a minimum of $15,000,000 (the "Funding Determination Date"), at which time all accrued amounts shall be due.

On December 28, 2022, we and CannBioRex, entered into a Third Amendment to Consultancy Agreement with Prof. Nanchahal (the "Third Nanchahal Amendment"). The Third Nanchahal Amendment amended the Consultancy Agreement to provide that the monthly cash fee payable to Prof. Nanchahal pursuant to such agreement would remain at its then current rate, £23,000 per month, through December 31, 2022, and then increase to £35,000 per month during the term of the Consultancy Agreement from January 1, 2023, until the end of the term of the Consultancy Agreement (collectively, the "Fee"). The Third Nanchahal Amendment also provided that the Fee will be adjusted yearly with the recommendation of the Board of Directors or the Compensation Committee of the Company, which will consider in its determination of the amount of such increase, the U.K. consumer price index and Prof. Nanchahal's contributions to advancing the Company's mission, among other things. The Third Nanchahal Amendment also provided that in the event the Consultancy Agreement is terminated by the Company for any reason other than cause, Prof. Nanchahal is entitled to a lump sum payment of 12 months of his monthly fee as at the date of termination.

Notwithstanding the above, the board of directors or Compensation Committee of the Company may grant Prof. Nanchahal additional bonuses from time to time in their discretion, in cash, stock or options.

The Consulting Agreement has an initial term of three years, and renews thereafter for additional three-year terms, until terminated as provided in the agreement. The Consulting Agreement can be terminated by either party with 12 months prior written notice (provided the Company's right to terminate the agreement may only be exercised if Prof. Nanchahal fails to perform his required duties under the Consulting Agreement), or by the Company immediately if (a) Prof. Nanchahal fails or neglects efficiently and diligently to perform the Services or is guilty of any breach of its or his obligations under the agreement (including any consent granted under it); (b) Prof. Nanchahal is guilty of any fraud or dishonesty or acts in a manner (whether in the performance of the Services or otherwise) which, in the reasonable opinion of the Company, has brought or is likely to bring Prof. Nanchahal, the Company or any of its affiliates into disrepute or is convicted of an arrestable offence (other than a road traffic offence for which a non-custodial penalty is imposed); or (c) Prof. Nanchahal becomes bankrupt or makes any arrangement or composition with his creditors. If the Consulting Agreement is terminated by the Company for any reason other than cause, Prof. Nanchahal is entitled to a lump sum payment of 12 months of his fee as at the date of termination.

The Consulting Agreement includes a 12 month non-compete and non-solicitation obligation of Prof. Nanchahal, preventing him from competing against the Company in any part of any country in which he was actively engaged in the Company's business, subject to certain exceptions, including research conducted at the University of Oxford. The Consulting Agreement also includes customary confidentiality and assignment of inventions provisions, in each case subject to the Company's previously existing agreements with various universities, including the University of Oxford, where Prof. Nanchahal serves as a Professor of Hand, Plastic and Reconstructive Surgery.

Service Agreement with Prof. Sir Marc Feldmann

On June 1, 2018, CannBioRex Pharma Limited ("CannBioRex") and Prof. Sir Marc Feldmann Ph.D., our Executive Co-Chairman, entered into a Service Agreement (the "Feldmann Employment Agreement"). Pursuant to the Feldmann Employment Agreement, Prof. Sir Feldmann serves as the Chairman, CEO and Executive Director of CannBioRex or in such other capacity consistent with his status. Prof. Sir Feldmann's responsibilities include those customary for the roles in which he serves. Prof. Sir Feldmann receives compensation of £115,000 per year, with annual compensation reviewed by the Board and eligibility for discretionary bonuses, as determined by the Board. CannBioRex also reimburses Prof. Sir Feldmann's travelling and other business expenses.

Pursuant to the Feldmann Employment Agreement, all intellectual property rights created by Prof. Sir Feldmann or related to his employment belong to and vest in CannBioRex.

The Feldmann Employment Agreement contains a customary non-compete clause prohibiting Prof. Sir Feldmann from working for any competing businesses during the term of his employment, or holding equity in other businesses, except he may hold or beneficially own securities of publicly-traded companies if the aggregate beneficial interests of him and his family does not exceed 5% of that class of securities.

Prof. Sir Feldmann is also prohibited for 12 months following termination (the "Post-Termination Period") be involved in any capacity with a competing business or potential joint venture in the United Kingdom or in any other country. During the Post-Termination Period, he may not solicit business from CannBioRex and its affiliates' customers; or any company with whom he was activity involved in the course of his employment; or about which he holds confidential information. Prof. Sir Feldmann further covenants to not interfere with CannBioRex's business relationships by inducing or attempting to induce suppliers to take adverse actions during the Post-Termination Period. He also agrees not to induce or attempt to induce any CannBioRex employee to leave the company during the Post-Termination Period. The Feldmann Employment Agreement contains customary non-disclosure and confidentiality obligations, sick leave and vacation time.

The Feldmann Employment Agreement does not have a fixed term. Either party may terminate the agreement by delivering written notice 9 months in advance. CannBioRex may also terminate the Feldmann Employment Agreement at any time with immediate effect by giving written notice. If CannBioRex terminates Prof. Sir Feldmann's employment without providing 9 months written notice, he will become entitled to a payment equal to his basic salary he would have been entitled to receive if 9 months' notice were given. The governing law for the Feldmann Employment Agreement is the law of England.

The Board of Directors, as recommended by the Compensation Committee of the Company (and/or the Compensation Committee) or separately, may also award Prof. Sir Feldmann bonuses from time to time (in stock, options, cash, or other forms of consideration) in its discretion.

On November 17, 2021, the Board of Directors, as recommended by the Compensation Committee, increased the salary of Prof. Sir Feldmann to $225,000 per annum.

Effective on April 27, 2022, CannBioRex and Prof. Sir Feldmann entered into an amendment to the consulting agreement, pursuant to which the parties agreed effective March 1, 2022, that Sir Feldmann's salary would be reduced by $225,000 (100%), and that such reduced amounts would be accrued and paid on the Funding Determination Date.

Lawrence Steinman, M.D. Consulting Agreement

On November 17, 2021, and effective on November 1, 2021, the Company entered into a Consulting Agreement with Lawrence Steinman, M.D., the Company's Executive Co-Chairman (the "Consulting Agreement"). Pursuant to the Consulting Agreement, Dr. Steinman agreed to provide certain consulting services to the Company, including, but not limited to, participating in defining and setting strategic objectives of the Company; actively seeking out acquisition and merger candidates; and having primary scientific responsibility for the Company's á7nAChR platform (collectively, the "Services"). The term of the agreement is for one year (the "Initial Term"); provided that the agreement automatically extends for additional one year periods after the Initial Term (each an "Automatic Renewal Term" and the Initial Term together with all Automatic Renewal Terms, if any, the "Term"), subject to the Renewal Requirements (described below), in the event that neither party provided the other written notice of their intent not to automatically extend the term of the agreement at least 30 days prior to the end of the Initial Term or any Automatic Renewal Term. The Term can only be extended for an Automatic Renewal Term, provided that (i) Dr. Steinman is re-elected to the Board of Directors (the "Board") at the Annual Meeting of Stockholders of the Company immediately preceding the date that such Automatic Renewal Term begins; (ii) the Board affirms his appointment as Co-Chairman for the applicable Automatic Renewal Term (or fails to appoint someone else as Co-Chairman prior to such applicable Automatic Renewal Term) and (iii) Dr. Steinman is continuing in his role of having the responsibility for the scientific development for the Company's á7nAChR platform (the "Renewal Requirements"). The Consulting Agreement also expires immediately upon the earlier of: (i) the date upon which Dr. Steinman no longer serves as Co-Chairman and no longer has primary scientific responsibility for our á7nAChR platform; and (ii) any earlier date requested by either (1) the Company (as evidenced by a vote of a majority of the Board (excluding Dr. Steinman) at a meeting of the Board), or (2) Dr. Steinman (as evidenced by written notice from Dr. Steinman to the Board). Additionally, the Company may terminate the Consulting Agreement immediately and without prior notice if Dr. Steinman is unable or refuses to perform the Services, and either party may terminate the Consulting Agreement immediately and without prior notice if the other party is in breach of any material provision of the Consulting Agreement.

The Company agreed to pay Dr. Steinman $225,000 per year during the term of the agreement, along with a one-time payment of $43,750, representing the difference between his old compensation and new compensation, dating back to April 1, 2021. Pursuant to the Consulting Agreement, Dr. Steinman agreed to not compete against the Company, unless approved in writing by the Board of Directors, during the term of the agreement, and also agreed to certain customary confidentiality provisions and assignment of inventions requirements. The Consulting Agreement also has a 12-month non-solicitation prohibition following its termination.

On December 8, 2021, Dr. Steinman was also granted stock options to purchase 1,250 shares of the Company's common stock, which have a term of 10 years; an exercise price equal to the fair market value of the Company's common stock on the date of grant, $79.00 per share, and are subject to the Company's 2020 Omnibus Incentive Plan. In addition, beginning in calendar year 2022, for each year during the Term of the Consulting Agreement, the Company will, subject to future approval by the Board, grant Dr. Steinman $125,000 of value of equity compensation. Future equity grants will vest over a 48-month period and be in accordance with the Plan. Timing of the future grants, nature of the equity grants (e.g., RSU, PSU, restricted stock, etc.) and any changes in the value of future equity will be recommended by the Company's Compensation Committee and/or Audit Committee and approved by the Board.

Effective on April 27, 2022, the Company and Dr. Steinman entered into an amendment to the consulting agreement, pursuant to which the parties agreed effective March 1, 2022, that Dr. Steinman's salary would be reduced by $56,250 (25%), and that such reduced amount would be accrued and paid on the Funding Determination Date.

Intellectual Property

Our success depends in significant part on our ability to protect the proprietary elements of our product candidates, technology and know-how, to operate without infringing on the proprietary rights of others, and to defend challenges and oppositions from others and prevent others from infringing on our proprietary rights. We have sought, and will continue to seek, patent protection in the U.S., U.K., Europe and other countries for our proprietary technologies. Our intellectual property portfolio as of March 31, 2023 includes sixteen patent families with issued and/or pending claims, pharmaceutical formulations, drug delivery and the therapeutic uses of SCAs, as well as know-how and trade secrets, when including patents held by our partners of which we have exclusive rights.

Within the U.S., we and/or our partners have licensed twelve issued patents and twelve pending patent applications under active prosecution. Outside of the U.S., assuming the E.U. as a single jurisdiction, there are an additional twelve issued patents and 23 pending patent applications under active prosecution. Our policy is to seek patent protection for the technology, inventions and improvements that we consider important to the development of our business, but only in those cases where we believe that the costs of obtaining patent protection is justified by the commercial potential of the technology, and typically only in those jurisdictions that we believe present significant commercial opportunities. We also rely on trademarks, trade secrets, know-how and continuing innovation to develop and maintain our competitive position.

The term of individual patents depends upon the countries in which they are obtained. In most countries in which we have filed, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the U.S., a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office ("USPTO"), in granting a patent, or may be shortened if a patent is terminally disclaimed over another patent.

The term of a patent that covers an FDA-approved drug may also be eligible for extension, which permits term restoration as compensation for the term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act) permits an extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Extensions cannot extend the remaining term of a patent beyond 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions to extend the term of a patent that covers an approved drug are available in Europe and other non-U.S. jurisdictions.

To protect our rights to any of our issued patents and proprietary information, we may need to litigate against infringing third parties, avail ourselves of the courts or participate in hearings to determine the scope and validity of those patents or other proprietary rights.

We also rely on trade secret protection for our confidential and proprietary information. Our policy requires our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us.

From time to time, in the normal course of our operations, we will be a party to litigation and other dispute matters and claims relating to intellectual property.

180LS' Research, Development and License Agreements

180LS has entered into research and licensing agreements with various parties, including the Hebrew University of Jerusalem and Oxford. For information regarding these agreements, see "Material Agreements", above.

Competition

Below is a description of the competitive environment of each of our product candidate development platforms and potential product candidates.

Dupuytren's Contracture

Our treatment is for early-stage Dupuytren's Contracture, for which, to our knowledge, there is no approved treatment. Existing treatments focus on late stage Dupuytren's Contracture, when the fingers are irreversibly curled into the palm. Surgery remains the typical standard treatment, but the relatively long post-operative rehabilitation has driven the reach for less invasive techniques. Xiaflex, a drug developed by Auxilium, has shown effective in treating patients with developed contractures although many patients experience relatively mild side effects. An alternative approach is disruption of the late-stage cords with a needle and data from a comparative clinical trial published in the Journal of Bone and Joint Surgery (American) in 2018 showed similar recurrence rates between collagenase and percutaneous needle fasciotomy at 2 years. A clinical trial funded by the National Institute for Health Research Health Technology Assessment Programme (U.K.) is currently underway in the U.K., comparing the cost efficacy of surgery for Dupuytren's Contracture with collagenase treatment. The aims of the study are to determine (i) whether collagenase injections are as effective and as safe as surgery for treating this condition and (ii) the costs of both treatments.

SCAs

Following the acquisition of *GW Pharmaceuticals PLC* and its Epidiolex (cannabidiol) and Sativex (THC & CBD) franchises, by *Jazz Pharmaceuticals (Ireland),* Jazz Pharma has become the prominent player in the cannabidiol space. Epidiolex is an oral cannabidiol solution approved for treating seizures in a range of childhood epileptic diseases, including Dravet's syndrome (formerly known as severe myoclonic epilepsy of infancy), Rett Syndrome, and Lennox-Gastaut Syndrome. Jazz Pharma is exploring whether Epidiolex is effective in Sturge-Weber Syndrome, in which abnormal development of blood vessels leads to defects in the brain, skin, and eyes from birth, and more broadly in Autism Spectrum Disorder. Clinical trials sponsored by Jazz Pharma testing effectiveness of Epidiolex in autoimmune diseases such as multiple sclerosis, ulcerative colitis, and Crohn's Disease are ongoing. Collectively, these efforts represent the most extensive cannabidiol clinical program.

To our knowledge, multiple companies are working in the cannabis therapeutic area and are pursuing regulatory approval for their product candidates, including:

- *Cardiol Therapeutics (Canada)* which is evaluating the effectiveness of their oral CBD liquid formulation on myocardial recovery in patients presenting with acute myocarditis.

- *Zynerba Pharmaceuticals (Pennsylvania)* which focuses on pharmaceutically produced transdermal cannabinoid therapies for rare and near-rare neuropsychiatric disorders. Zynerba currently is evaluating Zygel™, a patent-protected transdermal CBD gel for the treatment of Fragile X syndrome, for which it filed an NDA with the FDA, developmental and epileptic encephalopathies, 22q deletion syndrome, and Autism Spectrum Disorder.

- *Orcosa, (New Jersey) which* is testing their CBD, Oravexx (oral disintegrating tablets), to manage pain and inflammation with the hope of reducing clinical reliance on opioids. The particular indication is pain associated with osteoarthritis in the knee in a Phase 2 trial.

- *Stero Biotechs (Israel) which* sponsored a phase II trial in GVHD demonstrating that CBD administration (synthetic CBD in olive oil), either enhanced the therapeutic effect of steroids or reduced the steroid dosage while maintaining or improving the steroid's original therapeutic effect. Additional clinical trials are a Phase IIa, multi centered trial in steroid dependent Crohn's disease, a Phase IIa trial in chronic urticaia (Hives), and Phase I/II trial in severe Covid-19.

a7nAChR

Antibodies selective for TNFa (Humira) or TNFa receptor (Remicade) and nucleic acid aptamers are injectable reagents, which by their inherent nature have clinical limitations. An orally bioavailable inhibitor of TNFa is a natural complementary reagent to the antibody or aptamer strategy. This is particularly attractive if the mode of action differs between the varying therapeutic reagents. The antibodies and aptamers both are designed to interfere with TNFa signaling, whereas the orally bioavailable drug is an a7 nicotinic acetyl choline receptor agonist known to activate the vagus nerve and the brain- immune system interface.

The 180LS program to develop an orally bioavailable inhibitor of TNFa secretion has significant competition. The most prominent is the collection of Jak inhibitors (Xeljanz, Cibinqo, Olumiant, Rinvoq and Jyseleca) approved for treatment of rheumatoid arthritis, psoriatic arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, ulcerative colitis, atopic dermatitis and alopecia areata. The mode of action is the inhibition of the Jak-Stat pathway principally in cells of the macrophage lineages known to secrete a variety of proinflammatory cytokines including TNFa. The commercial success of these reagents provides practical support for the importance of developing an orally bioavailable product. These drugs are not involved in acetylcholine receptor pathway. Attenua Pharma, a small biotechnology that was using an α7nAChR agonist, bradanicline, in Phase 2 clinical trials for chronic cough was acquired by Coda therapeutics and this program has been discontinued.

The electroceutical companies can be viewed as competition, or a vast proof-of-concept. Because in many respects, the α7nAChR program can be considered as a chemical stimulation of the vagus nerve, and each of the indications benefiting from electrical stimulation, should be amenable to chemical stimulation. To our knowledge, the company closest to an approved product for inflammatory indications is SetPoint Medical Corporation, which has active for inflammatory bowel disease and rheumatoid arthritis. Their device is a miniaturized stimulator implant, which is surgically placed under general anesthesia on the vagus nerve through a small incision on the left side of the neck. An unexpected result is that a short electrical pulse leads to an extended period of reduction of inflammatory cytokines, of the order of 8-10 hours.

A final consideration is that each of the large pharmaceutical companies that initially developed α7nAChR agonists could revitalize their programs and use their drugs in clinical trials for inflammatory indications.

The electroceutical companies can be viewed as competition, or a vast proof-of-concept. Because in many respects, the α7nAChR program can be viewed as a chemical stimulation of the vagus nerve, and each of the indications benefiting from electrical stimulation, should be amenable to chemical stimulation.

Lastly, each of the large pharmaceutical companies that initially developed α7nAChR agonists could revitalize their programs and use their drugs in clinical trials for inflammatory indications.

Government Regulation

We have obtained regulatory approvals from the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) and the Dutch Centrale Commissie Mensgebonden Onderzoek (CCMO), as well as from the relevant accredited ethics committees, in order to perform clinical trials in the U.K. and The Netherlands solely for indications under the anti-TNF platform. Following the successful results of the Phase 2b Dupuytren's Contracture clinical trial, we are preparing a conditional marketing authorization application to be filed with the MHRA. We have not held any meetings with, and no applications or requests for approval have been submitted to, the U.S. Food and Drug Administration ("FDA") for any indications or products under the anti-TNF platform at this time.

FDA Approval Process

In the U.S., pharmaceutical products, including drugs and biologics, are subject to extensive regulation by FDA. Under the U.S. Federal Food, Drug, and Cosmetic Act (the "FDC Act"), a "*drug*" is defined to include "*articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals*" and "*articles (other than food) intended to affect the structure or any function of the body of man or other animals.*" 21 USC 321(g). Like all drugs, biological products are also used for the treatment, prevention or cure of disease in humans. However, in contrast to chemically synthesized small molecular weight drugs, which have a well-defined structure and can be thoroughly characterized, biological products are generally derived from living material, such as human, animal, or microorganism, are complex in structure, and thus are always fully characterized. The U.S. Public Health Servicer Act (the "PHS Act") defines a biological product as a "*virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product … applicable to the prevention, treatment, or cure of a disease or condition of human beings.*" 42 USC 262(i). FDA regulations and policies have established that biological products include blood-derived products, vaccines, in vivo diagnostic allergenic products, immunoglobulin products, products containing cells or microorganisms, and most protein products. Biological products subject to the PHS Act also meet the definition of *drugs* under the FDC Act. Biological products are a subset of drugs, and therefore both are regulated under provisions of the FDC Act. However, only biological products are licensed under section 351 of the PHS Act, although some therapeutic protein products have been approved under section 505 of the FDC Act rather than the PHS Act.)

The FDC Act, PHS Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of drugs and biologics. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as imposition of clinical holds, FDA refusal to approve pending NDAs or the FDA's Biologics License Application (BLAs) or supplements to approved NDAs/BLAs, withdrawal of approvals, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Drug and biologic development in the U.S. typically involves pre-clinical laboratory and animal tests, the submission to the FDA of an IND, which must become effective before clinical testing may commence. For commercial approval, the sponsor must submit adequate tests by all methods reasonably applicable to show that the drug/biologic is safe for use under the conditions prescribed, recommended or suggested in the proposed labeling. The sponsor must also submit substantial evidence, generally consisting of adequate, well-controlled clinical trials to establish that the drug/biologic will have the effect it purports or is represented to have under the conditions of use prescribed, recommended or suggested in the proposed labeling, including meeting FDA standards for safety, and efficacy for drugs or purity and potency for biologics. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product candidate or disease.

Pre-clinical tests include laboratory evaluation of product candidate chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product candidate. The conduct of the pre-clinical tests must comply with federal regulations and requirements, including FDA's Good Laboratory Practice ("GLP"), Good Clinical Practice ("GCP"), and Good Manufacturing Practice regulations ("GMP") regulations and the U.S. Department of Agriculture's regulations implementing the Animal Welfare Act of 1996. The results of pre-clinical testing are submitted to the FDA as part of an IND along with other information, including information about product candidate chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term pre-clinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has not imposed a clinical hold on the IND or otherwise commented or questioned the IND within this 30-day period, the IND is deemed issued, and the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug/biologic to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with GCP, an international standard and U.S. legal requirement meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors, (ii) in compliance with other federal regulations, and (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The trial protocol and informed consent information for patients in clinical trials must also be submitted to an Institutional Review Board ("IRB"), for approval. An IRB may also prevent a clinical trial from beginning or require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or may impose other conditions.

Clinical trials to support NDAs/BLAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap or otherwise vary in particular circumstances. In Phase 1, the initial introduction of the drug/biologic into healthy human subjects or patients, the drug/biologic is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug/biologic for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug/biologic and to provide adequate information for the labeling of the drug/biologic. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug/biologic. The FDA may, however, determine that a single Phase 3 trial with other confirmatory evidence may be sufficient in some instances. In some cases, the FDA may require post-market studies, known as Phase 4 studies, to be conducted as a condition of approval in order to gather additional information on the drug's/biologic's effect in various populations and any side effects associated with long-term use. Depending on the risks posed by the drugs/biologics, other post-market requirements may be imposed.

In response to specific requirements set forth in the 21st Century Cures Act to address the need for greater patient participation in drug development and evaluation, the FDA has issued its Plan for Issuances of Focused Drug Development Guidance, pursuant to which the FDA will issue a series of guidances intended to address, in a stepwise manner, how stakeholders can collect and submit patient experience data and other relevant information from patients and caregivers for medical product development and regulatory decision making. The guidances are expected to facilitate the advancement and use of systematic approaches to collect and use robust and meaningful patient and caregiver input that can better inform medical product development and regulatory decision making. To date, the FDA has issued three of the planned four guidances on these issues. We expect the issue of patient-centric drug development and evaluation to increase in priority and be more of a factor in clinical trial design, moving forward.

After completion of the required clinical testing, a New Drug Application ("NDA")/BLA is prepared and submitted to the FDA. The FDA approval of the NDA/BLA is required before marketing of the product candidate may begin in the U.S. The NDA/BLA must include the results of all pre-clinical, clinical, and other testing and a compilation of data relating to the product candidate's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA/BLA is substantial. Under federal law, the submission of most NDAs/BLAs is also subject to an application user fee, which, for the fiscal year 2023, is in the amount of approximately $3.2 million (where clinical data is required).

The FDA has 60 days from its receipt of an NDA/BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. Under the Prescription Drug User Fee Act, the FDA has agreed to certain performance goals in the review of NDAs/BLAs. The FDA's current performance goals call for the FDA to complete review of 90 percent of standard (non-priority) NDAs/BLAs within 10 months of receipt and within six months for priority NDAs/BLAs, but two additional months are added to standard and priority NDAs/BLAs for a new molecular entity/reference biologic. A drug/biologic is eligible for priority review if it addresses an unmet medical need in a serious or life-threatening disease or condition. The review process for both standard and priority review may be extended by FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission. These timelines are not legally binding on the FDA.

The FDA may also refer applications for novel drug/biologic products, or drug/biologic products that present difficult questions of safety or efficacy, to an advisory committee, which is typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA/BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product candidate unless compliance with GMPs, is satisfactory and the NDA/BLA contains data that provide substantial evidence that the drug is safe and effective, or the biologic meets the standards for safety, purity, and potency in the indication studied.

After the FDA evaluates the NDA/BLA and the manufacturing facilities, the FDA issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA/BLA, the FDA will issue an approval letter. The FDA has committed to reviewing 90 percent of resubmissions within two or six months depending on the type of information included. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

An approval letter authorizes commercial marketing of the drug/biologic with specific prescribing information for specific indications. As a condition of NDA/BLA approval, the FDA may require a Risk Evaluation and Mitigation Strategy ("REMS"), to help ensure that the benefits of the drug/biologic outweigh the potential risks. REMS can include medication guides, communication plans for health care professionals, and Elements to Assure Safe Use (ETASU). ETASU can include, but is not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug/biologic. Moreover, product candidate approval may require substantial post approval testing and surveillance to monitor the drug's/biologic's safety or efficacy. Once granted, product candidate approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

During the declaration of the COVID public health emergency FDA has been exercising enforcement discretion with respect to certain classes of products and has provided for the issuance of Emergency Use Authorizations (EUAs) which have enabled a number of products to enter the market without formal conventional FDA clearance or approval, and has also drawn FDA resources away from non-COVID related products. The U.S government has since declared the termination of the public health emergency effective May 11, 2023, and thus products authorized by EUAs or afforded enforcement discretion based on the COVID emergency will likely return to conventional clearance and approval requirements.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of certain FDA-regulated products, including prescription drugs/biologics, are required to register and disclose certain clinical trial information on a public website maintained by the U.S. National Institutes of Health. Information related to the product candidate, patient population, phase of investigation, study sites and investigator, and other aspects of the clinical trial is made public as part of the registration. Sponsors are also obligated to disclose the results of these trials after completion. The deadline for submitting the results of these trials can be extended for up to two years if the sponsor certifies that it is seeking approval of an unapproved product or that it will file an application for approval of a new indication for an approved product within one year. Competitors may use the publicly available information to gain knowledge regarding the design and progress of our development programs.

Fast Track Designation and Accelerated Approval

If our drug/biologic candidate meets the requirements of the FDA's fast track program, we would seek to have our drug/biologic candidate expedited through this program. The FDA has programs to facilitate the development, and expedite the review, of drugs/biologics that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the fast-track program, the sponsor of a new drug/biologic candidate may request that the FDA designate the drug/biologic candidate for a specific indication as a fast track drug/biologic concurrent with, or after, the filing of the IND for the drug/biologic candidate. The FDA must determine if the drug/biologic candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request. In addition to other benefits such as the ability to engage in more frequent interactions with the FDA, the FDA may initiate review of sections of a fast track drug's/biologic's NDA/BLA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing an application does not begin until the last section of the NDA/BLA is submitted. Additionally, the fast track designation may be withdrawn by the FDA if it believes that the designation is no longer supported by data emerging in the clinical trial process.

Under the FDA's accelerated approval regulations, the FDA may approve a drug/biologic for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug/biologic candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post- approval clinical trials to confirm clinical benefit. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug/biologic from the market on an expedited basis. Unless otherwise informed by the FDA, for an accelerated approval product/biologic, an applicant must submit to the FDA for consideration during the preapproval review period copies of all promotional materials, including promotional labeling as well as advertisements, intended for dissemination or publication within 120 days following marketing approval. After 120 days following marketing approval, unless otherwise informed by the FDA, the applicant must submit promotional materials at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement.

Breakthrough Therapy Designation

As with the FDA's fast track program, if our drug/biologic candidate meets the requirements to receive the FDA's Breakthrough Therapy designation, we would seek to have our drug/biologic candidate expedited through this program. The FDA's Breakthrough Therapy designation program is intended to expedite the development and review of products that treat serious or life-threatening diseases or conditions. A Breakthrough Therapy is defined, under the Food and Drug Administration Safety and Innovation Act, as a drug/biologic that is intended, alone or in combination with one or more other drugs/biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug/biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the features of fast-track designation, as well as more intensive FDA interaction and guidance. The Breakthrough Therapy designation is a distinct status from both accelerated approval and priority review, but these can also be granted to the same product candidate if the relevant criteria are met. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy. All requests for breakthrough therapy designation will be reviewed within 60 days of receipt, and the FDA will either grant or deny the request.

In addition, the 21st Century Cures Act created the Regenerative Medicine Advanced Therapy (RMAT) designation. RMAT applies to regenerative medicines as a class. Sponsors of certain cell therapies, therapeutic tissue engineering products, human cell and tissue products, and certain combination products may obtain the RMAT designation for their drug product if the drug is intended to treat serious or life-threatening diseases or conditions and if there is preliminary clinical evidence indicating that the drug has the potential to address unmet medical needs for that disease or condition. Sponsors may make such a request with or after submission of an investigational new drug application.

Sponsors of RMAT-designated products are eligible for increased and earlier interactions with the FDA, similar to those interactions available to sponsors of breakthrough-designated therapies. In addition, they may be eligible for priority review and accelerated approval. The meetings with sponsors of RMAT-designated products may include discussions of whether accelerated approval would be appropriate based on surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites.

Once approved, when appropriate, the FDA can permit fulfillment of post-approval requirements under accelerated approval through the submission of clinical evidence, clinical studies, patient registries, or other sources of real-world evidence such as electronic health records; through the collection of larger confirmatory datasets; or through post-approval monitoring of all patients treated with the therapy prior to approval.

Fast track designation, accelerated approval, priority review, and Breakthrough Therapy designation do not change the standards for approval but may expedite the development or approval process. Even if the FDA grants one of these designations, the FDA may later decide that the drug/biologic products no longer meet the conditions for qualification.

Orange Book Listing and Patent Certification

Based on amendments to the FDC Act made by the Drug Price Competition and Innovation Act of 1984 (commonly known as Hatch-Waxman), in seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product candidate or a claimed method of use of the product candidate. Upon approval of a drug, each of the eligible patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book must, in turn, be the subject of a special certification by the filer of an abbreviated new drug application ("ANDA"), for a generic version of the drug, or by the applicant of a hybrid application known as a 505(b)(2) application. An ANDA provides for marketing of a drug product candidate that has the same active ingredient(s) in the same strengths and dosage form as the reference listed innovator drug and has been shown to be bioequivalent to the reference listed drug. Other than the requirement for bioequivalence testing (absent a waiver), ANDA applicants are not required to conduct, or submit results of, pre-clinical or clinical tests to prove the safety or effectiveness of their drug product candidate. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, are considered therapeutically equivalent to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product candidate in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product candidate. The ANDA applicant may also elect to submit a "section viii statement", certifying that its proposed ANDA labeling does not contain (or carves out) any language regarding the patented method-of- use, rather than certify to a listed method-of-use patent.

If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product candidate will not infringe the already approved product candidate's listed patents, or that such patents are invalid or unenforceable, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of notice of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, a decision in the infringement case that is favorable to the ANDA applicant, or some other order of the court.

Sponsors may also seek to market versions of drug products via a section 505(b)(2) application, which is an NDA pathway that allows an applicant to seek approval for a drug product based on full safety and efficacy documentation, some of which may be from literature or conducted by others and for which the applicant does not have the right of reference. NDA Section 505(b)(2) applications may be submitted for drug products that represent a modification, such as a new indication or new dosage form, of a previously approved drug. Section 505(b)(2) applications may rely on the FDA's previous findings for the safety and effectiveness of the previously approved drug in addition to information obtained by the 505(b)(2) applicant to support the modification of the previously approved drug. Preparing Section 505(b)(2) applications may be less costly and time-consuming than preparing an NDA based entirely on new data and information. Section 505(b)(2) applications are subject to the same patent certification procedures as an ANDA.

New Chemical Entity Exclusivity and Clinical Investigation Exclusivity

Upon NDA approval of a new chemical entity ("NCE"), which is a drug that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which time the FDA cannot receive any ANDA or 505(b)(2) application seeking approval of a drug that references a version of the NCE drug. Certain changes to a drug, such as the addition of a new indication to the package insert with new clinical studies required for approval, are associated with a three-year period of exclusivity during which the FDA cannot approve an ANDA or 505(b)(2) application that includes the change.

An ANDA or 505(b)(2) application may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification and thus no ANDA or 505(b)(2) may be filed before the expiration of the exclusivity period.

For a botanical drug, FDA may determine that the active moiety is one or more of the principle components or the complex mixture as a whole. This determination would affect the utility of any five-year exclusivity as well as the ability of any potential generic competitor to demonstrate that it is the same drug as the original botanical drug.

Five-year and three-year exclusivities do not preclude FDA approval of a 505(b)(1) application for a version of the drug during the period of exclusivity, provided that the 505(b)(1) conducts or obtains a right of reference to all of the pre-clinical studies and adequate and well controlled clinical trials necessary to demonstrate safety and effectiveness.

Orphan Designation and Exclusivity

The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the U.S., or if it affects more than 200,000 individuals in the U.S. and there is no reasonable expectation that the cost of developing and making the drug for this type of disease or condition will be recovered from sales in the U.S.

Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical study costs, tax advantages, and user-fee waivers. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. In addition, the first NDA or BLA applicant to receive orphan drug designation for a particular drug is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years in the U.S., except in limited circumstances. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition.

Pediatric Studies and Exclusivity

NDAs and BLAs must contain data to assess the safety and effectiveness of an investigational new drug product for the claimed indications in all relevant pediatric populations in order to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults or full or partial waivers if certain criteria are met. Discussions about pediatric development plans can be discussed with the FDA at any time, but usually occur any time between the end-of-Phase 2 meeting and submission of the NDA or BLA. Unless otherwise required by regulation, the requirements for pediatric data do not apply to any drug for an indication for which orphan designation has been granted.

Pediatric exclusivity is another type of non-patent exclusivity in the U.S. that may be granted if certain FDA requirements are met, such as the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits, and the applicant agrees to perform and report on FDA-requested studies within a certain time frame. Pediatric exclusivity adds a period of six months of exclusivity to the end of all existing marketing exclusivity and patents held by the sponsor for that active moiety. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot accept or approve another application relying on the NDA or BLA sponsor's data.

Biologics Exclusivity and Biosimilars

The Patient Protection and Affordable Care Act of 2010, or Affordable Care Act, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCI Act, which amended the PHS Act to create an abbreviated approval pathway under section 351(k) of the PHS Act for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product originally licensed under section 351(a) of the PHS Act.

A reference biologic is granted twelve years of marketing exclusivity from the time of first licensure of the reference product, during which time a 351(k) application for a biosimilar of the reference product may not be approved. The reference biologic is also granted four years of so-called data exclusivity, during which time a 351(k) application for a biosimilar of the reference product may not be submitted for review. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitting under the abbreviated approval pathway for the lesser of (i) one year after the first commercial marketing, (ii) eighteen months after approval if there is no legal challenge, (iii) eighteen months after the resolution in the applicant's favor of a lawsuit challenging the biologics' patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period.

Biologic Patent Information

In contrast to small molecule drugs, for which applicants are required to submit patent information with their NDAs and certain supplements, an applicant seeking licensure of a biological product need not submit patent information in its BLA or supplements. Also, unlike small molecule drugs, for which the approvability of ANDAs and 505(b)(2) NDAs is impacted by the status of listed patents for the reference NDA drug product, the approvability of section 351(k) applications for biosimilar products is presently delinked from the various processes for resolving patent disputes. Biosimilar applicants have a choice whether to engage in the patent litigation provisions of the Biologics Price Competition and Innovation Act (BPCIA), colloquially known as the "patent dance," to identify and litigate a defined list of patents. However, unlike the listing of small molecule reference listed drugs and patents in the "Orange Book," there had not been a process for listing patents in the FDA's List of Licensed Biological Products, commonly known as the "Purple Book." However, in December 2020 Congress enacted the Biological Product Patent Transparency Act ("BPPT") (originally introduced as the Purple Book Continuity Act created section 351(k)(9) of the PHS Act. That section requires that a biological product reference sponsor that provides a biosimilar applicant with a patent list as part of the "Patent Dance" BPCIA patent litigation process must now submit those lists to the FDA within 30 days, and further, as of June 2021 the FDA is required to make those lists (along with any revisions or updates) public in the Purple Book database.

Patent Term Extension

After NDA or BLA approval, owners of relevant drug or biologic patents may apply for up to a five-year patent extension. The allowable patent term extension is calculated as half of the product's testing phase — the time between IND submission and NDA or BLA submission — and all of the review phase — the time between NDA submission and approval up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the United States Patent and Trademark Office (USPTO) must determine that approval of the product covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA or BLA has not been submitted.

Advertising and Promotion

Once an NDA or BLA is approved, a product candidate will be subject to certain post-approval requirements. For instance, FDA closely regulates the post-approval marketing and promotion of drugs and biologics, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet.

Drugs and biologics may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Post-Approval Changes

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA/BLA or NDA/BLA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Adverse Event Reporting and GMP Compliance

Adverse event reporting on an expedited basis and submission of periodic adverse event reports is required following FDA approval of an NDA or BLA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality-control, drug manufacture, packaging, and labeling procedures must continue to conform GMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with GMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with GMPs. Regulatory authorities may withdraw product approvals, issue warning letters, request product recalls or take other enforcement actions if a company fails to comply with regulatory standards, if it encounters problems following initial marketing or if previously unrecognized problems are subsequently discovered.

Special Protocol Assessment

A sponsor may reach an agreement with the FDA under the Special Protocol Assessment ("SPA"), process as to the required design and size of clinical trials intended to form the primary basis of an efficacy claim. According to its performance goals, the FDA has committed to evaluating 90 percent of the protocols within 45 days of its receipt of the requests to assess whether the proposed trial is adequate, and that evaluation may result in discussions and a request for additional information. An SPA request must be made before the proposed trial begins, and all open issues must be resolved before the trial begins. If a written agreement is reached, it will be documented and made part of the administrative record. Under the FDC Act and FDA guidance implementing the statutory requirement, an SPA is generally binding upon the FDA as to the design of the trial except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining safety or efficacy after the study begins, public health concerns emerge that were unrecognized at the time of the protocol assessment, the sponsor and FDA agree to the change in writing, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA.

Controlled Substances

The Controlled Substances Import and Export Act, as amended ("CSA") and the implementing regulations impose registration, security, recordkeeping and reporting, storage, manufacturing, distribution, dispensing, importation and other requirements on controlled substances under the oversight of the U.S. Drug Enforcement Administration ("DEA"). The DEA is the federal agency, responsible for regulating controlled substances, and requires those individuals or entities that manufacture, import, export, distribute, research, or dispense controlled substances to comply with the regulatory requirements in order to prevent the diversion and abuse of controlled substances.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances, depending on the substance's medical effectiveness and abuse potential. Pharmaceutical products having a currently accepted medical use that are otherwise approved for marketing may be listed as Schedule II, III, IV or V substances, with Schedule II substances presenting the highest potential for abuse and physical or psychological dependence, and Schedule V substances presenting the lowest relative potential for abuse and dependence. The DEA has placed certain drug products that include cannabidiol, on Schedule V.

Following NDA approval of a drug containing a Schedule I controlled substance, that substance must be rescheduled as a Schedule II, III, IV or V substance before it can be marketed. The Improving Regulatory Transparency for New Medical Therapies Act enacted on November 25, 2015 and its implementing regulations has removed uncertainty associated with the timing of the DEA rescheduling process after NDA approval, under which a manufacturer may market its product no later than 90 days after the later of: (1) the date on which DEA receives from FDA the scientific and medical evaluation and scheduling recommendation; or (2) the date on which DEA receives from FDA notification that FDA has approved the drug. The Act also clarifies that the seven-year orphan exclusivity period begins with the approval of the NDA or DEA scheduling, whichever is later. This changes the previous situation whereby the orphan "clock" began to tick upon FDA's NDA approval, even though the product could not be marketed until DEA scheduling was complete.

The CSA requires that facilities that manufacture, distribute, dispense, import or export any controlled substance must register annually with the DEA. Separate registrations are required for importation and manufacturing activities, and each registration authorizes the specific schedules of controlled substances the registrant may handle. Prior to issuance of a controlled substance registration, the DEA inspects all manufacturing facilities to review security, recordkeeping, reporting and handling of the controlled substances. The specific security requirements vary by, among other things, the type of business activity conducted, and the type, form, and quantity of controlled substances handled.

In addition, individual states have their own distinct controlled substance laws and regulations, including licensure, distribution, dispensing, recordkeeping and reporting requirements for controlled substances. State boards of pharmacy or similar authorities regulate use of controlled substances in each state. Failure to comply with applicable requirements, such as the loss or diversion of controlled substances, can result in administrative fines, suspension or revocation of licenses, and civil and criminal liabilities.

U.K./Europe/Rest of World Government Regulation

In addition to regulations in the U.S., we are and will be subject, either directly or through our distribution partners, to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales (including pricing and reimbursement) and distribution of our products, if approved.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of the product in those countries.

In the EU, medicinal products are subject to extensive pre- and post-marketing regulation by regulatory authorities at both the EU and national levels. Additional rules also apply at the national level to the manufacture, import, export, storage, distribution and sale of controlled substances. In many EU member states the regulatory authority responsible for medicinal products is also responsible for controlled substances. Responsibility is, however, split in some member states. Generally, any company manufacturing or distributing a medicinal product containing a controlled substance in the EU will need to hold a controlled substances license from the competent national authority and will be subject to specific record-keeping and security obligations. Separate import or export certificates are required for each shipment into or out of the member state.

In the U.K., medicinal products are subject to extensive regulation by the Medicines and Healthcare products Regulatory Agency ("MHRA"), which is an executive agency, sponsored by the Department of Health and Social Care. MHRA regulates by ensuring that medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality and efficacy, in addition to supporting innovation and research and development that is beneficial to public health.

Clinical Trials and Marketing Approval

Certain countries outside of the U.S. have a process that requires the submission of a clinical trial application much like an IND prior to the commencement of human clinical trials. In the EU/EEA, for example, a clinical trial application (a "CTA"), must be submitted via a single-entry portal for all clinical trials conducted in the EU/EEA (the "CTIS"). Once the CTA is approved in accordance with a country's requirements and a company has received favorable ethics committee approval, clinical trial development may proceed in that country.

In April 2014, the Clinical Trials Regulation, Reg. (EU) No 536/2014 (the "New Regulation") was adopted to replace the Clinical Trials Directive 2001/20/EC (the "Prior Directive"). To ensure that the rules for clinical trials are identical throughout the EU/EEA, new EU clinical trials legislation was passed as a "regulation" that is directly applicable to EU/EEA member states. The New Regulation requires the sponsor to submit a single CTA is planned for all EU/EEA member states, which will be submitted via the CTIS, an online portal to streamline the authorization process. The CTIS authorization procedure is composed of two parts: member states jointly cooperate in a Part I assessment, while Part II is assessed by each member state individually. This is a significant change, as under the Prior Directive sponsors had to seek separate approval from national authorities in each country where the trial was to be conducted. The New Regulation became applicable on January 31, 2022 – repealing the Prior Directive as of the same day – and introduced a one-year transition period (until January 31, 2023) during which sponsors could choose whether to submit new CTAs under either the old regime governed by the Prior Directive or the new CTIS. Following the transition period, from January 31, 2023, sponsors must apply for clinical trials under the New Regulation, and by January 31, 2025, all ongoing clinical trials approved under the Prior Directive will need to be transitioned to the New Regulation.

In the U.K., the Prior Directive (implemented by Medicines for Human Use (Clinical Trials) Regulations 2004/1031) still applies. On January 31, 2020 the U.K. left the EU and the European Union (Withdrawal) Act 2018 (the "EUWA") came into force. Section 1 of the EUWA repealed the European Communities Act 1972 (ECA 1972), which had previously enabled EU law to apply to the U.K. However, Section 1A of the EUWA immediately saved much of the effect of ECA 1972 (in modified form) for the duration of the transition period, and Section 1B saved U.K. legislation that implemented EU requirements. The practical effect of the EUWA was therefore that the New Regulation, which had not yet become applicable was repealed for the U.K., but the Prior Directive was retained. References to the U.K. in this section predominantly refer to Great Britain. Due to the Northern Ireland Protocol at Article 182 of the EUWA certain EU/EEA derived regulatory standards in Northern Ireland were not repealed and therefore in some circumstances still apply. Currently, new negotiations for the Northern Ireland Protocol are taking place and changes to it are expected during 2023. In the U.K., approval must be obtained from the MHRA when a clinical trial is planned. A CTA must be submitted and supported by an investigational medicinal product dossier along with additional supporting information pursuant to the Medicines for Human Use (Clinical Trials) Regulations 2004/1031 and other applicable guidance documents provided by the MHRA. Furthermore, a clinical trial may only commence after a competent ethics committee has issued a favorable opinion on the clinical trial application in the U.K.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country, even though there is already some degree of legal harmonization in the EU member states resulting from the national implementation of underlying EU legislation. In all cases, the clinical trials must be conducted in accordance with the International Conference on Harmonization guidelines on GCP and other applicable regulatory requirements.

To obtain regulatory approval to place a drug on the market in the U.K. or EU/EEA countries, we must submit a marketing authorization application. This application is similar to the NDA in the U.S., with the exception of, among other things, country-specific document requirements. All application procedures require an application in the common technical document, format, which includes the submission of detailed information about the manufacturing and quality of the product, and nonclinical and clinical trial information. In addition to using national authorization procedures (leading to a marketing authorization on valid in the relevant EU/EEA member state), drugs can be authorized in the EU/EEA by using (i) the centralized authorization procedure, (ii) the mutual recognition procedure, or (iii) the decentralized procedure. These three authorization methods available to the EU/EEA are no longer available to the U.K. Drugs can be authorized in the U.K. by the MHRA by using (i) the Innovative Licensing and Access Pathway, (ii) the 150-day assessment route, (iii) a "rolling review" route of evaluation for novel products and biotechnological products, (iv) a European Commission (EC) Decision reliance procedure, (v) a decentralized and mutual recognition reliance procedure, or (vi) an "unfettered access" route for marketing authorization applications approved in Northern Ireland.

The European Commission created the centralized procedure for the approval of human drugs to facilitate marketing authorizations that are valid throughout the EU and, by extension (after national implementing decisions) in Iceland, Liechtenstein and Norway, which, together with the EU member states, comprise the European Economic Area. Applicants file marketing authorization applications with the European Medicines Agency (EMA), where they are reviewed by a relevant scientific committee, in most cases the Committee for Medicinal Products for Human Use ("CHMP"). The European Medicines Agency ("EMA") forwards CHMP opinions to the European Commission, which uses them as the basis for deciding whether to grant a marketing authorization. This procedure results in a single marketing authorization granted by the European Commission that is valid across the EU, as well as in Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human drugs that are: (i) derived from biotechnology processes, such as genetic engineering, (ii) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases, (iii) officially designated "orphan drugs" (drugs used for rare human diseases) and (iv) advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines. The centralized procedure may at the voluntary request of the applicant also be used for human drugs that do not fall within the above-mentioned categories if the CHMP agrees that the human drug (a) contains a new active substance not yet approved on November 20, 2004; (b) constitutes a significant therapeutic, scientific or technical innovation or (c) authorization under the centralized procedure is in the interests of patients at the EU level. Although the U.K. can no longer utilize the EU centralized procedure, until December 31, 2023 the MHRA can utilize the decentralized and mutual recognition reliance procedure to authorize drugs by relying upon EC approvals under the EU centralized procedure. Beyond December 31, 2023, the MHRA intends to have a new regime for an international drug reliance framework.

Under the centralized procedure in the EU, the maximum time frame for the evaluation of a marketing authorization application by the EMA is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP), with adoption of the actual marketing authorization by the European Commission thereafter.

Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest from the point of view of therapeutic innovation, defined by three cumulative criteria: the seriousness of the disease to be treated; the absence of an appropriate alternative therapeutic approach, and anticipation of exceptional high therapeutic benefit. In this circumstance, EMA ensures that the evaluation for the opinion of the CHMP is completed within 150 days and the opinion issued thereafter.

For those medicinal products for which the centralized procedure is not available, the applicant must submit marketing authorization applications to the national medicines regulators through one of three procedures: (i) the mutual recognition procedure (which must be used if the product has already been authorized in at least one other EU/EEA member state, and in which the EU/EEA member states are required to grant an authorization recognizing the existing authorization in the other EU/EEA member state, unless they identify a serious risk to public health), (ii) the decentralized procedure (in which applications are submitted simultaneously in two or more EU/EEA member states) or (iii) national authorization procedures (which results in a marketing authorization in a single EU/EEA member state).

Conditional Marketing Authorization

The European Commission may grant a conditional marketing authorization to medicines that address unmet medical needs. This marketing authorization is "conditional" upon carrying out certain activities imposed when authorization is granted (e.g., completing ongoing or new studies or collecting additional data). This applies when the applicant is unable to provide comprehensive data on the efficacy and safety of the medicinal product under normal conditions of use, for objective, verifiable reasons and based on specific grounds, and all of the following criteria are met:

- the benefit-risk balance of the medicine is positive;
- it is likely that the applicant will be able to provide comprehensive data post-authorization;
- the medicine fulfils an unmet medical need; and
- the benefit of the medicine's immediate availability to patients is greater than the risk inherent in the fact that additional data is still required.

Conditional marketing authorizations are valid for one year and can be renewed annually.

In Great Britain (England, Scotland, Wales) the MHRA has introduced and regulates a national conditional marketing authorization, effective from January 1, 2021; in Northern Ireland, applications for conditional marketing authorization must be submitted to the EMA. The UK scheme has the same eligibility criteria as the EU scheme.

Mutual Recognition Procedure

The mutual recognition procedure ("MRP"), for the approval of human drugs is an alternative approach to facilitate individual national marketing authorizations within the EU/EEA. Basically, the MRP may be applied for all human drugs for which the centralized procedure is not obligatory. The MRP is applicable to the majority of conventional medicinal products and must be used if the product has already been authorized in one or more member states.

The characteristic of the MRP is that the procedure builds on an already-existing marketing authorization in member state that is used as a reference in order to obtain marketing authorizations in other EU/EEA member states. In the MRP, a marketing authorization for a drug already exists in one or more member states of the EU/EEA and subsequently marketing authorization applications are made in other member states by referring to the initial marketing authorization. The member state in which the marketing authorization was first granted will then act as the reference member state. The member states where the marketing authorization is subsequently applied for act as concerned member states. The concerned member states are required to grant an authorization recognizing the existing authorization in the reference member state, unless they identify a serious risk to public health.

The MRP is based on the principle of the mutual recognition by EU/EEA member states of their respective national marketing authorizations. Based on a marketing authorization in the reference member state, the applicant may apply for marketing authorizations in other member states. In such case, the reference member state is required to update its existing assessment report about the drug in 90 days. After the assessment is completed, copies of the report are sent to all concerned member states, together with the approved summary of product characteristics, labeling and package leaflet. The concerned member states then have 90 days to recognize the decision of the reference member state and the summary of product characteristics, labeling and package leaflet. National marketing authorizations shall be granted within 30 days after acknowledgement of the agreement.

Should any member state refuse to recognize the marketing authorization by the reference member state, on the grounds of potential serious risk to public health, the issue will be referred to a coordination group. Within a timeframe of 60 days, member states shall, within the coordination group, make all efforts to reach a consensus. If this fails, the procedure is submitted to an EMA scientific committee for arbitration. The opinion of this EMA Committee is then forwarded to the European Commission, for the start of the decision-making process. As in the centralized procedure, this process entails consulting various European Commission Directorates General and the Standing Committee on Human Medicinal Products.

Data Exclusivity

In the U.K. and EU, marketing authorization applications for generic medicinal products do not need to include the results of pre-clinical and clinical trials, but instead can refer to the data included in the marketing authorization of a reference product for which regulatory data exclusivity has expired. If a marketing authorization is granted for a medicinal product containing a new active substance, that product benefits from eight years of data exclusivity, during which generic marketing authorization applications referring to the data of that product may not be accepted by the regulatory authorities, and a further two years of market exclusivity, during which such generic products may not be placed on the market. The two-year period may be extended to three years if during the first eight years a new therapeutic indication with significant clinical benefit over existing therapies is approved.

Orphan Medicinal Products

The EMA's Committee for Orphan Medicinal Products ("COMP"), may recommend orphan medicinal product designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the EU. Additionally, orphan designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the product in the EU would be sufficient to justify the necessary investment in developing the medicinal product. The COMP may only recommend orphan medicinal product designation when the product in question offers a significant clinical benefit over existing approved products for the relevant indication. Following a positive opinion by the COMP, the European Commission generally grants orphan status within 30 days. When the draft decision of the European Commission is not aligned with the COMP opinion, the COMP will reassess orphan status in parallel with EMA review of a marketing authorization application and orphan status may be withdrawn at if the drug no longer fulfills the orphan criteria (for instance, because a new product was approved for the indication and no data is available to demonstrate a significant benefit over that new product). Orphan medicinal product designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following marketing authorization. During this period, the competent authorities may not accept or approve any similar medicinal product for the same therapeutic indication, unless it offers a significant clinical benefit or if the holder of the marketing authorization for the original orphan drug is unable to supply sufficient quantities of the drug. This period may be reduced to six years if the orphan medicinal product designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

EU/EEA orphan designations extend to Northern Ireland. Otherwise in the U.K. post-Brexit, applications for the designation of orphan medicinal products are submitted to the MHRA, which applies the same substantive criteria and with the same substantive effect as in the EU (save that, unlike the EU procedure, it is not possible to obtain early orphan designation; the application for designation must be made at the same time as the application for the U.K. marketing authorization). If a medicinal product has been designated orphan in the EU, then a Great Britain orphan marketing authorization application can be made to the MHRA; absent an EU orphan designation a U.K.-wide (including Northern Ireland) orphan marketing authorization application can be made to the MHRA.

Pediatric Development

In the EU and the U.K., companies developing a new medicinal product must agree to a Pediatric Investigation Plan ("PIP"), with the EMA or the MHRA and must conduct pediatric clinical trials in accordance with that PIP unless a waiver applies, for example, because the relevant disease or condition occurs only in adults. The marketing authorization application for the product must include the results of pediatric clinical trials conducted in accordance with the PIP, unless a waiver applies, or a deferral has been granted, in which case the pediatric clinical trials must be completed at a later date. Products that are granted a marketing authorization on the basis of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six-month extension of the protection under a supplementary protection certificate (if the product covered by it qualifies for one at the time of approval). This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

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If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

In addition, most countries are parties to the Single Convention on Narcotic Drugs 1961 and the Convention on Psychotropic Substances 1971, which governs international trade and domestic control of narcotic substances, including cannabis extracts. Countries may interpret and implement their treaty obligations in a way that creates a legal obstacle to our obtaining marketing approval for our product candidates in those countries. These countries may not be willing or able to amend or otherwise modify their laws and regulations to permit our product candidates to be marketed, or achieving such amendments to the laws and regulations may take a prolonged period of time. In that case, we would be unable to market our products in those countries in the near future or perhaps at all.

Reimbursement

Sales of pharmaceutical products in the U.S. will depend, in part, on the extent to which the costs of the products will be covered by third-party payers, such as government health programs, and commercial insurance and managed health care organizations. These third-party payers are increasingly challenging the prices charged for medical products and services. Additionally, the containment of health care costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, utilization management and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. If these third-party payers do not consider our future products to be cost effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), imposed requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries and included a major expansion of the prescription drug benefit under Medicare Part D. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Part D is available through both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Parts A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from nongovernmental payers.

On February 17, 2009, President Obama signed into law The American Recovery and Reinvestment Act of 2009. This law provides funding for the federal government to compare the effectiveness of different treatments for the same illness. This research is overseen by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures must be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payers, it is not clear how such a result could be avoided and what if any effect the research will have on the sales of our product candidates, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates. Decreases in third-party reimbursement for our product candidates or a decision by a third-party payer to not cover our product candidates could reduce physician usage of the product candidate and have a material adverse effect on our sales, results of operations and financial condition.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the "ACA") was enacted in March 2010. The ACA was enacted with the goal of expanding coverage for the uninsured while at the same time containing overall health care costs. With regard to pharmaceutical products, among other things, the ACA expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare D program. We still cannot fully predict the impact of the ACA on pharmaceutical companies as many of the ACA reforms require the promulgation of detailed regulations implementing the statutory provisions which has not yet been completed, and the Centers for Medicare & Medicaid Services has publicly announced that it is analyzing the ACA regulations and policies that have been issued to determine if changes should be made. In addition, although the U.S. Supreme Court has upheld the constitutionality of most of the ACA, some states have stated their intentions to not implement certain sections of the ACA and some members of Congress are still working to repeal the ACA. These challenges add to the uncertainty of the changes enacted as part of the ACA. In addition, the current legal challenges to the ACA, as well as Congressional efforts to repeal the ACA, add to the uncertainty of the legislative changes enacted as part of the ACA.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, some EU jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. Such differences in national pricing regimes may create price differentials between EU member states. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the U.S. In the EU, the downward pressure on healthcare costs in general, particularly prescription medicines, has become intense. As a result, barriers to entry of new products are becoming increasingly high and patients are unlikely to use a drug product that is not reimbursed by their government or other public or private payers.

Other Health Care Laws and Compliance Requirements

In the U.S., our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the CMS, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, the privacy provisions of the Health Insurance Portability and Accountability Act, and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992 ("VHCA"), each as amended. If future products are made available to authorized users of the federal supply schedule, additional laws and requirements apply. Under the VHCA, drug companies are required to offer certain drugs at a reduced price to a number of federal agencies including the U.S. Department of Veteran Affairs and U.S. Department of Defense, the Public Health Service and certain private Public Health Service-designated entities in order to participate in other federal funding programs including Medicare and Medicaid. In addition, discounted prices must be offered for certain U.S. Department of Defense purchases for its TRICARE program via a rebate system. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the federal acquisition regulations.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers and distributors who ship products into the state, even if such manufacturers or distributors have no place of business within the state. Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales and marketing activities or register their sales representatives. Other legislation has been enacted in certain states prohibiting certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws. Likewise, these activities are subject to authorization or license requirements, or other legal requirements, under EU or EU member states' law, or the law of other countries where we operate or have products manufactured or distributed.

Cost of Compliance with Environmental Laws

Our operations are subject to regulations under various federal, state, local and foreign laws concerning the environment, including laws addressing the discharge of pollutants into the air and water, the management and disposal of hazardous substances and wastes, and the cleanup of contaminated sites. We could incur substantial costs, including cleanup costs, fines and civil or criminal sanctions and third-party damage or personal injury claims, if in the future we were to violate or become liable under environmental laws. We are not aware of any costs or effects of our compliance with environmental laws.

Climate Change Related Regulation

Our operations are focused on research and development of pharmaceutical products, and a significant portion of such research and development is conducted outside of our facilities and by outsourced contract research organizations or universities. As a result, we do not anticipate any regulation surrounding climate change to impact our operations.

However, there is potential for more frequent and severe weather events and water availability challenges that may impact the facilities of our partners and our future suppliers. We cannot provide assurance that physical risks to the facilities of our partners and future suppliers and supply chain due to climate change will not occur in the future. We periodically review our vulnerability to potential weather-related risks and other natural disasters and update our assessments accordingly. Based on our reviews, we do not believe these potential risks are material to our operations at this time.

Employees and Human Capital Management

As of March 31, 2023, we and our subsidiaries had five full-time employees. One of these employees is located in the U.K., and four are located in the U.S.

In addition, we employ a limited number of part-time employees on a temporary basis, as well as scientific advisors, consultants and service providers, mainly through academic institutions and contract research organizations.

We have never had a work stoppage and none of our employees are covered by collective bargaining agreements or represented by a labor union. We believe that we have good relationships with our employees.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing, and integrating our existing and new employees, advisors, and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Corporate History

Formation

We were formed as a blank check company organized under the laws of the State of Delaware on September 7, 2016. We were formed for the purpose of effecting a merger, capital stock exchange, stock purchase, asset acquisition or other similar business combination with one or more operating businesses. Since formation, we focused our efforts on acquiring an operating company in the healthcare and related wellness industry although our efforts in identifying a prospective target business were not limited to a particular industry.

Initial Public Offering

On June 7, 2017, pursuant to the Company's Initial Public Offering (the "IPO"), the Company sold 11,500,000 Units at a purchase price of $10.00 per Unit, inclusive of 1,500,000 Units sold to the underwriters on June 23, 2017 upon the underwriters' election to fully exercise their over-allotment option, generating gross proceeds of $115,000,000. Each "Unit" consisted of one-twentieth of a share of the Company's common stock, one right to receive one-200th of one share of the Company's common stock upon the consummation of a business combination ("Right"), and one redeemable warrant to purchase one-fortieth of one share of the Company's common stock (the "Public Warrants"). Each Public Warrant entitles the holder to purchase one-fortieth of one share of common stock at an exercise price of $5.75 per $1/40^{th}$ of one share ($230.00 per whole share), subject to adjustment. No fractional shares will be issued upon exercise of the Public Warrants. The Public Warrants became exercisable 12 months from the closing of the IPO, and expire five years after the completion of the Business Combination (November 6, 2025).

The Company may redeem the Public Warrants, in whole and not in part, at a price of $0.01 per Public Warrant upon 30 days' notice ("30-day redemption period"), only in the event that the last sale price of the common stock equals or exceeds $360.00 per share for any 20 trading days within a 30-trading day period ending on the third trading day prior to the date on which notice of redemption is given, provided there is an effective registration statement with respect to the shares of common stock underlying such Public Warrants and a current prospectus relating to those shares of common stock is available throughout the 30-day redemption period. If the Company calls the Public Warrants for redemption as described above, the Company's management will have the option to require all holders that wish to exercise Public Warrants to do so on a "cashless basis." In determining whether to require all holders to exercise their Public Warrants on a "cashless basis," management will consider, among other factors, the Company's cash position, the number of Public Warrants that are outstanding and the dilutive effect on the Company's stockholders of issuing the maximum number of shares of common stock issuable upon the exercise of the Public Warrants. Each holder of a Right received one-200th (1/200) of one share of common stock upon consummation of the Business Combination. No fractional shares were issued upon exchange of the Rights.

Private Placement

Concurrent with the closing of the IPO, KBL IV Sponsor LLC (the "Sponsor") and the underwriters purchased an aggregate of 450,000 unregistered Units ("Private Units") at $10.00 per Unit, generating gross proceeds of $4,500,000 in a private placement. In addition, on June 23, 2017, the Company consummated the sale of an additional 52,500 Private Units at a price of $10.00 per Unit, which were purchased by the Sponsor and underwriters, generating gross proceeds of $525,000. Of these, 377,500 Private Units were purchased by the Sponsor and 125,000 Private Units were purchased by the underwriters. The proceeds from the Private Units were added to the net proceeds from the IPO held in a Trust Account (the "Trust Account"). The Private Units (including their component securities) were not transferable, assignable or salable until 30 days after the completion of the Business Combination (defined below) and the warrants included in the Private Units (the "Private Placement Warrants") will be non-redeemable so long as they are held by the Sponsor, the underwriters or their permitted transferees. If the Private Placement Warrants are held by someone other than the Sponsor, the underwriters or their permitted transferees, the Private Placement Warrants will be redeemable by the Company and exercisable by such holders on the same basis as the warrants included in the Units sold in the IPO. In addition, for as long as the Private Placement Warrants are held by the underwriters or its designees or affiliates, they may not be exercised after five years from the effective date of the registration statement related to the IPO. Otherwise, the Private Placement Warrants have terms and provisions that are identical to those of the warrants sold as part of the Units in the IPO and have no net cash settlement provisions.

Business Combination

On July 25, 2019, we entered into a Business Combination Agreement (as amended from time to time, the "Business Combination Agreement"), with KBL Merger Sub, Inc. ("Merger Sub"), 180 Life Corp. (f/k/a 180 Life Sciences Corp.)("180"), Katexco Pharmaceuticals Corp. ("Katexco"), CannBioRex Pharmaceuticals Corp. ("CBR Pharma"), 180 Therapeutics L.P. ("180 LP" and together with Katexco and CBR Pharma, the "180 Subsidiaries" and, together with 180 Life Sciences Corp., the "180 Parties"), and Lawrence Pemble, in his capacity as representative of the stockholders of the 180 Parties (the "Stockholder Representative"). The business combination described in the Business Combination Agreement (the "Business Combination"), closed and became effective on November 6, 2020 (the "Closing"). Pursuant to the Business Combination Agreement, among other things, Merger Sub merged with and into 180, with 180 continuing as the surviving entity and a wholly-owned subsidiary of the Company (the "Merger"). In connection with, and prior to, the Closing, 180 Life Sciences Corp. filed a Certificate of Amendment of its Certificate of Incorporation in Delaware to change its name to 180 Life Corp., and our company (which was known as of our entry into the Business Combination as KBL Merger Corp. IV, changed our name to 180 Life Sciences Corp.).

180 was incorporated in Delaware on January 28, 2019. Prior to the Closing of the Business Combination, 180 operated through three subsidiaries: 180 LP, a Delaware limited partnership formed on September 6, 2013; Katexco, a company incorporated in British Columbia, Canada on March 7, 2018; and CBR Pharma, a company incorporated in British Columbia, Canada on March 8, 2018.

In July 2019, 180 and each of 180 LP, Katexco and CBR Pharma completed a corporate restructuring, pursuant to which 180 LP, Katexco and CBR Pharma became wholly-owned subsidiaries of 180LS (the "Reorganization"). The corporate restructuring arrangements with respect to Katexco and CBR Pharma were completed under the *Business Corporations Act* (British Columbia).

On November 6, 2020 (the "Closing Date"), the Company consummated the Business Combination following a special meeting of stockholders held on November 5, 2020, where the stockholders of the Company considered and approved, among other matters, a proposal to adopt the Business Combination. Pursuant to the Business Combination Agreement, among other things, Merger Sub merged with and into 180, with 180 continuing as the surviving entity and as a wholly-owned subsidiary of the Company. The Merger became effective on November 6, 2020 (such time, the "Effective Time", and the closing of the Merger being referred to herein as the "Closing"). In connection with, and prior to, the Closing, 180 filed a Certificate of Amendment of its Certificate of Incorporation in Delaware to change its name to 180 Life Corp. and KBL Merger Corp. IV changed its name to 180 Life Sciences Corp.

At the Effective Time, each share of 180 common stock issued and outstanding prior to the Effective Time was automatically converted into the right to receive approximately 8.41892 shares of the common stock, par value $0.0001 per share, of the Company (such shares of Common Stock issuable to the common stockholders of 180 pursuant to the Business Combination Agreement, the "Merger Consideration Shares"). An aggregate of 874,737 shares of common stock have been issued to date to the common stockholders of 180 as Merger Consideration Shares, including the Escrow Shares (as defined below). Also at the Effective Time, each share underlying the 180 preferred stock issued and outstanding prior to the Effective Time was converted into the right to receive one Class C Special Voting Share of the Company, or one Class K Special Voting Share of the Company, as applicable (such shares, the "Special Voting Shares"). The Special Voting Shares entitle the holder thereof to an aggregate number of votes, on any particular matter, proposition or question, equal to the number of Exchangeable Shares (as defined below) of each of CannBioRex Purchaseco ULC and Katexco Purchaseco ULC, Canadian subsidiaries of 180, respectively, that are outstanding from time to time.

As a result of the Merger, the existing exchangeable shares (collectively, the "Exchangeable Shares") of CannBioRex Purchaseco ULC and/or Katexco Purchaseco ULC were adjusted in accordance with the share provisions in the articles of CannBioRex Purchaseco ULC or Katexco Purchaseco ULC, as applicable, governing the Exchangeable Shares such that they were multiplied by the exchange ratio for the Merger and became exchangeable into shares of Common Stock. The Exchangeable Shares entitle the holders to dividends and other rights that are substantially economically equivalent to those of holders of Common Stock, and holders of Exchangeable Shares have the right to vote at meetings of the stockholders of the Company. An aggregate of 264 shares of Common Stock are reserved for issuance to the holders of the Exchangeable Shares upon the exchange thereof.

Pursuant to the Business Combination Agreement, 52,500 of the Merger Consideration Shares (such shares, the "Escrow Shares") were deposited into an escrow account (the "Escrow Account") to serve as security for, and the exclusive source of payment of, the Company's indemnity rights under the Business Combination Agreement, all of which were planned to be released to the same stockholders 12 months following the Closing of the Business Combination, but for a claim made by Dr. Krauss against these shares which is pending.

As a result of the Business Combination, the former stockholders of 180 became the controlling stockholders of the Company and 180 became a wholly-owned subsidiary of the Company. The Business Combination was accounted for as a reverse merger, whereby 180 is considered the acquirer for accounting and financial reporting purposes.

In connection with the Closing, the Company withdrew $9,006,493 of funds from the Trust Account (as defined below) to fund the redemptions of 40,824 shares.

Reverse Stock Split

On December 15, 2022, at a Special Meeting of the Stockholders of 180 Life Sciences Corp., the stockholders of the Company approved an amendment to the Company's Second Amended and Restated Certificate of Incorporation, as amended, to effect a reverse stock split of our issued and outstanding shares of our common stock, par value $0.0001 per share, by a ratio of between one-for-four to one-for-twenty, inclusive, with the exact ratio to be set at a whole number to be determined by our Board of Directors or a duly authorized committee thereof in its discretion, at any time after approval of the amendment and prior to December 15, 2023 (the "Stockholder Authority"). On December 15, 2022, the Company's Board of Directors (the "Board"), with the Stockholder Authority, approved an amendment to our Second Amended and Restated Certificate of Incorporation to affect a reverse stock split of our common stock at a ratio of 1-for-20 (the "Reverse Stock Split").

Immediately after the Special Meeting and the approval thereof by the Board, on December 15, 2022, we filed a Certificate of Amendment to our Second Amended and Restated Certificate of Incorporation (the "Certificate of Amendment") with the Secretary of State of the State of Delaware to effect the Reverse Stock Split. A copy of the Certificate of Amendment is attached hereto as Exhibit 3.1 and is incorporated by reference herein.

Pursuant to the Certificate of Amendment, the Reverse Stock Split became effective on December 19, 2022 at 12:01 a.m. Eastern Time (the "Effective Time"). No change was made to the trading symbol for the Company's shares of common stock or public warrants, "ATNF" and "ATNFW", respectively, in connection with the Reverse Stock Split.

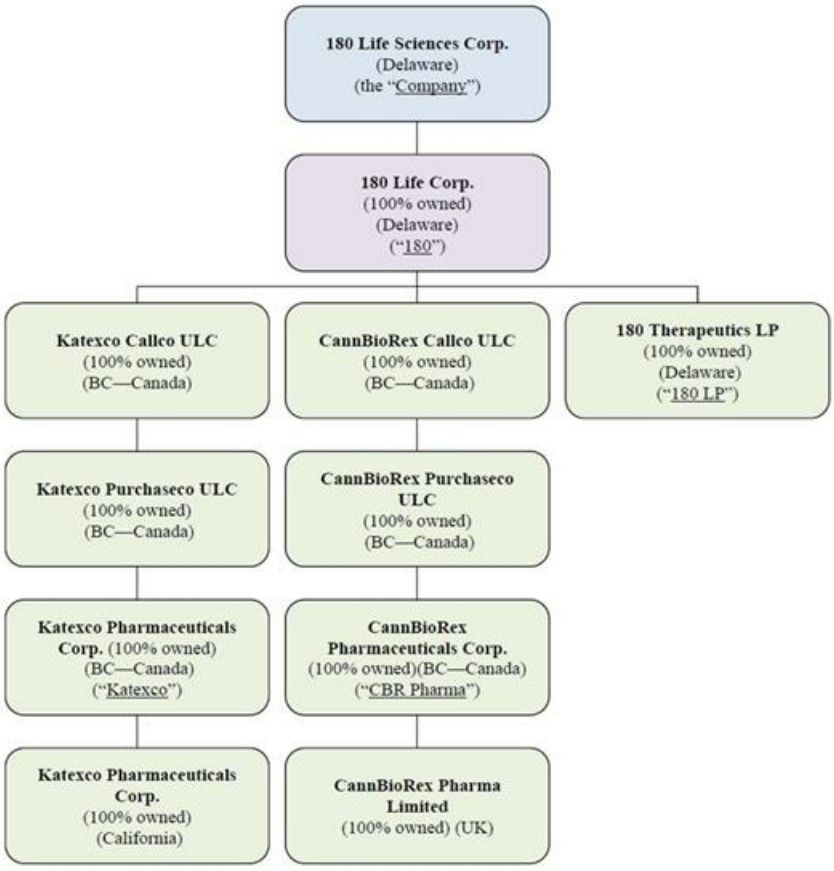
The Certificate of Amendment did not reduce the number of authorized shares of our common stock, nor alter the par value of our common stock or modify any voting rights or other terms of our common stock.

No fractional shares were issued in connection with the Reverse Stock Split and stockholders of record who otherwise would be entitled to receive fractional shares, were instead entitled to have their fractional shares rounded up to the nearest whole share.

The effects of the 1-for-20 Reverse Stock Split have been retroactively reflected throughout this Report.

Corporate Structure

The chart below shows our current organizational structure:



About Us

Our principal executive offices are located at 3000 El Camino Real, Bldg. 4, Suite 200, Palo Alto, CA 94306, and our telephone number is (650) 507-0669. We maintain a website at www.180lifesciences.com. We have not incorporated by reference into this Report the information in, or that can be accessed through, our website, and you should not consider it to be a part of this Report.

Jumpstart Our Business Startups Act

In April 2012, the Jumpstart Our Business Startups Act ("JOBS Act") was enacted into law. The JOBS Act provides, among other things, exemptions for "emerging growth companies" from certain financial disclosure and governance requirements for up to five years and provides a new form of financing to small companies. We ceased being an "emerging growth company" on December 31, 2022.

ITEM 1A. RISK FACTORS.

Summary Risk Factors

We face risks and uncertainties related to our business, many of which are beyond our control. In particular, risks associated with our business include:

- we are a clinical stage biotechnology company that had no revenue for the years ended December 31, 2022 and 2021, and do not anticipate generating revenue for the near future;
- our need for additional financing, both near term and long term, to support our operations, our ability to raise such financing as needed, the terms of such financing, if available, potential significant dilution associated therewith, and covenants and restrictions we may need to comply with in connection with such funding;
- our dependence on the success of our future product candidates, some of which may not receive regulatory approval or be successfully commercialized; problems in our manufacturing process for our new products and/or our failure to comply with manufacturing regulations, or unexpected increases in our manufacturing costs; problems with distribution of our products; and failure to adequately market our products;
- risks associated with the growth of our business, our ability to maintain such growth, difficulties in managing our growth, and executing our growth strategy;
- liability for previously restated financial statements and associated with ineffective controls and procedures, as well as costs and expenses related to the indemnification of current and former officers and directors;
- our dependence on our key personnel and our ability to attract and retain employees and consultants;
- risks from intense competition from companies with greater resources and experience than we have;
- our ability to receive regulatory approvals for our product candidates, and the timeline and costs associated therewith, including the uncertainties associated with the clinical development and regulatory approval of the Company's drug candidates, including potential delays in the enrollment and completion of clinical trials, issues raised by the FDA and the MHRA;
- risks that our future product candidates, if approved by regulatory authorities, may be unable to achieve the expected market acceptance and, consequently, limit our ability to generate revenue from new products;
- the outcome of currently pending and future claims and litigation, future government investigations, and other proceedings may adversely affect our business and results of operations;

- the fact that the majority of our license agreements provide the licensors and/or counter-parties the right to use, own and/or exploit such licensed intellectual property;

- preclinical studies and earlier clinical trials may not necessarily be predictive of future results and may not have favorable results; we have limited marketing experience, and our future ability to successfully commercialize any of our product candidates, even if they are approved in the future is unknown; and business interruptions could delay us in the process of developing our future product candidates and could disrupt our product sales;

- third-party payors may not provide coverage and adequate reimbursement levels for any future products;

- liability from lawsuits (including product liability lawsuits, stockholder lawsuits and regulatory matters), including judgments, damages, fines and penalties and including the outcome of currently pending litigation, potential future government investigations, and other proceedings that may adversely affect our business and results of operations;

- security breaches, loss of data and other disruptions which could prevent us from accessing critical information or expose us to liabilities or damages;

- risks associated with clinical trials that are expensive, time-consuming, uncertain and susceptible to change, delay or termination and which are open to differing interpretations, delays in the trials, testing, application, or approval process for drug candidates and/or our ability to obtain approval for promising drug candidates, and the costs associated therewith;

- our ability to comply with existing and future rules and regulations, including federal, state and foreign healthcare laws and regulations and implementation of, or changes to, such healthcare laws and regulations;

- our ability to adequately protect our future product candidates or our proprietary technology in the marketplace, claims and liability from third parties regarding our alleged infringement of their intellectual property;

- differences in laws and regulations between countries and other jurisdictions and changes in laws or regulations, including, but not limited to tax laws and controlled substance laws, or a failure to comply with any laws and regulations;

- conflicts of interest between our officers, directors, consultants and scientists;

- penalties associated with our failure to comply with certain pre-agreed contractual obligations and restrictions;

- dilution caused by future fund raising, the conversion/exercise of outstanding convertible securities, and downward pressure on the value of our securities caused by such future issuances/sales;

- negative effects on our business from the COVID-19 pandemic and other potential future pandemics;

- the extremely volatile nature of our securities and potential lack of liquidity thereof;

- the fact that our Certificate of Incorporation provides for indemnification of officers and directors, limits the liability of officers and directors, allows for the authorization of preferred stock without stockholder approval, and includes certain other anti-takeover provisions and exclusive forum provisions;

- our ability to maintain the listing of our common stock and warrants on NASDAQ and the costs of compliance with SEC and NASDAQ rules and requirements;

- failure of our information technology systems, including cybersecurity attacks or other data security incidents, that could significantly disrupt the operation of our business;

- the fact that we may acquire other companies which could divert our management's attention, result in additional dilution to our stockholders and otherwise disrupt our operations and harm our operating results and if we make any acquisitions, they may disrupt or have a negative impact on our business;

- the effect of high inflation, increasing interest rates and economic downturns, including potential recessions, as well as macroeconomic, geopolitical, health and industry trends, pandemics, acts of war (including the ongoing Ukraine/Russian conflict) and other large-scale crises, as well as the potential implications of a Congressional impasse over the U.S. debt limit or possible future U.S. governmental shutdowns over budget disagreements;

- the fact that we may apply working capital and future funding to uses that ultimately do not improve our operating results or increase the value of our securities; and

- our growth depends in part on the success of our strategic relationships with third parties.

You should be aware that there are substantial risks for an investment in our common stock. You should carefully consider these risk factors before you decide to invest in our common stock.

If any of the following risks were to occur, our business, financial condition, results of operations or other prospects, could be materially adversely affected, and the occurrence of any of these risks could materially affect our likelihood of success. If that happens, the market price of our common stock, if any, could decline, and prospective investors would lose all or part of their investment in our common stock.

Our business, financial condition and results of operations are subject to various risks and uncertainties, including those described below. This section discusses factors that, individually or in the aggregate, could cause our actual results to differ materially from expected and historical results. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. It is not possible to predict or identify all such factors. Consequently, the following description of Risk Factors is not a complete discussion of all potential risks or uncertainties applicable to our business.

Risks Related to Our Business Operations

Our current cash balance is only sufficient to fund our planned business operations through the second quarter of 2023. If additional capital is not available, we may not be able to pursue our planned business operations, may be forced to change our planned business operations, or may take other actions that could adversely impact our stockholders.

We are a clinical stage biotechnology company that currently has no revenue. Thus, our business does not generate the cash necessary to finance our planned business operations. We will require significant additional capital to: (i) develop FDA and/or MHRA-approved products and commercialize such products; (ii) fund research and development activities relating to, and obtain regulatory approval for, our product candidates; (iii) protect our intellectual property; (iv) attract and retain highly-qualified personnel; (v) respond effectively to competitive pressures; and (vi) acquire complementary businesses or technologies.

Our future capital needs depend on many factors, including: (i) the scope, duration and expenditures associated with our research, development and commercialization efforts; (ii) continued scientific progress in our programs; (iii) the outcome of potential partnering or licensing transactions, if any; (iv) competing technological developments; (v) our proprietary patent position; and (vi) the regulatory approval process for our products.

We will need to raise substantial additional funds through public or private equity offerings, debt financings or strategic alliances and licensing arrangements to finance our planned business operations. We may not be able to obtain additional financing on terms favorable to us, if at all. General market conditions, as well as the ongoing COVID-19 pandemic, raising interest rates and inflation, as well as global conflicts which as the ongoing conflict between Ukraine and Russia, as well as the potential implications of a Congressional impasse over the U.S. debt limit or possible future U.S. governmental shutdowns over budget disagreements, may make it difficult for us to seek financing from the capital markets, and the terms of any financing may adversely affect the holdings or the rights of our stockholders. For example, if we raise additional funds by issuing equity securities, further dilution to our stockholders will result, which may substantially dilute the value of their investment. Any equity financing may also have the effect of reducing the conversion or exercise price of our outstanding convertible or exercisable securities, which could result in the issuance (or potential issuance) of a significant number of additional shares of our common stock. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Debt financing, if available, may involve restrictive covenants that could limit our flexibility to conduct future business activities and, in the event of insolvency, could be paid before holders of equity securities received any distribution of our assets. We may be required to relinquish rights to our technologies or product candidates, or grant licenses through alliance, joint venture or agreements on terms that are not favorable to us, in order to raise additional funds. If adequate funds are not available, we may have to delay, reduce or eliminate one or more of our planned activities with respect to our business, or terminate our operations. These actions would likely reduce the market price of our common stock.

We will need additional capital which may not be available on commercially acceptable terms, if at all, which raises questions about our ability to continue as a going concern.

As of December 31, 2022, we had an accumulated deficit of $107,408,545 and working capital of $3,270,608, and for the year ended December 31, 2022, a net loss of $38,726,259 and cash used in operating activities of $12,127,585. As of March 29, 2023, we had cash on hand of approximately $2.7 million. The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As we are not generating revenues, we need to raise a significant amount of capital in order to pay our debts and cover our operating costs. While the Company recently raised funds through the sale of equity in July 2022 ($6.5 million of gross proceeds) and December 2022 ($6.0 million of gross proceeds), there is no assurance that we will be able to raise additional needed capital or that such capital will be available under favorable terms.

We are subject to all the substantial risks inherent in the development of a new business enterprise within an extremely competitive industry. Due to the absence of a long-standing operating history and the emerging nature of the markets in which we compete, we anticipate operating losses until we can successfully implement our business strategy, which includes all associated revenue streams. We may never ever achieve profitable operations or generate significant revenues.

We currently have a monthly cash requirement spend of approximately $900,000. We believe that in the aggregate, we will require significant additional capital funding to support and expand the research and development and marketing of our products, fund future clinical trials, repay debt obligations, provide capital expenditures for additional equipment and development costs, payment obligations, office space and systems for managing the business, and cover other operating costs until our planned revenue streams from products are fully-implemented and begin to offset our operating costs, if ever.

Since our inception, we have funded our operations with the proceeds from equity and debt financings. We have experienced liquidity issues due to, among other reasons, our limited ability to raise adequate capital on acceptable terms. We have historically relied upon the sale of equity and debt funding that is convertible into shares of our common stock to fund our operations and have devoted significant efforts to reduce that exposure. We anticipate that we will need to issue equity to fund our operations and fund our operating expenses for the foreseeable future. If we are unable to achieve operational profitability or we are not successful in securing other forms of financing, we will have to evaluate alternative actions to reduce our operating expenses and conserve cash.

These conditions raise substantial doubt about our ability to continue as a going concern for the next twelve months from the date of issuance of the auditor's report set forth herein. The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Accordingly, the consolidated financial statements do not include any adjustments relating to the recoverability of assets and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The consolidated financial statements included herein also include a going concern footnote.

Additionally, wherever possible, our Board of Directors will attempt to use non-cash consideration to satisfy obligations. In many instances, we believe that the non-cash consideration will consist of restricted shares of our common stock, preferred stock or warrants to purchase shares of our common stock. Our Board of Directors has authority, without action or vote of the stockholders, but subject to NASDAQ rules and regulations (which generally require stockholder approval for any transactions which would result in the issuance of more than 20% of our then outstanding shares of common stock or voting rights representing over 20% of our then outstanding shares of stock, subject to certain exceptions), to issue all or part of the authorized but unissued shares of common stock, preferred stock or warrants to purchase such shares of common stock. In addition, we may attempt to raise capital by selling shares of our common stock, possibly at a discount to market in the future. These actions will result in dilution of the ownership interests of existing stockholders, may further dilute common stock book value, and that dilution may be material. Such issuances may also serve to enhance existing management's ability to maintain control of us, because the shares may be issued to parties or entities committed to supporting existing management.

We have significant and increasing liquidity needs and require additional funding.

Research and development, management and administrative expenses, including legal expenses, and cash used for operations will continue to be significant and may increase substantially in the future in connection with new research and development initiatives, clinical trials, continued product commercialization efforts and the launch of our future product candidates. We will need to raise additional capital to fund our operations, continue to conduct clinical trials to support potential regulatory approval of marketing applications, and to fund commercialization of our future product candidates.

The amount and timing of our future funding requirements will depend on many factors, including, but not limited to:

- the timing of FDA and/or MHRA approval, if any, and approvals in other international markets of our future product candidates, if at all;
- the timing and amount of revenue from sales of our products, or revenue from grants or other sources;
- the rate of progress and cost of our clinical trials and other product development programs;
- costs of establishing or outsourcing sales, marketing and distribution capabilities;
- costs and timing of any outsourced growing and commercial manufacturing supply arrangements for our future product candidates;
- costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our future product candidates;
- the effect of competing technological and market developments;
- personnel, facilities and equipment requirements; and
- the terms and timing of any additional collaborative, licensing, co-promotion or other arrangements that we may establish.

While we expect to fund our future capital requirements from a number of sources, such as cash flow from operations and the proceeds from further public and/or private offerings, we cannot assure you that any of these funding sources will be available to us on favorable terms, or at all. Further, even if we can raise funds from all of the above sources, the amounts raised may not be sufficient to meet our future capital requirements.

We may need to raise additional capital, which may not be available on favorable terms, if at all, causing dilution to our stockholders, restricting our operations or adversely affecting our ability to operate our business.

We may not be able to obtain additional financing on terms favorable to us, if at all, including as a result of macroeconomic conditions such as a severe or prolonged economic downturn. Disruption, uncertainty or volatility in the capital markets could increase our cost of capital or limit our ability to raise funds needed to operate our business. Disruptions could be caused by Federal Reserve policies and actions, currency concerns, inflation, economic downturn or uncertainty, monetary policies, failures of financial institutions, U.S. debt management concerns, and U.S. debt limit and budget disputes, including government shutdowns, European and worldwide sovereign debt concerns, other global or geopolitical events, or other factors. Current macroeconomic conditions have negatively impacted the U.S. banking sector, including for example, the recent closures and FDIC receiverships of Silicon Valley Bank and Signature Bank. Although we do not have any accounts at or business relationships with these banks, we may be negatively impacted by other disruptions to the U.S. banking system caused by these or similar developments.

Our results of operations may be adversely affected by fluctuations in currency values.

We expend expenses in currencies other than the U.S. dollar. The Company's reporting currency is the United States dollar. The functional currency of certain subsidiaries is the Canadian Dollar ("CAD") or British Pound ("GBP"). The resulting translation adjustments are recognized in stockholders' equity as a component of accumulated other comprehensive income. Comprehensive income is defined as the change in equity of an entity from all sources other than investments by owners or distributions to owners and includes foreign currency translation adjustments as described above. During the years ended December 31, 2022 and 2021, the Company recorded other comprehensive (loss) income of ($3,702,963) and $180,554, respectively, as a result of foreign currency translation adjustments.

Foreign currency gains and losses resulting from transactions denominated in foreign currencies, including intercompany transactions, are included in results of operations. The Company recognized ($12,777) and ($69) of foreign currency transaction (losses) for the years ended December 31, 2022 and 2021, respectively. Such amounts have been classified within general and administrative expenses in the accompanying consolidated statements of operations and comprehensive loss.

Changes in the value of the currencies which we pay expenses (and in the future receive revenues), versus each other, and the U.S. dollar, could result in an adverse charge being recorded to our income statement.

Global economic conditions could materially adversely affect the Company's business, results of operations, financial condition and growth.

Adverse macroeconomic conditions, including inflation, slower growth or recession, new or increased tariffs, changes to fiscal and monetary policy, tighter credit, higher interest rates, high unemployment and currency fluctuations, as well as the potential implications of a Congressional impasse over the U.S. debt limit or possible future U.S. governmental shutdowns over budget disagreements, could materially adversely affect the Company's operations, expenses, access to capital and the market for the Company's planned future products. In addition, consumer confidence and spending could be adversely affected in response to financial market volatility, negative financial news, conditions in the real estate and mortgage markets, declines in income or asset values, changes to fuel and other energy costs, labor and healthcare costs and other economic factors.

In addition, uncertainty about, or a decline in, global or regional economic conditions could have a significant impact on the Company's funding sources, suppliers and partners. Potential effects include financial instability; inability to obtain credit to finance operations and purchases of the Company's future planned products; and insolvency.

A downturn in the economic environment could also lead to limitations on the Company's ability to sell equity or issue new debt; reduce liquidity; and result in declines in the fair value of the Company's financial instruments. These and other economic factors could materially adversely affect the Company's business, results of operations, financial condition and growth.

Our industry and the broader U.S. economy have experienced higher than expected inflationary pressures during 2022, related to continued supply chain disruptions, labor shortages and geopolitical instability. Should these conditions persist our business, future results of operations and cash flows could be materially and adversely affected.

Calendar 2022 has seen significant increases in the costs of certain materials, products and shipping costs, as a result of availability constraints, supply chain disruption, increased demand, labor shortages associated with a fully employed U.S. labor force, high inflation and other factors. Supply and demand fundamentals have been further aggravated by disruptions in global energy supply caused by multiple geopolitical events, including the ongoing conflict between Russia and Ukraine. Service, materials and shipping costs have also increased accordingly with general supply chain and inflation issues seen throughout the U.S. leading to increased operating costs. Recent supply chain constraints and inflationary pressures may adversely impact our operating costs and may negatively impact our future product costs, consulting costs and expenses which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Economic uncertainty may affect our access to capital and/or increase the costs of such capital.

Global economic conditions continue to be volatile and uncertain due to, among other things, consumer confidence in future economic conditions, fears of recession and trade wars, the price of energy, fluctuating interest rates, the availability and cost of consumer credit, the availability and timing of government stimulus programs, levels of unemployment, increased inflation, tax rates, and the war between Ukraine and Russia which began in February 2022, and the potential implications of a Congressional impasse over the U.S. debt limit or possible future U.S. governmental shutdowns over budget disagreements. These conditions remain unpredictable and create uncertainties about our ability to raise capital in the future. In the event required capital becomes unavailable in the future, or more costly, it could have a material adverse effect on our business, future results of operations, and financial condition.

We may not receive any amounts under our pre-merger directors' and officers' insurance policy in connection with certain litigation matters.

On June 29, 2022, AmTrust International Underwriters DAC ("AmTrust"), which was the premerger directors' and officers' insurance policy underwriter for KBL, filed a declaratory relief action against the Company in the U.S. District Court for the Northern District of California (the "Declaratory Relief Action") seeking declaration of AmTrust's obligations under the directors' and officers' insurance policy. In the Declaratory Relief Action, AmTrust is claiming that as a result of the merger, the Company is no longer the insured under the subject insurance policy, notwithstanding the fact that the fees which the Company seeks to recover from AmTrust relate to matters occurring prior to the merger. On September 20, 2022, the Company filed its Answer and Counterclaims against AmTrust for bad faith breach of AmTrust's insurance coverage obligations to the Company under the subject directors' and officers' insurance policy, and seeking damages of at least $2 million in compensatory damages, together with applicable punitive damages. In addition, the Company brought a Third-Party Complaint against its excess insurance carrier, Freedom Specialty Insurance Company ("Freedom") seeking declaratory relief that Freedom will also be required to honor its policy coverage as soon as the amount of AmTrust's insurance coverage obligations to the Company have been exhausted. On October 25, 2022, AmTrust filed its Answer to the Company's Counterclaims and, on October 27, 2022, Freedom filed its Answer to the Third-Party Complaint.

On November 22, 2022, the Company filed a Motion for Summary Adjudication against both AmTrust and Freedom. The Motion was fully briefed and a hearing was held on March 9, 2023. The Court took the matter under submission and has not yet issued a ruling. While the Company believes it has a strong case against AmTrust, there can be no assurance that the Company will prevail in this action.

We are dependent on the success of our future product candidates, some of which may not receive regulatory approval or be successfully commercialized.

Our success will depend on our ability to successfully develop and commercialize our future product candidates through our development programs, including our product candidate for the treatment of Dupuytren's Contracture and any other product candidates developed through our fibrosis & anti-TNF, CBD derivatives, and α7nAChR development platforms. We may never be able to develop products which receive regulatory approval in the U.S. or elsewhere. There can be no assurance that the FDA, MHRA, EMA or any other regulatory authority will approve these product candidates.

Our ability to successfully commercialize our future product candidates will depend on, among other things, our ability to successfully complete pre-clinical and other non-clinical studies and clinical trials and to receive regulatory approvals from the FDA, MHRA, EMA and similar foreign regulatory authorities. Delays in the regulatory process could have a material adverse effect on our business, results of operations and financial condition.

Our ability to generate revenue from any of our potential products is subject to our ability to obtain regulatory approval and fulfill numerous other requirements and we may never be successful in generating revenues or becoming profitable.

Our ability to become and remain profitable depends on our ability to generate revenue or execute other business development arrangements. We do not expect to generate significant revenue, if any, unless and until we are able to obtain regulatory approval for, and successfully commercialize the product candidates we are developing or may develop. Successful commercialization, to the extent it occurs, will require achievement of many key milestones, including demonstrating safety and efficacy in clinical trials, obtaining regulatory approval for these product candidates, manufacturing, marketing and selling, or entering into other agreements to commercialize, those products for which we may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we cannot accurately and precisely predict the timing and amount, if any, of revenues, the extent of any further losses or when we might achieve profitability. We may never succeed in these activities and, even if we do, we may never generate revenues that are sufficient enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our failure to become and remain profitable may depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

We have recently grown our business and will need to increase the size and complexity of our organization in the future, and we may experience difficulties in managing our growth and executing our growth strategy.

Our management, personnel and systems currently in place may not be adequate to support our business plan and future growth. We will need to increase our number of full-time equivalent employees in order to conduct Phase 1, 2 and 3 clinical trials of our future products and to establish a commercial organization and commercial infrastructure. As a result of these future activities, the complexity of our business operations is expected to substantially increase. We will need to develop and expand our scientific, manufacturing, sales and marketing, managerial, compliance, operational, financial and other resources to support our planned research, development, manufacturing and commercialization activities.

Our need to effectively manage our operations, growth and various projects requires that we:

- continue to improve our operational, financial, management and regulatory compliance controls and reporting systems and procedures;
- attract and retain sufficient numbers of talented employees;
- manage our commercialization activities effectively and in a cost-effective manner (currently trial and development for our clinical trials is very cost effective); and
- manage our development efforts effectively while carrying out our contractual obligations to contractors and other third parties.

We have utilized and continue to utilize the services of part-time outside consultants and contractors to perform a number of tasks for our company, including tasks related to compliance programs, clinical trial management, regulatory affairs, formulation development and other drug development functions. Our growth strategy may entail expanding our use of consultants and contractors to implement these and other tasks going forward. If we are not able to effectively expand our organization by hiring new employees and expanding our use of consultants and contractors, we may be unable to successfully implement the tasks necessary to effectively execute on our planned research, development, manufacturing and commercialization activities and, accordingly, may not achieve our research, development and commercialization goals.

We face liability for previously restated financial statements and/or certain actions of our prior management which led to such restatements.

We filed a Current Report on Form 8-K on December 31, 2020 and another Current Report on Form 8-K on February 3, 2021, where we announced that due to matters we discovered which related to KBL, prior to the Business Combination, certain historical financial statements were unreliable. As a result, we restated our financial statements for the three and six months ended June 30, 2020 and for the three and nine months ended September 30, 2020, because of errors in such financial statements which were identified after such financial statements were filed with the SEC in our original quarterly reports for the quarters ended June 30, 2020 and September 30, 2020. While we believe these restatements are the result of the actions of, and are the responsibility of, the management of KBL (none of whom remain employed by the Company), we may be subject to stockholder litigation, SEC actions, fines and penalties, rating downgrades, negative publicity and difficulties in attracting and retaining key clients, employees and management personnel as a result of such restatements. Additionally, our securities may trade at prices lower than similarly situated companies which have not had to restate their financial statements.

Our failure to appropriately adjust processes resulting from significant one-time transactions may result in a misstatement in the financial statements.

In the course of our annual audit but prior to filing, we discovered that an error occurred which caused the fair value of our public warrants to be overstated by an immaterial amount. This error was corrected before the 2022 financial statements were filed. While we believe that the fair value of warrants in the financial statements for the year ended December 31, 2022 are correctly stated, it is possible that similar errors which could have a material adverse effect on our financial condition and results of operations, could require us to restate our financial statements for prior periods or in the future.

Operating results may vary significantly in future periods.

Our financial results are unpredictable and may fluctuate, for among other reasons, due to commercial sales of our future product candidates; our achievement of product development objectives and milestones; clinical trial enrollment and expenses; research and development expenses; and the timing and nature of contract manufacturing and contract research payments. A high portion of our costs are predetermined on an annual basis, due in part to our significant research and development costs. Thus, small declines in future revenue could disproportionately affect financial results in a quarter.

We depend on our key personnel and our ability to attract and retain employees.

Our future growth and success depend on our ability to recruit, retain, manage and motivate our employees. We are highly dependent on our current management and scientific personnel, including our Chief Executive Officer, Dr. James N. Woody, our Co-Chairmen, Sir Marc Feldmann, Ph.D., and Lawrence Steinman, M.D., our Chief Scientific Officer, Jonathan Rothbard, Ph.D., and our scientist, Jagdeep Nanchahal. The inability to hire or retain experienced management personnel could adversely affect our ability to execute our business plan and harm our operating results. Due to the specialized scientific and managerial nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. The competition for qualified personnel in the biotechnological field is intense and we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

Problems in our manufacturing process for our future chemical entities, failure to comply with manufacturing regulations or unexpected increases in our manufacturing costs could harm our business, results of operations and financial condition.

We are responsible for the manufacture and supply of our future product candidates in the CBD derivatives and α7nAChR programs for commercial use and for use in clinical trials. The manufacturing of our future product candidates necessitates compliance with GMPs and other regulatory requirements in international jurisdictions. Our ability to successfully manufacture our future product candidates will involve manufacture of finished products and labeling and packaging, which includes product information, tamper proof evidence and anti-counterfeit features, under tightly controlled processes and procedures. In addition, we will have to ensure chemical consistency among our batches, including clinical trial batches and, if approved, marketing batches. Demonstrating such consistency may require typical manufacturing controls as well as clinical data. We will also have to ensure that our batches conform to complex release specifications. If we are unable to manufacture our future product candidates in accordance with regulatory specifications, or if there are disruptions in our manufacturing process due to damage, loss or otherwise, or failure to pass regulatory inspections of our manufacturing facilities, we may not be able to meet demand or supply sufficient product for use in clinical trials, and this may also harm our ability to commercialize our future product candidates on a timely or cost-competitive basis, if at all.

We may not develop and expand our manufacturing capability in time to meet demand for our product candidates, and the FDA, MHRA or other foreign regulatory authorities may not accept our facilities or those of our contract manufacturers as being suitable for the production of our products and product candidates. Any problems in our manufacturing process could materially adversely affect our business, results of operations and financial condition.

Our memorandum of understanding with Celltrion Healthcare may not result in the parties entering into a definitive agreement.

In September 2021, we entered into a non-binding memorandum of understanding with Celltrion Healthcare, a biopharmaceutical company, for the supply of an anti-TNF biosimilar drug used in our ongoing development of anti-TNF products. The parties have not entered into a definitive agreement regarding such relationship to date, and such definitive agreement may not ultimately be entered into on terms contemplated, if at all. In the event that we are unable to come to mutually agreeable definitive terms with Celltrion Healthcare, we will need to locate an alternative supplier of the anti-TNF biosimilar drug, and we may be unable to find an alternative supplier or such alternative supplier may require less favorable terms than are currently contemplated. Any of the above may materially adversely affect our business, results of operations and financial condition.

We expect to face intense competition from companies with greater resources and experience than we have; and may face competition from competitors seeking to market our products under a Section 505(b)(2) application.

The pharmaceutical industry is highly competitive and subject to rapid change. The industry continues to expand and evolve as an increasing number of competitors and potential competitors enter the market. Many of these competitors and potential competitors have substantially greater financial, technological, managerial and research and development resources and experience than our company. Some of these competitors and potential competitors have more experience than our company in the development of pharmaceutical products, including validation procedures and regulatory matters. In addition, our future product candidates, if successfully developed, will compete with product offerings from large and well-established companies that have greater marketing and sales experience and capabilities than our company or our collaboration partners have. In particular, Insys Therapeutics, Inc. is developing CBD in Infantile Spasms ("IS"), and potentially other indications. Zogenix, Inc. has reported positive data in two Phase 3 trials of low dose fenfluramine in Dravet syndrome and has commenced a Phase 3 trial with this product in Lennox Gastaut Syndrome. Biocodex recently received regulatory approval from the FDA for the drug Stiripentol (Diacomit) for the treatment of Dravet syndrome. Other companies with greater resources than our company may announce similar plans in the future. In addition, there are non-FDA approved CBD preparations being made available from companies in the medical marijuana industry, which might attempt to compete with our future product candidates.

Many of our competitors have significantly greater financial and technical resources, experience and expertise in:

- research and development;
- preclinical testing;
- designing and implementing clinical trials;
- regulatory processes and approvals;
- production and manufacturing; and
- sales and marketing of approved products.

Principal competitive factors in our industry include:

- the quality and breadth of an organization's technology;
- management of the organization and the execution of the organization's strategy;
- the skill and experience of an organization's employees and its ability to recruit and retain skilled and experienced employees;
- an organization's intellectual property portfolio;
- the range of capabilities, from target identification and validation to drug discovery and development to manufacturing and marketing; and
- the availability of substantial capital resources to fund discovery, development and commercialization activities.

Additionally, competitors may also seek to market versions of our drug products via a section 505(b)(2) application, which is a type of somewhat abbreviated NDA. NDA Section 505(b)(2) applications may be submitted for drug products that represent a modification, such as a new indication or new dosage form, of a previously approved drug. Section 505(b)(2) applications may rely on the FDA's previous findings for the safety and effectiveness of the previously approved drug in addition to information obtained by the 505(b)(2) applicant to support the modification of the previously approved drug. Preparing Section 505(b)(2) applications may be less costly and less time-consuming than preparing an NDA based entirely on new data and information. Section 505(b)(2) applications are subject to the same patent certification procedures as an ANDA.

If we are unable to compete successfully, our commercial opportunities will be reduced and our business, results of operations and financial conditions may be materially harmed.

Our future product candidates, if approved, may be unable to achieve the expected market acceptance and, consequently, limit our ability to generate revenue from new products.

Even when product development is successful and regulatory approval has been obtained, our ability to generate sufficient revenue depends on the acceptance of our products by physicians and patients. We cannot assure you that any of our future product candidates will achieve the expected level of market acceptance and revenue if and when they obtain the requisite regulatory approvals. The market acceptance of any product depends on a number of factors, including the indication statement, warnings required by regulatory authorities in the product label and new competing products. Market acceptance can also be influenced by continued demonstration of efficacy and safety in commercial use, physicians' willingness to prescribe the product, reimbursement from third-party payors such as government health care programs and private third-party payors, the price of the product, the nature of any post-approval risk management activities mandated by regulatory authorities, competition, and marketing and distribution support. Further, our U.S. distribution depends on the adequate performance of a reimbursement support hub and contracted specialty pharmacies in a closed-distribution network. An ineffective or inefficient U.S. distribution model at launch may lead to inability to fulfill demand, and consequently a loss of revenue. The success and acceptance of a product in one country may be negatively affected by its activities in another. If we fail to adapt our approach to clinical trials in the U.S. market to meet the needs of EMA, MHRA or other European regulatory authorities, or to generate the health economics and outcomes research data needed to support pricing and reimbursement negotiations or decisions in Europe, we may have difficulties obtaining marketing authorization for our products from EMA/European Commission or the MHRA and may have difficulties obtaining pricing and reimbursement approval for our products at a national level. Any factors preventing or limiting the market acceptance of our products could have a material adverse effect on our business, results of operations and financial condition.

All of our patents in the Anti-TNF and Fibrosis program are method of use patents, which may result in biosimilar drugs being used without our permission.

The success of our most advanced drug development platform depends on the enforceability of our method of use patents, as there are currently many biosimilar anti-TNF drugs in the market. If we are unable to obtain composition of matter patents, and enforce such patents, our ability to generate revenue from the anti-TNF platform may be significantly limited and competitors may be able to use our research to bring competing drugs to market which would reduce our market share.

The majority of our license agreements provide the licensors and/or counter-parties the right to use and/or exploit such licensed intellectual property.

The majority of our license agreements provide the licensors and/or counter-parties the right to use and/or exploit such licensed intellectual property, and in some cases provide them ownership of such intellectual property, know-how and research results. As such, we may be in competition with parties who we have license agreements with, will likely not have the sole right to monetize, sell or distribute our product candidates and may be subject to restrictions on use and territory of sales. Any or all of the above may have a material adverse effect on our results of operations and cash flows and ultimately the value of our securities.

Interim, topline and preliminary data from our clinical trials may change as more patient data becomes available, and is subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary, interim or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change as patient enrollment and treatment continues and more patient data become available. For example, any positive results from our preclinical testing, Phase 1 and Phase 2 clinical trials of our product candidate for any product candidate may not necessarily be predictive of the results from planned or future clinical trials for such product candidates. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical trials after achieving positive results in pre-clinical and early clinical development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, pre-clinical findings while clinical trials were underway or safety or efficacy observations in clinical trials, including adverse events. Adverse differences between previous preliminary or interim data and future interim or final data could significantly harm our business prospects. We may also announce topline data following the completion of a preclinical study or clinical trial, which may be subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data has been received and fully evaluated. Preliminary, interim, or topline data also remains subject to audit and verification procedures that may result in the final data being materially different from the data we previously published. As a result, preliminary, interim, and topline data should be viewed with caution until the final data is available.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine to be material or otherwise appropriate information to include in our disclosure. Moreover, our interpretation of clinical data or our conclusions based on the preclinical in vitro and in vivo models may prove inaccurate, as preclinical and clinical data can be susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA approval or a marketing authorization granted by the European Commission.

If we fail to produce positive results in our future clinical trials, the development timeline and regulatory approval and commercialization prospects for such product candidates, and, correspondingly, our business and financial prospects, would be materially adversely affected.

We have limited marketing experience, and we may not be able to successfully commercialize any of our future product candidates, even if they are approved in the future.

Our ability to generate revenues ultimately will depend on our ability to sell our approved products and secure adequate third-party reimbursement. We currently have no experience in marketing and selling our products. The commercial success of our future products depends on a number of factors beyond our control, including the willingness of physicians to prescribe our future products to patients, payors' willingness and ability to pay for our future products, the level of pricing achieved, patients' response to our future products, and the ability of our future marketing partners to generate sales. There can be no guarantee that we will be able to establish or maintain the personnel, systems, arrangements and capabilities necessary to successfully commercialize our future products or any product candidate approved by the FDA, MHRA or other regulatory authority in the future. If we fail to establish or maintain successful marketing, sales and reimbursement capabilities or fail to enter into successful marketing arrangements with third parties, our product revenues may suffer.

If the price for any of our future approved products decreases or if governmental and other third-party payors do not provide coverage and adequate reimbursement levels, our revenue and prospects for profitability will suffer.

Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals generally must be obtained on a country-by-country basis. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Even if we obtain coverage for our future product candidates, the resulting reimbursement payment rates may require co-payments that patients find unacceptably high. Patients may not use our future product candidates if coverage is not provided or reimbursement is inadequate to cover a significant portion of a patient's cost.

In addition, the market for our future product candidates in the U.S. will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. The current environment is putting pressure on companies to price products below what they may feel is appropriate. Our future revenues and overall success could be negatively impacted if we sell future product candidates at less than an optimized price. In addition, in the U.S., no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for our future product candidates may differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our future product candidates to each payor separately, with no assurance that coverage will be obtained. If we are unable to obtain coverage of, and adequate payment levels for, our future product candidates, physicians may limit how much or under what circumstances they will prescribe or administer them and patients may decline to purchase them. This could affect our ability to successfully commercialize our product candidates, and thereby adversely impact our profitability, results of operations, financial condition and future success.

In addition, where we have chosen to collaborate with a third party on product candidate development and commercialization, our partner may elect to reduce the price of our products to increase the likelihood of obtaining reimbursement approvals. In many countries, products cannot be commercially launched until reimbursement is approved and the negotiation process in some countries can exceed 12 months. In addition, pricing and reimbursement decisions in certain countries can be affected by decisions made in other countries, which can lead to mandatory price reductions and/or additional reimbursement restrictions across a number of other countries, which may adversely affect sales and profitability. In the event that countries impose prices that are not sufficient to allow us or our partners to generate a profit, our partners may refuse to launch the product in such countries or withdraw the product from the market, which would adversely affect sales and profitability.

Business interruptions could delay us in the process of developing our future product candidates and could disrupt our product sales.

Loss of our future manufacturing facilities, stored inventory or laboratory facilities through fire, theft or other causes, could have an adverse effect on our ability to meet demand for our future product candidates or to continue product development activities and to conduct our business. Failure to supply our partners with commercial products may lead to adverse consequences, including the right of partners to assume responsibility for product supply. Even if we obtain insurance coverage to compensate us for such business interruptions, such coverage may prove insufficient to fully compensate us for the damage to our business resulting from any significant property or casualty loss to our inventory.

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

Although we have never had any product liability claims or lawsuits brought against us, we face potential product liability exposure related to the testing of our future product candidates in human clinical trials, and we will face exposure to claims in jurisdictions where we market and distribute in the future. We may face exposure to claims by an even greater number of persons when we begin marketing and distributing our products commercially in the U.S. and elsewhere. In the future, an individual may bring a liability claim against us alleging that one of our future product candidates caused an injury. While we plan to take what we believe are appropriate precautions, we may be unable to avoid significant liability if any product liability lawsuit is brought against us. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects. Although we plan to purchase insurance to cover product liability lawsuits, if we cannot successfully defend our company against product liability claims, or if such insurance coverage is inadequate, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in decreased demand for our products, reputational damage, withdrawal of clinical trial participation participants, litigation costs, product recall costs, monetary awards, increased costs for liability insurance, lost revenues and business interruption.

Our employees may have previously engaged, and/or may in the future engage, in misconduct or other improper activities, including noncompliance with regulatory standards and legal requirements.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA, SEC or Office of Inspector General regulations, or regulations of any other applicable regulatory authority, failure to provide accurate information to the FDA or the SEC, failure to disclose accurate information in SEC filings, failure to comply with applicable manufacturing standards, other federal, state or foreign laws and regulations, report information or data accurately or disclose unauthorized activities. Employee misconduct could also involve the improper use of information, including information obtained in the course of clinical trials, or illegal appropriation of drug product, which could result in government investigations and serious harm to our reputation. Despite our adoption of a Code of Ethics, employee misconduct is not always possible to identify and deter. The precautions we take to detect and prevent these prohibited activities 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 be in compliance with such laws or regulations. If any such actions are instituted against our company, and we are not successful in defending our company or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We are subject to the U.S. Foreign Corrupt Practices Act and other anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the U.S. Foreign Corrupt Practices Act ("FCPA"), and other anti-corruption laws that apply in countries in which we do business. The FCPA and these other laws generally prohibit our company and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We and our commercial partners operate in a number of jurisdictions that pose a high risk of potential FCPA violations, and we participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the U.S., Canada, Israel, the U.K. and authorities in the EU, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the Trade Control Laws.

However, there is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA or other legal requirements, including Trade Control Laws. If we are not in compliance with the FCPA and other anti-corruption laws or Trade Control Laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the FCPA, other anti-corruption laws by the U.S. or other authorities could also have an adverse impact on our reputation, business, financial condition and results of operations.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business, prevent us from accessing critical information or expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of business, we expect to collect and store sensitive data, including legally protected patient health information, credit card information, personally identifiable information about our employees, intellectual property, and proprietary business information. The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers, or viruses, breaches or interruptions due to employee error, malfeasance or other disruptions, or lapses in compliance with privacy and security mandates. Any such virus, breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. We have measures in place that are designed to prevent, and if necessary, to detect and respond to such security incidents and breaches of privacy and security mandates. However, in the future, any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as HIPAA and European Union General Data Protection Regulation ("GDPR"), government enforcement actions and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to process samples, provide test results, share and monitor safety data, bill payors or patients, provide customer support services, conduct research and development activities, process and prepare company financial information, manage various general and administrative aspects of our business and may damage our reputation, any of which could adversely affect our business, financial condition and results of operations.

GDPR, which applies to all EU member states includes substantial fines for breaches of the data protection rules and may require us to put in place additional mechanisms ensuring compliance with the new and changing data protection rules. GDPR is a complex law and the regulatory guidance is still evolving, including with respect to how GDPR should be applied in the context of clinical trials or other transactions from which we may gain access to personal data. GDPR increases our costs of compliance and results in greater legal risks.

Our research and development programs and product candidates are in development. As a result, we are unable to predict if or when we will successfully develop or commercialize our product candidates.

Our clinical-stage product candidates as well as our other drug pipeline candidates will require significant further investment and regulatory approvals prior to commercialization. Each of our product candidates will require clinical trial designs that meet the standards and requirements of FDA, MHRA or other comparable foreign regulatory authorities, the selection of suitable end points and patients for our clinical trials and additional clinical development, management of clinical, preclinical and manufacturing activities, obtaining regulatory approval, obtaining manufacturing supply, building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA, MHRA or other comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. By such time, if ever, as we may receive necessary regulatory approvals for our product candidates, the standard of care for the treatment of diseases associated with our product candidates may have evolved such that it would be necessary to modify our plans for full approval and commercial acceptance of our products may be limited by a change in the standard of care.

Even if we obtain the required financing or establish a collaboration to enable us to conduct late-stage clinical development of our product candidates and pipeline assets, we cannot be certain that such clinical development would be successful, or that we will obtain regulatory approval or be able to successfully commercialize any of our product candidates and generate revenue. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the clinical trial process may fail to demonstrate that our product candidates are safe and effective for their proposed uses. Any such failure could cause us to abandon further development of any one or more of our product candidates and may delay development of other product candidates. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Any delay in, or termination of, our clinical trials will delay and possibly preclude the submission of any NDAs with the FDA, Marketing Authorisation Applications (MAA) or Conditional Marketing Authorisations (CMA) with the MHRA, or similar authorizations with other foreign regulatory agencies, and, ultimately, our ability to commercialize our product candidates and generate product revenue.

We have not previously submitted an NDA to the FDA, or MAA or CMA to the MHRA, or similar drug approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that any of our product candidates will receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenues will be dependent, in part, upon our or our collaborators' and future collaborators' ability to obtain regulatory approval for the companion diagnostics to be used with our product candidates, if required, and upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

Further, even if any product candidate we develop was to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to bear the risks that the FDA, MHRA or other similar foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies.

The successful commercialization of our product candidates, if approved, will depend on achieving market acceptance and we may not be able to gain sufficient acceptance to generate significant revenue.

Even if our product candidates are successfully developed and receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors such as private insurers or governments and other funding parties and the medical community. The degree of market acceptance for any of our products will depend on a number of factors, including:

- demonstration of the clinical efficacy and safety of our products;
- the prevalence and severity of any adverse side effects;
- limitations or warnings contained in the product's approved labeling;
- cost-effectiveness and availability of acceptable pricing;
- competitive product profile versus alternative treatment methods and the superiority of alternative treatment or therapeutics;
- the effectiveness of marketing and distribution methods and support for the products; and
- the availability of coverage and adequate reimbursement from third-party payors to the extent that our products receive regulatory approval.

Disease indications may be small subsets of a disease that could be parsed into smaller and smaller indications as different subsets of diseases are defined. This increasingly fine characterization of diseases could have negative consequences; including creating an approved indication that is so small as not to have a viable market for us. If future technology allows characterization of a disease in a way that is different from the characterization used for large pivotal studies, it may make those studies invalid or reduce their usefulness, and may require repeating all or a portion of the studies. Future technology may supply better prognostic ability which could reduce the portion of patients projected to need a new therapy. Even after being cleared by regulatory authorities, a product may later be shown to be unsafe or not to have its purported effect, thereby preventing its widespread use or requiring withdrawal from the market.

We may not be successful in establishing development and commercialization collaborations which could adversely affect, and potentially prohibit, our ability to develop our product candidates.

Developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved products is expensive, and therefore we have, and may in the future, seek to enter into collaborations with companies that have more resources and experience in order to continue to develop and commercialize our product candidates. We also may be required due to financial or scientific constraints to enter into additional collaboration agreements to research and/or to develop and commercialize our product candidates. The establishment and realization of such collaborations may not be possible or may be problematic. There can be no assurance that we will be able to establish such additional collaborations on favorable terms, if at all, or that our current or future collaborative arrangements will be successful or maintained for any specific product candidate or indication. If we are unable to reach successful agreements with suitable collaboration partners for the ongoing development and commercialization of our product candidates, we may face increased costs, we may be forced to limit the scope and number of our product candidates we can commercially develop or the territories in which we commercialize such product candidates, and we may be unable to commercialize products or programs for which a suitable collaboration partner cannot be found. If we fail to achieve successful collaborations, our operating results and financial condition will be materially and adversely affected.

In addition, the terms of any collaboration agreements may place restrictions on our activities with respect to other products, including by limiting our ability to grant licenses or develop products with other third parties, or in different indications, diseases or geographical locations, or may place additional obligations on us with respect to development or commercialization of our product candidates. If we fail to comply with or breach any provision of a collaboration agreement, a collaborator may have the right to terminate, in whole or in part, such agreement or to seek damages.

Our collaboration and licensing agreements are, and may in the future be, complex and involve sharing or division of ownership of certain data, know-how and intellectual property rights among the various parties. Accordingly, our collaborators could interpret certain provisions differently than we or our other collaborators which could lead to unexpected or inadvertent disputes with collaborators. In addition, these agreements might make additional collaborations, partnering or mergers and acquisitions difficult.

There is no assurance that a collaborator who is acquired by a third party would not attempt to change certain contract provisions that could negatively affect our collaboration. The acquiring company may also not accept the terms or assignment of our contracts and may seek to terminate the agreements. Any one of our collaborators could breach covenants, restrictions and/or sub-license agreement provisions leading us into disputes and potential breaches of our agreements with other partners.

We will not be able to successfully commercialize our product candidates without establishing sales and marketing capabilities internally or through collaborators.

We may not be able to find suitable sales and marketing staff and collaborators for all of our product candidates. The development of a marketing and sales capability will require significant expenditures, management resources and time. The cost of establishing such a sales force may exceed any potential product revenue, or our marketing and sales efforts may be unsuccessful. If we are unable to develop an internal marketing and sales capability in a timely fashion, or at all, or if we are unable to enter into a marketing and sales arrangement with a third party on acceptable terms, we may be unable to effectively market and sell approved products, if any, which would prevent us from being able to generate revenue and attain profitability. Further, we may not develop an internal marketing and sales capability if we are unable to successfully develop and seek regulatory approval for our product candidates.

We will rely upon third-party contractors and service providers for the execution of some aspects of our development programs. Failure of these collaborators to provide services of a suitable quality and within acceptable timeframes may cause the delay or failure of our development programs.

We outsource certain functions, tests and services to third parties, partners, medical institutions and collaborators and plan to outsource manufacturing to collaborators and/or contract manufacturers, and we will rely on third parties for quality assurance, clinical monitoring, clinical data management and regulatory expertise. In particular, we rely on our partners to run our clinical trials. There is no assurance that such individuals or organizations will be able to provide the functions, tests, drug supply or services as agreed upon or to acceptable quality standards, and we could suffer significant delays in the development of our products or processes. In particular, certain third-party service providers may be unable to comply with their contractual obligations to us due to disruptions caused by the COVID-19 pandemic, including reduced operations or headcount reductions, or otherwise, and in certain cases we may have limited recourse if the non-compliance is due to factors outside of the service provider's control.

Our business is highly dependent on the success of our product candidates. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize one or more of our product candidates, or if we experience delays in doing so, our business will be materially harmed.

Our future success and ability to generate significant revenue from our product candidates, which we do not expect will occur for several years, is dependent on our ability to successfully develop, obtain regulatory approval for and commercialize one or more of our product candidates, including our Dupuytren's Contracture product candidate, which has recently completed a successful Phase 2b clinical trial in the U.K., a condition that affects the development of fibrous connective tissue in the palm of the hand. All of our other product candidates are in earlier stages of development and will require substantial additional investment for manufacturing, preclinical testing, clinical development, regulatory review and approval in one or more jurisdictions. If any of our product candidates encounter safety or efficacy problems, development delays or regulatory issues or other problems, our development plans and business would be materially harmed.

We may not have the financial resources to continue development of our product candidates. Even if clinical trials are completed, we may experience other issues that may delay or prevent regulatory approval of, or our ability to commercialize, our product candidates, including:

- inability to demonstrate to the satisfaction of the FDA, MHRA or other comparable foreign regulatory authorities that our product candidates are safe and effective;
- insufficiency of our financial and other resources to complete the necessary clinical trials and preclinical studies;
- negative or inconclusive results from our clinical trials, preclinical studies or the clinical trials of others for product candidates that are similar to ours, leading to a decision or requirement to conduct additional clinical trials or preclinical studies or abandon a program;
- product-related adverse events experienced by subjects in our clinical trials, including unexpected toxicity results, or by individuals using drugs or therapeutic biologics similar to our product candidates;
- delays in submitting an Investigational New Drug application, or IND, or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial or a suspension or termination, or hold, of a clinical trial once commenced;
- conditions imposed by the FDA, the EMA, MHRA or other comparable foreign regulatory authorities regarding the scope or design of our clinical trials;
- poor effectiveness of our product candidates during clinical trials;
- better than expected performance of control arms, such as placebo groups, which could lead to negative or inconclusive results from our clinical trials;
- delays in enrolling subjects in clinical trials;

- high drop-out rates of subjects from clinical trials;
- inadequate supply or quality of product candidates or other materials necessary for the conduct of our clinical trials;
- greater than anticipated clinical trial or manufacturing costs;
- unfavorable FDA, EMA, MHRA or other comparable regulatory authority inspection and review of a clinical trial site;
- failure of our third-party contractors or investigators to comply with regulatory requirements or the clinical trial protocol or otherwise meet their contractual obligations in a timely manner, or at all;
- unfavorable FDA, EMA, MHRA or other comparable regulatory authority inspection and review of manufacturing facilities or inability of those facilities to maintain a compliance status acceptable to the FDA, EMA or comparable regulatory authorities;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our therapies in particular; or
- Varying interpretations of data by the FDA, EMA, MHRA and other comparable foreign regulatory authorities.

Our product candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA, EMA, MHRA and/or other applicable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that such product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure stockholders that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

Due to the significant resources required for the development of our product pipeline, and depending on our ability to access capital, we must prioritize the development of certain product candidates over others. Moreover, we may fail to expend our limited resources on product candidates or indications that may have been more profitable or for which there is a greater likelihood of success.

We have three separate programs for producing anti-inflammatory agents: (1) investigating new clinical opportunities for anti-TNF, (2) identifying orally available, small molecules that are agonists of α7 nicotinic acetylcholine receptor, and (3) identifying patentable analogs of CBD that initially will be used as pain medications, that are at various stages of preclinical development. Due to the significant resources required for the development of our product candidates, we must focus on specific diseases and disease pathways and decide which product candidates to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial products and may divert resources away from better opportunities. If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misinterpret trends in the pharmaceutical industry, our business, financial condition, and results of operations could be materially adversely affected. As a result, we may (i) fail to capitalize on viable commercial products or profitable market opportunities, (ii) be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or (iii) relinquish valuable rights to such product candidates through collaboration, licensing, or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

The timelines of our clinical trials may be impacted by numerous factors and any delays may adversely affect our ability to execute our current business strategy.

Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is uncertain as to outcome. We may experience delays in clinical trials at any stage of development and testing of our product candidates. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of subjects, or be completed on schedule, if at all.

Events which may result in a delay or unsuccessful completion of clinical trials include:

- inability to raise funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA, MHRA or other foreign regulators on final trial design;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA, MHRA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- delays in obtaining required institutional review board approval at each site;
- delays in having subjects complete participation in a trial or return for post-treatment follow-up;
- delays caused by subjects dropping out of a trial due to side effects or otherwise;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new clinical sites; and
- delays by our contract manufacturers to produce and deliver a sufficient supply of clinical trial materials.

If initiation or completion of any of our clinical trials for our product candidates are delayed for any of the above reasons or for other reasons, our development costs may increase, our approval process could be delayed, any periods after commercial launch and before expiration of patent protection may be reduced and our competitors may have more time to bring products to market before we do. Any of these events could impair the commercial potential of our product candidates and could have a material adverse effect on our business.

Clinical trials of our product candidates may not uncover all possible adverse effects that patients may experience.

Clinical trials are conducted in representative samples of the potential patient population, which may have significant variability. Clinical trials are by design based on a limited number of subjects and of limited duration for exposure to the product used to determine whether, on a potentially statistically significant basis, the planned safety and efficacy of any product candidate can be achieved. As with the results of any statistical sampling, we cannot be sure that all side effects of our product candidates may be uncovered, and it may be the case that only with a significantly larger number of patients exposed to the product candidate for a longer duration, that a more complete safety profile is identified. Further, even larger clinical trials may not identify rare serious adverse effects or the duration of such studies may not be sufficient to identify when those events may occur. Patients treated with our products, if approved, may experience adverse reactions and it is possible that the FDA, MHRA or other regulatory authorities may ask for additional safety data as a condition of, or in connection with, our efforts to obtain approval of our product candidates. If safety problems occur or are identified after our product candidates reach the market, we may, or regulatory authorities may require us to amend the labeling of our products, recall our products or even withdraw approval for our products.

Failure can occur at any stage of our drug development efforts.

We may experience numerous unforeseen events during, or as a result of, testing that could delay or prevent us from obtaining regulatory approval for, or commercializing our drug candidates, including but not limited to:

- regulators or Institutional Review Boards (IRBs) may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- conditions may be imposed upon us by the FDA and/or MHRA regarding the scope or design of our clinical trials, or we may be required to resubmit our clinical trial protocols to IRBs for review due to changes in the regulatory environment;
- the number of subjects required for our clinical trials may be larger, patient enrollment may take longer, or patients may drop out of our clinical trials at a higher rate than we anticipate;
- we may have to suspend or terminate one or more of our clinical trials if we, regulators, or IRBs determine that the participants are being subjected to unreasonable health risks;
- our third-party contractors, clinical investigators or contractual collaborators may fail to comply with regulatory requirements or fail to meet their contractual obligations to us in a timely manner;
- the FDA may not accept clinical data from trials that are conducted at clinical sites in countries where the standard of care is potentially different from the U.S.;
- our tests may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional testing; and
- the costs of our pre-clinical and/or clinical trials may be greater than we anticipate.

We rely on third parties to conduct our pre-clinical studies and clinical studies and trials, and if they do not perform their obligations to us, we may not be able to obtain approval for additional indications.

We do not currently have the ability to independently conduct pre-clinical studies or clinical studies and trials, and we have to date relied on third parties, such as third-party contract research and governmental organizations and medical institutions to conduct studies and trials for us. Our reliance on third parties for development activities reduces our control over these activities. These third parties may not complete activities on schedule or may not conduct our pre-clinical studies and our clinical studies and trials in accordance with regulatory requirements or our study design. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be adversely affected, and our efforts to obtain regulatory approvals for and commercialize indications may be delayed.

If we conduct studies with other parties, we may not have control over all decisions associated with that trial. To the extent that we disagree with the other party on such issues as study design, study timing and the like, it could adversely affect our drug development plans.

Although we also rely on third parties to manage the data from our studies and trials, we are responsible for confirming that each of our studies and trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies will require us to comply with applicable regulations and standards, including Good Laboratory Practice (GLP) and Good Clinical Practice (GCP), for conducting, recording and reporting the results of such studies and trials to assure that the data and the results are credible and accurate and that the human study and trial participants are adequately protected. Our reliance on third-parties does not relieve us of these obligations and requirements, and we may fail to obtain regulatory approval for any additional indications if these requirements are not met.

We will need to continue to develop and maintain distribution and production capabilities or relationships to be successful.

We may not be able to successfully manufacture any product, either independently or under manufacturing arrangements, if any, with third party manufacturers. Moreover, if any manufacturer should cease doing business with us or experience delays, shortages of supply or excessive demands on their capacity, we may not be able to obtain adequate quantities of product in a timely manner, or at all. Manufacturers, and in certain situations their suppliers, are required to comply with current NDA commitments and current good manufacturing practices (cGMP) requirements enforced by the FDA, and similar requirements of other countries. The failure by a manufacturer to comply with these requirements could affect its ability to provide us with products. Although we intend to rely on third-party contract manufacturers, we are ultimately responsible for ensuring that our products are manufactured in accordance with cGMP. In addition, if, during a preapproval inspection or other inspection of our third-party manufacturers' facility or facilities, the FDA determines that the facility is not in compliance with cGMP, any of our marketing applications that lists such facility as a manufacturer may not be approved or approval may be delayed until the facility comes into compliance with cGMP and completes a successful re-inspection by the FDA.

Any manufacturing problem, natural disaster, or epidemic, affecting manufacturing facilities, or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we will be reliant on third parties to supply the raw materials needed to manufacture our products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to future contract manufacture caused by problems at suppliers could delay shipment of products, increase our cost of goods sold and result in lost sales. If our suppliers were unable to supply us with adequate supply of our drugs, it could have a material adverse effect on our ability to successfully commercialize our drug candidates.

If we fail to discover, develop and commercialize other product candidates, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired. In addition, we may also seek to commercialize certain treatments that may not be proprietary to us.

Although the development and commercialization of our current product candidates are our initial focus, as part of our long-term growth strategy, we plan to develop other product candidates. While we believe our planned products may have potential applicability to other uses, we have not conducted any clinical trials on these other uses and we may not be successful in developing product candidates for other uses. In addition, we intend to devote capital and resources for basic research to discover and identify additional product candidates. These research programs require technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;

- product candidates that we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If we do not achieve our projected development and commercialization goals within the timeframes we expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed.

For planning purposes, we seek to estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings, or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval or a commercial launch of a product. The potential achievement of many of these milestones may be outside of our control. Each of these milestones is based on a variety of assumptions which, if not realized as expected, may cause the timing of such potential achievement of the respective milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the FDA, MHRA and other regulatory authorities and the timing thereof;

- clinical outcomes;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of materials used in the manufacture of our product candidates;
- the efforts of our collaborators with respect to the commercialization of our product candidates; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities.

If we fail to achieve any announced milestones in the timeframes we expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed, and it could negatively impact our share price performance. Please see "*Business*" for more information.

If we rely on a sole source of supply to manufacture our products we could be impacted by the viability of our supplier.

We intend to attempt to source our products from more than one supplier. We also intend to enter into contracts with any supplier of our products to contractually obligate them to meet our requirements. However, if we are reliant on a single supplier and that supplier cannot or will not meet our requirements (for whatever reason), our business could be adversely impacted.

We may not be able to sufficiently scale-up manufacturing of our drug candidates.

We may not be able to successfully increase in a sufficient manner the manufacturing capacity for our drug candidates, whether in collaboration with third-party manufacturers or on our own, in a timely or cost-effective manner or at all. If a contract manufacturer makes improvements in the manufacturing process for our drug candidates, we may not own, or may have to share, the intellectual property rights to those improvements.

Significant scale-up of manufacturing may require additional validation studies, which are costly and which the FDA must review and approve. In addition, quality issues may arise during those scale-up activities because of the inherent properties of a drug candidate itself or of a drug candidate in combination with other components added during the manufacturing and packaging process, or during shipping and storage of the finished product or active pharmaceutical ingredients. If we are unable to successfully scale-up manufacture of any of our drug candidates in sufficient quality and quantity, the development of that drug candidate and regulatory approval or commercial launch for any resulting drug products may be delayed or there may be a shortage in supply, which could significantly harm our business.

Our operations are subject to risks associated with ongoing and potential future global conflicts.

Currently, there is an ongoing conflict involving Russia and Ukraine and the war between the two countries continues to evolve as military activity proceeds and additional sanctions are imposed. The war is increasingly affecting economic and global financial markets and exacerbating ongoing economic challenges, including issues such as rising inflation and global supply-chain disruption. While we do not believe this conflict currently has a material impact on our financial accounting and reporting, the degree to which we will be affected in the future largely depends on the nature and duration of uncertain and unpredictable events, and our business could be impacted. Furthermore, future global conflicts or wars could create further economic challenges, including, but not limited to, increases in inflation and further global supply-chain disruption. Consequently, the ongoing Russia/Ukraine conflict and/or other future global conflicts could result in an increase in operating expenses and/or a decrease in any future revenue and could further have a material adverse effect on our results of operations and cash flow.

Risks Related to Development and Regulatory Approval of our Future Product Candidates

Clinical trials are expensive, time-consuming, uncertain and susceptible to change, delay or termination. The results of clinical trials are open to differing interpretations.

We have three separate programs for producing anti-inflammatory agents: (1) investigating new clinical opportunities for anti-TNF, (2) identifying orally available, small molecules that are agonists of α7 nicotinic acetylcholine receptor, and (3) identifying patentable analogs of CBD that initially will be used as pain medications. However, these programs, including the related clinical trials, are expensive, time consuming and difficult to design and implement.

Regulatory agencies may not accept clinical trial designs submitted by us, and may analyze or interpret the results of clinical trials differently than us. Even if the results of our clinical trials are favorable, the clinical trials for a number of its future product candidates are expected to continue for several years and may take significantly longer to complete. In addition, the FDA, MHRA or other regulatory authorities, including state, local and foreign authorities, or an IRB, with respect to a trial at our institution, may suspend, delay or terminate its clinical trials at any time, require us to conduct additional clinical trials, require a particular clinical trial to continue for a longer duration than originally planned, require a change to its development plans such that we conduct clinical trials for a product candidate in a different order, e.g., in a step-wise fashion rather than running two trials of the same product candidate in parallel, or could suspend or terminate the registrations and quota allotments we require in order to procure and handle controlled substances, for various reasons, including the following, any of which could have a material adverse effect on our business, financial condition and results of operations:

- lack of effectiveness of any product candidate during clinical trials;
- discovery of serious or unexpected toxicities or side effects experienced by trial participants or other safety issues, such as drug interactions, including those which cause confounding changes to the levels of other concomitant medications;
- slower than expected rates of subject recruitment and enrollment rates in clinical trials;
- difficulty in retaining subjects who have initiated a clinical trial but may withdraw at any time due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or for any other reason;
- delays or inability in manufacturing or obtaining sufficient quantities of materials for use in clinical trials due to regulatory and manufacturing constraints;
- inadequacy of or changes in our manufacturing process or product formulation;
- delays in obtaining regulatory authorization to commence a trial, including "clinical holds" or delays requiring suspension or termination of a trial by a regulatory agency, such as the FDA, before or after a trial is commenced;

- DEA related recordkeeping, reporting security or other violations at a clinical site, leading the DEA or state authorities to suspend or revoke the site's-controlled substance license and causing a delay or termination of planned or ongoing trials;
- changes in applicable regulatory policies and regulation, including changes to requirements imposed on the extent, nature or timing of studies;
- delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective clinical trial sites;
- uncertainty regarding proper dosing;
- delay or failure to supply product for use in clinical trials which conforms to regulatory specification;
- unfavorable results from ongoing pre-clinical studies and clinical trials;
- failure of our CROs, or other third-party contractors to comply with all contractual requirements or to perform their services in a timely or acceptable manner;
- failure by our company, our employees, our CROs or their employees to comply with all applicable FDA or other regulatory requirements relating to the conduct of clinical trials;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;
- regulatory concerns with CBD derivative products generally and the potential for abuse, despite only working with non-plant based non-psychoactive products;
- insufficient data to support regulatory approval;
- inability or unwillingness of medical investigators to follow our clinical protocols; or
- difficulty in maintaining contact with patients during or after treatment, which may result in incomplete data.

We may find it difficult to enroll patients in our clinical trials, which could delay or prevent clinical trials of our product candidates.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit eligible patients to participate in testing our product candidates. We have experienced delays in some of our clinical trials, and we may experience similar delays in the future. These delays could result in increased costs, delays in advancing our product development, or termination of the clinical trials altogether.

We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a study, to complete our clinical trials within the expected timeframe. Patient enrollment can be impacted by factors including, but not limited to:

- design and complexity and/or commitment of participation required in the study protocol;
- size of the patient population;
- eligibility criteria for the study in question;
- clinical supply availability;
- delays in participating site identification, qualification and subsequent activation to enroll;
- perceived risks and benefits of the product candidate under study, including as a result of adverse effects observed in similar or competing therapies;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- competition of site efforts to facilitate timely enrollment in clinical trials;
- participating site motivation;
- patient referral practices of physicians;
- activities of patient advocacy groups;
- ability to monitor patients adequately during and after treatment; and
- severity of the disease under investigation.

In particular, each of the conditions for which we plan to evaluate our product candidates are diseases with limited patient pools from which to draw for clinical trials. The eligibility criteria of our clinical trials will further limit the pool of available study participants. Additionally, the process of finding and diagnosing patients may prove costly. The treating physicians in our clinical trials may also use their medical discretion in advising patients enrolled in our clinical trials to withdraw from our studies to try alternative therapies. In addition, the ongoing COVID-19 pandemic may impact patient ability and willingness to travel to clinical trial sites as a result of quarantines and other restrictions, which may negatively impact enrollment in our clinical trials.

We may not be able to initiate or continue clinical trials if we cannot enroll the required eligible patients per protocol to participate in the clinical trials required by the FDA or the EMA, MHRA or other regulatory agencies. Our ability to successfully initiate, enroll and complete a clinical trial in any foreign country is subject to numerous risks unique to conducting business in foreign countries, including:

- difficulty in establishing or managing relationships with CROs and physicians;
- different standards for the conduct of clinical trials;
- our inability to locate qualified local consultants, physicians and partners;
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatment;
- ability to procure and deliver necessary clinical trial materials needed to perform the study; and
- inability to implement adequate training at participating sites remotely when in person training cannot be completed.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our ability to complete clinical trials and ultimately our results of operations.

Any failure by our company to comply with existing regulations could harm our reputation and operating results.

We are subject to extensive regulation by U.S. federal and state and foreign governments in each of the U.S., European and Canadian markets, in which we plan to sell our products, or in markets where we have product candidates progressing through the approval process.

We must adhere to all regulatory requirements including FDA's GLP, GCP and GMP requirements, pharmacovigilance requirements, advertising and promotion restrictions, reporting and recordkeeping requirements, and their European equivalents. If we or our suppliers fail to comply with applicable regulations, including FDA pre-or post-approval requirements, then the FDA or other foreign regulatory authorities could sanction our company. Even if a drug is approved by the FDA or other competent authorities, regulatory authorities may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-marketing trials. Any of our product candidates which may be approved in the U.S. will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, distribution, import, export, advertising, promotion, sampling, recordkeeping and submission of safety and other post-market information, including both federal and state requirements. In addition, manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to GMP. As such, we and our contract manufacturers (in the event contract manufacturers are appointed in the future) are subject to continual review and periodic inspections to assess compliance with GMP. Accordingly, we and others with whom we work will have to spend time, money and effort in all areas of regulatory compliance, including manufacturing, production, quality control and quality assurance. We will also be required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. Similar restrictions and requirements exist in the EU and other markets where we operate.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of the product, it may impose restrictions on that product or on our company, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may issue warning letters, impose civil or criminal penalties, suspend regulatory approval, suspend any of our ongoing clinical trials, refuse to approve pending applications or supplements to approved applications submitted by us, impose restrictions on our operations, or seize or detain products or require a product recall.

In addition, it is possible that our future products will be regulated by the DEA, under the Controlled Substances Act or under similar laws elsewhere. DEA scheduling is a separate process that can delay when a drug may become available to patients beyond an NDA approval date, and the timing and outcome of such DEA process is uncertain. See also "Risks Related to Controlled Substances", below.

In addition, any government investigation of alleged violations of law could require us to spend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our future product candidates. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our business and our operating results may be adversely affected.

Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation. We expect to spend significant resources on compliance efforts and such expenses are unpredictable. Changing laws, regulations and standards might also create uncertainty, higher expenses and increase insurance costs. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment might result in increased management and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

We are subject to federal, state and foreign healthcare laws and regulations and implementation of or changes to such healthcare laws and regulations could adversely affect our business and results of operations.

In both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our future product candidates. If we are found to be in violation of any of these laws or any other federal, state or foreign regulations, we may be subject to administrative, civil and/or criminal penalties, damages, fines, individual imprisonment, we from federal health care programs and the restructuring of our operations. Any of these could have a material adverse effect on our business and financial results. Since many of these laws have not been fully interpreted by the courts, there is an increased risk that we may be found in violation of one or more of their provisions. Any action against us for violation of these laws, even if we ultimately are successful in our defense, will cause us to incur significant legal expenses and divert our management's attention away from the operation of our business. In addition, in many foreign countries, particularly the countries of the EU the pricing of prescription drugs is subject to government control.

In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country.

For example, some EU jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. Such differences in national pricing regimes may create price differentials between EU member states. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the U.K. and EU do not follow price structures of the U.S. In the U.K. and EU, the downward pressure on healthcare costs in general, particularly prescription medicines, has become intense. As a result, barriers to entry of new products are becoming increasingly high and patients are unlikely to use a drug product that is not reimbursed by their government. We may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, the importation of foreign products may compete with any future product that we may market, which could negatively impact our profitability.

Specifically, in the U.S., we expect that the 2010 Affordable Care Act, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved product. There have been judicial challenges to certain aspects of the ACA and numerous legislative attempts to repeal and/or replace the ACA in whole or in part, and we expect there will be additional challenges and amendments to the ACA in the future. At this time, the full effect that the ACA will have on our business in the future remains unclear. An expansion in the government's role in the U.S. healthcare industry may cause general downward pressure on the prices of prescription drug products, lower reimbursements or any other product for which we obtain regulatory approval, reduce product utilization and adversely affect our business and results of operations. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize any of our future product candidates for which we may receive regulatory approval.

Information obtained from expanded access studies may not reliably predict the efficacy of our future product candidates in company-sponsored clinical trials and may lead to adverse events that could limit approval.

The expanded access studies we are currently supporting are uncontrolled, carried out by individual investigators and not typically conducted in strict compliance with GCPs, all of which can lead to a treatment effect which may differ from that in placebo-controlled trials. These studies provide only anecdotal evidence of efficacy for regulatory review. These studies contain no control or comparator group for reference and this patient data is not designed to be aggregated or reported as study results. Moreover, data from such small numbers of patients may be highly variable. Information obtained from these studies, including the statistical principles that we and the independent investigators have chosen to apply to the data, may not reliably predict data collected via systematic evaluation of the efficacy in company-sponsored clinical trials or evaluated via other statistical principles that may be applied in those trials. Reliance on such information to design our clinical trials may lead to trials that are not adequately designed to demonstrate efficacy and could delay or prevent our ability to seek approval of our future product candidates.

Expanded access programs provide supportive safety information for regulatory review. Physicians conducting these studies may use our future product candidates in a manner inconsistent with the protocol, including in children with conditions beyond those being studied in trials which we sponsor. Any adverse events or reactions experienced by subjects in the expanded access program may be attributed to our future product candidates and may limit our ability to obtain regulatory approval with labeling that we consider desirable, or at all.

There is a high rate of failure for drug candidates proceeding through clinical trials.

Generally, there is a high rate of failure for drug candidates proceeding through clinical trials. We may suffer significant setbacks in our clinical trials similar to the experience of a number of other companies in the pharmaceutical and biotechnology industries, even after receiving promising results in earlier trials. Further, even if we view the results of a clinical trial to be positive, the FDA, MHRA or other regulatory authorities may disagree with our interpretation of the data. In the event that we obtain negative results from clinical trials for product candidates or other problems related to potential chemistry, manufacturing and control issues or other hurdles occur and our future product candidates are not approved, we may not be able to generate sufficient revenue or obtain financing to continue our operations, our ability to execute on our current business plan may be materially impaired, and our reputation in the industry and in the investment community might be significantly damaged. In addition, our inability to properly design, commence and complete clinical trials may negatively impact the timing and results of our clinical trials and ability to seek approvals for our drug candidates.

If we are found in violation of federal or state "fraud and abuse" laws or similar laws in other jurisdictions, we may be required to pay a penalty and/or be suspended from participation in federal or state health care programs, which may adversely affect our business, financial condition and results of operations.

In the U.S., we are subject to various federal and state health care "fraud and abuse" laws, including anti-kickback laws, false claims laws and other laws intended to reduce fraud and abuse in federal and state health care programs, which could affect our company particularly upon successful commercialization of our products in the U.S. The Medicare and Medicaid Patient Protection Act of 1987, or federal Anti-Kickback Statute, makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce the referral of business, including the purchase, order or prescription of a particular drug for which payment may be made under a federal health care program, such as Medicare or Medicaid. Under federal law, some arrangements, known as safe harbors, are deemed not to violate the federal Anti-Kickback Statute. Although we seek to structure our business arrangements in compliance with all applicable requirements, it is often difficult to determine precisely how the law will be applied in specific circumstances. Accordingly, it is possible that our practices may be challenged under the federal Anti-Kickback Statute and Federal False Claims Act. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and/or exclusion or suspension from federal and state health care programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the government under the federal False Claims Act as well as under the false claims laws of several states.

While we believe that we have structured our business arrangements to comply with these laws, the government could allege violations of, or convict us of violating, these laws. If we are found in violation of one of these laws, we could be required to pay a penalty and could be suspended or excluded from participation in federal or state health care programs, and our business, results of operations and financial condition may be adversely affected.

The Member States of the EU and other countries also have anti-kickback laws and can impose penalties in case of infringement, which, in some jurisdictions, can also be enforced by competitors.

Serious adverse events or other safety risks could require us to abandon development and preclude, delay or limit approval of our future product candidates, limit the scope of any approved label or market acceptance, or cause the recall or loss of marketing approval of products that are already marketed.

If any of our future product candidates prior to or after any approval for commercial sale, cause serious or unexpected side effects, or are associated with other safety risks such as misuse, abuse or diversion, a number of potentially significant negative consequences could result, including:

- regulatory authorities may interrupt, delay or halt clinical trials;
- regulatory authorities may deny regulatory approval of our future product candidates;
- regulatory authorities may require certain labeling statements, such as warnings or contraindications or limitations on the indications for use, and/or impose restrictions on distribution in the form of a REMS in connection with approval or post-approval;
- regulatory authorities may withdraw their approval, require more onerous labeling statements, impose more restrictive REMS, or require us to recall any product that is approved;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- our relationships with our collaboration partners may suffer;

- we could be sued and held liable for harm caused to patients; or

- our reputation may suffer. The reputational risk is heightened with respect to those of our future product candidates that are being developed for pediatric indications.

We may voluntarily suspend or terminate our clinical trials if at any time we believe that the products present an unacceptable risk to participants, or if preliminary data demonstrates that our future product candidates are unlikely to receive regulatory approval or unlikely to be successfully commercialized. Following receipt of approval for commercial sale of a product, we may voluntarily withdraw or recall that product from the market if at any time we believe that its use, or a person's exposure to it, may cause adverse health consequences or death. To date, we have not withdrawn, recalled or taken any other action, voluntary or mandatory, to remove an approved product from the market. In addition, regulatory agencies, IRBs or data safety monitoring boards may at any time recommend the temporary or permanent discontinuation of our clinical trials or request that we cease using investigators in the clinical trials if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, or that they present an unacceptable safety risk to participants. Although we have never been asked by a regulatory agency, IRB or data safety monitoring board to temporarily or permanently discontinue a clinical trial, if we elect or are forced to suspend or terminate a clinical trial of any of our future product candidates, the commercial prospects for that product will be harmed and our ability to generate product revenue from that product may be delayed or eliminated. Furthermore, any of these events may result in labeling statements such as warnings or contraindications. In addition, such events or labeling could prevent us or our partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our future product candidates and impair our ability to generate revenue from the commercialization of these products either by our company or by our collaboration partners.

The development of REMS for our future product candidates could cause delays in the approval process and would add additional layers of regulatory requirements that could impact our ability to commercialize our future product candidates in the U.S. and reduce their market potential.

Even if the FDA approves our NDA for any of our future product candidates without requiring a REMS as a condition of approval of the NDA, the FDA may, post-approval, require a REMS for any of our future product candidates if it becomes aware of new safety information that makes a REMS necessary to ensure that the benefits of the drug outweigh the potential risks. REMS elements can include medication guides, communication plans for health care professionals, and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. We may be required to adopt a REMS for our future product candidates to ensure that the benefits outweigh the risks of abuse, misuse, diversion and other potential safety concerns. There can be no assurance that the FDA will approve a manageable REMS for our future product candidates, which could create material and significant limits on our ability to successfully commercialize our future product candidates in the U.S. Delays in the REMS approval process could result in delays in the NDA approval process. In addition, as part of the REMS, the FDA could require significant restrictions, such as restrictions on the prescription, distribution and patient use of the product, which could significantly impact our ability to effectively commercialize our future product candidates, and dramatically reduce their market potential, thereby adversely impacting our business, financial condition and results of operations. Even if initial REMS are not highly restrictive, if, after launch, our future product candidates were to be subject to significant abuse/non-medical use or diversion from illicit channels, this could lead to negative regulatory consequences, including a more restrictive REMS.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

We are not permitted to commercialize, market, promote or sell any product candidate in the U.S. without obtaining regulatory approval from the FDA. Foreign regulatory authorities, such as the EMA and MHRA, impose similar requirements. The time required to obtain approval by the FDA and comparable foreign authorities is inherently unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. To date, we have not submitted an NDA to the FDA or similar drug approval submissions to comparable foreign regulatory authorities for our most advanced product candidate for the early stage treatment of Dupuytren's Contracture, or any other product candidate. We must complete additional preclinical studies and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we will be able to obtain these approvals.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We cannot guarantee that any clinical trial design that we submit will be accepted by FDA, MHRA or other comparable foreign regulatory authorities, or that clinical trials will be conducted as planned or completed on schedule, if at all. The clinical development of our initial and potential additional product candidates is susceptible to the risk of failure inherent at any stage of development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements, and determination by the FDA, MHRA or any other comparable foreign regulatory authority that a product candidate may not continue development or is not approvable. It is possible that even if any of our product candidates has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of such product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials, we may fail to detect toxicity of, or intolerability caused by, such product candidate, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case. Serious adverse events, or SAEs, or other adverse effects, as well as tolerability issues, could hinder or prevent market acceptance of the product candidate at issue.

Our current and future product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, MHRA or other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, MHRA or other comparable foreign regulatory authorities that a product candidate is safe and effective for our proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, MHRA or other comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA, MHRA or other comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA to the FDA or other submission or to obtain regulatory approval in the U.S., the EU or elsewhere;
- the FDA, MHRA or other comparable foreign regulatory authorities may find deficiencies with the manufacturing processes of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, MHRA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of clinical trial results may result in us failing to obtain regulatory approval to market any product candidate we develop, which would substantially harm our business, results of operations and prospects. The FDA, MHRA or other comparable foreign authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be granted for any product candidate that we develop. Even if we believe the data collected from future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with labeling that does not include the claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Risks Related to our Reliance Upon Third Parties

Our existing collaboration arrangements and any that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our future product candidates.

We are a party to, and may seek additional, collaboration arrangements with pharmaceutical or biotechnology companies for the development or commercialization of our future product candidates. We may, with respect to our future product candidates, enter into new arrangements on a selective basis depending on the merits of retaining commercialization rights for ourselves as compared to entering into selective collaboration arrangements with leading pharmaceutical or biotechnology companies for each product candidate, both in the U.S. and internationally. To the extent that we decide to enter into collaboration agreements, we will face significant competition in seeking appropriate collaborators and the terms of any collaboration or other arrangements that we may establish may not be favorable to us.

Any existing or future collaboration that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding development, intellectual property, regulatory or commercialization matters, can lead to delays in the development process or commercialization of the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Any such termination or expiration could harm our business reputation and may adversely affect it financially.

We expect to depend on a limited number of suppliers for materials and components in order to manufacture our future product candidates. The loss of these suppliers, or their failure to supply us on a timely basis, could cause delays in our current and future capacity and adversely affect our business.

We expect to depend on a limited number of suppliers for the materials and components required to manufacture our future product candidates. As a result, we may not be able to obtain sufficient quantities of critical materials and components in the future. A delay or interruption by our suppliers may also harm our business, results of operations and financial condition. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify for and, in some cases, obtain regulatory approval for a new supplier could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results. Our dependence on single-source suppliers exposes us to numerous risks, including the following: our suppliers may cease or reduce production or deliveries, they may be subject to government investigations and regulatory actions that limit or prevent production capabilities for an extended period of time, raise prices or renegotiate terms; our suppliers may become insolvent; we may be unable to locate a suitable replacement supplier on acceptable terms or on a timely basis, or at all; and delays caused by supply issues may harm our reputation, frustrate our customers and cause them to turn to our competitors for future needs.

Risks Related to our Intellectual Property

We may not be able to adequately protect our future product candidates or our proprietary technology in the marketplace.

Our success will depend, in part, on our ability to obtain patents, protect our trade secrets and operate without infringing on the proprietary rights of others. We rely upon a combination of patents, trade secret protection (i.e., know-how), and confidentiality agreements to protect the intellectual property of our future product candidates. The strengths of patents in the pharmaceutical field involve complex legal and scientific questions and can be uncertain. Where appropriate, we seek patent protection for certain aspects of our products and technology. Filing, prosecuting and defending patents globally can be prohibitively expensive.

Our policy is to look to patent technologies with commercial potential in jurisdictions with significant commercial opportunities. However, patent protection may not be available for some of the products or technology we are developing. If we must spend significant time and money protecting, defending or enforcing our patents, designing around patents held by others or licensing, potentially for large fees, patents or other proprietary rights held by others, our business, results of operations and financial condition may be harmed. We may not develop additional proprietary products that are patentable. As of the date hereof, we have an extensive portfolio of patents, including many granted patents and patents pending approval.

The patent positions of pharmaceutical products are complex and uncertain. The scope and extent of patent protection for our future product candidates are particularly uncertain. Our future product candidates will be based on medicinal chemistry instead of cannabis plants. While we have sought patent protection, where appropriate, directed to, among other things, composition-of-matter for its specific formulations, their methods of use, and methods of manufacture, we do not have and will not be able to obtain composition of matter protection on these previously known CBD derivatives per se. We anticipate that the products we develop in the future will be based upon synthetic compounds we may discover. Although we have sought, and will continue to seek, patent protection in the U.S., Europe and other countries for our proprietary technologies, future product candidates, their methods of use, and methods of manufacture, any or all of them may not be subject to effective patent protection. If any of our products are approved and marketed for an indication for which we do not have an issued patent, our ability to use our patents to prevent a competitor from commercializing a non-branded version of our commercial products for that non-patented indication could be significantly impaired or even eliminated.

Publication of information related to our future product candidates by our company or others may prevent us from obtaining or enforcing patents relating to these products and product candidates. Furthermore, others may independently develop similar products, may duplicate our products, or may design around our patent rights. In addition, any of our issued patents may be opposed and/or declared invalid or unenforceable. If we fail to adequately protect our intellectual property, we may face competition from companies who attempt to create a generic product to compete with our future product candidates. We may also face competition from companies who develop a substantially similar product to our future product candidates that is not covered by any of our patents.

Many companies have encountered significant problems in protecting, defending and enforcing intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property rights, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business.

If third parties claim that intellectual property used by our company infringes upon their intellectual property, our operating profits could be adversely affected.

There is a substantial amount of litigation, both within and outside the U.S., involving patent and other intellectual property rights in the pharmaceutical industry. We may, from time to time, be notified of claims that we are infringing upon patents, trademarks, copyrights or other intellectual property rights owned by third parties, and we cannot provide assurances that other companies will not, in the future, pursue such infringement claims against us, our commercial partners or any third-party proprietary technologies we have licensed. If we were found to infringe upon a patent or other intellectual property right, or if we failed to obtain or renew a license under a patent or other intellectual property right from a third party, or if a third party from whom we were licensing technologies was found to infringe upon a patent or other intellectual property rights of another third party, we may be required to pay damages, including damages of up to three times the damages found or assessed, if the infringement is found to be willful, suspend the manufacture of certain products or reengineer or rebrand our products, if feasible, or we may be unable to enter certain new product markets. Any such claims could also be expensive and time consuming to defend and divert management's attention and resources. Our competitive position could suffer as a result. In addition, if we have declined or failed to enter into a valid non-disclosure or assignment agreement for any reason, we may not own the invention or its intellectual property, and our products may not be adequately protected. Thus, we cannot guarantee that any of our future product candidates, or our commercialization thereof, does not and will not infringe any third party's intellectual property.

If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be significantly diminished.

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with current and former employees, consultants, outside scientific collaborators, sponsored researchers, contract manufacturers, vendors and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, we cannot guarantee that we have executed these agreements with each party that may have or have had access to our trade secrets. Any party with whom we or they have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Also, some courts inside and outside the U.S. are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they disclose such trade secrets, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third-party, our competitive position would be harmed.

The expiration or loss of patent protection may adversely affect our future revenues and operating earnings.

We rely on patent, trademark, trade secret and other intellectual property protection in the discovery, development, manufacturing and sale of our product candidates. In particular, patent protection is important in the development and eventual commercialization of our product candidates. Patents covering our product candidates normally provide market exclusivity, which is important in order to improve the probability that our product candidates are able to become profitable.

One of our patents relating to our Fibrosis and anti-TNF program will expire in 2033; however, the majority of the patent portfolio has a longer lifespan. While we are seeking additional patent coverage which may protect the technology underlying these patents, there can be no assurances that such additional patent protection will be granted, or if granted, that these patents will not be infringed upon or otherwise held enforceable. Even if we are successful in obtaining a patent, patents have a limited lifespan. In the U.S., the natural expiration of a utility patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection of our product candidates, we may be open to competition from generic versions of such methods and compositions.

If we do not obtain protection under the Hatch-Waxman Amendments by extending the patent term, our business may be harmed.

Our commercial success will largely depend on our ability to obtain and maintain patent and other intellectual property in the U.S. and other countries with respect to our product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after such candidates begin to be commercialized. We expect to seek extensions of patent terms in the U.S. and, if available, in other countries where we are prosecuting patents.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension, or PTE, under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during development and the FDA regulatory review process, which is limited to the approved indication (and potentially additional indications approved during the period of extension) covered by the patent. This extension is limited to only one patent that covers the approved product, the approved use of the product, or a method of manufacturing the product. However, the applicable authorities, including the FDA and the USPTO in the U.S., and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time-period or the scope of patent protection afforded could be less than we request. Even if we are able to obtain an extension, the patent term may still expire before or shortly after we receive FDA marketing approval. If we are unable to extend the expiration date of our existing patents or obtain new patents with longer expiry dates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products following our patent expiration and launch their product earlier than might otherwise be the case.

Risks Related to Controlled Substances

Controlled substance legislation differs between countries, and legislation in certain countries may restrict or limit our ability to sell our future product candidates.

Most countries are parties to the Single Convention on Narcotic Drugs 1961 and the Convention on Psychotropic Substances 1971, which governs international trade and domestic control of narcotic substances, including cannabis extracts. Countries may interpret and implement their treaty obligations in a way that creates a legal obstacle to us obtaining marketing approval for our future products in those countries. These countries may not be willing or able to amend or otherwise modify their laws and regulations to permit our future products to be marketed, or achieving such amendments to the laws and regulations may take a prolonged period of time. In that case, we would be unable to market our future product candidates in those countries in the near future or perhaps at all.

The product candidates that we are developing may be subject to U.S. controlled substance laws and regulations and failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations, may adversely affect the results of our business operations, both during clinical development and post approval, and our financial condition.

The product candidates that we are developing may contain controlled substances as defined in The United States Federal Controlled Substances Act of 1970 and the CSA. Controlled substances that are pharmaceutical products are subject to a high degree of regulation under the CSA, which establishes, among other things, certain registration, manufacturing quotas, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. The DEA classifies controlled substances into five schedules: Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse, no currently "accepted medical use" in the U.S., lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the U.S. Pharmaceutical products approved for use in the U.S. which contain a controlled substance are listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances.

While cannabis is a Schedule I controlled substance, products approved for medical use in the U.S. that contain cannabis or cannabis extracts should be placed in Schedules II-V, since approval by the FDA satisfies the "accepted medical use" requirement. If and when any of our future product candidates receive FDA approval, the DEA will make a scheduling determination. If the FDA, the DEA or any foreign regulatory authority determines that our future product candidates may have potential for abuse, it may require us to generate more clinical or other data than we currently anticipate to establish whether or to what extent the substance has an abuse potential, which could increase the cost and/or delay the launch of that product.

Facilities conducting research, manufacturing, distributing, importing or exporting, or dispensing controlled substances must be registered (licensed) to perform these activities and have the security, control, recordkeeping, reporting and inventory mechanisms required by the DEA to prevent drug loss and diversion. All these facilities must renew their registrations annually, except dispensing facilities, which must renew every three years. The DEA conducts periodic inspections of certain registered establishments that handle controlled substances. Obtaining the necessary registrations may result in delay of the importation, manufacturing or distribution of our future products. Furthermore, failure to maintain compliance with the CSA, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, financial condition and results of operations. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

Individual states have also established controlled substance laws and regulations. Although state-controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule our future product candidates as well. State scheduling may delay commercial sale of any product for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. We or our partners must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

Because our products may be controlled substances in the U.S., to conduct clinical trials in the U.S., each of our research sites must submit a research protocol to the DEA and obtain and maintain a DEA researcher registration that will allow those sites to handle and dispense our products and to obtain product from our importer. If the DEA delays or denies the grant of a research registration to one or more research sites, the clinical trial could be significantly delayed, and we could lose clinical trial sites. The importer for the clinical trials must also obtain an importer registration and an import permit for each import.

The legislation on cannabis in the EU differs among the member states, as this area is not yet fully harmonized. In Germany, for example, cannabis is regulated as a controlled substance (*Betäubungsmittel*) and its handling requires specific authorization.

The legalization and use of medical and recreational cannabis in the U.S. and abroad may impact our business.

There is a substantial amount of change occurring in the U.S. regarding the use of medical and recreational cannabis products. While cannabis products not approved by the FDA are Schedule I substances as defined under federal law, and their possession and use is not permitted according to federal law (except for research purposes, under DEA registration), according to worldpoplulationreview.com, at least 39 states and the District of Columbia have enacted state laws to enable possession and use of cannabis for medical purposes, and at least 19 states and the District of Columbia for recreational purposes. The U.S. Farm Bill, which was passed in 2018, descheduled certain material derived from hemp plants with extremely low THC content. Although our business is quite distinct from that of online and dispensary cannabis companies, future legislation authorizing the sale, distribution, use, and insurance reimbursement of non-FDA approved cannabis products could affect our business.

Accounting Risks

Our goodwill and intangible assets have been impaired in the past and are subject to future impairment risks.

As discussed in the following risk factor, we had material impairment charges to our goodwill and in process R&D during the year ended December 31, 2022.

Our intangible assets were approximately $10.7 million as of December 31, 2022, representing 55% of our total assets. The Company assesses the potential impairment of indefinite-lived intangible assets and goodwill at least annually and otherwise when there is evidence that events or changes in circumstances indicate that an impairment condition may exist. Many of the factors used in assessing fair value are outside the control of management, and it is reasonably likely that assumptions and estimates will change in future periods. These changes could result in future impairments. Events and circumstances that the Company considers important which could trigger impairment include the following:

- Significant underperformance relative to historical or projected future operating results;
- Significant changes in the Company's strategy for its overall business or use of acquired assets;
- Significant negative industry or economic trends;
- Significant decline in the Company's stock price for a sustained period;
- Decreased market capitalization relative to net book value;
- Unanticipated technological change or competitive activities;
- Change in consumer demand;
- Loss of key personnel; and
- Acts by governments and courts.

When there is indication that the carrying value of intangible assets may not be recoverable based upon the existence of one or more of the above indicators, an impairment loss is recognized if the carrying amount of the asset exceeds its fair value. When there is an indication of impairment of goodwill, an impairment loss is recognized to the extent that the carrying amount of the goodwill exceeds its implied fair value.

It is possible that changes in circumstances, existing at that time or at other times in the future, or in the numerous variables associated with the assumptions and estimates made by the Company in assessing the appropriate valuation of its indefinite-lived intangible assets or goodwill, could in the future require the Company to record impairment charges, which would adversely affect future reported results of operations and stockholders' equity, although such charges would not affect our cash flow.

We have in the past, and may in the future, impair long-lived assets and intangible assets, including goodwill and acquired in-process research and development.

The Company reviews long-lived assets and certain identifiable assets (including intangible assets) for impairment whenever circumstances and situations change such that there is an indication that the carrying amounts may not be recovered. An impairment exists when the carrying value of the long-lived or intangible asset (including goodwill and acquired in-process research and development) is not recoverable and exceeds its estimated fair value. Goodwill represents the difference between the purchase price and the fair value of assets and liabilities acquired in a business combination. The Company reviews goodwill yearly, or more frequently whenever circumstances and situations change such that there is an indication that the carrying amounts may not be recovered, for impairment by initially considering qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount, including goodwill, as a basis for determining whether it is necessary to perform a quantitative analysis. If it is determined that it is more likely than not that the fair value of reporting unit is less than its carrying amount, a quantitative analysis is performed to identify goodwill impairment.

The Company's publicly traded stock closed at $78.00 per share as of December 31, 2021; during 2022, the market value of the Company's single reporting unit significantly declined. As of March 31, 2022, June 30, 2022, September 30, 2022 and December 31, 2022, the market value of the Company's publicly traded stock fell to $51.80, $16.96, $13.30 and $3.39, per share, respectively, and as such, the Company elected to conduct a quantitative analysis of goodwill to assess for impairment as of September 30, 2022 and December 31, 2022. The Company determined the fair market value of its single reporting unit and compared that value with the carrying amount of the reporting unit and determined that goodwill was impaired as of both measurement dates. As of September 30, 2022 and December 31, 2022, the carrying value exceeded the fair market value by $18,872,850 and $14,674,428, respectively. To recognize the impairment of goodwill, the Company recorded losses for these amounts at the end of the third and fourth quarters, which appear as a loss on goodwill impairment of $33,547,278 on the income statement for the year ended December 31, 2022. See "Note 5 – Intangible Assets and Impairment of Long-lived Assets" in the consolidated financial statements included herein beginning on page F-1, for further information.

Intangible assets and in-process research and development ("IP R&D") assets represent the fair value assigned to technologies that were acquired on July 16, 2019 in connection with the Reorganization, which have not reached technological feasibility and have no alternative future use. IP R&D assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development projects. During the period that the IP R&D assets are considered indefinite-lived, they are tested for impairment on an annual basis, or more frequently if the Company becomes aware of any events occurring or changes in circumstances that indicate that the fair value of the IP R&D assets are less than their carrying amounts. If and when development is complete, which generally occurs upon regulatory approval, and the Company is able to commercialize products associated with the IP R&D assets, these assets are then deemed definite-lived and are amortized based on their estimated useful lives at that point in time. If development is terminated or abandoned, the Company may record a full or partial impairment charge related to the IP R&D assets, calculated as the excess of the carrying value of the IP R&D assets over their estimated fair value.

As of December 31, 2022, the carrying amount of the IP R&D assets on the balance sheet was $12,405,084 (which consists of carrying amounts of $1,462,084 and $10,943,000 related to the Company's CBR Pharma subsidiary and its 180 LP subsidiary, respectively). Per the valuation obtained from a third party as of year-end, the fair market value of the Company's IP R&D assets was determined to be $9,063,000 (which consists of fair values of $0 and $9,063,000 related to the Company's CBR Pharma subsidiary and 180 LP subsidiary, respectively). As of this measurement date, the carrying values of the CBR Pharma and 180 LP subsidiaries' assets exceeded their fair market values by $1,462,084 and $1,880,000, respectively. As such, management determined that the consolidated IP R&D assets were impaired by $3,342,084 and, in order to recognize the impairment, the Company recorded a loss for this amount during the fourth quarter of 2022, which appears as a loss on impairment to IP R&D assets on the income statement. This reduced the IP R&D asset balances of its CBR Pharma subsidiary and its 180 LP subsidiary to zero and $9,063,000, respectively, as of December 31, 2022; the total consolidated IP R&D asset balance is $9,063,000 after impairment. See "Note 5 – Intangible Assets and Impairment of Long-lived Assets" in the consolidated financial statements included herein beginning on page F-1, for further information.

A continued period of low trading prices of our common stock may force us to incur further material impairments of our reporting units, which could have a material effect on the value of our assets and cause the value of our securities to decline in value. Additionally, we have in the past, and may in the future, determine that impairments in our intangible assets, including acquired in-process research and development, are necessary and may be material. An impairment recognized in one period may not be reversed in a subsequent period, even if the value of our common stock increases in the future. We have in the past and could in the future incur additional impairments of long-lived assets and/or intangible assets, including acquired in-process research and development and goodwill, which may be material.

We have identified material weaknesses in our disclosure controls and procedures and internal control over financial reporting. If not remediated, our failure to establish and maintain effective disclosure controls and procedures and internal control over financial reporting could result in material misstatements in our financial statements and a failure to meet our reporting and financial obligations, each of which could have a material adverse effect on our financial condition and the trading price of our securities.

Management of the Company, including our principal financial officer, conducted an evaluation of the effectiveness of the Company's internal control over financial reporting as of December 31, 2022 using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in "Internal Control - Integrated Framework" (2013).

Management concluded that certain aspects of the Company's internal control over financial reporting was not effective as of December 31, 2022, based on those criteria. Specifically, management's conclusion was based on the following material weakness:

- The Company's review and control procedures did not operate at the appropriate level of precision to detect an error in fair-value of warrants related to a one-time reverse stock split and the fair value of IP R&D assets.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. Accordingly, a material weakness increases the risk that the financial information we report contains material errors. A control deficiency exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis.

Maintaining effective disclosure controls and procedures and effective internal control over financial reporting are necessary for us to produce reliable financial statements and the Company is committed to remediating its material weaknesses in such controls as promptly as possible. However, there can be no assurance as to when these material weaknesses will be remediated or that additional material weaknesses will not arise in the future. Any failure to remediate the material weaknesses, or the development of new material weaknesses in our internal control over financial reporting, could result in material misstatements in our financial statements and cause us to fail to meet our reporting and financial obligations on a timely and accurate basis. If our financial statements are not accurate, investors may not have a complete understanding of our operations or may lose confidence in our reported financial information. Likewise, if our financial statements are not filed on a timely basis as required by the SEC and NASDAQ, we could face severe consequences from those authorities. In any of these cases, it could result in a material adverse effect on our business, on our financial condition or have a negative effect on the trading price of our common stock and warrants. Further, if we fail to remedy this deficiency (or any other future deficiencies) or maintain the adequacy of our disclosure controls and procedures and our internal controls, we could be subject to regulatory scrutiny, civil or criminal penalties or stockholder litigation against us or our management.

We can give no assurance that the measures we have taken and plan to take in the future will remediate the material weakness identified or that any additional material weaknesses or restatements of our financial statements will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or circumvention of those controls.

Further, in the future, if we cannot conclude that we have effective internal control over our financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified opinion regarding the effectiveness of our internal control over financial reporting (to the extent we may be required in the future), investors could lose confidence in the reliability of our financial statements, which could lead to a decline in our stock price. Failure to comply with reporting requirements could also subject us to sanctions and/or investigations by the SEC or NASDAQ, as applicable, or other regulatory authorities.

In addition, even if we are successful in strengthening our controls and procedures, those controls and procedures may not be adequate to prevent or identify irregularities or facilitate the fair presentation of our financial statements or our periodic reports filed with the SEC. This may require us to restate prior financial statements.

We may experience adverse impacts on our reported results of operations as a result of adopting new accounting standards or interpretations.

Our implementation of and compliance with changes in accounting rules, including new accounting rules and interpretations, could adversely affect our reported financial position or operating results or cause unanticipated fluctuations in our reported operating results in future periods.

Risks Related to our Common Stock and Warrants

The market price of our common stock has been extremely volatile and may continue to be volatile due to numerous circumstances beyond our control.

The market price of our common stock has fluctuated, and may continue to fluctuate, widely, due to many factors, some of which may be beyond our control. These factors include, without limitation:

- "short squeezes";
- comments by securities analysts or other third parties, including blogs, articles, message boards and social and other media;
- large stockholders exiting their position in our securities or an increase or decrease in the short interest in our securities;
- actual or anticipated fluctuations in our financial and operating results;
- risks and uncertainties associated with the ongoing COVID-19 pandemic;
- changes in foreign currency exchange rates;
- the commencement, enrollment or results of our planned or future clinical trials of our product candidates or those of our competitors;
- the success of competitive drugs or therapies;

- regulatory or legal developments in the U.S. and other countries;
- the success of competitive products or technologies;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to our product candidates or clinical development programs;
- litigation matters, including amounts which may or may not be recoverable pursuant to the Company's officer and director insurance policies, regulatory actions affecting the Company and the outcome thereof;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- our inability to obtain or delays in obtaining adequate drug supply for any approved drug or inability to do so at acceptable prices;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems, including coverage and adequate reimbursement for any approved drug;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the U.S. and abroad; and
- investors' general perception of us and our business.

Stock markets in general and our stock price in particular have recently experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies and our company. For example, during 2022, the sale prices of our common stock ranged from a post-split adjusted high of $80.70 per share (on January 5, 2022) to a low of $1.18 per share (on December 23, 2022). During this time, we have not experienced any material changes in our financial condition or results of operations that would explain such price volatility or trading volume; however, we have sold equity which was dilutive to existing stockholders. These broad market fluctuations may adversely affect the trading price of our securities. Additionally, these and other external factors have caused and may continue to cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent our stockholders from readily selling their shares of our common stock and may otherwise negatively affect the liquidity of our common stock.

Information available in public media that is published by third parties, including blogs, articles, message boards and social and other media may include statements not attributable to the Company and may not be reliable or accurate.

We are aware of a large volume of information being disseminated by third parties relating to our operations, including in blogs, message boards and social and other media. Such information as reported by third parties may not be accurate, may lead to significant volatility in our securities and may ultimately result in our common stock or other securities declining in value.

Our outstanding options and warrants may adversely affect the trading price of our securities.

As of December 31, 2022, we had (i) outstanding stock options to purchase an aggregate of 162,956 shares of common stock at a weighted average exercise price of $84.63 per share; (ii) outstanding warrants to purchase 3,435,728 shares of common stock at a weighted average exercise price of $33.94 per share. For the life of the options and warrants, the holders have the opportunity to profit from a rise in the market price of our common stock without assuming the risk of ownership. The issuance of shares upon the exercise of outstanding securities will also dilute the ownership interests of our existing stockholders.

The availability of these shares for public resale, as well as any actual resales of these shares, could adversely affect the trading price of our common stock. We cannot predict the size of future issuances of our common stock pursuant to the exercise of outstanding options or warrants or conversion of other securities, or the effect, if any, that future issuances and sales of shares of our common stock may have on the market price of our common stock. Sales or distributions of substantial amounts of our common stock (including shares issued in connection with an acquisition), or the perception that such sales could occur, may cause the market price of our common stock to decline.

In addition, the common stock issuable upon exercise/conversion of outstanding convertible securities may represent overhang that may also adversely affect the market price of our common stock. Overhang occurs when there is a greater supply of a company's stock in the market than there is demand for that stock. When this happens the price of our stock will decrease, and any additional shares which stockholders attempt to sell in the market will only further decrease the share price. If the share volume of our common stock cannot absorb shares sold by holders of our outstanding convertible securities, then the value of our common stock will likely decrease.

Our outstanding public warrants are significantly out of the money.

Each Public Warrant entitles the holder to purchase one-fortieth of one share of common stock at an exercise price of $5.75 per $1/40^{th}$ of one share ($230.00 per whole share), subject to adjustment. No fractional shares will be issued upon exercise of the Public Warrants. The Public Warrants became exercisable 12 months from the closing of the IPO and expire five years after the completion of the Business Combination (November 6, 2025). The Public Warrants are significantly out of the money and because no fractional shares will be issued upon exercise of the Public Warrants, the Public Warrants are only exercisable in multiples of 40. As a result, the Public Warrants may not have any significant value. Additionally, warrant holders not holding at least 40 Public Warrants or who hold Public Warrants which would be exercisable for a fractional share of common stock, must sell any warrants to obtain value from the fractional interest. As a result, the trading of the Public Warrants may be limited or sporadic, and such Public Warrants may not have any significant value. Any holder of Public Warrants holding less than 40 Public Warrants or a number of Public Warrants not evenly divisible by 40 will not receive any common stock upon the exercise of Public Warrant, as no fractional shares of common stock are issuable upon exercise thereof.

A significant number of our shares are eligible for sale and their sale or potential sale may depress the market price of our common stock.

Sales of a significant number of shares of our common stock in the public market could harm the market price of our common stock. Most of our common stock is available for resale in the public market, including (a) options to purchase 162,956 shares of common stock with a weighted average exercise price of $84.63 per share; and (b) warrants to purchase 3,435,728 shares of common stock with a weighted average exercise price of $33.94 per share. If a significant number of shares were sold, such sales would increase the supply of our common stock, thereby potentially causing a decrease in its price. Some or all of our shares of common stock may be offered from time to time in the open market pursuant to effective registration statements and/or compliance with Rule 144, which sales could have a depressive effect on the market for our shares of common stock. Subject to certain restrictions, a person who has held restricted shares for a period of six months may generally sell common stock into the market. The sale of a significant portion of such shares when such shares are eligible for public sale may cause the value of our common stock to decline in value.

There may not be sufficient liquidity in the market for our securities in order for investors to sell their shares. The market price of our common stock may continue to be volatile.

The market price of our common stock will likely continue to be highly volatile. Some of the factors that may materially affect the market price of our common stock are beyond our control, such as conditions or trends in the industry in which we operate or sales of our common stock. This situation is attributable to a number of factors, including the fact that we are a small company which is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable.

As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a mature issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. It is possible that a broader or more active public trading market for our common stock will not develop or be sustained, or that trading levels will not continue. These factors may materially adversely affect the market price of our common stock, regardless of our performance. In addition, the public stock markets have experienced extreme price and trading volume volatility. This volatility has significantly affected the market prices of securities of many companies for reasons frequently unrelated to the operating performance of the specific companies. These broad market fluctuations may adversely affect the market price of our common stock.

We face significant penalties and damages in the event registration statements we have previously filed to register certain securities sold in our prior offerings are subsequently suspended or terminated.

Pursuant to certain prior private offerings of securities, we entered into registration rights agreements which required us to file certain registration statements to register the resale of the privately sold shares and certain securities issuable upon exercise/conversion thereof, and to maintain the effectiveness of such registration statements for certain periods of time. To date, all such required registration statements have been declared effective by the SEC. However, in the event the registration statements are subsequently suspended or terminated, or we otherwise fail to meet certain requirements set forth in the registration rights agreements, we could be required to pay significant penalties which could adversely affect our cash flow and cause the value of our securities to decline in value.

Provisions of the warrants granted in July 2022 could discourage an acquisition of us by a third party.

Certain provisions of the common stock warrants granted by us in July 2022 could make it more difficult or expensive for a third party to acquire us. The common stock warrants granted by us in July 2022 prohibit us from engaging in certain transactions constituting "fundamental transactions" unless, among other things, the surviving entity assumes our obligations under the common stock warrants. Further, the common stock warrants granted by us in July 2022 provide that, in the event of certain transactions constituting "fundamental transactions," with some exception, holders of such warrants will have the right, at their option, to require us to repurchase such common stock warrants at a price described in such warrants (based on the Black Scholes Value of such warrants). These and other provisions of the common stock warrants could prevent or deter a third party from acquiring us even where the acquisition could be beneficial to stockholders.

Future sales and issuances of our common stock or rights to purchase common stock, could result in additional dilution to our stockholders and could cause the price of our common stock to decline.

We may issue additional common stock, convertible securities, or other equity in the future. We also issue common stock to our employees, directors, and other service providers pursuant to our equity incentive plans. Such issuances could be dilutive to investors and could cause the price of our common stock to decline. New investors in such issuances could also receive rights senior to those of current stockholders.

Resales of our common stock in the public market may cause the market price of our common stock to fall.

Sales of a substantial number of shares of our common stock could occur at any time. The issuance of new shares of our common stock could result in resales of our common stock by our current stockholders concerned about the potential ownership dilution of their holdings. In turn, these resales could have the effect of depressing the market price for our common stock.

Future sales of our common stock could cause our stock price to decline.

If our stockholders sell substantial amounts of our common stock in the public market, the market price of our common stock could decrease significantly. The perception in the public market that our stockholders might sell shares of our common stock could also depress the market price of our common stock. Up to $125,000,000 in total aggregate value of securities have been registered by us on a "shelf" registration statement on Form S-3 that we filed with the Securities and Exchange Commission on June 3, 2022, and which was declared effective on June 24, 2022. As of March 28, 2023, there is an aggregate of over $6.0 million in securities which are eligible for sale in the public markets from time to time. Additionally, if our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline significantly. The market price for shares of our common stock may drop significantly when such securities are sold in the public markets. A decline in the price of shares of our common stock might impede our ability to raise capital through the issuance of additional shares of our common stock or other equity securities.

Risks Associated with Our Governing Documents and Delaware Law

Our Certificate of Incorporation provides for indemnification of officers and directors at our expense and limits their liability, which may result in a major cost to us and hurt the interests of our stockholders because corporate resources may be expended for the benefit of officers or directors.

Our Certificate of Incorporation provides for indemnification as follows: "To the fullest extent permitted by applicable law, the Corporation is authorized to provide indemnification of, and advancement of expenses to, such agents of the Corporation (and any other persons to which Delaware law permits the Corporation to provide indemnification) through Bylaw provisions, agreements with such agents or other persons, vote of stockholders or disinterested directors or otherwise, in excess of the indemnification and advancement otherwise permitted by Section 145 of the Delaware General Corporation Law, subject only to limits created by applicable Delaware law (statutory or non-statutory), with respect to actions for breach of duty to the Corporation, its stockholders and others."

We have been advised that, in the opinion of the SEC, indemnification for liabilities arising under federal securities laws is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification for liabilities arising under federal securities laws, other than the payment by us of expenses incurred or paid by a director, officer or controlling person in the successful defense of any action, suit or proceeding, is asserted by a director, officer or controlling person in connection with our activities, we will (unless in the opinion of our counsel, the matter has been settled by controlling precedent) submit to a court of appropriate jurisdiction, the question whether indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue. The legal process relating to this matter if it were to occur is likely to be very costly and may result in us receiving negative publicity, either of which factors is likely to materially reduce the market and price for our shares.

Our Certificate of Incorporation contains a specific provision that limits the liability of our directors for monetary damages to the Company and the Company's stockholders and requires us, under certain circumstances, to indemnify officers, directors and employees.

The limitation of monetary liability against our directors, officers and employees under Delaware law and the existence of indemnification rights to them may result in substantial expenditures by us and may discourage lawsuits against our directors, officers and employees.

Our Certificate of Incorporation contains a specific provision that limits the liability of our directors for monetary damages to the Company and the Company's stockholders. We also have contractual indemnification obligations under our employment and engagement agreements with our executive officers and directors. The foregoing indemnification obligations could result in us incurring substantial expenditures to cover the cost of settlement or damage awards against our directors and officers, which the Company may be unable to recoup. These provisions and resultant costs may also discourage us from bringing a lawsuit against our directors and officers for breaches of their fiduciary duties and may similarly discourage the filing of derivative litigation by our stockholders against our directors and officers, even though such actions, if successful, might otherwise benefit us and our stockholders.

Our directors have the right to authorize the issuance of shares of preferred stock and additional shares of our common stock.

Our directors, within the limitations and restrictions contained in our Certificate of Incorporation and without further action by our stockholders, have the authority to issue shares of preferred stock from time to time in one or more series and to fix the number of shares and the relative rights, conversion rights, voting rights, and terms of redemption, liquidation preferences and any other preferences, special rights and qualifications of any such series. Any issuance of shares of preferred stock could adversely affect the rights of holders of our common stock. Should we issue additional shares of our common stock at a later time, each investor's ownership interest in our stock would be proportionally reduced.

Anti-takeover provisions in our Second Amended and Restated Certificate of Incorporation, as amended, and our Amended and Restated Bylaws, as well as provisions of Delaware law, might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Our Second Amended and Restated Certificate of Incorporation, as amended and our Amended and Restated Bylaws and Delaware law contain provisions that may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock or warrants. These provisions may also prevent or delay attempts by our stockholders to replace or remove our management. Our corporate governance documents include the following provisions:

- a classified board of directors, as a result of which our board of directors is divided into two classes, with each class serving for staggered two-year terms;
- the removal of directors only for cause;

- requiring advance notice of stockholder proposals for business to be conducted at meetings of our stockholders and for nominations of candidates for election to our Board of Directors;

- prohibiting stockholders' ability to take action via written consents to action;

- providing that special meeting of stockholders may be called only by the Chairman of the Board, Chief Executive Officer, or the Board pursuant to a resolution adopted by a majority of the Board;

- authorizing blank check preferred stock, which could be issued with voting, liquidation, dividend and other rights superior to our common stock; and

- limiting the liability of, and providing indemnification to, our directors and officers.

As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders holding shares representing more than 15% of the voting power of our outstanding voting stock from engaging in certain business combinations with us. Any provision of our Second Amended and Restated Certificate of Incorporation, as amended or our Amended and Restated Bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock or warrants. They could also deter potential acquirers of our company, thereby reducing the likelihood that you could receive a premium for your common stock or warrants in an acquisition.

Our Second Amended and Restated Certificate of Incorporation, as amended, contains exclusive forum provisions that may discourage lawsuits against us and our directors and officers.

Our Second Amended and Restated Certificate of Incorporation, as amended provides that unless the corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware, will be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Company, (ii) any action asserting a claim for breach of a fiduciary duty owed by any current or former director, officer, employee or stockholder of the Company to the Company or the Company's stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our Second Amended and Restated Certificate of Incorporation, as amended or Bylaws, or (iv) any action asserting a claim governed by the internal affairs doctrine.

The choice of forum provision in our Second Amended and Restated Certificate of Incorporation, as amended, does not waive our compliance with our obligations under the federal securities laws and the rules and regulations thereunder. Moreover, the provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act or by the Securities Act. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder, and Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts with respect to suits brought to enforce a duty or liability created by the Securities Act or the rules and regulations thereunder. Accordingly, both state and federal courts have jurisdiction to entertain claims under the Securities Act.

These exclusive forum provisions may limit the ability of the Company's stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with the Company or the Company's directors or officers, which may discourage such lawsuits against the Company and the Company's directors and officers. Alternatively, if a court were to find one or more of these exclusive forum provisions inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings described above, we may incur additional costs associated with resolving such matters in other jurisdictions or forums, which could materially and adversely affect our business, financial condition or results of operations.

Our Second Amended and Restated Certificate of Incorporation, as amended, contains provisions whereby we renounced any interest in any corporate opportunity offered to any director or officer, subject to certain exceptions.

Our Section Amended and Restated Certificate of Incorporation, as amended, provides that to the extent allowed by law, the doctrine of corporate opportunity, or any other analogous doctrine, does not apply with respect to the Company or any of its officers or directors, or any of their respective affiliates, and that the Company renounces any expectancy that any of the directors or officers of the Company will offer any such corporate opportunity of which he or she may become aware to the Company, except that the doctrine of corporate opportunity shall apply with respect to any of the directors or officers of the Company only with respect to a corporate opportunity (i) that was offered to such person solely in his or her capacity as a director or officer of the Company, (ii) that is one the Company is legally and contractually permitted to undertake and would otherwise be reasonable for the Company to pursue, and (iii) to the extent the director or officer is permitted to refer such opportunity to the Company without violating any legal obligation.

Additionally, each of our officers and directors presently has, and any of them in the future may have, additional fiduciary or contractual obligations to other entities pursuant to which such officer or director may be required to present a business opportunity to such entity, subject to his or her fiduciary duties under applicable law. Accordingly, there may arise conflicts of interest in whether to present a potential business combination opportunity to our company. These conflicts may not be resolved in our favor. Our renouncement of corporate opportunities may have a material adverse effect on our results of operations moving forward and/or create conflicts of interest or perceived conflicts of interest which may have a material adverse effect on the value of our securities.

Our directors allocate their time to other businesses thereby causing conflicts of interest in their determination as to how much time to devote to our affairs.

Our directors are not required to, and do not, commit their full time to our affairs, and certain of our directors hold positions, including other directorships, with other companies in the life sciences industry, which may result in a conflict of interest in allocating their time between our operations and others which they provide services to. If our directors' other business affairs require them to devote substantial amounts of time to such affairs in excess of their current commitment levels, it could limit their ability to devote time to our affairs which may have a negative impact on our operations. Additionally, such persons may have conflicts of interest in allocating their time among various business activities. These conflicts may not be resolved in our favor. Additionally, our directors may, because of our corporate opportunity waiver, discussed above, may choose to, or be required to, provide corporate opportunities to the other companies which they are affiliated with. Actual or perceived conflicts of interest may have a material adverse effect on our results of operations which may have a material adverse effect on the value of our securities.

Compliance, Reporting and Listing Risks

We incur significant costs to ensure compliance with U.S. and NASDAQ Capital Market reporting and corporate governance requirements.

We incur significant costs associated with our public company reporting requirements and with applicable U.S. and NASDAQ Capital Market corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002 and other rules implemented by the SEC and The NASDAQ Capital Market. The rules of The NASDAQ Capital Market include requiring us to maintain independent directors, comply with other corporate governance requirements and pay annual listing and stock issuance fees. All of such SEC and NASDAQ obligations require a commitment of additional resources including, but not limited, to additional expenses, and may result in the diversion of our senior management's time and attention from our day-to-day operations. We expect all of these applicable rules and regulations to significantly increase our legal and financial compliance costs and to make some activities more time consuming and costly. We also expect that these applicable rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers.

We incur increased costs as a result of being a reporting company, and given our limited capital resources, such additional costs may have an adverse impact on our profitability.

We are an SEC-reporting company. The rules and regulations under the Exchange Act require reporting companies to provide periodic reports with interactive data files, which require that we engage legal, accounting and auditing professionals, and eXtensible Business Reporting Language (XBRL) and EDGAR (Electronic Data Gathering, Analysis, and Retrieval) service providers. The engagement of such services can be costly, and we may continue to incur additional losses, which may adversely affect our ability to continue as a going concern. In addition, the Sarbanes-Oxley Act of 2002, as well as a variety of related rules implemented by the SEC, have required changes in corporate governance practices and generally increased the disclosure requirements of public companies. For example, as a result of being a reporting company, we are required to file periodic and current reports and other information with the SEC and we have adopted policies regarding disclosure controls and procedures and regularly evaluate those controls and procedures.

The additional costs we continue to incur in connection with being a reporting company (expected to be several hundred thousand dollars per year) will continue to further stretch our limited capital resources. Due to our limited resources, we have to allocate resources away from other productive uses in order to continue to comply with our obligations as an SEC reporting company. Further, there is no guarantee that we will have sufficient resources to continue to meet our reporting and filing obligations with the SEC as they come due.

We have not been in compliance in the past with the continued listing standards of NASDAQ and may not be able to comply with NASDAQ's continued listing standards in the future.

Our common stock and warrants trade on The NASDAQ Capital Market under the symbols "ATNF" and "ATNFW," respectively. Notwithstanding such listing, there can be no assurance any broker will be interested in trading our securities. Therefore, it may be difficult to sell our securities publicly. There is also no guarantee that we will be able to maintain our listings on The NASDAQ Capital Market for any period of time by perpetually satisfying NASDAQ's continued listing requirements. While we are currently in compliance with NASDAQ's continued listing standards, we have in the past been out of compliance with such continued listing standards and our failure to continue to meet these requirements may result in our securities being delisted from NASDAQ.

Conditions required for continued listing on The NASDAQ Capital Market include requiring that we maintain at least $2.5 million in stockholders' equity, $35 million of market value of listed securities, or $500,000 in net income over the prior two years or two of the prior three years, having a majority of independent directors, a three member audit committee (consisting of all independent directors), and maintaining a bid price above $1.00 per share. Our stockholders' equity may not remain above NASDAQ's $2.5 million minimum, our market value of listed securities may not remain above $35 million, we may not generate over $500,000 of yearly net income, and we may not be able to maintain independent directors or maintain a stock price above $1.00.

If we fail to comply with NASDAQ rules and requirements, our stock may be delisted. In addition, even if we demonstrate compliance with the requirements above, we will have to continue to meet other objective and subjective listing requirements to continue to be listed on The NASDAQ Capital Market. Delisting from The NASDAQ Capital Market could make trading our common stock and/or warrants more difficult for investors, potentially leading to declines in our share price and liquidity. Without a NASDAQ Capital Market listing, stockholders may have a difficult time getting a quote for the sale or purchase of our stock, the sale or purchase of our stock would likely be made more difficult and the trading volume and liquidity of our stock could decline. Delisting from The NASDAQ Capital Market could also result in negative publicity and could also make it more difficult for us to raise additional capital. The absence of such a listing may adversely affect the acceptance of our common stock and/or warrants as currency or the value accorded by other parties. Further, if we are delisted, we would also incur additional costs under state blue sky laws in connection with any sales of our securities. These requirements could severely limit the market liquidity of our common stock and/or warrants and the ability of our stockholders to sell our common stock and/or warrants in the secondary market. If our common stock and/or warrants are delisted by NASDAQ, our common stock and/or warrants may be eligible to trade on an over-the-counter quotation system, such as the OTCQB Market, where an investor may find it more difficult to sell our stock or obtain accurate quotations as to the market value of our common stock and/or warrants. In the event our common stock and/or warrants are delisted from The NASDAQ Capital Market, we may not be able to list our common stock and/or warrants on another national securities exchange or obtain quotation on an over-the counter quotation system.

General Risk Factors

Provisions in our Certificate of Incorporation and Delaware law may inhibit a takeover of us, which could limit the price investors might be willing to pay in the future for our common stock and could entrench management.

Our Certificate of Incorporation contains provisions that may discourage unsolicited takeover proposals that stockholders may consider to be in their best interests. These provisions include a staggered board of directors and the ability of the board of directors to designate the terms of and issue new series of preferred shares, which may make it more difficult for the removal of management and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our securities. We are also subject to anti-takeover provisions under Delaware law, which could delay or prevent a change of control. Together, these provisions may make it more difficult for the removal of management and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our securities.

Failure to adequately manage our planned aggressive growth strategy may harm our business or increase our risk of failure.

For the foreseeable future, we intend to pursue an aggressive growth strategy for the expansion of our operations through increased product development and marketing. Our ability to rapidly expand our operations will depend upon many factors, including our ability to work in a regulated environment, market value-added products effectively to independent pharmacies, establish and maintain strategic relationships with suppliers, and obtain adequate capital resources on acceptable terms. Any restrictions on our ability to expand may have a materially adverse effect on our business, results of operations, and financial condition. Accordingly, we may be unable to achieve our targets for sales growth, and our operations may not be successful or achieve anticipated operating results.

Additionally, our growth may place a significant strain on our managerial, administrative, operational, and financial resources and our infrastructure. Our future success will depend, in part, upon the ability of our senior management to manage growth effectively. This will require us to, among other things:

- implement additional management information systems;
- further develop our operating, administrative, legal, financial, and accounting systems and controls;
- hire additional personnel;
- develop additional levels of management within our company;
- locate additional office space;

- maintain close coordination among our engineering, operations, legal, finance, sales and marketing, and client service and support organizations; and
- manage our expanding international operations.

As a result, we may lack the resources to deploy our services on a timely and cost-effective basis. Failure to accomplish any of these requirements could impair our ability to deliver services in a timely fashion or attract and retain new customers.

Our proprietary information, or that of our customers, suppliers and business partners, may be lost or we may suffer security breaches.

In the ordinary course of our business, we expect to collect and store sensitive data, including valuable and commercially sensitive intellectual property, clinical trial data, its proprietary business information and that of our future customers, suppliers and business partners, and personally identifiable information of our customers, clinical trial subjects and employees, patients, in its data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, regulatory penalties, disrupt our operations, damage our reputation, and cause a loss of confidence in our products and our ability to conduct clinical trials, which could adversely affect our business and reputation and lead to delays in gaining regulatory approvals for our future product candidates. Although we maintain business interruption insurance coverage, our insurance might not cover all losses from any future breaches of our systems.

Failure of our information technology systems, including cybersecurity attacks or other data security incidents, could significantly disrupt the operation of our business.

Our business increasingly depends on the use of information technologies, which means that certain key areas such as research and development, production and sales are to a large extent dependent on our information systems or those of third-party providers. Our ability to execute our business plan and to comply with regulators' requirements with respect to data control and data integrity, depends, in part, on the continued and uninterrupted performance of our information technology systems, or IT systems and the IT systems supplied by third-party service providers. As information systems and the use of software and related applications by our company, our business partners, suppliers, and customers become more cloud-based, there has been an increase in global cybersecurity vulnerabilities and threats, including more sophisticated and targeted cyber-related attacks that pose a risk to the security of our information systems and networks and the confidentiality, availability and integrity of data and information. In addition, our IT systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and backup measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we and our third-party service providers have taken to prevent unanticipated problems that could affect our IT systems, a successful cybersecurity attack or other data security incident could result in the misappropriation and/or loss of confidential or personal information, create system interruptions, or deploy malicious software that attacks our systems. It is also possible that a cybersecurity attack might not be noticed for some period of time. In addition, sustained or repeated system failures or problems arising during the upgrade of any of our IT systems that interrupt our ability to generate and maintain data, and in particular to operate our proprietary technology platform, could adversely affect our ability to operate our business. The occurrence of a cybersecurity attack or incident could result in business interruptions from the disruption of our IT systems, or negative publicity resulting in reputational damage with our stockholders and other stakeholders and/or increased costs to prevent, respond to or mitigate cybersecurity events. In addition, the unauthorized dissemination of sensitive personal information or proprietary or confidential information could expose us or other third parties to regulatory fines or penalties, litigation and potential liability, or otherwise harm our business.

We may acquire other companies which could divert our management's attention, result in additional dilution to our stockholders and otherwise disrupt our operations and harm our operating results.

We may in the future seek to acquire businesses, products or technologies that we believe could complement or expand our product offerings, enhance our technical capabilities or otherwise offer growth opportunities. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. If we acquire additional businesses, we may not be able to integrate the acquired personnel, operations and technologies successfully, effectively manage the combined business following the acquisition or realize anticipated cost savings or synergies. We also may not achieve the anticipated benefits from the acquired business due to a number of factors, including:

- incurrence of acquisition-related costs;
- diversion of management's attention from other business concerns;
- unanticipated costs or liabilities associated with the acquisition;
- harm to our existing business relationships with collaboration partners as a result of the acquisition;
- harm to our brand and reputation;
- the potential loss of key employees;
- use of resources that are needed in other parts of our business; and
- use of substantial portions of our available cash to consummate the acquisition.

In the future, if our acquisitions do not yield expected returns, we may be required to take charges to our operating results arising from the impairment assessment process. Acquisitions may also result in dilutive issuances of equity securities or the incurrence of debt, which could adversely affect our operating results. In addition, if an acquired business fails to meet our expectations, our business, results of operations and financial condition may be adversely affected.

If we make any acquisitions, they may disrupt or have a negative impact on our business.

If we make acquisitions in the future, funding permitting, which may not be available on favorable terms, if at all, we could have difficulty integrating the acquired company's assets, personnel and operations with our own. We do not anticipate that any acquisitions or mergers we may enter into in the future would result in a change of control of the Company. In addition, the key personnel of the acquired business may not be willing to work for us. We cannot predict the effect expansion may have on our core business. Regardless of whether we are successful in making an acquisition, the negotiations could disrupt our ongoing business, distract our management and employees and increase our expenses. In addition to the risks described above, acquisitions are accompanied by a number of inherent risks, including, without limitation, the following:

- the difficulty of integrating acquired products, services or operations;
- the potential disruption of the ongoing businesses and distraction of our management and the management of acquired companies;

- difficulties in maintaining uniform standards, controls, procedures and policies;
- the potential impairment of relationships with employees and customers as a result of any integration of new management personnel;
- the potential inability or failure to achieve additional sales and enhance our customer base through cross-marketing of the products to new and existing customers;
- the effect of any government regulations which relate to the business acquired;
- potential unknown liabilities associated with acquired businesses or product lines, or the need to spend significant amounts to retool, reposition or modify the marketing and sales of acquired products or operations, or the defense of any litigation, whether or not successful, resulting from actions of the acquired company prior to our acquisition; and
- potential expenses under the labor, environmental and other laws of various jurisdictions.

Our business could be severely impaired if and to the extent that we are unable to succeed in addressing any of these risks or other problems encountered in connection with an acquisition, many of which cannot be presently identified. These risks and problems could disrupt our ongoing business, distract our management and employees, increase our expenses and adversely affect our results of operations.

We may apply working capital and future funding to uses that ultimately do not improve our operating results or increase the value of our securities.

In general, we have complete discretion over the use of our working capital and any new investment capital we may obtain in the future. Because of the number and variety of factors that could determine our use of funds, our ultimate expenditure of funds (and their uses) may vary substantially from our current intended operating plan for such funds.

We intend to use existing working capital and future funding to support the development of our products and services, product purchases in our wholesale distribution division, the expansion of our marketing, or the support of operations to educate our customers. We will also use capital for market and network expansion, acquisitions, and general working capital purposes. However, we do not have more specific plans for the use and expenditure of our capital. Our management has broad discretion to use any or all of our available capital reserves. Our capital could be applied in ways that do not improve our operating results or otherwise increase the value of a stockholder's investment.

We have never paid or declared any dividends on our common stock.

We have never paid or declared any dividends on our common stock or preferred stock. Likewise, we do not anticipate paying, in the near future, dividends or distributions on our common stock. Any future dividends on common stock will be declared at the discretion of our board of directors and will depend, among other things, on our earnings, our financial requirements for future operations and growth, and other facts as we may then deem appropriate. Since we do not anticipate paying cash dividends on our common stock, return on your investment, if any, will depend solely on an increase, if any, in the market value of our common stock.

Stockholders may be diluted significantly through our efforts to obtain financing and satisfy obligations through the issuance of additional shares of our common stock.

Wherever possible, our board of directors will attempt to use non-cash consideration to satisfy obligations. In many instances, we believe that the non-cash consideration will consist of restricted shares of our common stock or where shares are to be issued to our officers, directors and applicable consultants. Our board of directors has authority, without action or vote of the stockholders, but subject to NASDAQ rules and regulations (which generally require stockholder approval for any transactions which would result in the issuance of more than 20% of our then outstanding shares of common stock or voting rights representing over 20% of our then outstanding shares of stock, subject to certain exceptions), to issue all or part of the authorized but unissued shares of common stock. In addition, we may attempt to raise capital by selling shares of our common stock, possibly at a discount to market. These actions will result in dilution of the ownership interests of existing stockholders, which may further dilute common stock book value, and that dilution may be material. Such issuances may also serve to enhance existing management's ability to maintain control of the Company because the shares may be issued to parties or entities committed to supporting existing management.

Our growth depends in part on the success of our strategic relationships with third parties.

In order to grow our business, we anticipate that we will need to continue to depend on our relationships with third parties, including our technology providers. Identifying partners, and negotiating and documenting relationships with them, requires significant time and resources. Our competitors may be effective in providing incentives to third parties to favor their products or services, or utilization of, our products and services. In addition, acquisitions of our partners by our competitors could result in a decrease in the number of our current and potential customers. If we are unsuccessful in establishing or maintaining our relationships with third parties, our ability to compete in the marketplace or to grow our revenue could be impaired and our results of operations may suffer. Even if we are successful, we cannot assure you that these relationships will result in increased customer use of our products or increased revenue.

Claims, litigation, government investigations, and other proceedings may adversely affect our business and results of operations.

We are currently subject to, and expect to continue to be regularly subject to, actual and threatened claims, litigation, reviews, investigations, and other proceedings. In addition, we have filed lawsuits against certain parties for matters we discovered which related to KBL, prior to the Business Combination. Any of these types of proceedings may have an adverse effect on us because of legal costs, disruption of our operations, diversion of management resources, negative publicity, and other factors. Our current legal proceedings are described in "Note 11 - Commitments and Contingencies", under the heading "Litigation and Other Loss Contingencies", in the consolidated financial statements included herein beginning on page F-1. The outcomes of these matters are inherently unpredictable and subject to significant uncertainties. Determining legal reserves and possible losses from such matters involves judgment and may not reflect the full range of uncertainties and unpredictable outcomes. Until the final resolution of such matters, we may be exposed to losses in excess of the amount recorded, and such amounts could be material. Should any of our estimates and assumptions change or prove to have been incorrect, it could have a material effect on our business, consolidated financial position, results of operations, or cash flows. In addition, it is possible that a resolution of one or more such proceedings, including as a result of a settlement, could require us to make substantial future payments, prevent us from offering certain products or services, require us to change our business practices in a manner materially adverse to our business, requiring development of non-infringing or otherwise altered products or technologies, damaging our reputation, or otherwise having a material effect on our operations.

Changes in laws or regulations, or a failure to comply with any laws and regulations, may adversely affect our business, investments and results of operations.

We are subject to laws, regulations and rules enacted by national, regional and local governments. In particular, we are required to comply with certain SEC, NASDAQ and other legal or regulatory requirements. Compliance with, and monitoring of, applicable laws, regulations and rules may be difficult, time consuming and costly. Those laws, regulations and rules and their interpretation and application may also change from time to time and those changes could have a material adverse effect on our business, investments and results of operations. In addition, a failure to comply with applicable laws, regulations and rules, as interpreted and applied, could have a material adverse effect on our business and results of operations.

Certain of our executive officers and directors are now, and all of them may in the future become, affiliated with entities engaged in business activities similar to those conducted by us and, accordingly, may have conflicts of interest in determining to which entity a particular business opportunity should be presented.

Our executive officers and directors are, or may in the future become, affiliated with entities that are engaged in business activities similar to those that are conducted by us. Our officers and directors also may become aware of business opportunities which may be appropriate for presentation to us and the other entities to which they owe certain fiduciary or contractual duties. Accordingly, they may have conflicts of interest in determining whether a particular business opportunity should be presented to our company or to another entity. These conflicts may not be resolved in our favor and a potential opportunity may be presented to another entity prior to its presentation to us. Our Certificate of Incorporation provides that we renounce our interest in any corporate opportunity offered to any director or officer unless such opportunity is expressly offered to such person solely in his or her capacity as a director or officer of our company and such opportunity is one we are legally and contractually permitted to undertake and would otherwise be reasonable for us to pursue.

Our executive officers, directors, security holders and their respective affiliates may have competitive pecuniary interests that conflict with our interests.

We have not adopted a policy that expressly prohibits our directors, executive officers, security holders or affiliates from having a direct or indirect pecuniary or financial interest in any investment to be acquired or disposed of by us or in any transaction to which we are a party or have an interest. In fact, we may enter into a strategic transaction with a target business that is affiliated with our directors or executive officers. Nor do we have a policy that expressly prohibits any such persons from engaging for their own account in business activities of the types conducted by us. Accordingly, such persons or entities may have a conflict between their interests and ours. Certain of our officers and directors hold positions with companies which may be competitors of us. See also the biographies of our officers and directors incorporated by reference herein below under "Directors, Officers and Corporate Governance".

Our business has been, and may continue to be, adversely affected by the COVID-19 pandemic.

In December 2019, a novel strain of coronavirus (COVID-19) was reported to have surfaced in Wuhan, China. In January 2020, COVID-19 spread to other parts of the word, including the U.S. and Europe, and efforts to contain its spread have intensified, with varying degrees of success. As a result, businesses have closed and limits have been placed on travel and everyday activities. The extent to which COVID-19 may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, travel restrictions and social distancing in the U.S. and other countries, business closures or business disruptions, and the effectiveness of actions taken in the U.S. and other countries to contain and treat the disease. Should the COVID-19 pandemic continue, our plans could be delayed or interrupted. The spread of COVID-19 has also created global economic uncertainty, which may cause partners, suppliers and potential customers to closely monitor their costs and reduce their spending budget. The foregoing could materially adversely affect the clinical trials, supply chain, financial condition and financial performance of our company.

Enrollment of patients in our clinical trials, maintaining patients in our ongoing clinical trials, doing follow up visits with recruited patients and collecting data have been, and may continue to be, delayed or limited as certain of our clinical trial sites limit their onsite staff or temporarily close as a result of the COVID-19 pandemic and ongoing government restrictions. In addition, patients may not be able or willing to visit clinical trial sites for dosing or data collection purposes due to limitations on travel and physical distancing imposed or recommended by federal or state governments or patients' reluctance to visit the clinical trial sites during the pandemic. These factors resulting from the COVID-19 pandemic could delay or prevent the anticipated readouts from our clinical trials, which could ultimately delay or prevent our ability to generate revenues and could have a material adverse effect on our results of operations. The foregoing could materially adversely affect the clinical trials, supply chain, financial condition and financial performance of our company.

Additionally, our Frozen Shoulder trial has been adversely affected. The trial was opened to recruitment at the end of May 2022 following delays in gaining approvals due to backlogs in the National Institute of Health Research (NIHR) system due to COVID-19 and consequential staff vacancies. Nine participants were recruited for participation in the trial through mid-February 2023. The U.K. research system has faced unprecedented challenges following the COVID-19 pandemic both in terms of support services and at the point of delivery of clinical care. This has resulted in the NIHR instituting their Recovery and Reset program to identify and close trials that are facing challenges. Our Frozen Shoulder trial was considered to be one of such trials, due to the considerable challenges we faced to open recruitment sites and enroll sufficient participants. Therefore, the NIHR has asked the chief investigators to close the trial for further recruitment. This closure or future closures or difficulties relating to the recruitment of participants in future studies could have a material adverse effect on our ability to complete studies, the timeline for future drugs and our ability to generate revenues and support our operations.

We may be adversely affected by climate change or by legal, regulatory or market responses to such change.

The long-term effects of climate change are difficult to predict; however, such effects may be widespread. Impacts from climate change may include physical risks (such as rising sea levels or frequency and severity of extreme weather conditions—which may affect our current operations due to among other things, the fact that a majority of our operations we are based in California, which is prone to inclement weather), social and human effects (such as population dislocations or harm to health and well-being), compliance costs and transition risks (such as regulatory or technology changes) and other adverse effects. The effects of climate change could increase the cost of certain products, commodities and energy (including utilities), which in turn may impact our ability to procure goods or services required for the operation of our business. Climate change could also lead to increased costs as a result of physical damage to or destruction of our facilities, loss of inventory, and business interruption due to weather events that may be attributable to climate change. These events and impacts could materially adversely affect our business operations, financial position or results of operation.

Environmental, social and governance matters may impact our business and reputation.

Governmental authorities, non-governmental organizations, customers, investors, external stakeholders and employees are increasingly sensitive to environmental, social and governance, or ESG, concerns, such as diversity and inclusion, climate change, water use, recyclability or recoverability of packaging, and plastic waste. This focus on ESG concerns may lead to new requirements that could result in increased costs associated with developing, manufacturing and distributing our products. Our ability to compete could also be affected by changing customer preferences and requirements, such as growing demand for more environmentally friendly products, packaging or supplier practices, or by failure to meet such customer expectations or demand. We risk negative stockholder reaction, including from proxy advisory services, as well as damage to our brand and reputation, if we do not act responsibly, or if we are perceived to not be acting responsibly in key ESG areas, including equitable access to medicines, product quality and safety, diversity and inclusion, environmental stewardship, support for local communities, corporate governance and transparency, and addressing human capital factors in our operations. If we do not meet the ESG expectations of our investors, customers and other stakeholders, we could experience reduced demand for our products, loss of customers, and other negative impacts on our business and results of operations.

The U.K.'s withdrawal from the EU could result in increased regulatory and legal complexity, which may make it more difficult for us to do business in the U.K. and/or Europe and impose additional challenges in securing regulatory approval of our product candidates in the U.K. and/or Europe.

The U.K.'s exit from the EU as of January 31, 2020, with a transitional period up to December 31, 2020, commonly referred to as "Brexit", has caused political and economic uncertainty, including in the regulatory framework applicable to our operations and product candidates in the U.K. and the EU, and this uncertainty may persist for years. Brexit could, among other outcomes, disrupt the free movement of goods, services and people between the U.K. and the EU, and result in increased legal and regulatory complexities, as well as potential higher costs of conducting business in Europe. As one of the Brexit consequences, the EMA has relocated from the U.K. to the Netherlands. This has led to a significant reduction of the EMA workforce, which has resulted and could further result in significant disruption and delays in its administrative procedures, such as granting clinical trial authorization or opinions for marketing authorization, disruption of importation and export of active substance and other components of new drug formulations, and disruption of the supply chain for clinical trial product and final authorized formulations.

The cumulative effects of the disruption to the regulatory framework may add considerably to the development lead time to marketing authorization and commercialization of products in the EU and/or the U.K. It is possible that there will be increased regulatory complexities, which can disrupt the timing of our clinical trials and regulatory approvals. In addition, changes in, and legal uncertainty with regard to, national and international laws and regulations may present difficulties for our clinical and regulatory strategy. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the U.K. and/or the EU and restrict our ability to generate revenues and achieve and sustain profitability.

In addition, as a result of Brexit, other European countries may seek to conduct referenda with respect to their continuing membership with the EU. Given these possibilities and others we may not anticipate, as well as the absence of comparable precedent, it is unclear what financial, regulatory and legal implications the withdrawal of the U.K. from the EU will have, how such withdrawal will affect us, and the full extent to which our business could be adversely affected.

The increasing use of social media platforms presents new risks and challenges to our business.

Social media is increasingly being used to communicate about pharmaceutical companies' research, product candidates, and the diseases such product candidates are being developed to prevent. Social media practices in the pharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us. For example, subjects may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. When such events occur, there is a risk that we fail to monitor and comply with applicable adverse event reporting obligations, or we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our investigational product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social media or networking website. Certain data protection regulations, such as the GDPR, apply to personal data contained on social media. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur harm to our business, including damage to our reputation.

We may incur indebtedness in the future which could reduce our financial flexibility, increase interest expense and adversely impact our operations and our costs.

We may incur significant amounts of indebtedness in the future. Our level of indebtedness could affect our operations in several ways, including the following:

- a significant portion of our cash flows is required to be used to service our indebtedness;
- a high level of debt increases our vulnerability to general adverse economic and industry conditions;
- covenants contained in the agreements governing our outstanding indebtedness limit our ability to borrow additional funds and provide additional security interests, dispose of assets, pay dividends and make certain investments;
- a high level of debt may place us at a competitive disadvantage compared to our competitors that are less leveraged and, therefore, may be able to take advantage of opportunities that our indebtedness may prevent us from pursuing; and
- debt covenants may affect our flexibility in planning for, and reacting to, changes in the economy and in our industry.

A high level of indebtedness increases the risk that we may default on our debt obligations. We may not be able to generate sufficient cash flows to pay the principal or interest on our debt, and future working capital, borrowings or equity financing may not be available to pay or refinance such debt. If we do not have sufficient funds and are otherwise unable to arrange financing, we may have to sell significant assets or have a portion of our assets foreclosed upon which could have a material adverse effect on our business, financial condition and results of operations.

We may be adversely impacted by changes in accounting standards.

Our consolidated financial statements are subject to the application of U.S. GAAP, which periodically is revised or reinterpreted. From time to time, we are required to adopt new or revised accounting standards issued by recognized authoritative bodies, including the Financial Accounting Standards Board ("FASB") and the SEC. It is possible that future accounting standards may require changes to the accounting treatment in our consolidated financial statements and may require us to make significant changes to our financial systems. Such changes might have a materially adverse impact on our financial position or results of operations.

For all of the foregoing reasons and others set forth herein, an investment in our securities involves a high degree of risk.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

The Company's headquarters are located in Palo Alto, California. The Company believes its existing leased office space is suitable for the conduct of its business.

ITEM 3. LEGAL PROCEEDINGS.

From time to time, we may be a party to litigation that arises in the ordinary course of our business.

Such current litigation or other legal proceedings are described in, and incorporated by reference in, this "Item 3. Legal Proceedings" of this Annual Report on Form 10-K from, "Note 11 - Commitments and Contingencies", under the heading "Litigation and Other Loss Contingencies", in the consolidated financial statements included herein beginning on page F-1. The Company believes that the resolution of currently pending matters will not individually or in the aggregate have a material adverse effect on our financial condition or results of operations. However, assessment of the current litigation or other legal claims could change in light of the discovery of facts not presently known to the Company or by judges, juries or other finders of fact, which are not in accord with management's evaluation of the possible liability or outcome of such litigation or claims.

Additionally, the outcome of litigation is inherently uncertain. If one or more legal matters were resolved against the Company in a reporting period for amounts in excess of management's expectations, the Company's financial condition and operating results for that reporting period could be materially adversely affected.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock and warrants are listed on the NASDAQ Capital Market under the symbols "ATNF" and "ATNFW," respectively.

Holders

As of March 31, 2023, there were 3,746,906 shares of common stock issued and outstanding held by 123 holders of record, and 3,435,728 shares of common stock underlying 11,500,000 public warrants outstanding to purchase shares of our common stock. Each public warrant entitles the registered holder to purchase one-fortieth of one share of our common stock at a price of $5.75 per $1/40^{th}$ of one share or $230 per whole share, subject to adjustment as discussed below, at any time commencing on December 6, 2020 (30 days after our initial business combination) and ending on November 6, 2025 (five years after our initial business combination), at 5:00 p.m., New York City time, or earlier upon redemption or liquidation. If a warrant holder holds 40 warrants, such warrants will be exercisable for one share of our common stock. No fractional shares will be issued upon exercise of the warrants and warrants must be exercised for whole shares only.

Securities Authorized for Issuance Under Equity Compensation Plans

We have reserved 185,907 shares of our common stock for grant under our 2020 Omnibus Incentive Plan ("2020 OIP"), of which 2,111 shares are available for future awards as of the date of this Report and 120,000 shares of common stock for grant under our 2022 Omnibus Incentive Plan ("2022 OIP" and together with the 2020 OIP, the "OIPs"), of which 113,526 shares are available for future awards as of the date of this Report. The OIPs are intended to be a vital component of our compensation program and equity plans we use to grant equity-based incentive awards to our directors, officers, employees and consultants. Our Board believes that granting equity awards under the OIPs will serve to align the interests of the key services providers of the Company and its subsidiaries with the Company's stockholders, and that it would be in the best interest of the Company and its stockholders to make such grants.

Dividend Policy

We have never paid or declared any cash dividends on our common stock and do not anticipate paying cash dividends in the foreseeable future. We anticipate that we will retain all of our future earnings for use in the operation of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our board of directors. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

Special Voting Shares

We have two classes of preferred stock designated, named our Class C Special Voting Shares and our Class K Special Voting Shares (collectively, the "Special Voting Shares"), with the rights and preferences specified below.

The Special Voting Shares have a par value of $0.0001 per share. The rights and preferences of each Special Voting Shares consists of the following:

- the right to vote in all circumstances in which our common stock have the right to vote, with the common stock as one class;
- the Special Voting Shares entitle the holder Odyssey Trust Company (the Trustee) to an aggregate number of votes equal to the number of shares of common stock that were issuable to the holders of the previously outstanding shares of CannBioRex Purchaseco ULC and/or Katexco Purchaseco ULC, Canadian subsidiaries of 180 (the "Exchangeable Shares");
- the holder of the Special Voting Shares (and, indirectly, the holders of the Exchangeable Shares) has the same rights as the holders of the common stock as to notices, reports, financial statements and attendance at all stockholder meetings;
- no entitlement to dividends;
- the holder of the Special Voting Shares is not entitled to any portion of any related distribution upon windup, dissolution or liquidation of the Company; and
- the Company may cancel the Special Voting Shares when there are no Exchangeable Shares outstanding and no option or other commitment of CannBioRex Purchaseco ULC and Katexco Purchaseco ULC which could require either CannBioRex Purchaseco ULC and Katexco Purchaseco ULC to issue more Exchangeable Shares.

As set forth above, the holders of the Exchangeable Shares, through the applicable Special Voting Share, have voting rights and other attributes corresponding to the Common Stock. The Exchangeable Shares provide an opportunity for certain former Canadian resident holders of CBR Pharma or Katexco securities to obtain a deferral of taxable capital gains for Canadian income tax purposes in connection with the Reorganization.

As of the date of this Report, the Class C Special Voting Shares and our Class K Special Voting Shares have the right to vote 0 and 264 total voting shares, respectively.

ITEM 6. [RESERVED]

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

The following discussion and analysis of the results of operations and financial condition of 180 Life Sciences Corp. as of and for the years ended December 31, 2022 and 2021 should be read in conjunction with our consolidated financial statements and the notes to those consolidated financial statements that are included elsewhere in this Annual Report. This Management's Discussion and Analysis of Financial Condition and Results of Operations contains statements that are forward-looking. See "Cautionary Statement Regarding Forward-Looking Information" *above. Actual results could differ materially because of the factors discussed in "Risk Factors" elsewhere in this Annual Report, and other factors that we may not know.*

As of December 31, 2022, we had an accumulated deficit of $107,408,545 and working capital of $3,270,608, and for the year ended December 31, 2022, a net loss of $38,726,259 and cash used in operating activities of $12,127,585. The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As we are not generating revenues, we need to raise a significant amount of capital in order to pay our debts and cover our operating costs. While the Company raised capital in August 2021, July 2022 and December 2022, there is no assurance that we will be able to raise additional needed capital or that such capital will be available under favorable terms.

We are subject to all the substantial risks inherent in the development of a new business enterprise within an extremely competitive industry. Due to the absence of a long-standing operating history and the emerging nature of the markets in which we compete, we anticipate operating losses until we can successfully implement our business strategy, which includes all associated revenue streams. We may never ever achieve profitable operations or generate significant revenues.

We currently have a minimum monthly cash requirement spend of approximately $900,000. We believe that in the aggregate, we will require significant additional capital funding to support and expand the research and development and marketing of our products, fund future clinical trials, repay debt obligations, provide capital expenditures for additional equipment and development costs, payment obligations, office space and systems for managing the business, and cover other operating costs until our planned revenue streams from products are fully-implemented and begin to offset our operating costs, if ever.

Since our inception, we have funded our operations with the proceeds from equity and debt financings. We have experienced liquidity issues due to, among other reasons, our limited ability to raise adequate capital on acceptable terms. We have historically relied upon the issuance equity and promissory notes that are convertible into shares of our common stock to fund our operations and have devoted significant efforts to reduce that exposure. We anticipate that we will need to issue equity to fund our operations and repay our outstanding debt for the foreseeable future. If we are unable to achieve operational profitability or we are not successful in securing other forms of financing, we will have to evaluate alternative actions to reduce our operating expenses and conserve cash.

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Accordingly, the consolidated financial statements do not include any adjustments relating to the recoverability of assets and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The consolidated financial statements included in this prospectus also include a going concern footnote.

Additionally, wherever possible, our Board of Directors will attempt to use non-cash consideration to satisfy obligations. In many instances, we believe that the non-cash consideration will consist of restricted shares of our common stock, preferred stock or warrants to purchase shares of our common stock. Our Board of Directors has authority, without action or vote of the shareholders, but subject to NASDAQ rules and regulations (which generally require shareholder approval for any transactions which would result in the issuance of more than 20% of our then outstanding shares of common stock or voting rights representing over 20% of our then outstanding shares of stock), to issue all or part of the authorized but unissued shares of common stock, preferred stock or warrants to purchase such shares of common stock. In addition, we may attempt to raise capital by selling shares of our common stock, possibly at a discount to market in the future. These actions will result in dilution of the ownership interests of existing shareholders, may further dilute common stock book value, and that dilution may be material. Such issuances may also serve to enhance existing management's ability to maintain control of us, because the shares may be issued to parties or entities committed to supporting existing management.

Organization of MD&A

Our Management's Discussion and Analysis of Financial Condition and Results of Operations (the "MD&A") is provided in addition to the accompanying consolidated financial statements and notes to assist readers in understanding our results of operations, financial condition, and cash flows. MD&A is organized as follows:

- **Business Overview and Recent Events.** A summary of the Company's business and certain material recent events.
- **Significant Financial Statement Components.** A summary of the Company's significant financial statement components.

- **Results of Operations**. An analysis of our financial results comparing the twelve months ended December 31, 2022 and 2021.

- **Liquidity and Capital Resources**. An analysis of changes in our balance sheets and cash flows and discussion of our financial condition.

- **Critical Accounting Policies and Estimates**. Accounting estimates that we believe are important to understanding the assumptions and judgments incorporated in our reported financial results and forecasts.

Business Overview and Recent Events

This MD&A and the related financial statements for the year ended December 31, 2022 primarily covers the operations of 180, which is a clinical stage biotechnology company headquartered in Palo Alto, California, focused on the development of therapeutics for unmet medical needs in chronic pain, inflammation, fibrosis and other inflammatory diseases, where anti-TNF therapy will provide a clear benefit to patients, by employing innovative research, and, where appropriate, combination therapy. We have three product development platforms:

- fibrosis and anti-tumor necrosis factor ("TNF");

- drugs which are derivatives of cannabidiol ("CBD"); and

- alpha 7 nicotinic acetylcholine receptor ("α7nAChR").

We have several future product candidates in development, including one product candidate which has recently completed a successful Phase 2b clinical trial in the United Kingdom for Dupuytren's Contracture, a condition that affects the development of fibrous connective tissue in the palm of the hand. 180 was founded by several world-leading scientists in the biotechnology and pharmaceutical sectors.

We intend to invest resources to successfully complete the clinical programs that are underway, discover new drug candidates, and develop new molecules to build up on our existing pipeline to address unmet clinical needs. The product candidates are designed via a platform comprised of defined unit operations and technologies. This work is performed in a research and development environment that evaluates and assesses variability in each step of the process in order to define the most reliable production conditions.

We may rely on third-party contract manufacturing organizations ("CMOs") and other third parties for the manufacturing and processing of the product candidates in the future. We believe the use of contract manufacturing and testing for the first clinical product candidates is cost-effective and has allowed us to rapidly prepare for clinical trials in accordance with our development plans. We expect that third-party manufacturers will be capable of providing and processing sufficient quantities of these product candidates to meet anticipated clinical trial demands.

Significant Financial Statement Components

Research and Development

To date, 180's research and development expenses have related primarily to discovery efforts and preclinical and clinical development of its three product platforms: (1) fibrosis and anti-TNF; (2) drugs which are derivatives of CBD, and (3) α7nAChR. Research and development expenses consist primarily of costs associated with those three product platforms, which include:

- expenses incurred under agreements with 180's collaboration partners and third-party contract organizations, investigative clinical trial sites that conduct research and development activities on its behalf, and consultants;

- costs related to production of clinical materials, including fees paid to contract manufacturers;

- laboratory and vendor expenses related to the execution of preclinical and clinical trials;
- employee-related expenses, which include salaries, benefits and stock-based compensation; and
- facilities and other expenses, which include expenses for rent and maintenance of facilities, depreciation and amortization expense and other supplies.

We expense all research and development costs in the periods in which they are incurred. We accrue for costs incurred as services are provided by monitoring the status of each project and the invoices received from our external service providers. We adjust our accrual as actual costs become known. When contingent milestone payments are owed to third parties under research and development arrangements or license agreements, the milestone payment obligations are expensed when the milestone results are achieved.

Research and development activities are central to our business model. Product 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 that research and development expenses will increase over the next several years as clinical programs progress and as we seek to initiate clinical trials of additional product candidates. It is also expected that increased research and development expenses will be incurred as additional product candidates are selectively identified and developed. However, it is difficult to determine with certainty the duration and completion costs of current or future preclinical programs and clinical trials of product candidates.

The duration, costs and timing of clinical trials and development of product candidates will depend on a variety of factors that include, but are not limited to, the following:

- per patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the impact of COVID-19 on the length of our trials;
- the duration of patient follow-up; and
- the efficacy and safety profile of the product candidates.

In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. We will determine which programs to pursue and fund in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate’s commercial potential.

Because the product candidates are still in clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of product candidates or whether, or when, we may achieve profitability. Due to the early-stage nature of these programs, we do not track costs on a project-by-project basis. As these programs become more advanced, we intend to track the external and internal cost of each program.

General and Administrative

General and administrative expenses consist primarily of salaries and other staff-related costs, including stock-based compensation for shares of common stock issued and options granted to founders, directors and personnel in executive, commercial, finance, accounting, legal, investor relations, facilities, business development and human resources functions and include vesting conditions.

Other significant general and administrative costs include costs relating to facilities and overhead costs, legal fees relating to corporate and patent matters, litigation, SEC filings, insurance, investor relations costs, fees for accounting and consulting services, and other general and administrative costs. General and administrative costs are expensed as incurred, and we accrue amounts for services provided by third parties related to the above expenses by monitoring the status of services provided and receiving estimates from our service providers and adjusting our accruals as actual costs become known.

It is expected that the general and administrative expenses will increase over the next several years to support our continued research and development activities, manufacturing activities, potential commercialization of our product candidates and the increased costs of operating as a public company. These increases are anticipated to include increased costs related to the hiring of additional personnel, developing commercial infrastructure, fees to outside consultants, lawyers and accountants, and increased costs associated with being a public company, as well as expenses related to services associated with maintaining compliance with Nasdaq listing rules and SEC requirements, insurance and investor relations costs.

Other Income

Other income primarily represents fees earned for research and development work performed for other companies, some of which are related parties.

Interest Expense

Interest expense consists primarily of interest expense related to debt instruments.

Gain (Loss) on Extinguishment of Convertible Notes

Gain (loss) on extinguishment of convertible notes represents the shortfall (excess) of the reacquisition cost of convertible notes as compared to their carrying value.

Loss on Goodwill Impairment

Loss on goodwill impairment represents the excess of the carrying value of the asset over its estimated fair market value during the reporting period which is not recoverable.

Loss on IP R&D assets impairment

Loss on IP R&D assets impairment represents the excess of the carrying value of the assets over its estimated fair market value during the reporting period which is not recoverable.

Change in Fair Value of IR R&D assets

Change in fair value of IP R&D assets represents the non-cash change in fair value of the assets during the reporting period.

Change in Fair Value of Derivative Liabilities

Change in fair value of derivative liabilities represents the non-cash change in fair value of derivative liabilities during the reporting period. Gains/losses resulting from change in fair value of derivative liabilities during the years ended December 31, 2022 and 2021, were driven by decreases/increases in stock price during the period, resulting in a lower/higher fair value of the underlying liability.

Offering Costs Allocated to Warrant Liabilities

Change in offering costs allocated to warrant liabilities represents placement agent fees and offering expenses which were allocated to the Private Investment in Public Equity ("PIPE") Warrants and expensed immediately as they are liability classified.

Change in Fair Value of Accrued Issuable Equity

Change in fair value of accrued issuable equity represents the non-cash change in fair value of accrued equity prior to its formal issuance.

CONSOLIDATED RESULTS OF OPERATIONS

Consolidated Results of Operations

For the Year Ended December 31, 2022 Compared to the Year Ended December 31, 2021

	For the Years Ended December 31,	
	2022	**2021**
Operating Expenses:		
Research and development	$ 2,191,834	$ 1,000,769
Research and development - related parties	240,731	2,947,536
General and administrative	15,459,788	11,230,118
General and administrative - related parties	5,612	462,580
Total Operating Expenses	17,897,965	15,641,003
Loss From Operations	(17,897,965)	(15,641,003)
Other (Expense) Income:		
Gain on settlement of liabilities	-	926,829
Other expense	-	(146,822)
Interest expense	(28,175)	(135,953)
Interest expense – related parties	1,508	(50,255)
Loss on extinguishment of convertible notes payable, net	-	(9,737)
Loss on goodwill impairment	(33,547,278)	-
Loss on IP R&D assets impairment	(3,342,084)	-
Change in fair value of derivative liabilities	15,144,986	(4,677,388)
Change in fair value of accrued issuable equity	-	(9,405)
Offering costs allocated to warrant liabilities	-	(604,118)
Total Other Expense, Net	(21,771,043)	(4,706,849)
Loss Before Income Taxes	(39,669,008)	(20,347,852)
Income tax benefit	942,749	23,204
Net Loss	$ (38,726,259)	$ (20,324,648)

Research and Development

During the year ended December 31, 2022, we incurred research and development expenses of $2,191,834 compared to $1,000,769 incurred for the year ended December 30, 2021, representing an increase of $1,191,065 or 119%. The increase includes a $1,000,000 increase in stock-based compensation expense, a $430,000 increase in expenses related to Oxford University agreements, a $290,000 increase in salaries expense, a $270,000 increase in expenses related to the Scientific Advisory Board, an increase in consulting expenses of $120,000, as well as increases of $100,000 related to patents and licenses. This activity was offset by decreases in expenses related to contracts with Yissum and Gallily Ruth of $460,000 and $250,000, respectively, a decrease related to a tax credit of $210,000 and a decrease in related-party consulting expenses of $110,000.

Research and Development – Related Parties

During the year ended December 31, 2022, we incurred research and development expenses – related parties of $240,731 compared to $2,947,536 incurred for the year ended December 31, 2021, representing a decrease of $2,706,805 or 92%. The decrease includes a decrease in stock-based compensation expense of $2,300,000; this decrease is comprised of approximately $800,000 paid to Jagdeep Nanchahal in the prior year for his research in the Phase 2b clinical trial for Dupuytren's Contracture (RIDD), as well as stock-based compensation expense of approximately $1,400,000 paid to Mr. Nanchahal in the prior year as well. There was also a decrease in consulting expenses of $460,000.

General and Administrative

During the year ended December 31, 2022, we incurred general and administrative expenses of $15,459,788 compared to $11,230,118 incurred for the year ended December 31, 2021, representing an increase of $4,229,670 or 38%. The increase is attributable to an increase in legal fees of $3,700,000, an increase of $880,000 in directors' and officers' insurance expenses as well as an increase in salaries expense of $550,000, offset by decreases in exchange-related penalties of $530,000, a decrease in settlement expenses of $360,000, a decrease in stock-based compensation expense of $180,000 and a decrease in consulting expenses of $40,000.

General and Administrative – Related Parties

During the year ended December 31, 2022, we incurred general and administrative expenses – related parties of $5,612 compared to $462,580 incurred for the year ended December 31, 2021, representing a decrease of $456,968, or 99%. The decrease is primarily related to a decrease in related party consulting expenses of $125,000, as well as a decrease in bad debt expense of $300,000 incurred in connection with a receivable from related parties.

Other Expense, Net

During the year ended December 31, 2022, we incurred other expenses, net of $21,771,043 compared to $4,706,849 for the year ended December 31, 2021, representing an increase in other expenses of $17,064,194 or 363%. The increase in expenses was primarily due to the following: i) an impairment to goodwill in the current year of $33,547,278, ii) an impairment to IP R&D assets in the current year of $3,342,084 and iii) a gain on the settlement of liabilities of $926,829 in the prior year that was absent from the current year, offset by iv) a change in the current year in the fair value of derivative liabilities of $19,822,374 and v) $604,118 of warrant costs due to an offering in the prior year.

Liquidity and Capital Resources

As of December 31, 2022 and 2021, we had cash balances of $6,970,110 and $8,224,508, respectively, and working capital of $3,270,608 and a working capital deficit of $8,498,193, respectively.

For the years ended December 31, 2022 and 2021, cash used in operating activities was $12,127,585 and $19,371,428, respectively. Our cash used in operations for the year ended December 31, 2022 was primarily attributable to our net loss of $38,726,259, adjusted for non-cash expenses in the aggregate amount of $23,876,048, as well as $2,722,626 of net cash used in changes in the levels of operating assets and liabilities. A significant portion of the non-cash expenses during the year relates to $36.9 million of non-recurring expenses associated with the impairment of goodwill and IP R&D assets (see Note 5 – Intangible Assets and Impairment of Long-lived Assets), offset by changes in fair value of derivative liabilities of $15,144,986 for the year. Our cash used in operations for the year ended December 31, 2021 was primarily attributable to our net loss of $20,324,648, adjusted for non-cash expenses in the aggregate amount of $9,760,161, as well as $8,806,941 of net cash used in changes in the levels of operating assets and liabilities. A significant portion of cash used in operations during the year relates to $4.8 million of non-recurring expenses associated with the business combination.

For the years ended December 31, 2022 and 2021, there was no cash provided by investing activities.

For the years ended December 31, 2022 and 2021, cash provided by financing activities was $10,873,606 and $25,411,919, respectively. Cash provided by financing activities during the year ended December 31, 2022 was primarily comprised of proceeds from the sale of July 2022 common stock and common stock warrants of $6,499,737, proceeds from the sale of December 2022 common stock and common warrants of $5,999,851 and proceeds from loans payable of $1,060,890, partially offset by offering costs paid in connection with our July 2022 and December 2022 Offerings of $529,982 and $484,991, respectively, and repayments of loans payable and loans payable – related parties of $1,591,035 and $81,277, respectively. Cash provided by financing activities during the year ended December 31, 2021 was comprised of proceeds from the sale of common stock and warrants of $26,666,200 and proceeds from loans payable in the amount of $1,618,443, partially offset by repayments of convertible debt and loans payable of ($10,000) and ($807,594), respectively, and offering costs paid of ($2,055,130).

Our product candidates may never achieve commercialization and we anticipate that we will continue to incur losses for the foreseeable future. We expect that our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. As a result, until such time, if ever, as we are able to generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements, which may not be available on favorable terms, if at all. The sale of additional equity or debt securities, if accomplished, may result in dilution to our then stockholders. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, license payments or milestone obligations that may arise, laboratory and related supplies, clinical costs, potential manufacturing costs, legal and other regulatory expenses and general overhead costs.

Our material cash requirements and time periods of such requirements from known contractual and other obligations include milestone and royalty payments related to license agreements with Oxford University and Yissum, payments related to the D&O insurance, payments to consultants and payments related to outside consulting firms, such as legal counsel, auditors, accountants, etc. These cash requirements, in the aggregate, amount to approximately $10,000,000 for 2023 and $27,000,000 for the years 2024 through 2027.

Further, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities. We currently have no credit facility or committed sources of capital. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development programs.

We have not yet achieved profitability and expect to continue to incur cash outflows from operations. It is expected that our research and development and general and administrative expenses will continue to increase and, as a result, we will eventually need to raise additional capital to fund our operations. If we are unable to obtain adequate funds on reasonable terms, we may be required to significantly curtail or discontinue operations or obtain funds by entering into financing agreements on unattractive terms. Our operating needs include the planned costs to operate our business, including amounts required to fund working capital and capital expenditures. As of December 31, 2022, the conditions outlined above indicated that there was a substantial doubt about our ability to continue as a going concern within one year after the financial statement issuance date. However, in August 2021, July 2022 and December 2022, the Company raised additional capital of approximately $13.9 million, $6.0 million and $5.5 million, respectively, and with current cash on hand of approximately $2.7 million as of March 29, 2023, the Company expects to be able to continue as a going concern through the third quarter of 2023.

Our consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"), which contemplate continuation of the Company as a going concern and the realization of assets and satisfaction of liabilities in the normal course of business. The carrying amounts of assets and liabilities presented in the consolidated financial statements do not necessarily purport to represent realizable or settlement values. The consolidated financial statements do not include any adjustment that might result from the outcome of this uncertainty.

Recent Financing and Settlement Transactions

Convertible Debt Conversions

From November 27, 2020 to February 5, 2021, the holders of the Company's convertible promissory notes converted an aggregate of $4,782,107 owed under such convertible notes into an aggregate of 99,338 shares of common stock, pursuant to the terms of such notes, as amended, at conversion prices of between $40.00 and $65.80 per share.

During the third quarter of 2021, certain noteholders elected to convert certain convertible notes payable with an aggregate principal balance of $1,234,334 and an aggregate accrued interest balance of $105,850 into an aggregate of 23,357 shares of the Company's common stock at conversion prices ranging from $49.00-$65.80 per share. The shares issued upon the conversion of the convertible promissory notes had a fair value at issuance of $1,941,125.

February 2021 Offering

On February 19, 2021, the Company entered into a Securities Purchase Agreement with a number of institutional investors (the "Purchasers") pursuant to which the Company agreed to sell to the Purchasers an aggregate of 128,200 shares (the "Shares") of the Company's common stock and warrants to purchase up to an aggregate of 128,200 shares of the Company's common stock (the "SPA Warrants"), at a combined purchase price of $91.00 per Share and accompanying SPA Warrant (the "Offering"). Aggregate gross proceeds from the Offering were approximately $11.7 million, prior to deducting placement agent fees and estimated offering expenses payable by the Company. Net proceeds to the Company from the Offering, after deducting the placement agent fees and offering expenses payable by the Company, were approximately $10.8 million. The Offering closed on February 23, 2021.

Maxim Group LLC (the "Placement Agent") acted as exclusive placement agent in connection with the Offering pursuant to an Engagement Letter between the Company and the Placement Agent dated January 26, 2021 (as amended on February 18, 2021). Pursuant to the Engagement Letter, the Placement Agent received a commission equal to seven percent (7%) of the aggregate gross proceeds of the Offering, or $816,634.

Conversion of Bridge Notes

On March 8, 2021, the holders of the Company's convertible bridge notes, which were issued on December 27, 2019 and January 3, 2020 to various purchasers, converted an aggregate of $432,383, which included accrued interest of $66,633 owed under such convertible bridge notes, into an aggregate of 7,920 shares of common stock pursuant to the terms of such notes, as amended, at a conversion price of $54.60 per share.

Earlybird Capital Settlement Agreement

On April 23, 2021, the Company settled the amounts due pursuant to a certain finder agreement entered into with EarlyBird Capital, Inc. ("EarlyBird") on October 17, 2017 (the "Finder Agreement"). The Company's Board of Directors determined it was in the best interests to settle all claims which had been made or could be made with respect to the Finder Agreement and entered into a settlement agreement (the "Settlement Agreement"). Pursuant to the Settlement Agreement, the Company paid EarlyBird a cash payment of $275,000 and issued 11,250 shares of the Company's restricted common stock with a grant date value of $1,973,250 to EarlyBird, in full satisfaction of accounts payable in the amount of $1,750,000. The Company recorded a loss of $223,250 in connection with the Settlement Agreement, which is included in (loss) gain on settlement of liabilities in the accompanying condensed consolidated statements of operations.

Alpha Capital Settlement Agreement

On July 31, 2021, the Company reached an agreement to settle the amounts allegedly due pursuant to a certain convertible note agreement entered into with Alpha Capital Anstalt ("Alpha") on September 8, 2020 (the "Alpha Note"). The Company's Board of Directors determined it was in the best interest of the Company to settle all claims which had been made or could be made with respect to the Alpha Note and entered into a settlement agreement ("Alpha Settlement Agreement"). Pursuant to the Alpha Settlement Agreement, the Company issued 7,500 shares of common stock and three-year warrants to purchase 1,250 shares of the Company's common stock at an exercise price of $141.40 per share, in exchange for full and complete satisfaction of the Alpha Note.

August 2021 Offering

On August 23, 2021, the Company entered into a Securities Purchase Agreement with certain purchasers (the "August 2021 Purchasers"), pursuant to which the Company agreed to sell an aggregate of 125,000 shares of common stock (the "August 2021 Shares") and warrants to purchase up to an aggregate of 125,000 shares of common stock (the "August 2021 PIPE Warrants"), at a combined purchase price of $120.00 per share and August 2021 PIPE Warrant (the "August 2021 Offering"). Aggregate gross proceeds from the offering were approximately $15 million. Net proceeds to the Company from the offering, after deducting the placement agent fees and estimated offering expenses payable by the Company, were approximately $13.9 million. The placement agent fees and offering expenses were accounted for as a reduction of additional paid in capital. The Placement Agent received a commission equal to seven percent (7%) of the aggregate gross proceeds of the Offering, or $1,050,000. The offering closed on August 23, 2021.

In connection with the August 2021 Offering, the Company also entered into a Registration Rights Agreement, dated as of August 23, 2021, with the August 2021 Purchasers (the "August 2021 Registration Rights Agreement"). Pursuant to the August 2021 Registration Rights Agreement, the Company agreed to file a registration statement with the SEC on or prior to September 12, 2021 to register the resale of the August 2021 Shares and the shares of common stock issuable upon exercise of the August 2021 PIPE Warrants (the "Warrant Shares"), and to cause such registration statement to be declared effective on or prior to October 22, 2021 (or, in the event of a "full review" by the SEC, November 21, 2021). The registration statement was filed with the SEC on August 31, 2021 and the SEC declared it effective on September 9, 2021.

Exchanges of Related Party Loans and Convertible Notes

On September 30, 2021, Dr. Lawrence Steinman and Sir Marc Feldmann, Ph.D., each of whom serve as Co-Executive Chairmen of the Company's Board of Directors, agreed with the Company to convert amounts owed under outstanding loans with an aggregate principal balance of $693,371 and an aggregate accrued interest balance of $157,741 into an aggregate of 7,093 shares of the Company's common stock at the conversion price of $120.00 per share, pursuant to the terms of the agreement, which conversion rate was above the closing consolidated bid price of the Company's common stock on the date the binding agreement was entered into. (See Note 9 – Loans Payable and Note 10 – Convertible Notes Payable for more information.)

Mintz Levin Settlement

In September 2021, the Company entered into a settlement agreement with Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. ("Mintz"), whereby the Company agreed to pay $800,000 to Mintz for legal services rendered. Mintz had billed the Company an aggregate of $1,454,240 before factoring any interest charges. The Company recorded a gain of approximately $650,000 after making payment pursuant to the settlement agreement.

Cantor Fitzgerald& Co. Litigation Settlement

On October 12, 2021, the Company and Cantor Fitzgerald & Co. entered into a settlement agreement, whereby the Company agreed to pay to Cantor $200,000 in return for dismissal of the case against the Company. The Company sent the funds to Cantor on October 13, 2021. As of September 30, 2021, the Company recorded an accrual for the settlement amount as per the agreement.

On October 21, 2021, the Company received a notice of discontinuance and as a result, the matter between the Company and Cantor is settled and closed.

July 2022 Offering

On July 17, 2022, the Company entered into a Securities Purchase Agreement with certain purchasers, pursuant to which the Company agreed to sell an aggregate of 175,000 shares of common stock, pre-funded warrants to purchase up to an aggregate of 131,604 shares of common stock ("July 2022 Pre-Funded Warrants"), and common stock warrants to purchase up to an aggregate of 306,604 shares of common stock (the "July 2022 Common Warrants"), at a combined purchase price of $21.20 per share and warrant (the "July 2022 Offering"). Aggregate gross proceeds from the July 2022 Offering were $6,499,737. Net proceeds to the Company from the offering, after deducting the placement agent fees and other estimated offering expenses payable by the Company, were approximately $6.0 million. The placement agent fees and offering expenses of approximately $530,000 were accounted for as a reduction of additional paid in capital. The July 2022 Offering closed on July 20, 2022.

December 2022 Offering

On December 20, 2022, the Company entered into a Securities Purchase Agreement with certain purchasers, pursuant to which the Company agreed to sell an aggregate of 215,000 shares of common stock, pre-funded warrants to purchase up to an aggregate of 1,499,286 shares of common stock ("December 2022 Pre-Funded Warrants"), and common stock warrants to purchase up to an aggregate of 2,571,429 shares of common stock (the "December 2022 Common Warrants"), at a combined purchase price of $3.50 per share and warrant (the "December 2022 Offering"). Aggregate gross proceeds from the December 2022 Offering were $5,999,851. Net proceeds to the Company from the offering, after deducting the placement agent fees and other estimated offering expenses payable by the Company, were approximately $5.5 million. The placement agent fees and offering expenses of approximately $500,000 were accounted for as a reduction of additional paid in capital. The December 2022 Offering closed on December 22, 2022.

Critical Accounting Policies and Estimates

The Company's consolidated financial statements are prepared in accordance with accounting principles that are generally accepted in the United States. The preparation of these consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of its assets, liabilities, revenue and expenses. The Company has identified certain policies and estimates as critical to its business operations and the understanding of its past or present results of operations related to (i) goodwill and (ii) intangible assets and in-process research and development ("IP R&D"). These policies and estimates are considered critical because they had a material impact, or they have the potential to have a material impact, on the Company's consolidated financial statements and because they require management to make significant judgments, assumptions or estimates. The Company believes that the estimates, judgments and assumptions made when accounting for the items described below were reasonable, based on information available at the time they were made. However, actual results may differ from those estimates, and these differences may be material.

Goodwill/Intangible Assets and In-Process Research and Development

The Company has a significant amount of goodwill, intangible assets and IP R&D assets that are assessed at least annually for impairment. The impairment analyses of these assets are considered critical because of their significance to the Company. Intangible assets arising from business combinations or acquisitions, such as goodwill, patents and IP R&D assets are initially recorded at estimated fair value. Licensed patents are amortized over the remaining life of the patent. IP R&D assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development projects. Our goodwill was derived from acquisitions where the purchase price exceeded the fair value of the net assets acquired The Company is required to reassign goodwill to reporting units whenever reorganizations of the internal reporting structure change the composition of its reporting units. The Company identified one reporting unit which represents its sole operating segment.

The Company is required to assess goodwill/intangible assets and IP R&D assets at least annually, or more frequently, if an event occurs or circumstances change that indicates it is more likely than not the fair value of the Company's reporting unit was less than its carrying value. In assessing goodwill/intangible assets and IP R&D assets for impairment, the Company may first assess qualitative factors to determine whether it is more likely than not that the fair value of its reporting unit is less than its carrying value.

Goodwill Impairment. The first step of the goodwill asset impairment test used to identify potential impairment compares the fair value of the reporting unit with its carrying amount, including goodwill assets. The Company determined the fair market value of its single reporting unit as of December 31, 2021 to be its market capitalization of $132,760,914, which represents $78.00 per share (the market close price) multiplied by 1,702,063 shares (consisting of 1,701,799 shares of common stock plus 264 special voting shares which are exchangeable into common stock for no additional consideration) on December 31, 2021. The carrying amount of the reporting unit as of December 31, 2021 was $39,322,695 (total assets of $62.7 million less total liabilities of $23.4 million).

Since the fair value of the Company ($132,760,914) exceeded the carrying value of the Company ($39,322,695) as of December 31, 2021, and the carrying value of the Company is greater than zero, management concluded the goodwill assets of the reporting unit was not impaired.

The Company's publicly traded stock closed at $78.00 per share as of December 31, 2021; during 2022, the market value of the Company's single reporting unit significantly declined. As of March 31, 2022, June 30, 2022, September 30, 2022 and December 31, 2022, the market value of the Company's publicly traded stock fell to $51.80, $16.96, $13.30 and $3.39, per share, respectively, and as such, the Company elected to conduct a quantitative analysis of goodwill to assess for impairment as of September 30, 2022 and December 31, 2022. The Company determined the fair market value of its single reporting unit and compared that value with the carrying amount of the reporting unit and determined that goodwill was impaired as of both measurement dates. As of September 30, 2022 and December 31, 2022, the carrying value exceeded the fair market value by $18,872,850 and $14,674,428, respectively. To recognize the impairment of goodwill, the Company recorded losses for these amounts at the end of the third and fourth quarters, which appear as a loss on goodwill impairment of $33,547,278 on the income statement for the year ended December 31, 2022. See Note 5 – Intangible Assets and Impairment of Long-lived Assets for further information.

IP R&D Assets Impairment

As of December 31, 2022, the carrying amount of the IP R&D assets on the balance sheet was $12,405,084 (which consists of carrying value of $1,462,084 and $10,943,000 related to the Company's CBR Pharma subsidiary and its 180 LP subsidiary, respectively). Per the valuation obtained from a third party as of year-end, the fair market value of the Company's IP R&D assets was determined to be $9,063,000 (which consists of fair market values of $0 and $9,063,000 related to the Company's CBR Pharma subsidiary and 180 LP subsidiary, respectively). As of this measurement date, the carrying value of the CBR Pharma and 180 LP subsidiaries' assets exceeded their fair market values by $1,462,084 and $1,880,000, respectively. As such, management determined that the consolidated IP R&D assets were impaired by $3,342,084 and, in order to recognize the impairment, the Company recorded a loss for this amount during the fourth quarter of 2022, which appears as a loss on impairment of IP R&D assets on the income statement. This reduced the IP R&D asset balances of its CBR Pharma subsidiary and its 180 LP subsidiary to zero and $9,063,000, respectively, as of December 31, 2022; the total consolidated IP R&D asset balance is $9,063,000 after impairment. See Note 5 – Intangible Assets and Impairment of Long-lived Assets for further information.

The Company will continue to perform goodwill/intangible assets and IP R&D assets Impairment testing on an annual basis, or as needed if there are changes to the composition of its reporting unit.

Recently Issued Accounting Pronouncements

See Note 3 – Summary of Significant Accounting Policies of our consolidated financial statements included within this Annual Report for a summary of recently issued and adopted accounting pronouncements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Pursuant to Item 305(e)) of Regulation S-K (§ 229.305(e)), the Company is not required to provide the information required by this Item as it is a "smaller reporting company," as defined by Rule 229.10(f)(1), however, the Company has provided the following information below relating to interest rate risk.

Interest Rate Risk

We are exposed to market risks in the ordinary course of its business. These risks primarily include interest rate sensitivities. As of December 31, 2022, we had $6,970,110 in cash and cash equivalents. We intend to hold our cash in interest-bearing money market accounts. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and the low risk profile of its investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTAL DATA.

The information required by this Item is included in this Report as set forth in the "Index to Consolidated Financial Statements" which appears on page F-1 of this Annual Report on Form 10-K, after the signature pages of this Report, and is incorporated by reference herein.

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

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures, as such term is defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Securities and Exchange Act of 1934, as amended (the "Exchange Act") as of December 31, 2022. Based on such evaluation, the principal executive officer and the principal financial officer have concluded that the Company's disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting

Management of 180 Life Sciences Corp. is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Internal control over financial reporting is a process designed by, or under the supervision of, our principal executive officer and principal financial officer, or persons performing similar functions, and effected by our board of directors to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation, 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.

We are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K under the Securities Act. For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies.

Management of 180 Life Sciences Corp., including our principal financial officer, conducted an evaluation of the effectiveness of the Company's internal control over financial reporting as of December 31, 2022 using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in "Internal Control - Integrated Framework" (2013).

Management concluded that certain aspects of the Company's internal control over financial reporting was not effective as of December 31, 2022, based on those criteria. Specifically, management's conclusion was based on the following material weakness:

- The Company's review and control procedures did not operate at the appropriate level of precision to detect an error in fair value of warrants related to a one-time reverse stock split and the fair value of IP R&D assets.

A material weakness is a control deficiency or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. As a company with limited accounting resources, a significant amount of management's time and attention has been and will be diverted from our business to ensure compliance with these regulatory requirements.

Remediation Plan

Management intends to take steps to develop and enhance its internal controls over financial reporting, including:

- Implement an analysis of fluctuations and variances on a quarterly basis for the Income Statement which would detect material movements in account balances from both a dollar amount and percentage change perspective and research any differences over a defined threshold.

- Implement an additional layer of review over the SEC reporting process and ensure that the overall financial statements and preparation are subject to concurring review by a member of the SEC reporting team other than the SEC reporting manager.

Remediation Of Material Weaknesses in Internal Control over Financial Reporting

The Company had previously reported that, as of December 31, 2021, it had identified the following two material weaknesses in its internal control over financial reporting:

- Financial Reporting Systems: The Company did not maintain a fully integrated financial consolidation and reporting system throughout the period and as a result, extensive manual analysis, reconciliation and adjustments were required in order to produce financial statements for external reporting purposes.

- Ineffective review controls over period end financial disclosure and reporting processes related to stock-based compensation and payroll expense classification.

During the year ended December 31, 2022, the Company has taken corrective action and/or placed in operation, controls to address the two material weaknesses described above, including Financial Reporting Systems and review controls over the stock-based compensation process. We have performed the following steps in 2022:

1. Retained the same accounting personnel throughout all reporting periods in 2022 to establish continuity of processes and implement sustainable improvements and efficiencies in the financial reporting and consolidation tools and procedures.

2. We have successfully implemented a consolidation tool that links to our ERP, which has accomplished the following:

    a. Strengthened the chart of accounts to require roll ups;

    b. Included a comprehensive review of mapping before implementation and new procedures to enhance the controls on future changes, and

    c. Automated reporting and calculations whenever possible.

3. Implemented additional steps as part of Management reviews to include additional high-level steps such as mapping considerations to financial reporting and detailed reviews of annual schedules to ensure the completeness and appropriate classification of expenses in the financial disclosure and reporting process.

Based on the corrective actions described above, and testing completed for the year ended December 31, 2022, management has concluded that the two material weaknesses noted above that existed as of December 31, 2021 have been remediated.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Changes in Internal Control over Financial Reporting

There have been no changes in the Company's internal control over financial reporting during the quarter ended December 31, 2022, that materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

Because this Annual Report on Form 10-K is being filed within four business days from the date of the reportable event discussed below, we have elected to make the following disclosures in this Annual Report on Form 10-K instead of in a Current Report on Form 8-K under Item 8.01, as applicable:

Item 8.01 Other Events.

As previously disclosed, on January 18, 2023, Mr. Quan Vu resigned as Chief Operating/Chief Business Officer of the Company effective the same date and entered into a Separation and Release Agreement with the Company (the "Separation Agreement"). On March 29, 2023, an error in the Separation Agreement was corrected by the parties' entry into a First Amendment to Separation Agreement (the "First Amendment"), effective as of the date of the original agreement, which clarified that none of the amount received by Mr. Vu pursuant to the Separation Agreement related to a bonus for 2021. The First Amendment did not change the total aggregate consideration paid to Mr. Vu under the Separation Agreement, or any of the other terms thereof.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

None.

PART III

Information required by Items 10, 11, 12, 13 and 14 of Part III is omitted from this Annual Report and will be filed in a definitive proxy statement or by an amendment to this Annual Report not later than 120 days after the end of the fiscal year covered by this Annual Report.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information required by this Item is included under the headings "Election of Directors", "Executive Officers", "Corporate Governance", "Code of Ethics", "Board Committee Membership", and "Delinquent Section 16(a) Reports" (to the extent applicable and warranted) in the Company's 2023 Proxy Statement to be filed with the U.S. Securities and Exchange Commission ("SEC") within 120 days after December 31, 2022, in connection with the solicitation of proxies for the Company's 2023 annual meeting of stockholders and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by this Item is included under the headings "Executive and Director Compensation", "Executive Compensation", "Director Compensation", "Outstanding Equity Awards at Fiscal Year-End", "Compensation Committee Interlocks and Insider Participation" and "Compensation Committee Report" (to the extent required), in the Company's 2023 Proxy Statement to be filed with the SEC within 120 days after December 31, 2022 and is incorporated herein by reference.

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

The information required by this Item is included under the heading "Voting Rights and Principal Stockholders" and "Equity Compensation Plan Information" in the Company's 2023 Proxy Statement to be filed with the SEC within 120 days after December 31, 2022, and is incorporated herein by reference.

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

The information required by this Item is included under the headings "Certain Relationships and Related Transactions" and "Corporate Governance" - "Director Independence" in the Company's 2023 Proxy Statement to be filed with the SEC within 120 days after December 31, 2022 and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

Our independent public accounting firm is Marcum LLP, San Francisco, CA, PCAOB Auditor ID Auditor Firm Id: 688.

The information required by this Item is included under the heading "Ratification of Appointment of Auditors"-"Audit Fees" in the Company's 2023 Proxy Statement to be filed with the SEC within 120 days after December 31, 2022 and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENTS AND SCHEDULES

(a) Documents filed as part of this Annual Report:

The following is an index of the financial statements, schedules and exhibits included in this Form 10-K or incorporated herein by reference.

(1) All Financial Statements

Index to Consolidated Financial Statements

(2) Consolidated Financial Statement Schedules

Except as provided above, all financial statement schedules have been omitted, since the required information is not applicable or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the consolidated financial statements and notes thereto included in this Form 10-K.

(3) Exhibits

EXHIBIT INDEX

Exhibit No.	Description	Filed/ Furnished Herewith	Incorporated by Reference			
			Form	File No.	Exhibit	Filing Date
1.1	Placement Agent Agreement dated July 17, 2022, between 180 Life Sciences Corp. and A.G.P./Alliance Global Partners		8-K	001-38105	1.1	7/19/2022
1.2	Placement Agent Agreement, dated December 20, 2022, between 180 Life Sciences Corp. and A.G.P./Alliance Global Partners		8-K	001-38105	1.1	12/22/2022
3.1	Certificate of Incorporation.		S-1	333-217475	3.1	4/26/2017
3.2	Amended and Restated Certificate of Incorporation.		8-K	001-38105	3.1	6/7/2017
3.3	Amendment to Amended and Restated Certificate of Incorporation.		8-K	001-38105	3.1	3/8/2019
3.4	Second Amendment to Amended and Restated Certificate of Incorporation.		8-K	001-38105	3.1	6/6/2019
3.5	Third Amendment to Amended and Restated Certificate of Incorporation.		8-K	001-38105	3.1	12/6/2019
3.6	Fourth Amendment to Amended and Restated Certificate of Incorporation		8-K	001-38105	3.1	4/8/2020
3.7	Fifth Amendment to Amended and Restated Certificate of Incorporation		8-K	001-38105	3.1	7/13/2020
3.8	Second Amended and Restated Certificate of Incorporation		8-K	001-38105	3.1	11/12/2020
3.9	Certificate of Amendment of Second Amended and Restated Certificate of Incorporation of 180 Life Sciences Corp., filed with the Secretary of State of Delaware on December 15, 2022		8-K	001-38105	3.1	12/16/2022
3.1	Amended and Restated Bylaws of 180 Life Sciences Corp.		8-K	001-38105	3.1	8/10/2021
4.1	Specimen Unit Certificate.		S-1	333-217475	4.1	4/26/2017
4.2	Specimen Common Stock Certificate.		S-1	333-217475	4.2	4/26/2017
4.3	Specimen Warrant Certificate.		S-1	333-217475	4.3	4/26/2017
4.4	Specimen Right Certificate.		S-1	333-217475	4.5	5/26/2017
4.5	Warrant Agreement, dated as of June 1, 2017, between Continental Stock Transfer & Trust Company and the Company.		8-K	001-38105	4.1	6/7/2017
4.6	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934, as amended	X				

4.7	Form of 10% Senior Secured Convertible Promissory Note issued June 2020.	8-K	001-38105	4.8	7/2/2020
4.8	Form of 10% Senior Secured Convertible Promissory Note	8-K	001-38105	4.1	9/14/2020
4.9	Form of Warrant (February 2021 Private Offering)	8-K	001-38105	4.1	2/24/2021
4.1	Form of Pre-Funded Warrant (July 2022 Offering)	8-K	001-38105	4.1	7/19/2022
4.2	Form of Common Warrant (July 2022 Offering)	8-K	001-38105	4.2	7/19/2022
4.3	Form of Pre-Funded Warrant (December 2022 Offering)	8-K	001-38105	4.1	12/22/2022
4.4	Form of Common Warrant (December 2022 Offering)	8-K	001-38105	4.2	12/22/2022
4.5	Warrant Amendment, dated January 12, 2023, by and between 180 Life Sciences Corp. and the Purchaser	8-K	001-38105	4.1	1/12/2023
10.1	Investment Management Trust Account Agreement between Continental Stock Transfer & Trust Company and the Company.	8-K	001-38105	10.1	6/7/2017
10.2	Registration Rights Agreement among the Company and certain securityholders.	8-K	001-38105	10.3	6/7/2017
10.3	Form of Indemnity Agreement.	S-1	333-217475	10.8	4/26/2017
10.4	Securities Purchase Agreement, dated June 12, 2020, by and among the Company and the purchasers signatory thereto.	8-K	001-38105	10.1	7/2/2020
10.5	Registration Rights Agreement, dated as of June 12, 2020, by and among the Company and the parties signatory thereto.	8-K	001-38105	10.2	7/2/2020
10.6	Securities Purchase Agreement, dated September 8, 2020, by and among the Company and the purchasers signatory thereto	8-K	001-38105	10.1	9/14/2020
10.7	Registration Rights Agreement, dated September 8, 2020, by and among the Company and the parties signatory thereto	8-K	001-38105	10.2	9/14/2020
10.8	Amended and Restated Promissory Note, dated September 2020, issued to KBL IV Sponsor LLC	S-1	333-249539	10.24	10/19/2020
10.9	Escrow Agreement dated November 6, 2020, by and between the registrant, Continental Stock Transfer & Trust Company, and Lawrence Pemble.	8-K	001-38105	10.2	11/12/2020
10.10£	Securities Purchase Agreement dated as of February 19, 2021, by and between 180 Life Sciences Corp. and the purchasers identified on the signature pages thereto.	8-K	001-38105	10.1	2/24/2021
10.11	Engagement Letter dated January 26, 2021, between 180 Life Sciences Corp. and Maxim Group LLC.	8-K	001-38105	10.2	2/24/2021
10.12	Amendment to Engagement Letter between 180 Life Sciences Corp. and Maxim Group LLC dated February 18, 2021.	8-K	001-38105	10.3	2/24/2021
10.13	Registration Rights Agreement dated as of February 23, 2021, by and between 180 Life Sciences Corp. and the purchasers signatory thereto.	8-K	001-38105	10.4	2/24/2021
10.14#	Consultancy Agreement dated February 22, 2021, by and between 180 Life Sciences Corp. and Prof Jagdeep Nanchahal	8-K	001-38105	10.1	3/3/2021
10.15#	Amended and Restated Employment Agreement dated February 25, 2021, and effective November 6, 2020, by and between 180 Life Sciences Corp. and James N. Woody	8-K	001-38105	10.2	3/3/2021
10.16#	James N. Woody - Stock Option Agreement effective February 26, 2021 (70,000 shares)	8-K	001-38105	10.3	3/3/2021

10.17#	Employment Agreement dated February 24, 2021, and effective November 6, 2020, by and between 180 Life Sciences Corp. and Ozan Pamir and Amendment and Correction Thereto dated March 1, 2021	8-K	001-38105	10.4	3/3/2021
10.18#	Ozan Pamir - Stock Option Agreement effective February 26, 2021 (9,000 shares)	8-K	001-38105	10.5	3/3/2021
10.19#	First Amendment to Consultancy Agreement dated March 31, 2021, by and between 180 Life Sciences Corp. and Prof Jagdeep Nanchahal	8-K	001-38105	10.2	4/2/2021
10.20#	Second Amendment to Employment Agreement dated May 27, 2021, and effective November 6, 2020, by and between 180 Life Sciences Corp., Katexco Pharmaceuticals Corp. and Ozan Pamir	8-K	001-38105	10.2	5/27/2021
10.21#	Form of Director Nominee Offer Letter (May 2021)	8-K	001-38105	10.1	5/27/2021
10.22#	Form of August 21, 2019 Employment Agreement between KBL Merger Corp. IV and Jonathan Rothbard	10-K	001-38105	10.44	7/9/2022
10.23£	Sir Marc Feldmann Confirmation of Rescission of Note Amendments effective February 25, 2021	10-Q	001-38105	10.15	7/19/2021
10.24	Dr. Lawrence Steinman Confirmation of Rescission of Note Amendments effective February 25, 2021	10-Q	001-38105	10.16	7/19/2021
10.25	Common Stock Purchase Warrant dated July 31, 2021, to purchase 1,250 shares of common stock of 180 Life Sciences Corp., granted to Alpha Capital Anstalt	8-K	001-38105	4.1	8/2/2021
10.26	Form of Stock Option Agreement (Independent Directors August 2021 Grants)	10-Q	001-38105	10.9	8/6/2021
10.27	Form of Purchaser Warrant (August 2021 Offering)	8-K	001-38105	4.1	8/24/2021
10.28£	Securities Purchase Agreement dated as of August 19, 2021, by and between 180 Life Sciences Corp. and the purchasers identified on the signature pages thereto	8-K	001-38105	10.1	8/24/2021
10.29	Engagement Letter dated August 17, 2021, between 180 Life Sciences Corp. and Maxim Group LLC	8-K	001-38105	10.2	8/24/2021
10.30	Registration Rights Agreement dated as of August 23, 2021, by and between 180 Life Sciences Corp. and the purchasers signatory thereto	8-K	001-38105	10.3	8/24/2021

10.31#	180 Life Sciences Corp. 2020 Omnibus Incentive Plan	S-8	333-259918	4.1	9/30/2021
10.32	Form of Stock Option Agreement 180 Life Sciences Corp. 2020 Omnibus Incentive Plan	S-8	333-259918	4.2	9/30/2021
10.33	Form of Restricted Stock Grant Agreement Stock Option Agreement 180 Life Sciences Corp. 2020 Omnibus Incentive Plan	S-8	333-259918	4.3	9/30/2021
10.34#	October 29, 2021, Employment Agreement between 180 Life Sciences Corp. and Quan Anh Vu	8-K	001-38105	10.1	10/29/2021
10.35#	Sir Marc Feldmann Confirmation of Rescission of Note Amendments effective February 25, 2021	10-Q	001-38105	10.15	7/19/2021
10.36#	Dr. Lawrence Steinman Confirmation of Rescission of Note Amendments effective February 25, 2021	10-Q	001-38105	10.16	7/19/2021
10.37	Common Stock Purchase Warrant dated July 31, 2021, to purchase 1,250 shares of common stock of 180 Life Sciences Corp., granted to Alpha Capital Anstalt	8-K	001-38105	4.1	8/2/2021
10.38#	Form of Stock Option Agreement (Independent Directors August 2021 Grants)	10-Q	001-38105	10.9	8/16/2021
10.39#	Consulting Agreement dated November 17, 2021, by and between 180 Life Science Corp. and Lawrence Steinman, M.D.	8-K	001-38105	10.1	11/18/2021
10.40#	First Amendment to Amended and Restated Employment Agreement dated April 27, 2022, between 180 Life Sciences Corp. and James N. Woody, M.D., Ph.D.	8-K	001-38105	10.1	4/28/2022
10.41#	First Amendment to Employment Agreement dated April 27, 2022, between 180 Life Sciences Corp. and Quan Anh Vu	8-K	001-38105	10.2	4/28/2022
10.42#	First Amendment to Employment Agreement dated April 27, 2022, between 180 Life Sciences Corp. and Jonathan Rothbard, Ph.D.	8-K	001-38105	10.3	4/28/2022
10.43#	First Amendment to Employment Agreement dated April 27, 2022, between Cannbiorex Pharma Ltd. and Sir Marc Feldmann, Ph.D.	8-K	001-38105	10.4	4/28/2022
10.44#	First Amendment to Consulting Agreement dated April 27, 2022, between 180 Life Sciences Corp. and Lawrence Steinman, M.D.	8-K	001-38105	10.5	4/28/2022
10.45#	Second Amendment to Consulting Agreement dated April 27, 2022, between Cannbiorex Pharma Ltd. and Prof. Jagdeep Nanchahal	8-K	001-38105	10.6	4/28/2022
10.46#	Second Amendment to Employment Agreement dated May 26, 2022 and effective as of June 1, 2022, between 180 Life Sciences Corp. and James N. Woody, M.D., Ph.D.	8-K	001-38105	10.1	5/26/2022
10.47#	Second Amendment to Employment Agreement dated May 26, 2022 and effective as of June 1, 2022, between 180 Life Sciences Corp. and Quan Anh Vu	8-K	001-38105	10.2	5/26/2022
10.48#	Second Amendment to Employment Agreement dated May 26, 2022 and effective as of June 1, 2022, between 180 Life Sciences Corp. and Jonathan Rothbard, Ph.D.	8-K	001-38105	10.3	5/26/2022
10.49#	Second Amendment to Consulting Agreement dated May 26, 2022 and effective as of June 1, 2022, between 180 Life Sciences Corp. and Lawrence Steinman, M.D	8-K	001-38105	10.4	5/26/2022
10.50#	180 Life Sciences Corp. 2022 Omnibus Incentive Plan	8-K	001-38105	10.1	6/14/2022
10.51£	Securities Purchase Agreement dated July 17, 2022, by and between 180 Life Sciences Corp. and the Purchaser	8-K	001-38105	10.1	7/19/2022

10.52£	Securities Purchase Agreement, dated December 20, 2022, by and between 180 Life Sciences Corp. and the Purchaser		8-K	001-38105	10.1	12/20/2022
10.53	Warrant Agent Agreement for the Pre-Funded Warrants, dated December 22, 2022, by and between 180 Life Sciences Corp. and Continental Stock Transfer & Trust Company		8-K	001-38105	10.2	12/20/2022
10.54	Warrant Agent Agreement for the Common Warrants, dated December 22, 2022, by and between 180 Life Sciences Corp. and Continental Stock Transfer & Trust Company		8-K	001-38105	10.3	12/20/2022
10.55#	Form of Lock-Up Agreement (December 2022 Offering)		8-K	001-38105	10.4	12/20/2022
10.56#	Third Amendment to Consulting Agreement dated December 28, 2022, between 180 Life Sciences Corp., Cannbiorex Pharma Ltd. and Prof. Jagdeep Nanchahal		8-K	001-38105	10.1	12/29/2022
10.57#	Separation and Release Agreement, dated January 18, 2023, by and between 180 Life Sciences Corp. and Quan Vu		8-K	001-38105	10.1	1/20/2023
10.58	Amendment to the Warrant Agent Agreement, dated January 13, 2023, by and between 180 Life Sciences Corp. and the Warrant Agent		8-K	001-38105	10.1	1/18/2023
10.59*#	First Amendment to Separation and Release Agreement, dated March 29, 2023, by and between 180 Life Sciences Corp. and Quan Vu	X				
14.1#	Code of Business and Ethics		S-1	333-217475	14	4/26/2017
21.1*	List of Subsidiaries	X				
23.1*	Marcum LLP	X				
31.1*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act	X				
31.2*	Certification of Principal Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act	X				
32.1**	Certification of Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act	X				
32.2**	Certification of Principal Accounting Officer Pursuant to Section 906 of the Sarbanes-Oxley Act	X				
99.1	Form of Audit Committee Charter.		S-1	333-217475	99.1	4/26/2017
99.2	Form of Compensation Committee Charter.		S-1	333-217475	99.2	4/26/2017
99.3	Nominating and Corporate Governance Committee Charter		8-K	001-38105	99.8	11/12/2020
99.4	Risk, Safety and Regulatory Committee Charter		10-K	001-38105	99.4	7/9/2021
101.INS*	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document	X				
101.SCH*	Inline XBRL Taxonomy Extension Schema	X				
101.CAL*	Inline XBRL Taxonomy Calculation Linkbase	X				
101.DEF*	Inline XBRL Definition Linkbase Document	X				
101.LAB*	Inline XBRL Taxonomy Label Linkbase	X				
101.PRE*	Inline XBRL Definition Linkbase Document	X				
104*	Inline XBRL for the cover page of this Quarterly Report on Form 10-K, included in the Exhibit 101 Inline XBRL Document Set	X				

* Filed herewith.

** Furnished herewith.

Management contract or compensatory plans or arrangements.

£ Certain schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule or exhibit will be furnished supplementally to the Securities and Exchange Commission upon request; provided, however that 180 Life Sciences Corp. may request confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, for any schedule or exhibit so furnished.

ITEM 16. FORM 10–K SUMMARY

None.

SIGNATURES

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

180 LIFE SCIENCES CORP.

Date: March 31, 2023

/s/ James N. Woody

By: James N. Woody, Chief Executive Officer
(Principal Executive Officer)

Date: March 31, 2023

/s/ Ozan Pamir

By: Ozan Pamir, Interim Chief Financial Officer
(Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ James N. Woody James N. Woody	Chief Executive Officer and Director (Principal Executive Officer)	March 31, 2023
/s/ Ozan Pamir Ozan Pamir	Interim Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2023
/s/ Marc Feldmann Marc Feldmann	Co-Executive Chairman and Director	March 31, 2023
/s/ Lawrence Steinman Lawrence Steinman	Co-Executive Chairman and Director	March 31, 2023
/s/ Larry Gold Larry Gold, Ph.D.	Director	March 31, 2023
/s/ Donald A. McGovern, Jr. Donald A. McGovern, Jr.	Lead Director	March 31, 2023
/s/ Pamela G. Marrone Pamela G. Marrone	Director	March 31, 2023
/s/ Francis Knuettel II Francis Knuettel II	Director	March 31, 2023
/s/ Russell T. Ray *Russell T. Ray*	Director	March 31, 2023
/s/ Teresa DeLuca *Teresa DeLuca*	Director	March 31, 2023

180 LIFE SCIENCES CORP. AND SUBSIDIARIES
CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2022 AND 2021

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
180 Life Sciences Crop.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of 180 Life Sciences Crop. (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive income (loss), changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2022, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has a significant working capital deficiency, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 audit**s** provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below 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. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Valuation of In Process Research and Development assets and impairment

Description of the Matter

As discussed in Note 3 and 5 to the consolidated financial statements, the Company tests In-Process Research and Development assets (IPR&D) for impairment annually (or under certain circumstances, more frequently) at each IPR&D component level using either a qualitative or quantitative approach. In assessing IPR&D assets for impairment, the Company may first assess qualitative factors to determine whether it is more likely than not that the fair value of its IPR&D assets is less than it's carrying value. Under the quantitative approach to test for IPR&D assets impairment, the Company compares the fair value of IPR&D assets at each asset components level to their net carrying value. Generally, the Company estimates the fair value of its IPR&D at each asset components level using a Multi-Period Excess Earnings Method.

Auditing the Company's quantitative impairment tests involved subjective auditor judgment due to the significant estimation required in management's determination of the fair value of the IPR&D. The significant estimation was primarily due to the sensitivity of the underlying assumptions including projected revenue based on market projections, probability of approval, EBITDA margins and the weighted average cost of capital, discount rate, royalty rate, contributory charges. These assumptions relate to the expected future earnings of the Company's IPR&D assets, are forward-looking, and are sensitive to and affected by economic, industry and company-specific qualitative factors.

How We Addressed the Matter in Our Audit

To evaluate the estimated fair value of the Company's IPR&D assets, we performed audit procedures that included, among others, evaluating the valuation methodologies used and testing the significant assumptions discussed above used by the Company in its analysis. We involved our valuation specialists to assist in testing the significant assumptions and complex valuation method used by the Company. We also compared the significant assumptions to the company's historical estimate, actual performance, current industry, market and economic trends.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2019

San Francisco, CA
March 31, 2023

PCAOB ID #688

180 LIFE SCIENCES CORP. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(Expressed in US Dollars)

	December 31, 2022	December 31, 2021
Assets		
Current Assets:		
Cash	$ 6,970,110	$ 8,224,508
Prepaid expenses and other current assets	1,958,280	2,976,583
Total Current Assets	8,928,390	11,201,091
Intangible assets, net	1,658,858	1,948,913
In-process research and development	9,063,000	12,575,780
Goodwill	-	36,987,886
Total Assets	$ 19,650,248	$ 62,713,670
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,801,210	$ 586,611
Accrued expenses	2,284,516	1,964,580
Accrued expenses - related parties	188,159	18,370
Loans payable - current portion	1,308,516	1,828,079
Loans payable - related parties	-	81,277
Derivative liabilities	75,381	15,220,367
Total Current Liabilities	5,657,782	19,699,284
Loans payable - noncurrent portion	31,189	48,165
Deferred tax liability	2,617,359	3,643,526
Total Liabilities	8,306,330	23,390,975
Commitments and contingencies (Note 11)		
Stockholders' Equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized; (see designations and shares authorized for Series A, Class C and Class K preferred stock)		
Class C Preferred Stock; 1 share authorized, issued and outstanding at December 31, 2022 and 2021	-	-
Class K Preferred Stock; 1 share authorized, issued and outstanding at December 31, 2022 and 2021	-	-
Common stock, $0.0001 par value; 100,000,000 shares authorized; 3,746,906 and 1,701,799 shares issued and outstanding at December 31, 2022 and 2021, respectively	375	170
Additional paid-in capital	121,637,611	107,187,371
Accumulated other comprehensive income	(2,885,523)	817,440
Accumulated deficit	(107,408,545)	(68,682,286)
Total Stockholders' Equity	11,343,918	39,322,695
Total Liabilities and Stockholders' Equity	$ 19,650,248	$ 62,713,670

The accompanying notes are an integral part of these consolidated financial statements.

180 LIFE SCIENCES CORP. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Expressed in US Dollars)

	For the Year Ended December 31,	
	2022	**2021**
Operating Expenses:		
Research and development	$ 2,191,834	$ 1,000,769
Research and development - related parties	240,731	2,947,536
General and administrative	15,459,788	11,230,118
General and administrative - related parties	5,612	462,580
Total Operating Expenses	17,897,965	15,641,003
Loss From Operations	(17,897,965)	(15,641,003)
Other (Expenses) Income:		
Gain on settlement of liabilities	-	926,829
Other expense	-	(146,822)
Interest expense	(26,667)	(186,208)
Loss on extinguishment of convertible notes payable, net	-	(9,737)
Loss on goodwill impairment	(33,547,278)	-
Loss on IP R&D impairment	(3,342,084)	-
Change in fair value of derivative liabilities	15,144,986	(4,677,388)
Change in fair value of accrued issuable equity	-	(9,405
Offering costs allocated to warrant liabilities	-	(604,118
Total Other Expense, Net	(21,771,043)	(4,706,849)
Loss Before Income Taxes	(39,669,008)	(20,347,852)
Income tax benefit	942,749	23,204
Net Loss Attributable to Common Stockholders	$ (38,726,259)	$ (20,324,648)
Other Comprehensive (Loss) Income:		
Foreign currency translation adjustments	(3,702,963)	180,554
Total Comprehensive Loss	$ (42,429,222)	$ (20,144,094)
Basic and Diluted Net Loss per Common Share	$ (20.38)	$ (12.96)
Weighted Average Number of Common Shares Outstanding:	1,900,397	1,567,772

The accompanying notes are an integral part of these consolidated financial statements.

180 LIFE SCIENCES CORP. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Expressed in US Dollars)

	For The Year Ended December 31, 2022					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance - January 1, 2022	1,701,799	$ 170	$ 107,187,371	$ 817,440	$ (68,682,286)	$ 39,322,695
Adjustments related to reverse stock-split	9,591	1	(1)	-	-	-
Issuance of July 2022 pre-funded warrants	-	-	2,562,265	-	-	2,562,265
Shares issued from exercise of July 2022 pre-funded warrants	131,604	13	250	-	-	263
Shares issued in connection with July 2022 Offering	175,000	18	3,407,472	-	-	3,407,490
Issuance of December 2022 pre-funded warrants	-	-	4,823,187	-	-	4,823,187
Shares issued from exercise of December 2022 pre-funded warrants	1,499,286	150	-	-	-	150
Shares issued in connection with December 2022 Offering	215,000	22	691,651	-	-	691,673
Shares issued for professional services to directors	14,026	1	331,590	-	-	331,591
Stock-based compensation	600	-	2,633,826	-	-	2,633,826
Comprehensive loss:						
Net loss	-	-	-	-	(38,726,259)	(38,726,259)
Other comprehensive loss	-	-	-	(3,702,963)	-	(3,702,963)
Balance - December 31, 2022	3,746,906	$ 375	$ 121,637,611	$ (2,885,523)	$ (107,408,545)	$ 11,343,918

The accompanying notes are an integral part of these consolidated financial statements.

180 LIFE SCIENCES CORP. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY, continued
(Expressed in US Dollars)

	For The Year Ended December 31, 2021					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance - January 1, 2021	1,308,562	$ 131	$ 78,007,490	$ 636,886	$ (48,357,638)	$ 30,286,869
Shares issued upon conversion of KBL debt (Note 10)	23,357	2	1,941,123	-	-	1,941,125
Shares issued upon conversion of 180 debt (Note 10)	7,920	1	432,382	-	-	432,383
Shares issued in connection with the financing, net of financing costs (Note 12)	128,200	13	10,731,057	-	-	10,731,070
Offering costs allocated to warrant liabilities (Note 12)	-	-	604,118	-	-	604,118
Warrants issued in connection with private offering, reclassified to derivative liabilities (Note 8)	-	-	(7,294,836)	-	-	(7,294,836)
Shares issued upon exchange of common stock equivalents (Note 12)	87,253	9	(9)	-	-	-
Shares issued to settle accounts payable (Note 11)	11,250	1	1,973,249	-	-	1,973,250
Shares issued in connection with the August 2021 Offering, net of financing costs (Note 12)	125,000	13	13,879,987	-	-	13,880,000
Shares issued to settle convertible debt and derivative liabilities with Alpha Capital (Note 10)	7,500	1	1,060,499	-	-	1,060,500
Shares issued in connection with the repayment of related party loans and convertible notes (Note 12)	7,093	1	851,111	-	-	851,112
Stock based compensation (Note 12):						
Common stock	15,878	2	2,148,887	-	-	2,148,889
Options	-	-	2,852,309	-	-	2,852,309
Shares Cancelled	(20,214)	(4)	4	-	-	-
Comprehensive income (loss):						
Net loss	-	-	-	-	(20,324,648)	(20,324,648)
Other comprehensive income	-	-	-	180,554	-	180,554
Balance - December 31, 2021	1,701,799	$ 170	$ 107,187,371	$ 817,440	$ (68,682,286)	$ 39,322,695

The accompanying notes are an integral part of these consolidated financial statements.

180 LIFE SCIENCES CORP. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Expressed in US Dollars)

	For the Years Ended December 31,	
	2022	**2021**
Cash Flows From Operating Activities		
Net loss	$ (38,726,259)	$ (20,324,648)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation		
Shares issued for services	331,591	2,148,889
Amortization of stock options and restricted stock units	2,633,826	2,852,309
Impairment of goodwill	33,547,278	-
Impairment of IP R&D assets	3,342,084	
Amortization of intangibles	109,004	109,947
Bad debt expense - related parties	-	300,000
Gain on settlement of liabilities, net	-	(926,829)
Loss on extinguishment of convertible note payable	-	9,737
Deferred tax liability	(942,749)	(24,803)
Offering costs allocated to warrant liabilities	-	604,118
Change in fair value of derivative liabilities	(15,144,986)	4,677,388
Change in fair value of accrued issuable equity	-	9,405
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,018,303	(1,377,247)
Accounts payable	1,214,599	(5,515,042)
Accounts payable – related parties	-	(215,495)
Accrued expenses	319,936	(1,210,076)
Accrued expenses – related parties	169,788	(436,581)
Accrued issuable equity	-	(52,500)
Total adjustments	26,598,674	953,220
Net Cash Used In Operating Activities	(12,127,585)	(19,371,428)
Cash Flows From Financing Activities		
Shares issued for cash, net of issuance costs	-	26,666,200
Offering costs in connection with 2021 sale of stock and warrants	-	(2,055,130)
Offering costs in connection with July 2022 sale of common stock and common stock warrants	(529,982)	-
Offering costs in connection with December 2022 sale of common stock and common stock warrants	(484,991)	-
Proceeds from loans payable	1,060,890	1,618,443
Repayment of convertible debt – related parties	-	(10,000)
Repayment of loans payable, net of adjustments (Note 9)	(1,591,035)	(375,789)
Repayment of loans payable – related parties	(81,277)	(431,805)
Proceeds from sale of July 2022 common stock and common stock warrants	6,499,737	-
Proceeds from sale of December 2022 common stock and common stock warrants	5,999,851	-
Proceeds from exercise of July 2022 pre-funded warrants	263	-
Proceeds from exercise of December 2022 pre-funded warrants	150	-
Net Cash Provided By Financing Activities	10,873,606	25,411,919

The accompanying notes are an integral part of these consolidated financial statements.

180 LIFE SCIENCES CORP. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS, continued
(Expressed in US Dollars)

	For the Years Ended December 31,	
	2022	**2021**
Effect of Exchange Rate Changes on Cash	(419)	75,473
Net (Decrease) Increase In Cash	(1,254,398)	6,115,964
Cash - Beginning of Period	8,224,508	2,108,544
Cash - End of Period	$ 6,970,110	$ 8,224,508
Supplemental Disclosures of Cash Flow Information:		
Cash paid during the period for income taxes	$ -	$ -
Cash paid during the period for interest	$ 15,060	$ 35,351
Non-cash investing and financing activities:		
Common stock issued upon conversion of KBL debt	$ -	$ 1,931,388
Common stock issued upon conversion of 180 debt	$ -	$ 432,383
Common stock issued in connection with repayment of related party loans and convertible notes	$ -	$ 851,112
Shares and warrants issued for Alpha Settlement	$ -	$ 1,013,331
Exchange of common stock equivalents for common stock	$ -	$ 146
Shares issued to settle accounts payable	$ -	$ 1,750,000
Reclassification of accrued issuable equity	$ -	$ 43,095

The accompanying notes are an integral part of these consolidated financial statements.

NOTE 1 - BUSINESS ORGANIZATION AND NATURE OF OPERATIONS

180 Life Sciences Corp., formerly known as KBL Merger Corp. IV ("180LS", or together with its subsidiaries, the "Company"), was a blank check company organized under the laws of the State of Delaware on September 7, 2016. The Company was formed for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more businesses.

180 Life Corp. ("180", f/k/a 180 Life Sciences Corp. and CannBioRx Life Sciences Corp.) is a wholly-owned subsidiary of the Company and was incorporated in the State of Delaware on January 28, 2019. The Company is located in the United States ("U.S.") and is a medical pharmaceutical company focused upon unmet medical needs in the areas of inflammatory diseases, fibrosis, and chronic pain by employing innovative research and, where appropriate, combination therapies, through 180's three wholly-owned subsidiaries, 180 Therapeutics L.P. ("180 LP"), CannBioRex Pharmaceuticals Corp. ("CBR Pharma"), and Katexco Pharmaceuticals Corp. ("Katexco"). 180 LP, CBR Pharma and Katexco are together, the "180 Subsidiaries." Katexco was incorporated on March 7, 2018 under the provisions of the British Corporation Act of British Columbia. Additionally, 180's wholly-owned subsidiaries Katexco Callco, ULC, Katexco Purchaseco, ULC, CannBioRex Callco, ULC, and CannBioRex Purchaseco, ULC were formed in the Canadian Province of British Columbia on May 31, 2019 to facilitate the acquisition of Katexco, CBR Pharma and 180 LP. On July 1, 2021, the assets and liabilities of the Canadian companies (Katexco and CBR Pharma) were transferred to their respective subsidiaries, which are Katexco Pharmaceuticals Corp. ("Katexco U.S.") and CannBioRex Pharma Limited ("CBR Pharma U.K.").

The Company is a clinical stage biotechnology company focused on the development of therapeutics for unmet medical needs in chronic pain, inflammation, fibrosis and other inflammatory diseases, where anti-TNF therapy will provide a clear benefit to patients, by employing innovative research, and, where appropriate, combination therapy. We have three product development platforms:

- fibrosis and anti-tumor necrosis factor ("TNF");
- drugs which are derivatives of cannabidiol ("CBD"); and
- alpha 7 nicotinic acetylcholine receptor ("α7nAChR").

Reverse Stock-Split during 2022

On December 15, 2022, the Company held a special meeting of stockholders of the Company whereby the Company's stockholders approved an amendment to the Second Amended and Restated Certificate of Incorporation, as amended, to effect a reverse stock split of the issued and outstanding shares of common stock, par value $0.0001 per share, in a range of between one-for-four and one-for-twenty shares, in the discretion of the Board of Directors. The Board of Directors subsequently approved a reverse stock split in a ratio of one-for-twenty shares (the "Reverse Stock Split"). Pursuant to the Certificate of Amendment filed with the Secretary of State of Delaware to affect the Reverse Stock Split, with new CUSIP number: 68236V203. No change was made to the trading symbol for the Company's shares of common stock or public warrants, "ATNF" and "ATNFW", respectively, in connection with the Reverse Stock Split.

Because the Certificate of Amendment did not reduce the number of authorized shares of common stock, the effect of the Reverse Stock Split was to increase the number of shares of common stock available for issuance relative to the number of shares issued and outstanding. The Reverse Stock Split did not alter the par value of the common stock or modify any voting rights or other terms of the common stock. Any fractional shares remaining after the Reverse Stock Split were rounded up to the nearest whole share.

With regards to the Company's 2020 Omnibus Incentive Plan and the 2022 Omnibus Incentive Plan, the Company's Compensation Committee and Board deemed it in the best interests of the Company and its stockholders to (i) adjust the number of shares of Company common stock available for issuance under the Incentive Plans downward by a factor of 20 (with any fractional shares rounded down to the nearest whole share); (ii) reduce the number of shares of common stock issuable upon each outstanding option to purchase shares of common stock of the Company, and all other outstanding awards, by a factor of 20 (with any fractional shares rounded down to the nearest whole share); and (iii) adjust the exercise price of any outstanding options to purchase shares of common stock previously granted under the Incentive Plans up by a factor of 20 (rounded up to the nearest whole cent), in each case to adjust equitably for the exchange ratio of the Reverse Stock Split, which such adjustments effective automatically upon effectiveness of the Reverse Stock Split. The effects of the one-for-twenty reverse stock split have been retroactively reflected throughout the financial statements and notes to the financial statements.

Risks and Uncertainties

Management continues to evaluate the impact of the COVID-19 pandemic and Russia-Ukraine war on the economy and the capital markets and has concluded that, while it is reasonably possible that such events could have negative effects on the Company's financial position, the specific impacts are not readily determinable as of the date of these financial statements. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

The current challenging economic climate may lead to adverse changes in cash flows, working capital levels and/or debt balances, which may also have a direct impact on the Company's future operating results and financial position. The ultimate duration and magnitude of the impact and the efficacy of government interventions on the economy and the financial effect on the Company is not known at this time. The extent of such impact will depend on future developments, which are highly uncertain and not in the Company's control.

NOTE 2 - GOING CONCERN AND MANAGEMENT'S PLANS

The Company has not generated any revenues and has incurred significant losses since inception. As of December 31, 2022, we had an accumulated deficit of $107,408,545 and working capital of $3,270,608 and for the year ended December 31, 2022, a net loss of $38,726,259 and cash used in operating activities of $12,127,585. The Company expects to invest a significant amount of capital to fund research and development. As a result, the Company expects that its operating expenses will increase significantly, and consequently will require significant revenues to become profitable. Even if the Company does become profitable, it may not be able to sustain or increase profitability on a quarterly or annual basis. The Company cannot predict when, if ever, it will be profitable. There can be no assurance that the intellectual property of the Company, or other technologies it may acquire, will meet applicable regulatory standards, obtain required regulatory approvals, be capable of being produced in commercial quantities at reasonable costs, or be successfully marketed. The Company plans to undertake additional laboratory studies with respect to the intellectual property, and there can be no assurance that the results from such studies or trials will result in a commercially viable product or will not identify unwanted side effects.

These consolidated financial statements have been prepared under the assumption of a going concern, which assumes that the Company will be able to realize its assets and discharge its liabilities in the normal course of business. The Company's ability to continue its operations is dependent upon obtaining new financing for its ongoing operations. Future financing options available to the Company include equity financings and loans and if the Company is unable to obtain such additional financing timely, or on favorable terms, the Company may have to curtail its development, marketing and promotional activities, which would have a material adverse effect on its business, financial condition and results of operations, and it could ultimately be forced to discontinue its operations and liquidate. These matters raise substantial doubt about the Company's ability to continue as a going concern for a reasonable period of time, which is defined as within one year after the date that the consolidated financial statements are issued. Realization of the Company's assets may be substantially different from the carrying amounts presented in these consolidated financial statements and the accompanying consolidated financial statements do not include any adjustments that may become necessary, should the Company be unable to continue as a going concern.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries 180 LP, CBR Pharma, Katexco and 180 Life Corp. ("180LC"). All inter-company balances and transactions among the companies have been eliminated upon consolidation. The consolidated financial statements are presented in U.S. Dollars.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates, judgments, and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, together with amounts disclosed in the related notes to the consolidated financial statements. The Company's significant estimates and assumptions used in these financial statements include, but are not limited to, the fair value of financial instruments, warrants, options and derivative liabilities; R&D tax credits and accruals, and the estimates and assumptions related to the impairment analysis of goodwill and other intangible assets. Certain of the Company's estimates could be affected by external conditions, including those unique to the Company and general economic conditions. It is reasonably possible that these external factors could have an effect on the Company's estimates and may cause actual results to differ from those estimates.

Foreign Currency Translation

The Company's reporting currency is the United States dollar. The functional currency of certain subsidiaries is the Canadian Dollar ("CAD") or British Pound ("GBP"). Assets and liabilities are translated based on the exchange rates at the balance sheet date (0.7369 and 0.7874 for the CAD, 1.2098 and 1.3510 for the GBP as of December 31, 2022 and 2021, respectively), while expense accounts are translated at the weighted average exchange rate for the period (0.7689 and 0.7977 for the CAD, and 1.2173 and 1.3753 for the GBP for the years ended December 31, 2022 and 2021, respectively). Equity accounts are translated at historical exchange rates. The resulting translation adjustments are recognized in stockholders' equity as a component of accumulated other comprehensive income.

Comprehensive income is defined as the change in equity of an entity from all sources other than investments by owners or distributions to owners and includes foreign currency translation adjustments as described above. During the years ended December 31, 2022 and 2021, the Company recorded other comprehensive (loss) income of ($3,702,963) and $180,554, respectively, as a result of foreign currency translation adjustments.

Foreign currency gains and losses resulting from transactions denominated in foreign currencies, including intercompany transactions, are included in results of operations. The Company recognized ($12,777) and ($69) of foreign currency transaction (losses) for the years ended December 31, 2022 and 2021, respectively. Such amounts have been classified within general and administrative expenses in the accompanying consolidated statements of operations and comprehensive loss.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents in the financial statements. The Company had no cash equivalents at December 31, 2022 or 2021. As of December 31, 2022, the Company had bank accounts in the United States and the United Kingdom; of its available cash balance, $25,079 is restricted cash. The Company's cash deposits in United States and English financial institutions may at times be in excess of the Federal Deposit Insurance Corporation ("FDIC") or the Financial Services Compensation Scheme ("FSCS") insurance limits, respectively. The Company has not experienced losses in such accounts and periodically evaluates the creditworthiness of its financial institutions.

Goodwill

Goodwill represents the difference between the purchase price and the fair value of assets and liabilities acquired in a business combination. The Company reviews goodwill yearly, or more frequently whenever circumstances and situations change such that there is an indication that the carrying amounts may not be recovered, for impairment by initially considering qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount, including goodwill, as a basis for determining whether it is necessary to perform a quantitative analysis. If it is determined that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, a quantitative analysis is performed to identify goodwill impairment. If it is determined that it is not more likely than not that the fair value of the reporting unit is less than its carrying amount, it is unnecessary to perform a quantitative analysis. The Company may elect to bypass the qualitative assessment and proceed directly to performing a quantitative analysis. See "Note 5 – Intangible Assets and Impairment of Long-lived Assets" for further information.

Intangible Assets and In-Process Research and Development ("IP R&D")

Intangible assets consist of licensed patents held by Katexco as well as technology licenses acquired in connection with the Reorganization. Licensed patents are amortized over the remaining life of the patent. Technology licenses represent the fair value of licenses acquired for the development and commercialization of certain licenses and knowledge. The technology licenses are amortized on a straight-line basis over the estimated useful lives of the underlying patents. It will be necessary to monitor and possibly adjust the useful lives of the licensed patents and technology licenses depending on the results of the Company's research and development activities.

IP R&D assets represent the fair value assigned to technologies that were acquired on July 16, 2019 in connection with the Reorganization, which have not reached technological feasibility and have no alternative future use. IP R&D assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development projects. During the period that the IP R&D assets are considered indefinite-lived, they are tested for impairment on an annual basis, or more frequently if the Company becomes aware of any events occurring or changes in circumstances that indicate that the fair value of the IP R&D assets are less than their carrying amounts. If and when development is complete, which generally occurs upon regulatory approval, and the Company is able to commercialize products associated with the IP R&D assets, these assets are then deemed definite-lived and are amortized based on their estimated useful lives at that point in time. If development is terminated or abandoned, the Company may record a full or partial impairment charge related to the IP R&D assets, calculated as the excess of the carrying value of the IP R&D assets over their estimated fair value. See "Note 5 – Intangible Assets and Impairment of Long-lived Assets" for further information.

Fair Value of Financial Instruments

The Company measures the fair value of financial assets and liabilities based on the guidance of Accounting Standards Codification ("ASC") 820 "Fair Value Measurements" ("ASC 820"), which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 820 describes 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; and
- Level 3 - Inputs that are unobservable (for example, cash flow modeling inputs based on assumptions).

The carrying amounts of certain of the Company's financial instruments, consisting primarily of loans payable, approximate their fair values as presented in these consolidated financial statements due to the short-term nature of those instruments. The Company's derivative liabilities were valued using level 3 inputs (see Note 8 – Derivative Liabilities for additional information).

Accrued Issuable Equity

The Company records accrued issuable equity when it is contractually obligated to issue shares and there has been a delay in the issuance of such shares. Accrued issuable equity is recorded and carried at fair value with changes in its fair value recognized in the Company's consolidated statements of operations. Once the underlying shares of common stock are issued, the accrued issuable equity is reclassified as of the share issuance date at the then current fair market value of the common stock.

Stock-Based Compensation

The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. The fair value of the award is measured on the grant date and is estimated by management based on observations of the recent cash sales prices of common stock. The fair value amount is then recognized over the period during which services are required to be provided in exchange for the award, usually the vesting period. Upon the exercise of an option or warrant, the Company issues new shares of common stock out of its authorized but unissued shares.

Derivative Liabilities and Convertible Instruments

The Company evaluates its debt and equity issuances to determine if those contracts or embedded components of those contracts qualify as derivatives requiring separate recognition in the Company's financial statements. Entities must consider whether to classify contracts that may be settled in its own stock, such as warrants, as equity of the entity or as an asset or liability. If an event that is not within the entity's control could require net cash settlement, then the contract should be classified as an asset or a liability rather than as equity.

The result of this accounting treatment is that the fair value of the embedded derivative is marked-to-market at each balance sheet date and recorded as a liability and the change in fair value is recorded in other (expense) income, net in the consolidated statements of operations. In circumstances where there are multiple embedded instruments that are required to be bifurcated, the bifurcated derivative instruments are accounted for as a single, compound derivative instrument. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is reassessed at the end of each reporting period. Equity instruments that are initially classified as equity that become subject to reclassification are reclassified to liability at the fair value of the instrument on the reclassification date. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument is expected within twelve months of the balance sheet date.

If the embedded conversion options do not require bifurcation, the Company then evaluates for the existence of a beneficial conversion feature by comparing the fair value of the Company's underlying stock as of the commitment date to the effective conversion price of the instrument (the intrinsic value).

Debt discounts under these arrangements are amortized over the term of the related debt to their stated date of redemption and are classified in interest expense in the consolidated statements of operations. Preferred stock discounts are only accreted to their redemption value if redemption becomes probable.

Amendments to convertible instruments are evaluated as to whether they should be accounted for as a modification of the original instrument with no change to the accounting or, if the terms are substantially changed, as an extinguishment of the original instrument and the issuance of a new instrument.

The Company has computed the fair value of warrants and options issued using the Black-Scholes option pricing model. The expected term used for warrants, convertible notes and convertible preferred stock are the contractual life and the expected term used for options issued is the estimated period of time that options granted are expected to be outstanding. The Company utilizes the "simplified" method to develop an estimate of the expected term of "plain vanilla" option grants. The Company is utilizing an expected volatility figure based on a review of the historical volatilities, over a period of time, equivalent to the expected life of the instrument being valued, of similarly positioned public companies within its industry. The risk-free interest rate was determined from the implied yields from U.S. Treasury zero-coupon bonds with a remaining term consistent with the expected term of the instrument being valued.

Net Loss Per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net (loss) per common share is computed by dividing net (loss) by the weighted average number of common shares outstanding, plus the number of additional common shares that would have been outstanding if the common share equivalents had been issued (computed using the treasury stock or if converted method), if dilutive.

The following common share equivalents are excluded from the calculation of weighted average common shares outstanding, because their inclusion would have been anti-dilutive:

	For the Years Ended December 31,	
	2022	**2021**
Options	162,956	137,050
Warrants	3,435,728	557,695
Total potentially dilutive shares	3,598,684	694,745

Research and Development

Research and development expenses are charged to operations as incurred. During the years ended December 31, 2022 and 2021, the Company incurred $2,191,834 and $1,000,769, respectively, of research and development expenses. As of December 31, 2022 and 2021, research and development expenses – related parties were $240,731 and $2,947,536, respectively. See Note 14 – Related Parties for more information on research and development expenses – related parties.

Income Taxes

The Company accounts for income taxes under the provisions of ASC Topic 740 "Income Taxes" ("ASC 740").

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 Company utilizes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Company's policy is to classify assessments, if any, for tax related interest as interest expense and penalties as general and administrative expenses in the consolidated statements of operations and comprehensive loss.

Recently Issued Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2020-06 "Debt with Conversion and Other Options (Topic 470) and Derivatives and Hedging-Contracts in Entity's Own Equity (Topic 815). The amendments in ASU 2020-06 are intended to simplify the accounting for certain financial instruments with characteristics of liabilities and equity by eliminating certain accounting models in Subtopic 470-20, for convertible debt instruments. Under the amendments in this update, the embedded conversion features no longer are separated from the host contract for convertible instruments with conversion features that are not required to be accounted for as derivatives under Topic 815, Derivatives and Hedging, or that do not result in substantial premiums accounted for as paid-on capital. A convertible debt instrument will be accounted for as a single liability measured at its amortized cost and convertible preferred stock will be accounted for as a single equity instrument measured at its historical cost, as long as no other features require bifurcation and recognition as derivatives. By removing the separation models, the interest rate of convertible debt instruments typically will be closer to the coupon interest rate when applying the guidance in Topic 835, Interest. These amendments to the derivatives scope exception for contracts in an entity's own equity change the population of contracts that are recognized as assets or liabilities. For a freestanding instrument, an entity should record it in equity if the instrument qualifies for the derivatives scope exception under the amendments. For an embedded feature, if the feature qualifies for the derivatives scope exception under the amendments, an entity should no longer separate the feature and account for it individually. The Company adopted ASU 2020-06 upon issuance did not have a material impact on the Company's consolidated financial statements.

On May 3, 2021, the FASB issued ASU No. 2021-04, Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options. This standard provided clarification and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (such as warrants) that remain equity classified after modification or exchange. This standard was effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Issuers should apply the new standard prospectively to modifications or exchanges occurring after the effective date of the new standard. Early adoption was permitted, including adoption in an interim period. If an issuer elected to early adopt the new standard in an interim period, the guidance should be applied as of the beginning of the fiscal year that includes that interim period. The Company adopted ASU 2021-04 effective for January 1, 2022, and its adoption did not have a material impact on the Company's consolidated financial statements and related disclosures.

On July 19, 2021, the FASB issued Accounting Standards Update (ASU) 2021-05, Leases (Topic 842): Lessors—Certain Leases with Variable Lease Payments. As part of the postimplementation review (PIR) of leases (FASB Accounting Standards Codification (FASB ASC) 842), the FASB was made aware of an issue being encountered by lessors wherein following the guidance in FASB ASC 842 requiring them to recognize a loss at lease commencement for certain sales-type lease with variable payments, even if the lessor expects the arrangement will be profitable overall. The Company adopted ASU 2021-05 effective for January 1, 2022, and its adoption did not have a material impact on the Company's consolidated financial statements and related disclosures.

NOTE 4 - PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses consist of the following as of December 31, 2022 and 2021:

	December 31,	
	2022	**2021**
Insurance [(1)]	$ 1,027,292	$ 1,937,693
Research and development expense tax credit receivable	546,563	644,513
Professional fees [(1)]	310,017	294,577
Value-added tax receivable	48,774	24,411
Taxes	25,634	25,634
Other	-	49,755
	$ 1,958,280	$ 2,976,583

(1) In the previously filed Annual Report on Form 10-K for the year ended December 31, 2021, the Insurance line item above included $213,974 of expenses related to Oxford agreements for our CBR Pharma subsidiary. In the current year, those same expenses are grouped into the Professional fees grouping. As such, for comparative purposes, that amount has been moved from the Insurance grouping to the Professional fees grouping for the 2021 period.

NOTE 5 - INTANGIBLE ASSETS AND IMPAIRMENT OF LONG-LIVED ASSETS

Intangible assets consist of the following as of December 31, 2022 and 2021:

	Remaining Amortization Period in Years at December 31, 2022	As of December 31, 2022			As of December 31, 2021		
		Gross Asset Value	Accumulated Amortization	Net Carrying Value	Gross Asset Value	Accumulated Amortization	Net Carrying Value
Licensed patents	13.5	$ 596,259	$ (142,654)	$ 453,605	$ 603,919	$ (110,759)	$ 493,160
Technology license	16.6	1,485,159	(279,906)	1,205,253	1,658,550	(202,797)	1,455,753
		$ 2,081,418	$ (422,560)	$ 1,658,858	$ 2,262,469	$ (313,556)	$ 1,948,913

Changes in the gross asset value of licensed patents and technology licenses from the dates acquired are the result of changes in the foreign currency exchange rate.

The Company recorded amortization expense of $109,004 and $116,297 during the years ended December 31, 2022 and 2021, respectively, related to intangible assets, which is included in general and administrative expense on the accompanying consolidated statements of operations and comprehensive loss.

Future amortization related to intangible assets is as follows:

For the Years Ending December 31,	
2023	$ 109,489
2024	109,489
2025	109,489
2026	109,489
2027	109,489
Thereafter	1,111,413
	$ 1,658,858

Goodwill Impairment

The Company's publicly traded stock closed at $78.00 per share as of December 31, 2021; during 2022, the market value of the Company's single reporting unit significantly declined. As of March 31, 2022, June 30, 2022, September 30, 2022 and December 31, 2022, the market value of the Company's publicly traded stock fell to $51.80, $16.96, $13.30 and $3.39, per share, respectively, and as such, the Company elected to conduct a quantitative analysis of goodwill to assess for impairment as of September 30, 2022 and December 31, 2022. The Company determined the fair market value of its single reporting unit and compared that value with the carrying amount of the reporting unit and determined that goodwill was impaired as of both measurement dates. As of September 30, 2022 and December 31, 2022, the carrying value exceeded the fair market value by $18,872,850 and $14,674,428, respectively. To recognize the impairment of goodwill, the Company recorded losses for these amounts at the end of the third and fourth quarters, which appear as a loss on goodwill impairment of $33,547,278 on the income statement for the year ended December 31, 2022.

The following is a summary of goodwill activity for the year ended December 31, 2022 for the Company's single reporting unit, which includes the recorded losses on goodwill impairment described above.

	CBR Pharma Goodwill	180 LP Goodwill	Consolidated Goodwill
Balance, December 31, 2021	$ 23,749,631	$ 13,238,255	$ 36,987,886
Currency translation	(664,353)	-	(664,353)
Balance, March 31, 2022	23,085,278	13,238,255	36,323,533
Currency translation	(1,734,582)	-	(1,734,582)
Balance, June 30, 2022	21,350,696	13,238,255	34,588,951
Currency translation	(1,750,386)	-	(1,750,386)
Balance before impairment	19,600,310	13,238,255	32,838,565
Impairment of goodwill	(11,264,612)	(7,608,238)	(18,872,850)
Balance, September 30, 2022	8,335,698	5,630,017	13,965,715
Currency translation	708,713	-	708,713
Balance before impairment	9,044,411	5,630,017	14,674,428
Impairment of goodwill	(9,044,411)	(5,630,017)	(14,674,428)
Balance, December 31, 2022	$ -	$ -	$ -

IP R&D Assets Impairment

As of December 31, 2022, the carrying amount of the IP R&D assets on the balance sheet was $12,405,084 (which consists of carrying amounts of $1,462,084 and $10,943,000 related to the Company's CBR Pharma subsidiary and its 180 LP subsidiary, respectively). Per the valuation obtained from a third party as of year-end, the fair market value of the Company's IP R&D assets was determined to be $9,063,000 (which consists of fair values of $0 and $9,063,000 related to the Company's CBR Pharma subsidiary and 180 LP subsidiary, respectively). As of this measurement date, the carrying values of the CBR Pharma and 180 LP subsidiaries' assets exceeded their fair market values by $1,462,084 and $1,880,000, respectively. As such, management determined that the consolidated IP R&D assets were impaired by $3,342,084 and, in order to recognize the impairment, the Company recorded a loss for this amount during the fourth quarter of 2022, which appears as a loss on impairment to IP R&D assets on the income statement. This reduced the IP R&D asset balances of its CBR Pharma subsidiary and its 180 LP subsidiary to zero and $9,063,000, respectively, as of December 31, 2022; the total consolidated IP R&D asset balance is $9,063,000 after impairment.

The following is a summary of IP R&D activity for the year ended December 31, 2022 for the Company, which includes the recorded loss for the IP R&D assets described above.

	CBR Pharma IP R&D Assets	180 LP IP R&D Assets	Consolidated IP R&D Assets
Balance, December 31, 2021	$ 1,632,780	$ 10,943,000	$ 12,575,780
Currency translation	(45,674)	-	(45,674)
Balance, March 31, 2022	1,587,106	10,943,000	12,530,106
Currency translation	(119,252)	-	(119,252)
Balance, June 30, 2022	1,467,854	10,943,000	12,410,854
Currency translation	(120,338)	-	(120,338)
Balance, September 30, 2022	1,347,516	10,943,000	12,290,516
Currency translation	114,568	-	114,568
Balance before impairment	1,462,084	10,943,000	12,405,084
Impairment of IP R&D assets	(1,462,084)	(1,880,000)	(3,342,084)
Balance, December 31, 2022	$ -	$ 9,063,000	$ 9,063,000

NOTE 6 - ACCRUED EXPENSES

Accrued expenses consist of the following as of December 31, 2022 and 2021:

	December 31,	
	2022	**2021**
Consulting fees	$ 531,829	$ 548,281
Professional fees	3,945	252,973
Litigation accrual [(1)]	125,255	300,000
Employee and director compensation	1,558,024	725,569
Research and development fees	22,023	91,737
Interest	36,422	25,433
Other	7,018	20,587
	$ 2,284,516	$ 1,964,580

(1) See Note 11 - Commitments and Contingencies, *Potential Legal Matters*.

As of December 31, 2022 and 2021, accrued expenses - related parties were $188,159 and $18,370, respectively. See Note 11 – Commitments & Contingencies and Note 14 - Related Parties for details.

NOTE 7 - ACCRUED ISSUABLE EQUITY

A summary of the accrued issuable equity activity during the year ended December 31, 2021 is presented below:

Balance at January 1, 2021	$ 43,095
Reclassification to equity	(43,095)
Balance at December 31, 2021	$ -

During the year ended December 31, 2020, the Company entered into a contractual arrangement for services in exchange for shares of common stock of the Company for fixed dollar amounts. Pursuant to the contractual agreement, the Company will issue an aggregate value of $5,000 of common shares on a monthly basis and an aggregate of $30,000 of common shares at the end of each quarter. As of December 31, 2020, the Company recorded $43,095 of accrued issuable equity related to services. During the first quarter of 2021, this balance was reclassified to equity and as of December 31, 2021, there was no accrued issuable equity.

NOTE 8 - DERIVATIVE LIABILITIES

The following table sets forth a summary of the changes in the fair value of Level 3 derivative liabilities (except the Public Special Purpose Acquisition Companies ("SPAC") warrants as defined below, which are Level 1 derivative liabilities) that are measured at fair value on a recurring basis:

	For the Year Ended December 31, 2022					
	Warrants					
	Public SPAC	Private SPAC	PIPE	Other	Convertible Notes	Total
Balance as of January 1, 2022	$ 8,048,850	$ 467,325	$ 6,516,300	$ 187,892	$ -	$ 15,220,367
Change in fair value of derivative liabilities	(8,017,225)	(466,069)	(6,474,200)	(187,492)	-	(15,144,986)
Balance as of December 31, 2022	$ 31,625	$ 1,256	$ 42,100	$ 400	$ -	$ 75,381

	For the Year Ended December 31, 2021					
	Warrants					
	Public SPAC	Private SPAC	PIPE	Other	Convertible Notes	Total
Balance as of January 1, 2021	$ 3,795,000	$ 256,275	$ -	$ 165,895	$ 225,800	$ 4,442,970
Extinguishment of derivative liabilities in connection with conversion of debt [1]	-	-	-	-	(591,203)	(591,203)
Warrants issued in connection with the financing	-	-	7,294,836	-	-	7,294,836
Warrants issued relates to Alpha settlement [1]	-	-	-	95,677	-	95,677
Extinguishment of derivative liabilities in connection with the Alpha settlement [1]	-	-	-	-	(699,301)	(699,301)
Change in fair value of derivative liabilities	4,253,850	211,050	(778,536)	(73,680)	1,064,704	4,677,388
Balance as of December 31, 2021	$ 8,048,850	$ 467,325	$ 6,516,300	$ 187,892	$ -	$ 15,220,367

(1) See Note 10 – Convertible Notes Payable

The fair value of the derivative liabilities as of December 31, 2022 and 2021 were estimated using the Black Scholes option pricing model, with the following assumptions used:

	December 31, 2022
Risk-free interest rate	2.30% - 4.50%
Expected term in years	1.59 – 3.90
Expected volatility	76.0% – 105.0%
Expected dividends	0%

SPAC Warrants

Public SPAC Warrants

Participants in KBL's initial public offering received an aggregate of 11,500,000 Public SPAC Warrants ("Public SPAC Warrants"). Each Public SPAC Warrant entitles the holder to purchase one-fortieth of one share of the Company's common stock at an exercise price of $5.75 per 1/40th of one share, or $230.00 per whole share, subject to adjustment. No fractional shares will be issued upon exercise of the Public Warrants. The Public Warrants are currently exercisable and will expire on November 6, 2025, or earlier upon redemption or liquidation. The Company may redeem the Public Warrants, in whole and not in part, at a price of $0.01 per Public Warrant upon 30 days' notice ("30-day redemption period"), only in the event that the last sale price of the common stock equals or exceeds $360.00 per share for any 20 trading days within a 30-trading day period ending on the third trading day prior to the date on which notice of redemption is given, provided there is an effective registration statement with respect to the shares of common stock underlying such Public Warrants and a current prospectus relating to those shares of common stock is available throughout the 30-day redemption period. If the Company calls the Public Warrants for redemption as described above, the Company's management will have the option to require all holders that wish to exercise Public Warrants to do so on a "cashless basis." Management has determined that the Public Warrants contain a tender offer provision which could result in the Public Warrants settling for the tender offer consideration (including potentially cash) in a transaction that didn't result in a change-in-control. This feature results in the Public Warrants being precluded from equity classification. Accordingly, the Public Warrants are classified as liabilities measured at fair value, with changes in fair value each period reported in earnings. The fair value of the Public SPAC Warrants on the date of the issuance was $1,978,000. At December 31, 2022 and 2021 the Public SPAC Warrants were revalued at $31,625 and $8,048,850, respectively, which resulted in a $8,017,225 decrease in fair value and a $4,253,850 increase in the fair value of the derivative liabilities during the years ended December 31, 2022 and 2021, respectively. The decrease and increase in fair value of these derivative liabilities were recorded in the accompanying consolidated statement of operations.

Private SPAC Warrants

Participants in KBL's initial private placement received an aggregate of 502,500 Private SPAC Warrants ("Private SPAC Warrants"). Each Private Warrant entitles the holder to purchase one-fortieth of one share of the Company's common stock at an exercise price of $5.75 per 1/40th of one share, or $230.00 per whole share, subject to adjustment. No fractional shares will be issued upon exercise of the warrants. The Private Warrants are currently exercisable and will expire five years after the completion of the Business Combination or earlier upon redemption or liquidation. The Private Warrants are non-redeemable so long as they are held by original holders or their permitted transferees. If the Private Warrants are held by other parties, the Company may redeem the Private Warrants, in whole and not in part, at a price of $0.01 per Warrant upon 30 days' notice ("30-day redemption period"), only in the event that the last sale price of the common stock equals or exceeds $360.00 per share for any 20 trading days within a 30-trading day period ending on the third trading day prior to the date on which notice of redemption is given, provided there is an effective registration statement with respect to the shares of common stock underlying such Warrants and a current prospectus relating to those shares of common stock is available throughout the 30-day redemption period. If the Company calls the Private Warrants for redemption as described above, the Company's management will have the option to require all holders that wish to exercise Private Warrants to do so on a "cashless basis." Management has determined that the Private Warrants contain a tender offer provision which could result in the Private Warrants settling for the tender offer consideration (including potentially cash) in a transaction that didn't result in a change-in-control. This feature (amongst others) results in the Private Warrants being precluded from equity classification. Accordingly, the Private Warrants are classified as liabilities measured at fair value, with changes in fair value each period reported in earnings. The fair value of the Private SPAC Warrants on the date of the issuance was $587,925. At December 31, 2022 and 2021, the Private SPAC Warrants were revalued at $1,256 and $467,325, respectively, which resulted in a $466,069 decrease and a $211,050 increase in the fair value of the derivative liabilities during the years ended December 31, 2022 and 2021, respectively. The decrease and increase in fair value of these derivative liabilities were recorded in the accompanying consolidated statement of operations.

PIPE Warrants

On February 23, 2021, the Company issued five-year warrants (the "PIPE Warrants") to purchase 128,200 shares of common stock at an exercise price of $100.00 per share in connection with the private offering (see Note 12 – Stockholders' Equity, Common Stock). The PIPE Warrants did not meet the requirements for equity classification due to the existence of a tender offer provision that could potentially result in cash settlement of the PIPE Warrants that didn't meet the limited exception in the case of a change-in-control. Accordingly, the PIPE Warrants are liability-classified and the Company recorded the $7,294,836 fair value of the PIPE Warrants, which was determined using the Black-Scholes option pricing model, as derivative liabilities. The PIPE Warrants were revalued on December 31, 2022 and 2021 at $42,100 and $6,516,300, respectively, which resulted in decreases in the fair value of the derivative liabilities of $6,474,200 and $778,536 during the years ended December 31, 2022 and 2021, respectively.

The following assumptions were used to value the PIPE Warrants at issuance:

	February 23, 2021
Risk-free interest rate	0.59%
Expected term in years	5.00
Expected volatility	85%
Expected dividends	0%

Other Warrants

AGP Warrant

In connection with the closing of the Business Combination on November 6, 2020, the Company became obligated to assume five-year warrants for the purchase of 3,183 shares of the Company's common stock at an exercise price of $105.60 per share (the "AGP Warrant Liability") that had originally been issued by KBL to an investment banking firm in connection with a prior private placement.

On March 12, 2021, the Company issued a warrant to AGP (the "AGP Warrant") to purchase up to an aggregate of 3,183 shares of the Company's common stock at a purchase price of $105.60 per share, subject to adjustment, in full satisfaction of the existing AGP Warrant Liability. The exercise of the AGP Warrant is limited at any given time to prevent AGP from exceeding beneficial ownership of 4.99% of the then total number of issued and outstanding shares of the Company's common stock upon such exercise. The warrant is exercisable at any time between May 2, 2021 and May 2, 2025. The newly issued AGP Warrant did not meet the requirements for equity classification due to the existence of a tender offer provision that could potentially result in cash settlement of the AGP Warrant that did not meet the limited exception in the case of a change-in-control. Accordingly, the AGP Warrant will continue to be liability-classified. The AGP Warrant was revalued on December 31, 2022 and 2021 at $400 and $144,331, respectively, which resulted in decreases in the fair value of the derivative liabilities of $143,931 and $21,564 during the years ended December 31, 2022 and 2021, respectively.

The following assumptions were used to value the AGP Warrant at issuance:

	March 12, 2021
Risk-free interest rate	0.68%
Expected term in years	3.84
Expected volatility	85%
Expected dividends	0%

Alpha Capital Anstalt ("Alpha") Warrant

In connection with the Alpha Settlement Agreement (see Note 10 – Convertible Notes Payable) that was agreed to on July 29, 2021 (signed on July 31, 2021), the Company issued a three-year warrant for the purchase of 1,250 shares of the Company's common stock at an exercise price of $141.40 per share (the "Alpha Warrant Liability" and the "Alpha Warrant"). The exercise of shares of the Alpha Warrant is limited at any given time to prevent Alpha from exceeding a beneficial ownership of 4.99% of the then total number of issued and outstanding shares of the Company's common stock upon such exercise. The warrant is exercisable until August 2, 2024. The newly issued Alpha Warrant did not meet the requirements for equity classification due to the existence of a tender offer provision that could potentially result in cash settlement of the Alpha Warrant that did not meet the limited exception in the case of a change-in-control. Accordingly, the Alpha Warrant is liability-classified and the Company recorded the $95,677 fair value of the Alpha Warrant, which was determined using the Black-Scholes option pricing model, as a derivative liability. The Alpha Warrant was revalued on December 31, 2022 and 2021 at $0 and $43,561, respectively, which resulted in decreases in the fair value of the derivative liabilities of $43,561 and $52,116 during the years ended December 31, 2022 and 2021, respectively.

The following assumptions were used to value the Alpha Warrant at issuance:

	July 29, 2021
Risk-free interest rate	0.37%
Expected term in years	3.00
Expected volatility	85%
Expected dividends	0%

Convertible Notes

The convertible notes issued in 2020 had embedded features that were bifurcated and recorded as derivative liabilities. Between January 15, 2021 and February 5, 2021, the fair value of derivative liabilities extinguished in connection with the conversion of debt (see Note 10 – Convertible Notes Payable) was estimated using the Black Scholes option pricing model with the following assumptions used:

	January 15, 2021 to February 5, 2021
Risk-free interest rate	0.00% - 0.14%
Expected term in years	0.02 - 0.18
Expected volatility	120% - 161%
Expected dividends	0%

At the end of the second quarter of 2021, the Alpha Capital Note (see Note 10 – Convertible Notes Payable) that was the only convertible note with an outstanding balance and the full amount of the July 31, 2021 Alpha Settlement Agreement was accrued as of that date. On July 31, 2021, the Company recorded the extinguishment of the Alpha Capital Note, the related derivative liabilities and the balance of the settlement accrual. See Note 10 - Convertible Notes Payable for additional details.

Warrant Activity

A summary of the warrant activity (including certain warrants granted in August 2021, July 2022 and December 2022 as part of private offerings, all of which are equity-classified; see Note 12 - Stockholders' Equity) during the years ended December 31, 2022 and 2021 is presented below:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life in Years	Intrinsic Value
Outstanding, January 1, 2021	303,245	$ 228.69	4.9	-
Issued	254,450	124.77		
Exercised	-	-		
Cancelled	-	-		
Expired	-	-		
Outstanding, December 31, 2021	577,695	$ 181.20	4.1	-
Issued	4,508,923	3.44	5.4	
Exercised	(1,630,890)	0.0001	-(1)	
Cancelled	-	-		
Expired	-	-		
Outstanding, December 31, 2022	3,435,728	$ 33.94	5.1	-
Exercisable, December 31, 2022	577,695	$ 181.28	3.1	-

(1) Note that the warrants are exercisable until they are exercised in full and have no expiration date; as such, they have been excluded from this calculation.

A summary of outstanding and exercisable warrants as of December 31, 2022 is presented below:

Warrants Outstanding		Warrants Exercisable	
Exercise Price	Number of Shares	Weighted Average Remaining Life in Years	Number of Shares
$ 100.00	128,200	3.2	128,200
$ 105.60	3,183	2.3	3,183
$ 141.40	1,250	1.6	1,250
$ 150.00	125,000	3.6	125,000
$ 230.00	300,062	2.9	300,062
$ 21.20	306,604	-	-
$ 3.50	2,571,429	-	-
	3,435,728	3.1	577,695

A summary of outstanding and exercisable warrants as of December 31, 2021 is presented below:

Warrants Outstanding		Warrants Exercisable	
Exercise Price	Number of Shares	Weighted Average Remaining Life in Years	Number of Shares
$ 100.00	128,200	4.2	128,200
$ 105.60	3,183	3.3	3,183
$ 141.40	1,250	2.6	1,250
$ 150.00	125,000	4.6	125,000
$ 230.00	300,062	3.9	300,062
	577,695	4.1	577,695

NOTE 9 - LOANS PAYABLE

The following tables summarize the activity of loans payable during the years ended December 31, 2022 and 2021:

	Principal Balance at January 1, 2022	Adjustments	Principal Repaid in Cash	New Issuances	Effect of Foreign Exchange Rates	Principal Balance at December 31, 2022
Paycheck Protection Program	$ 41,312	$ -	$ (41,312)	$ -	$ -	$ -
Bounce Back Loan Scheme	61,169	-	(11,646)	-	(6,394)	43,129
First Assurance – 2021	1,618,443	(14,042)[1]	(1,604,401)	-		-
First Assurance – 2022	-	-	-	1,060,890	-	1,060,890
Other loans payable	155,320	80,366[2]		-	-	235,686
Total loans payable	1,876,244	$ 66,324	$ (1,657,359)	$ 1,060,890	$ (6,394)	1,339,705
Less: loans payable – current portion	1,828,079					1,308,516
Loans payable – non-current portion	$ 48,165					$ 31,189

(1) Note that this amount was related to finance charges and was reclassified.

(2) Note that this amount was reclassified from related party payables.

	Principal Balance at January 1, 2021	Forgiveness/ Adjusted to Other Income	Principal Repaid in Cash	New Issuances	Effect of Foreign Exchange Rates	Principal Balance at December 31, 2021
Kingsbrook	$ 150,000	$ -	$ (150,000)	$ -	$ -	$ -
Paycheck Protection Program	53,051	(11,670)	(69)	-	-	41,312
Bounce Back Loan Scheme	68,245	-	(4,724)	-	(2,352)	61,169
First Assurance - 2020	655,593	-	(655,593)	1,618,443	-	1,618,443
Other loans payable	155,320	-	-	-	-	155,320
Total loans payable	1,082,209	$ (11,670)	$ (810,386)	$ 1,618,443	$ (2,352)	1,876,244
Less: loans payable - current portion	968,446					1,828,079
Loans payable - non-current portion	$ 113,763					$ 48,165

Loans Payable, Current Portion

	Simple Interest Rate	December 31, 2022	December 31, 2021
Loan payable issued September 18, 2019	8%	$ 50,000	$ 50,000
Loan payable issued September 18, 2019	8%	50,000	-
Loan payable issued October 8, 2019	0%	4,000	-
Loan payable issued October 29, 2019	8%	69,250	69,250
Loan payable issued December 31, 2019	0%	5,000	-
Loan payable issued February 5, 2020	8%	3,500	3,500
Loan payable issued February 5, 2020	8%	3,500	-
Loan payable issued March 31, 2020	8%	4,537	4,537
Loan payable issued March 31, 2020	8%	4,537	-
Loan payable issued June 8, 2020	8%	-	5,000
Loan payable issued June 8, 2020	0%	5,000	5,000
Loan payable issued June 17, 2020	8%	485	-
Loan payable issued July 15, 2020 *	8%	4,695	4,695
Loan payable issued July 15, 2020	8%	5,503	-
Loan payable issued October 8, 2020 *	8%	7,798	-
Loan payable issued October 13, 2020	8%	13,337	13,337
Loan payable issued October 14, 2020	8%	4,544	-
Current portion of PPP Loans [1]	1%	-	41,312
Current portion of Bounce Back Loans [1] [2]	1%	11,940	13,005
First Assurance Funding payable issued December 10, 2021[2]	2%	1,060,890	1,618,443
		$ 1,308,516	$ 1,828,079

* These loans are denominated in currencies other than USD.

(1) See Loans Payable, Non-Current Portion for a description of the PPP Loans and the Bounce Back Loans.

(2) Note that these loans are not currently in default.

Loans Payable, Non-Current Portion

The non-current portion of the Company's loans payable as of December 31, 2022 and 2021 are as follows:

	Simple Interest Rate	December 31, 2022	December 31, 2021	Maturity Date
PPP loan payable issued May 5, 2020	1.0%	-	$ 41,312	5/4/2022
BBLS loan payable issued June 10, 2020	2.5%	43,129	61,170	6/10/2026
Subtotal		43,129	102,482	
Less: Current portions of BBLS/PPP loans, respectively (see above)		(11,940)	(54,317)	
Non-current portion		$ 31,189	$ 48,165	

During April and May 2020, Katexco received loans in the aggregate amount of $53,051 (the "PPP Loans"), under the Payroll Protection Program ("PPP"), to support continuing employment during the COVID-19 pandemic.

Effective March 27, 2020, legislation referred to as the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was passed to benefit companies in the U.S. that were significantly impacted by the pandemic. Under the terms of the CARES Act, as amended by the Paycheck Protection Program Flexibility Act of 2020, the Company is eligible to apply for and receive forgiveness for all or a portion of their respective PPP Loans. Such forgiveness will be determined, subject to limitations, based on the use of the loan proceeds for certain permissible purposes as set forth in the PPP, including, but not limited to, payroll costs (as defined under the PPP) and mortgage interest, rent or utility costs (collectively, "Qualifying Expenses") incurred during the 24 weeks subsequent to funding, and on the maintenance of employee and compensation levels, as defined, following the funding of the PPP Loan. The Company believes it used the proceeds of the PPP Loans for Qualifying Expenses. Any amounts not forgiven incur interest at 1.0% per annum and monthly repayments of principal and interest are deferred for six months after the date of disbursement.

On May 19, 2021, the Company applied for loan forgiveness for the amount of $51,051 in connection with amounts borrowed by Katexco under the Paycheck Protection Program. On August 5, 2021, the Company was notified that $9,670 was forgiven in connection with the PPP Loans.

On September 30, 2021, the Company adjusted a portion of the PPP Loans in the amount of $2,000 to other income since such amount was a grant to 180LS by the government, and it did not need to be repaid.

As of December 31, 2021, the Company recorded accrued interest of $163 related to the PPP loans and interest expense of $1,636. On May 27, 2022, the Company repaid in full the remainder of the PPP Loans in the amount of $41,312.

On June 10, 2020, the Company received GBP £50,000 (USD $64,353) of cash proceeds pursuant to the Bounce Back Loan Scheme ("BBLS"), which provides financial support to businesses across the UK that are losing revenue, and seeing their cashflow disrupted, as a result of the COVID-19 outbreak. The BBLS is unsecured and bears interest at 2.5% per annum. The maximum loan amount is GBP £50,000 and the length of the loan is six years, with payments beginning 12 months after the date of disbursement. Early repayment is allowed, without early repayment fees. As of December 31, 2022 and 2021, the Company recorded accrued interest of GBP £778 (USD $1,051) and GBP £514 (USD $702), respectively, related to the BBLS loan. During the years ended December 31, 2021 and 2020, the Company recorded interest expense of GBP £778 (USD $1,051) and GBP£514 (USD $702), respectively, related to the BBLS loan.

On June 12, 2020, the Company entered into a promissory note agreement with Kingsbrook Opportunities Master Fund LP for the borrowing of the aggregate principal sum of $150,000, which bears interest at 15% per annum and matures on August 31, 2021. On March 3, 2021, the Company repaid the Kingsbrook loans payable in cash for an aggregate of $162,452, which included the principal amount of $150,000 and accrued interest of $12,452.

During the year ended December 31, 2021, the Company paid an aggregate of $655,593 in full satisfaction of the 2020 directors and officers insurance policy and $4,724 in partial satisfaction of the Bounce Back Loan Scheme.

On December 10, 2021, the Company entered into a financing arrangement for a Directors and Officers Insurance Policy (the "D&O Insurance") with First Assurance Funding to finance $1,618,443 of a total D&O Insurance amount of $2,005,502 inclusive of premiums, taxes, and fees. As of December 31, 2022, a total of $1,060,890 remains financed in loans payable, due in monthly installments of $161,844.

Loans Payable – Related Parties

Loans payable to related parties (the "Related Party Loans") consist of loans payable to certain of the Company's officers, directors and a greater than 10% stockholder. The Company had the following loans payable to related parties outstanding as of December 31, 2022 and 2021:

	Simple Interest Rate	December 31, 2022[(1)]	December 31, 2021
Loan payable issued September 18, 2019	8%	$ -	$ 50,000
Loan payable issued October 8, 2019	0%	-	4,000
Loan payable issued February 5, 2020	8%	-	3,500
Loan payable issued March 31, 2020	8%	-	4,537
Loan payable issued June 17, 2020	8%	-	485
Loan payable issued July 15, 2020	8%	-	5,503
Loan payable issued October 8, 2020 *	8%	-	8,708
Loan payable issued October 14, 2020	8%	-	4,544
		$ -	$ 81,277

* These are loans denominated in currencies other than USD.

(1) The loan payables listed belong to holders that are no longer considered related parties as of this date.

At issuance, the Related Party Loans provided for a maturity date upon the earliest of (a) the consummation of the Business Combination; (b) June 30, 2020; or (c) 60 days after the respective issuance date. On July 1, 2020, the Company amended the terms of the Related Party Loans to extend the maturity terms to the earlier of (a) the closing of a qualified financing; or (b) November 1, 2020. The terms of all loan extensions were reviewed and were deemed to be modifications, rather than extinguishments.

On February 10, 2021, the Company entered into amended loan agreements to modify the terms of certain loan agreements in the aggregate principal amount of $432,699, previously entered into with Sir Marc Feldmann and Dr. Lawrence Steinman, the Co-Executive Chairmen of the Board of Directors. The loan agreements were extended and modified to be paid back at the Company's discretion, either by 1) repayment in cash, or 2) by converting the outstanding amounts into shares of common stock at the same price per share as the next financing transaction. Subsequently, on February 25, 2021, and effective as of the date of the original February 10, 2021 amendments, the Company determined that such amendments were entered into in error and each of Sir Feldmann and Dr. Steinman rescinded such February 10, 2021 amendments pursuant to their entry into Confirmations of Rescission acknowledgements. As such, the amendments to allow Sir Feldmann and Dr. Steinman the option to convert such loans into shares of common stock were never effective.

On April 12, 2021, the Company entered into amended loan agreements with Sir Marc Feldmann and Dr. Lawrence Steinman, the Co-Executive Chairman of the Board of Directors, which extended the maturity date of all of their outstanding loan agreements to September 30, 2021.

On that day, they elected to exchange an aggregate principal of $433,374 and aggregate accrued interest of $61,530 into an aggregate of 4,124 shares of the Company's common stock at a price of $120.00 per share, pursuant to the terms of the agreement (see Note 12 - Stockholders' Equity*)*.

Interest Expense on Loans Payable

For the year ended December 31, 2022, the Company recognized interest expense and interest income — related parties associated with outstanding loans, of $14,156 and $1,490, respectively.

For the year ended December 31, 2021, the Company recognized interest expense and interest expense — related parties associated with outstanding loans, of $24,019 and $38,874, respectively.

As of December 31, 2022, the Company had accrued interest and accrued interest — related parties associated with outstanding loans, of $37,960 and $16,770, respectively. See Note 14 — Related Parties for additional details.

As of December 31, 2021, the Company had accrued interest and accrued interest — related parties associated with outstanding loans, of $24,212 and $812, respectively. See Note 14 — Related Parties for additional details.

NOTE 10 - CONVERTIBLE NOTES PAYABLE

The table below details the convertible notes payable activity during the year ended December 31, 2021 (there was no activity during 2022, as all convertible notes payable balances were zero as of December 31, 2021):

	Effective Date	Maturity Date (as amended, if applicable)	01/01/21 Principal Balance	Impact of Extinguishment	Conversions to Common Stock	Common Shares Issued	12/31/21 Principal Balance
Dominion	06/12/20	02/11/21	$ 833,334	$ -	$ (833,334)	16,920	$ -
Kingsbrook	06/12/20	02/11/21	101,000	-	(101,000)	1,689	-
Alpha Capital	06/12/20	02/11/21	616,111	(316,111)	(300,000)	4,748	-
Bridge Note	12/27/19	08/28/21	365,750	-	(365,750)	7,915	-
Total			$ 1,916,195	$ (316,111)	$ (1,600,084)	31,272	$ -

The following table details the convertible notes payable – related party activities during the years ended December 31, 2021 (there was no activity during 2022, as the balance was zero as of December 31, 2021):

	For the Year Ended December 31, 2021							
	Effective Date	Maturity Date (as amended, if applicable)	01/01/21 Principal Balance	Debt Issued	Unpaid Interest Capitalized to Principal	Settlement Debt	Conversions to Common Stock	12/31/21 Principal Balance
180 LP Convertible Note	09/24/13	09/25/15	160,000	-	-	-	(160,000)	-
180 LP Convertible Note	06/16/14	06/16/17	10,000	-	-	(10,000)	-	-
180 LP Convertible Note	07/08/14	07/08/17	100,000	-	-	-	(100,000)	-
Total			$ 270,000	$ -	$ -	$ (10,000)	$ (260,000)	$ -

Dominion, Kingsbrook and Alpha Convertible Promissory Note

Upon closing of the Business Combination, the Dominion (defined below), Kingsbrook and Alpha (defined below) Convertible Promissory Notes were assumed.

Dominion Convertible Promissory Notes

	Dominion		
	Principal	Debt Discount	Net
Balance at January 1, 2021	$ 833,334	$ -	$ 833,334
Impact of conversion	(833,334)	-	(833,334)
Balance at December 31, 2021	$ -	$ -	$ -

On June 12, 2020 (the "Dominion Issue Date"), KBL entered into a $1,666,667 10% Secured Convertible Promissory Note and $138,889 10% Senior Secured Convertible Extension Promissory Note (together the "Dominion Convertible Promissory Notes") with Dominion Capital LLC ("Dominion"), which was issued to Dominion in conjunction with 20,000 shares of common stock (the "Dominion Commitment Shares") and assumed a discount of $722,996, which has been amortized to interest expense over the term of the debt. The Company agreed to pay the principal amount with interest, which was due and payable on February 11, 2021, unless converted under terms and provisions as set forth within the Dominion Convertible Promissory Notes. The Dominion Convertible Promissory Notes provided Dominion with the right to convert, at any time, all or any part of the outstanding principal and accrued but unpaid interest into shares of the Company's common stock at a conversion price of $105.60 per share.

During the year ended December 31, 2021, the Company recorded interest expense of $31,080 as of December 31, 2021 associated with the Dominion Convertible Promissory Notes. See Convertible Debt Conversions of the Dominion, Kingsbrook and Alpha Convertible Promissory Notes further on in this note for the details related to the 2021 conversions of the notes.

Kingsbrook Convertible Promissory Note

	Kingsbrook		
	Principal	Debt Discount	Net
Balance at January 1, 2021	$ 101,000	$ -	$ 101,000
Impact of conversion	(101,000)	-	(101,000)
Balance at December 31, 2021	$ -	$ -	$ -

On June 12, 2020 (the "Kingsbrook Issue Date"), KBL entered into a $1,657,522 10% Secured Convertible Promissory Note and $138,889 10% Senior Secured Convertible Extension Promissory Note (together with "Kingsbrook Convertible Promissory Notes") with Kingsbrook Opportunities Master Fund LP ("Kingsbrook"), which was issued to Kingsbrook in conjunction with 1,250 shares of common stock (the "Kingsbrook Commitment Shares") and an assumed debt discount of $685,615, which has been amortized to interest expense over the term of the debt. The Company has agreed to pay the principal amount with guaranteed interest, which was due and payable on February 11, 2021, unless converted under terms and provisions as set forth within the Kingsbrook Convertible Promissory Notes. The Kingsbrook Convertible Promissory Notes provide Kingsbrook with the right to convert, at any time, all or any part of the outstanding principal and accrued but unpaid interest into shares of the Company's common stock at a conversion price of $105.60 per share.

During the year ended December 31, 2021, the Company recorded interest expense of $10,010 as of December 31, 2021 associated with the Kingsbrook Convertible Promissory Notes. See Convertible Debt Conversions of the Dominion, Kingsbrook and Alpha Convertible Promissory Notes further on in this note for the details related to the 2021 conversions of the notes.

Alpha Convertible Promissory Note

	Alpha		
	Principal	**Debt Discount**	**Net**
Balance at January 1, 2021	$ 616,111	$ -	$ 616,111
Impact of extinguishment	(316,111)	-	(316,111)
Impact of conversion	(300,000)	-	(300,000)
Balance at December 31, 2021	$ -	$ -	$ -

On September 8, 2020 (the "Alpha Issue Date"), KBL entered into a $1,111,111 10% Secured Convertible Promissory Note (the "Alpha Convertible Promissory Note") with Alpha Capital Anstalt ("Alpha"), which was issued to the Holder in conjunction with 5,000 shares of common stock and an assumed debt discount of $800,421, which has been amortized to interest expense over the term of the debt. The Company has promised to pay the principal and guaranteed interest, which was due and payable on April 7, 2021 unless converted under terms and provisions as set forth within the Alpha Capital Anstalt Convertible Note. The Alpha Convertible Promissory Note provides Alpha with the right to convert, at any time, all or any part of the outstanding principal and accrued but unpaid interest into shares of the Company's common stock at a conversion price of $105.60 per share.

During the year ended December 31, 2021, the Company recorded interest expense of $58,510 as of December 31, 2021 associated with the Alpha Convertible Promissory Notes. See Convertible Debt Conversions of the Dominion, Kingsbrook and Alpha Convertible Promissory Notes further on in this note for the details related to the 2021 conversions of the notes.

2021 Convertible Debt Conversion/Extinguishment of the Dominion, Kingsbrook and Alpha Convertible Promissory Notes

The holders of the Secured Convertible Promissory Notes elected to convert principal and interest into shares of the Company's common stock during 2021 as follows:

	Principal Balance Converted	**Interest Converted**	**Derivative Liabilities Converted**	**Total Amount Converted**	**Common Shares Issued**	**Fair Value of Shares Issued**	**Loss on Extinguishment of Convertible Notes**
Dominion Convertible Promissory Note	$ 833,333	$ 83,333	$ 133,033	$ 1,049,700	16,920	$ 1,255,037	$ (205,337)
Kingsbrook Convertible Promissory Note	101,000	10,100	136,800	247,900	1,689	174,253	73,647
Alpha Capital Convertible Promissory Note	300,000	12,417	321,370	633,787	4,748	511,834	121,953
Total	$ 1,234,333	$ 105,850	$ 591,203	$ 1,931,387	23,357	$ 1,941,124	$ (9,737)

During the third quarter of 2021, certain noteholders elected to convert certain convertible notes payable with an aggregate principal balance of $1,234,333 and an aggregate accrued interest balance of $105,850 into an aggregate of 23,357 shares of the Company's common stock at conversion prices ranging from $49.00-$65.80 per share. The shares issued upon the conversion of the convertible promissory notes had a fair value at issuance of $1,941,124.

Alpha – Extinguishment

On February 3, 2021, an event of default was triggered under a convertible note held by Alpha Capital Anstalt ("Alpha" and the "Alpha Capital Note"); on July 29, 2021, the Company reached a settlement agreement with Alpha (the "Alpha Settlement Agreement") which provided for Alpha to convert the remaining principal and accrued interest associated with the convertible note in exchange for 7,500 shares of the Company's common stock plus a three-year warrant to purchase 1,250 additional shares of the Company's common stock at an exercise price of $141.40 per share. The Company determined that the shares and warrants had an aggregate value of $1,156,177 as of July 29, 2021. On July 29, 2021, the $1,156,177 aggregate carrying value of the principal, accrued interest, derivative liability and settlement accrual associated with the Alpha Capital Note were extinguished while the $1,060,500 fair value of the common stock was recorded within equity and the $95,677 fair value of the Alpha Warrant was recorded as a derivative liability (see Note 8, Derivative Liabilities for additional information).

Bridge Notes

On January 3, 2020 and December 27, 2019, the Company issued convertible bridge notes in the aggregate amount of $82,500 and $250,000 under the same terms. The total outstanding principal amount of convertible bridge notes of $332,500 (the "Bridge Notes") and the respective accrued interest will automatically convert into a portion of the 17.5 million shares of KBL common stock to be received upon the consummation of the Business Combination Agreement at a conversion price equal to the lesser of $6.00 per KBL share or 60% of the implied valuation at such time, as defined. The Bridge Notes accrue interest at 15% per annum. On July 7, 2020, the Company entered into an amendment agreement with each Bridge Noteholder (the "Amended Bridge Notes"). Pursuant to the terms of the Amended Bridge Notes, the principal under each Amended Bridge Note is increased by 10%, which can be converted; the number of conversion shares is equal to (A) the outstanding principal amount plus interest being converted, divided by (B) the lesser of (i) $4.23 per share or (ii) the per share price equal to 0.60 multiplied by the per share price of one share of common stock sold by the Company as part of a PIPE transaction. On October 7, 2020, the Company entered into an additional amendment with each Amended Bridge Noteholder pursuant to which the Amended Bridge Notes will no longer mature upon the date that the Registration Statement is declared effective by the SEC. Since the change in cash flows was not more than 10%, this amendment was deemed to be a modification. On March 8, 2021, the holders of the Company's convertible bridge notes, which were issued on December 27, 2019 and January 3, 2020 to various purchasers, converted an aggregate of $432,384, which included accrued interest of $66,633 owed under such convertible bridge notes, into an aggregate of 7,920 shares of common stock pursuant to the terms of such notes, as amended, at a conversion price of $54.60 per share.

180 LP Convertible Notes

In connection with the Reorganization, the Company assumed $270,000 of debt related to convertible notes payable (the "Notes"); during the second quarter of 2021, the Company repaid a certain related party convertible note payable in cash for the principal amount of $10,000 and $1,873 of accrued interest. During the third quarter of 2021, the $260,000 remaining principal balance of convertible notes payable owed to a related party, plus $96,208 of related accrued interest, was converted into 2,969 shares of the Company's common stock, pursuant to a debt conversion agreement dated September 30, 2021.

Interest on Convertible Notes

During the years ended December 31, 2021, the Company recorded interest expense of $109,767 related to convertible notes payable, and recorded interest expense - related parties of $42,529 related to convertible notes payable - related parties.

NOTE 11 - COMMITMENTS AND CONTINGENCIES

Litigation and Other Loss Contingencies

The Company records liabilities for loss contingencies arising from claims, assessments, litigation, fines, penalties and other sources when it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. The Company has no liabilities recorded for loss contingencies as of December 31, 2022. See Potential Legal Matters – Action Against Former Executives of KBL and Cantor Fitzgerald & Co. Breach of Contract below for information related to a December 31, 2022 accrual.

Potential Legal Matters

Action Against Former Executive of KBL

On September 1, 2021, the Company initiated legal action in the Chancery Court of Delaware against Dr. Marlene Krauss, the Company's former Chief Executive Officer and director ("Dr. Krauss") and two of her affiliated companies, KBL IV Sponsor, LLC and KBL Healthcare Management, Inc. (collectively, the "KBL Affiliates") for, among other things, engaging in unauthorized monetary transfers of the Company's assets, non-disclosure of financial liabilities within the Company's Consolidated Financial Statements, issuing shares of stock without proper authorization; and improperly allowing stockholder redemptions to take place. The Company's complaint alleges causes of action against Dr. Krauss and/or the KBL Affiliates for breach of fiduciary duties, ultra vires acts, unjust enrichment, negligence and declaratory relief, and seeks compensatory damages in excess of $11,286,570, together with interest, attorneys' fees and costs. There can be no assurance that the Company will be successful in its legal actions. As of December 31, 2022, the Company has a legal accrual of $125,255 recorded to cover the legal expenses of the former executives of KBL.

On October 5, 2021, Dr. Krauss and the KBL Affiliates filed an Answer, Counterclaims and Third-Party Complaint (the "Krauss Counterclaims") against the Company and twelve individuals who are, or were, directors and/or officers of the Company, i.e., Marc Feldmann, Lawrence Steinman, James N. Woody, Teresa DeLuca, Frank Knuettel II, Pamela Marrone, Lawrence Gold, Donald A. McGovern, Jr., Russell T. Ray, Richard W. Barker, Shoshana Shendelman and Ozan Pamir (collectively, the "Third-Party Defendants"). On October 27, 2021, the Company and Ozan Pamir filed an Answer to the Krauss Counterclaims, and all of the other Third-Party Defendants filed a Motion to Dismiss as to the Third-Party Complaint.

On January 28, 2022, in lieu of filing an opposition to the Motion to Dismiss, Dr. Krauss and the KBL Affiliates filed a Motion for leave to file amended counterclaims and third-party complaint, and to dismiss six of the current and former directors previously named, i.e., to dismiss Teresa DeLuca, Frank Knuettel II, Pamela Marrone, Russell T. Ray, Richard W. Barker and Shoshana Shendelman. The Motion was granted by stipulation and, on February 24, 2022, Dr. Krauss filed an amended Answer, Counterclaims and Third-Party Complaint (the "Amended Counterclaims"). In essence, the Amended Counterclaims allege (a) that the Company and the remaining Third-Party Defendants breached fiduciary duties to Dr. Krauss by making alleged misstatements against Dr. Krauss in SEC filings and failing to register her shares in the Company so that they could be traded, and (b) the Company breached contracts between the Company and Dr. Krauss for registration of such shares, and also failed to pay to Dr. Krauss the amounts alleged to be owing under a promissory note in the principal amount of $371,178, plus an additional $300,000 under Dr. Krauss's resignation agreement. The Amended Counterclaims seek unspecified amounts of monetary damages, declaratory relief, equitable and injunctive relief, and attorney's fees and costs.

On March 16, 2022, Donald A. McGovern, Jr. and Lawrence Gold filed a Motion to Dismiss the Amended Counterclaims against them, and the Company and the remaining Third-Party Defendants filed an Answer to the Amended Counterclaims denying the same. On April 19, 2022, Dr. Krauss stipulated to dismiss all of her counterclaims and allegations against both Donald A. McGovern, Jr. and Lawrence Gold, thereby mooting their Motion to Dismiss the Amended Counterclaims against them. The Company and the Third-Party Defendants intend to continue to vigorously defend against all of the Amended Counterclaims, however, there can be no assurance that they will be successful in the legal defense of such Amended Counterclaims. In April 2022, Donald A. McGovern, Jr. and Lawrence Gold were dismissed from the lawsuit as parties. Discovery has not yet commenced in the case. The Company and the Third-Party Defendants intend to continue to vigorously defend against all of the Amended Counterclaims, however, there can be no assurance that they will be successful in the legal defense of such Amended Counterclaims.

Action Against the Company by Dr. Krauss

On August 19, 2021, Dr. Krauss initiated legal action in the Chancery Court of Delaware against the Company. The original Complaint sought expedited relief and made the following two claims: (1) it alleged that the Company is obligated to advance expenses including, attorney's fees, to Dr. Krauss for the costs of defending against the SEC and certain Subpoenas served by the SEC on Dr. Krauss; and (2) it alleged that the Company is also required to reimburse Dr. Krauss for the costs of bringing this lawsuit against the Company. On or about September 3, 2021, Dr. Krauss filed an Amended and Supplemental Complaint (the "Amended Complaint") in this action, which added the further claims that Dr. Krauss is also allegedly entitled to advancement by the Company of her expenses, including attorney's fees, for the costs of defending against the Third-Party Complaint in the Tyche Capital LLC action referenced below, and the costs of defending against the Company's own Complaint against Dr. Krauss as described above. On or about September 23, 2021, the Company filed its Answer to the Amended Complaint in which the Company denied each of Dr. Krauss' claims and further raised numerous affirmative defenses with respect thereto.

On November 15, 2021, Dr. Krauss filed a Motion for Summary Adjudication as to certain of the issues in the case, which was opposed by the Company. A hearing on such Motion was held on December 7, 2021, and, on March 7, 2022, the Court issued a decision in the matter denying the Motion for Summary Adjudication in part and granting it in part. The Court then issued an Order implementing such a decision on March 29, 2022. The parties are now engaging in proceedings set forth in that implementing Order. The Court granted Dr. Krauss's request for advancement of some of the legal fees which Dr. Krauss requested in her Motion, and the Company was required to pay a portion of those fees while it objects to the remaining portion of disputed fees. These legal fees have been accrued on the Company's balance sheet.

On October 10, 2022, Dr. Krauss filed an Application to compel the Company to pay the full amount of fees requested by Dr. Krauss for May-July 2022, and to modify the Court's Order. The Company filed its Opposition thereto. On January 18, 2023, Dr. Krauss filed a Second Application to compel the Company to pay the full amount of fees requested by Dr. Krauss for August-October 2022, and to modify the Court's Order. The Company filed its Opposition thereto. On March 13, 2023, the Court telephonically informed the attorneys for the parties that it intended to grant both of Dr. Krauss' Applications; however, to date, the Court has not yet issued such ruling. Notwithstanding such apparent decision and any requirement therein by the Court for the Company to advance attorneys' fees to Dr. Krauss, such a ruling will not constitute any final adjudication as to whether Dr. Krauss will ultimately be entitled to permanently retain such advancements. The Company is seeking payment for a substantial portion of such amounts from its director and officers' insurance policy, of which no assurance can be provided that the directors and officers insurance policy will cover such amounts. See "*Declaratory Relief Action Against the Company by AmTrust International"* below.

Action Against Tyche Capital LLC

The Company commenced and filed an action against defendant Tyche Capital LLC ("Tyche") in the Supreme Court of New York, in the County of New York, on April 15, 2021. In its Complaint, the Company alleged claims against Tyche arising out of Tyche's breach of its written contractual obligations to the Company as set forth in a "Guarantee And Commitment Agreement" dated July 25, 2019, and a "Term Sheet For KBL Business Combination With CannBioRex" dated April 10, 2019 (collectively, the "Subject Guarantee"). The Company alleges in its Complaint that, notwithstanding demand having been made on Tyche to perform its obligations under the Subject Guarantee, Tyche has failed and refused to do so, and is currently in debt to the Company for such failure in the amount of $6,776,686, together with interest accruing thereon at the rate set forth in the Subject Guarantee.

On or about May 17, 2021, Tyche responded to the Company's Complaint by filing an Answer and Counterclaims against the Company alleging that it was the Company, rather than Tyche, that had breached the Subject Guarantee. Tyche also filed a Third-Party Complaint against six third-party defendants, including three members of the Company's management, Sir Marc Feldmann, Dr. James Woody, and Ozan Pamir (collectively, the "Individual Company Defendants"), claiming that they allegedly breached fiduciary duties to Tyche with regards to the Subject Guarantee. In that regard, on June 25, 2021, each of the Individual Company Defendants filed a Motion to Dismiss Tyche's Third-Party Complaint against them.

On November 23, 2021, the Court granted the Company's request to issue an Order of attachment against all of Tyche's shares of the Company's stock that had been held in escrow. In so doing, the Court found that the Company had demonstrated a likelihood of success on the merits of the case based on the facts alleged in the Company's Complaint.

On February 18, 2022, Tyche filed an Amended Answer, Counterclaims and Third-Party Complaint. On March 22, 2022, the Company and each of the Individual Company Defendants filed a Motion to Dismiss all of Tyche's claims. A hearing on such Motion to Dismiss was held on August 25, 2022, and the Court granted the Motion to Dismiss entirely as to each of the Individual Company Defendants, and also as to three of the four Counterclaims brought against the Company, only leaving Tyche's declaratory relief claim. On September 9, 2022, Tyche filed a Notice of Appeal as to the Court's decision, which has not yet been briefed or adjudicated. On August 26, 2022, Tyche filed a Motion to vacate or modify the Company's existing attachment Order against Tyche's shares of the Company's stock held in escrow. The Company has filed its Opposition thereto, and the Court summarily denied such Motion without hearing on January 3, 2023. Tyche subsequently filed a Notice of Appeal as to that denial and filed its Opening Brief on January 30, 2023. The Company filed its opposition brief on March 2, 2023, and no hearing date has been set.

On January 30, 2023, the Company filed a Notice of Motion for Summary Judgment and to Dismiss Affirmative Defenses against Tyche. Tyche has recently filed its Opposition, and the Company will now file a reply. No hearing has yet been set on this matter. The Company and the Individual Company Defendants intend to continue to vigorously defend against all of Tyche's claims, however, there can be no assurance that they will be successful in the legal defense of such claims. Written discovery proceedings and depositions have occurred among the parties.

Action Against Ronald Bauer & Samantha Bauer

The Company and two of its wholly-owned subsidiaries, Katexco Pharmaceuticals Corp. and CannBioRex Pharmaceuticals Corp. (collectively, the "Company Plaintiffs"), initiated legal action against Ronald Bauer and Samantha Bauer, as well as two of their companies, Theseus Capital Ltd. and Astatine Capital Ltd. (collectively, the "Bauer Defendants"), in the Supreme Court of British Columbia on February 25, 2022. The Company Plaintiffs are seeking damages against the Bauer Defendants for misappropriated funds and stock shares, unauthorized stock sales, and improper travel expenses, in the combined sum of at least $4,395,000 CAD [$3,178,025 USD] plus the additional sum of $2,721,036 USD. The Bauer Defendants filed an answer to the Company Plaintiffs' claims on May 6, 2022. There can be no assurance that the Company Plaintiffs will be successful in this legal action.

Declaratory Relief Action Against the Company by AmTrust International

On June 29, 2022, AmTrust International Underwriters DAC ("AmTrust"), which was the premerger directors' and officers' insurance policy underwriter for KBL, filed a declaratory relief action against the Company in the U.S. District Court for the Northern District of California (the "Declaratory Relief Action") seeking declaration of AmTrust's obligations under the directors' and officers' insurance policy. In the Declaratory Relief Action, AmTrust is claiming that as a result of the merger the Company is no longer the insured under the subject insurance policy, notwithstanding the fact that the fees which the Company seeks to recover from AmTrust relate to matters occurring prior to the merger.

On September 20, 2022, the Company filed its Answer and Counterclaims against AmTrust for bad faith breach of AmTrust's insurance coverage obligations to the Company under the subject directors' and officers' insurance policy, and seeking damages of at least $2 million in compensatory damages, together with applicable punitive damages. In addition, the Company brought a Third-Party Complaint against its excess insurance carrier, Freedom Specialty Insurance Company ("Freedom") seeking declaratory relief that Freedom will also be required to honor its policy coverage as soon as the amount of AmTrust's insurance coverage obligations to the Company have been exhausted. On October 25, 2022, AmTrust filed its Answer to the Company's Counterclaims and, on October 27, 2022, Freedom filed its Answer to the Third-Party Complaint.

On November 22, 2022, the Company filed a Motion for Summary Adjudication against both AmTrust and Freedom. The Motion was fully briefed and a hearing was held on March 9, 2023. The Court took the matter under submission and has not yet issued a ruling. While the Company believes it has a strong case against AmTrust, there can be no assurance that the Company will prevail in this action.

Yissum Research and License Agreement

On May 13, 2018, CBR Pharma entered into a worldwide research and license agreement with Yissum Research Development Company of the Hebrew University of Jerusalem, Ltd. ("Yissum Agreement") allowing CBR Pharma to utilize certain patent (the "Licensed Patents"). The Licensed Patents shall expire, if not earlier terminated pursuant to the provisions of the Yissum Agreement, on a country-by-country, product-by-product basis, upon the later of: (i) the date of expiration in such country of the last to expire Licensed Patent included in the Licensed Technology; (ii) the date of expiration of any exclusivity on the product granted by a regulatory or government body in such country; or (iii) the end of a period of twenty (20) years from the date of the First Commercial Sale in such country. Should the periods referred to in items (i) or (ii) above expire in a particular country prior to the period referred to in item (iii), above, the license in that country or those countries shall be deemed a license to the Know-How during such post-expiration period.

Royalties will be payable to Yissum if sales of any products which use, exploit or incorporate technology covered by the Licensed Patents ("Net Sales") are US $500,000,000 or greater, calculated at 3% for the first annual $500,000,000 of Net Sales and at 5% of Net Sales thereafter.

Pursuant to the Yissum Agreement, if Yissum achieves the following milestones, CBR Pharma will be obligated to make the following payments:

i) $75,000 for successful point of care in animals;

ii) $75,000 for submission of the first investigational new drug testing;

iii) $100,000 for commencement of one phase I/II trial;

iv) $150,000 for commencement of one phase III trial;

v) $100,000 for each product market authorization/clearance (maximum of $500,000); and

vi) $250,000 for every $250,000,000 in accumulated sales of the product until $1,000,000,000 in sales is achieved.

In the event of an exit event ("Event"), which may be defined as either, a transaction or series of transactions under which the receipt of any consideration, monetary or otherwise by the Company or its shareholders is received in consideration for the sale of shares of the Company or shareholders, or an initial public offering ("IPO") of the Company, but for greater certainty excludes a reorganization of the Company where the ultimate equity holders of the reorganized entity remain substantially the same as that of the Company, the Company will issue 5% of the issued and outstanding shares, on a fully diluted basis, to Yissum prior to the closing of an Event. These shares will be subject to: (a) as to half of such shares, a lock-up period ending 12 months from the Event date and as to the other half of such shares, a lock-up period ending 24 months from the Event date, and (b) in any event, any resale restrictions (including lock-ups and hold periods). See Note 12 – Stockholders' Equity for more information on the shares issued to Yissum as part of the business combination.

CBR Pharma is also party to consulting agreements with Yissum, whereby Yissum has agreed to provide two of its employees as consultants to the Company for $100,000 per annum per person for a term of three years, commencing May 13, 2018. As of December 31, 2022, these consulting agreements have not been renewed.

On January 1, 2020, CBR Pharma entered into a first amendment to the Yissum Agreement ("First Amendment") with Yissum, allowing CBR Pharma to sponsor additional research performed by two Yissum professors. Pursuant to the terms of the First Amendment, the Company will pay Yissum $200,000 per year plus 35% additional for University overhead for the additional research performed by each professor over an 18-month period, starting May 1, 2019. As of December 31, 2021, the Company owes no outstanding balance in connection with the Yissum Agreement (as amended). During the years ended December 31, 2022 and 2021, the Company recognized research and development expenses of $0 and $443,151, respectively, related to this agreement.

Additional Yissum Agreement

On November 11, 2019 (the "Effective Date"), CBR Pharma entered into a new worldwide research and license agreement with Yissum (the "Additional Yissum Agreement"), allowing CBR Pharma to obtain a license and perform the research, development and commercialization of the licensed patents (the "Licensed Patents") in the research of cannabinoid salts relating to arthritis and pain management. Within 60 days after the end of the first anniversary of the Effective Date, Yissum will present the Company with a detailed written report summarizing the results of their research.

The Licensed Patents shall expire, if not earlier terminated pursuant to the provisions of the Additional Yissum Agreement, on a country-by-country, product-by-product basis, upon the later of: (i) the date of expiration in such country of the last to expire Licensed Patent included in the Licensed Technology; (ii) the date of expiration of any exclusivity on the product granted by a regulatory or government body in such country; or (iii) the end of a period of twenty (20) years from the date of the first commercial sale in such country. Should the periods referred to in items (i) or (ii) above expire in a particular country prior to the period referred to in item (iii), above, the license in that country or those countries shall be deemed a license to the know-how during such post-expiration period.

Pursuant to the terms of the Additional Yissum Agreement, CBR Pharma paid Yissum a non-refundable license fee of $70,000 and will pay an aggregate of $398,250 of research, development and consulting fees over the term of the Additional Yissum Agreement, as well as an annual license maintenance fee of $25,000, beginning on the first anniversary of the Effective Date.

The Company shall pay Yissum the following amounts in connection with the achievement of the following milestones:

- Submission of the first Investigational New Drug application: $75,000
- Dosing of first patient in phase II trial: $100,000
- Dosing of first patient in phase Ill trial: $150,000
- Upon first market authorization/clearance: $150,000
- Upon second market authorization/clearance: $75,000
- For every $250,000,000.00 US in accumulated Net Sales of the Product until $1,000,000,000.00 US in sales: $250,000

Upon the commercialization of the license, the Company shall pay Yissum a royalty equal to 3% of the first aggregate $500,000,000 of annual net sales and 5% thereafter. As of December 31, 2022 and 2021, the Company had no balances in either accounts payable and accrued expenses, respectively, relating to the Additional Yissum Agreement. During the years ended December 31, 2022 and 2021, the Company recorded $0 and $246,753, respectively, of research and development expenses.

Stanford License Agreement

On May 8, 2018, Katexco entered into a six-month option agreement (the "Stanford Option") with Stanford University ("Stanford") under which Stanford granted the Company a six-month option to acquire an exclusive license for patents (the "Licensed Patents") which are related to biological substances used to treat auto- immune diseases. In consideration for the Stanford Option, the Company paid Stanford $10,000 (the "Option Payment"), which was creditable against the first anniversary license maintenance fee payment.

On July 25, 2018, Katexco exercised their six-month option and entered into an exclusive license agreement (the "Stanford License Agreement") with Stanford. Pursuant to the Stanford License Agreement, beginning upon the first anniversary of the effective date, and each anniversary thereafter, the Company will pay Stanford, in advance, a yearly license maintenance fee of $20,000, on each of the first and second anniversaries and $40,000 on each subsequent anniversary, which will be expensed on a straight-line basis annually.

Furthermore, the Company will be obligated to make the following milestone payments:

i) $100,000 upon initiation of Phase II trial,

ii) $500,000 upon the first U.S. Food and Drug Administration approval of a product (the "Licensed Product") resulting from the Licensed Patents; and

iii) $250,000 upon each new Licensed Product thereafter.

The Stanford License Agreement is cancellable by the Company with 30 days' notice. Royalties, calculated at 2.5% of 95% of net product sales, will be payable to Stanford. Also, the Company will reimburse Stanford for patent expenses as per the agreement. The Company paid Stanford $20,000 for the annual license maintenance fee that was recorded to prepaid expenses and is being expensed on a straight-line basis over 12 months, which had a zero balance as of December 31, 2021. During the years ended December 31, 2022 and 2021, the Company recorded patent and license fees of $69,278 and $78,245, respectively, related to the Stanford License Agreement, which is included in general and administrative expenses on the accompanying statements of operations and comprehensive loss.

Oxford University Agreements

On September 18, 2020, CBR Pharma entered into a 3 year research and development agreement (the "3 Year Oxford Agreement") with Oxford to research and investigate the mechanisms underlying fibrosis in exchange for aggregate consideration of $1,085,738 (£795,468), of which $109,192 (£80,000) is to be paid 30 days after the project start date and the remaining amount is to be paid in four equal installments of $244,136 (£178,867) on the six month anniversary and each of the annual anniversaries of the project start date. The agreement can be terminated by either party upon written notice or if the Company remains in default on any payments due under this agreement for more than 30 days. During the year ended December 31, 2022 and 2021, the Company recognized $322,767 (£265,156) and $364,673 (£264,938), respectively, of research and development expenses in connection with the 3 Year Oxford Agreement.

On September 21, 2020, CBR Pharma entered into a 2 year research and development agreement (the "2 Year Oxford Agreement") with Oxford University for the clinical development of cannabinoid drugs for the treatment of inflammatory diseases in exchange for aggregate consideration of $625,124 (£458,000), of which $138,917 (£101,778) is to be paid 30 days after the project start date and the remaining amount is to be paid every 6 months after the project start date in 4 installments, whereby $138,917 (£101,778) is to be paid in the first 3 installments and $69,456 (£50,888) is to be paid as the final installment. The agreement can be terminated by either party upon written notice or if the Company remains in default on any payments due under this agreement for more than 30 days. During the years ended December 31, 2022 and 2021, the Company recognized $123,891 (£101,778) and $139,977 (£101,778) of research and development expenses, respectively, in connection with the 2 Year Oxford Agreement, which is reflected within accrued expenses on the accompanying consolidated balance sheet.

As of December 31, 2022 and 2021, the Company owed Oxford no monies for the 2-year agreement.

On May 24, 2021, the Company entered into a research agreement with the University of Oxford ("Oxford" and the "Fifth Oxford Agreement"), pursuant to which the Company will sponsor work at the University of Oxford to conduct a multi-center, randomized, double blind, parallel group, feasibility study of anti-TNF injection for the treatment of adults with frozen shoulder during the pain-predominant phase. As consideration, the Company agreed to make the following payments to Oxford:

Milestone	Amount Due (excluding VAT)	
Upon signing of the Fifth Oxford Agreement	£	70,546
6 months post signing of the Fifth Oxford Agreement	£	70,546
12 months post signing of the Fifth Oxford Agreement	£	70,546
24 months post signing of the Fifth Oxford Agreement	£	70,546

The Company paid the first milestone of $97,900 (£70,546) on September 3, 2021, which was due upon signing of the Fifth Oxford Agreement, which was recorded to prepaid expenses and will be amortized over the term of the agreement on a straight-line basis. During the years ended December 31, 2022 and 2021, the Company recorded $271,931 (£223,394) and $210,215 (£152,848), respectively, of research and development expenses and has prepaid balances of $14,233 (£11,756) and $80,852 (£58,788), respectively, related to the Fifth Oxford Agreement.

On November 2, 2021, the Company and Oxford University entered into a twenty-year licensed technology agreement of the HMGB1 molecule, which is related to tissue regeneration, whereby Oxford University agreed to license the technology to the Company for research, development and use of the licensed patents. The Company agreed to pay Oxford University for past patent costs $66,223 (£49,207), an initial License fee of $13,458 (£10,000), future royalties based on sales and milestones, and an annual maintenance fee of $4,037 (£3,000). The Company has the option to terminate the agreement after the third anniversary of the agreement. During the year ended December 31, 2022, the Company recorded $10,581 of research and development expenses related to this agreement.

Kennedy License Agreement

On September 27, 2019, 180 LP entered into a license agreement (the "Kennedy License Agreement") with the Kennedy Trust for Rheumatology Research ("Kennedy") exclusively in the U.S., Japan, United Kingdom and countries of the EU, for certain licensed patents (the "Kennedy Licensed Patents"), including the right to grant sublicenses, and the right to research, develop, sell or manufacture any pharmaceutical product (i) whose research, development, manufacture, use, importation or sale would infringe the Kennedy Licensed Patents absent the license granted under the Kennedy License Agreement or (ii) containing an antibody that is a fragment of or derived from an antibody whose research, development, manufacture, use, importation or sale would infringe the Kennedy Licensed Patents absent the license granted under the Kennedy License Agreement, for all human uses, including the diagnosis, prophylaxis and treatment of diseases and conditions.

As consideration for the grant of the Kennedy Licensed Patents, 180 LP paid Kennedy an upfront fee of GBP £60,000, (USD $74,000) on November 22, 2019, which was recognized as an intangible asset for the purchase of the licensed patents and is being amortized over the remaining life of the patents. 180 LP will also pay Kennedy royalties equal to (i) 1% of the net sales for the first annual GBP £1 million (USD $1,283,400) of net sales, and (ii) 2% of the net sales after the net sales are at or in excess of GBP £1 million, as well as 25% of all sublicense revenue, provided that the amount of such percentage of sublicense revenue based on amounts which constitute royalties shall not be less than 1% on the first cumulative GBP £1 million of net sales of the products sold by such sublicenses or their affiliates, and 2% on that portion of the cumulative net sales of the products sold by such sublicenses or their affiliates in excess of GBP £1 million.

The term of the royalties paid by the Company to Kennedy will expire on the later of (i) the last valid claim of a patent included in the Kennedy Licensed Patents which covers or claims the exploitation of a product in the applicable country; (ii) the expiration of regulatory exclusivity for the product in the country; or (iii) 10 years from the first commercial sale of the product in the country. The Kennedy License Agreement may be terminated without cause by providing a 90-day notice.

Petcanna Sub-License Agreement

On August 20, 2018, CBR Pharma entered into a sub-license agreement (the "Sub-License Agreement") with its wholly owned subsidiary, Petcanna Pharma Corp. ("Petcanna"), of which the Company's former Chief Financial Officer is a director. Petcanna is a private company with one common principal with the Company.

Pursuant to the terms of the Sub-license Agreement, the Company has granted a sub-license on the Licensed Patents to pursue development and commercialization for the treatment of any and all veterinary conditions. In consideration, Petcanna will (a) issue 450,000 common shares of its share capital (the "Petcanna Shares") 30 days after the effective date; and (b) pay royalties of 1% of net sales. The Company will be issued 85% and Yissum will be issued 15% of the 450,000 common shares of the Petcanna subsidiary. The Petcanna shares are deemed to be founders shares with no value. The Petcanna shares have not been issued as of December 31, 2022.

360 Life Sciences Corp. Agreement - Related Party (Acquisition of ReFormation Pharmaceuticals Corp.)

On July 1, 2020, the Company entered into an amended agreement with ReFormation Pharmaceuticals, Corp. ("ReFormation") and 360 Life Sciences Corp. ("360"), whereby 360 has entered into an agreement to acquire 100% ownership of ReFormation, on or before July 31, 2020 ("Closing Date"). The Company shares officers and directors with each of ReFormation and 360. Upon the Closing Date, 360 will make tranche payments in tranches to 180 LP in the aggregate amount of $300,000. The parties agree that the obligations will be paid by 360 to 180 LP by payments of $100,000 for every $1,000,000 raised through the financing activities of 360, up to a total of $300,000, however, not less than 10% of all net financing proceeds received by 360 shall be put towards the obligation to the Company until paid in full. This transaction closed on July 31, 2020.

On February 26, 2019, 180 LP entered into a one-year agreement (the "Pharmaceutical Agreement") with ReFormation, a related party that shares directors and officers of 180 LP, pursuant to which the ReFormation agreed to pay 180 LP $1.2 million for rights of first negotiation to provide for an acquisition of any arising intellectual property or an exclusive licensing, partnering, or collaboration transaction to use any arising intellectual property with respect to a contemplated research agreement between the Company and Oxford (see Oxford University Agreements, above), which was signed on March 22, 2019 and therefore is the start date of the project. Of the $1.2 million receivable from Reformation pursuant to the Pharmaceutical Agreement, $0.9 million was received by the Company on March 14, 2019 and the remaining $0.3 million will be received over the one-year term of the agreement.

180 LP is recognizing the income earned in connection with the Pharmaceutical Agreement on a straight-line basis over the term of the agreement. During the years ended December 31, 2022 and 2021, 180 LP recognized no income related to the Pharmaceutical Agreement, which is included in other income in the accompanying consolidated statement of operations and other comprehensive income loss. As of December 31, 2021, the Company charged the $300,000 receivable to bad debt expense.

Operating Leases

In February 2016, the FASB issued ASU 2016-02, *Leases,* and the related Accounting Standards Codification Topic 842, *Leases* ("ASC 842"). The new standard requires most leases to be recognized on the balance sheet as a right-of-use ("ROU") asset and a lease liability. The right-of-use asset is initially measured at the present value of amounts expected to be paid over the lease term. Recognition of the costs of these leases on the income statement will be disaggregated and recognized as both operating expense (for the amortization of the right-of-use asset) and interest expense (for the portion of the lease payment related to interest). This standard was adopted by the Company upon issuance.

In accordance with ASC 842, the Company can elect (by asset class) not to record on the balance sheet a lease whose term is 12 months or less and does not include a purchase option that the lessee is reasonably certain to exercise. If elected, the lease would be treated like an operating lease under previous GAAP; payments would be recognized on a straight-line basis over the lease term. When determining whether the lease qualifies for this election, the Company would include renewal options only if they are considered part of the lease term, i.e., those options the Company is reasonably certain to exercise. If the lease term increases to more than 12 months, or if it is reasonably certain the Company will exercise a purchase option, the Company would no longer be able to apply this practical expedient and would apply ASC 842 guidance.

With regards to the Company and its leases (of which it currently has none), the Company expects to use the practical expedient for short-term operating leases that are 12 months or less. This practical expedient has been elected as a package and will be applied consistently to all leases. Additionally, if the Company's leases are considered operating in nature and therefore not reflected on the balance sheet, the Company will recognize the short-term lease payments as rent/lease expense on a monthly basis on the income statement.

As of December 31, 2022 and 2021, the Company had no active leases and no lease or rent expense as of those dates.

Consulting Agreements

Nanchahal Consulting Agreement

On February 22, 2021, the Company entered into a consultancy agreement (as amended, the "Consulting Agreement") with a related party, Prof. Jagdeep Nanchahal (the "Consultant"). The Consulting Agreement was effective December 1, 2020.

Pursuant to the Consulting Agreement, the Company agreed to pay the Consultant 15,000 British Pounds (GBP) per month (approximately $20,800) during the term of the agreement, increasing to 23,000 GBP per month (approximately $32,000) on the date (a) of publication of the data from the phase 2b clinical trial for Dupuytren's Contracture (RIDD) and (b) the date that the Company has successfully raised over $15 million in capital. The Company also agreed to pay the Consultant the following bonus amounts:

- the sum of £100,000 (approximately $138,000) upon submission of the Dupuytren's Contracture clinical trial data for publication in a peer-reviewed journal ("Bonus 1");
- the sum of £434,673 GBP (approximately $605,000) ("Bonus 2"), which is earned and payable upon the Company raising a minimum of $15 million in additional funding, through the sale of debt or equity, after December 1, 2020 (the "Vesting Date"). Bonus 2 is payable within 30 days of the Vesting Date and shall not be accrued, due or payable prior to the Vesting Date. Bonus 2 is payable, at the election of the Consultant, at least 50% (fifty percent) in shares of the Company's common stock, at the lower of (i) $60.00 per share, or (ii) the trading price on the date of the grant, with the remainder paid in GBP;
- the sum of £5,000 (approximately $7,000) on enrollment of the first patient to the phase 2 frozen shoulder trial ("Bonus 3"); and
- the sum of £5,000 (approximately $7,000) for enrollment of the first patient to the phase 2 delirium/POCD trial ("Bonus 4").

The Consulting Agreement has an initial term of three years, and renews thereafter for additional three-year terms, until terminated as provided in the agreement. The Consulting Agreement can be terminated by either party with 12 months prior written notice (provided the Company's right to terminate the agreement may only be exercised if the Consultant fails to perform his required duties under the Consulting Agreement), or by the Company immediately under certain conditions specified in the Consulting Agreement if (a) the Consultant fails or neglects efficiently and diligently to perform the services required thereunder or is guilty of any breach of its or his obligations under the agreement (including any consent granted under it); (b) the Consultant is guilty of any fraud or dishonesty or acts in a manner (whether in the performance of the services or otherwise) which, in the reasonable opinion of the Company, has brought or is likely to bring the Consultant, the Company or any of its affiliates into disrepute or is convicted of an arrestable offence (other than a road traffic offence for which a non-custodial penalty is imposed); or (c) the Consultant becomes bankrupt or makes any arrangement or composition with his creditors. If the Consulting Agreement is terminated by the Company for any reason other than cause, the Consultant is entitled to a lump sum payment of 12 months of his fee as of the date of termination.

Effective March 30, 2021, in satisfaction of amounts owed to the Consultant for 50% of Bonus 2, the Company issued 5,035 shares of the Company's common stock to the Consultant. Additionally, on April 15, 2021, in satisfaction of amounts owed to the Consultant for an additional 19% of Bonus 2, the Company issued 1,886 of the Company's common stock to the Consultant.

Effective August 27, 2021, in satisfaction of amounts owed to the Consultant for the remainder of Bonus 2, the Company issued 3,077 shares of the Company's common stock to the Consultant since the Company raised $15 million in a financing transaction, as per the agreement. All issuances were made under the Company's 2020 Omnibus Incentive Plan. See Note 12 – Stockholders' Equity.

In December 2021, the Dupuytren's Contracture clinical trial data was submitted for publication in a peer-reviewed journal and Bonus 1 was paid to the Consultant.

On April 27, 2022, the Company entered into an Amendment to the Consulting Agreement, whereby upon acceptance of the data for the Phase 2b clinical trial for Dupuytren's Contracture for publication, the Consultant's monthly fee will increase to £23,000, provided that £4,000 of such increase will be accrued and £19,000 of such fees will be payable monthly per the payroll practices of the Company in cash effective March 1, 2022 and until the earlier of (a) November 1, 2022 or (b) the date upon which the Company has sufficient cash on hand to pay the accrued amount, which the Company expects will not be until it has raised a minimum of $15,000,000 (the "Funding Determination Date"), at which time the accrued amount will be due.

On December 28, 2022, the Company entered into an Amendment to the Consulting Agreement, whereby the Consultant's monthly fee will increase to £35,000 beginning on January 1, 2023 until the end of the term of the agreement; if the agreement is terminated by the Company for any reason other than cause, the consultant will be entitled to a lump sum payment of 12 months of his monthly fee as of the date of termination.

Larsen Consulting Agreements

On April 29, 2021, the Company entered into a consulting agreement with Glenn Larsen, the former Chief Executive Officer of 180 LP, to act in the capacity as negotiator for the licensing of four patents. In consideration for services provided, the Company agreed to compensate Mr. Larsen with $50,000 of its restricted common stock (valued based on the closing sales price of the Company's common stock on the date the Board of Directors approved the agreement, which shares have not been issued to date). The fully vested shares will be issued to Mr. Larsen pursuant to the 2020 Omnibus Incentive Plan, upon the Company entering into a licensing transaction with the assistance of Mr. Larsen. On November 2, 2021, the Company and Oxford University entered into a license agreement and therefore 272 shares were issued to Mr. Larsen on November 3, 2021 pursuant to the Company's 2020 Omnibus Incentive Plan.

On February 22, 2023, the Company entered into a second consulting agreement with Glenn Larsen to provide consulting services; in consideration for the services provided, the Company agreed to compensate Mr. Larsen in the amount of $10,000 per month; the amounts owed may be settled in cash or shares of the Company's common stock (which will be subject to the Company's 2022 Omnibus Incentive Plan or another approved equity compensation plan) or a combination of both at the option of Mr. Larsen. No shares may be issued and cash will be the default payment method for fees until an increase in shares available in the Plan is approved and any issuance is conditioned upon the Company having sufficient shares in the Plan to be issued. Mr. Larsen is also eligible to participate in the Company's stock option plan, subject to approval from the Board of Directors. The initial term of the agreement is for three years from the effective date of the contract and shall automatically extend for additional one-year periods. As of December 31, 2022, the Company has accrued a balance of $60,000 for consulting services payable to Mr. Larsen.

Steinman Consulting Agreement

On November 17, 2021, and effective on November 1, 2021, the Company entered into a Consulting Agreement with Lawrence Steinman, M.D., the Company's Executive Co-Chairman (the "Consulting Agreement"). Pursuant to the Consulting Agreement, Dr. Steinman agreed to provide certain consulting services to the Company, including, but not limited to, participating in defining and setting strategic objectives of the Company; actively seeking out acquisition and merger candidates; and having primary scientific responsibility for the Company's á7nAChR platform (collectively, the "Services"). The term of the agreement is for one year (the "Initial Term"); provided that the agreement automatically extends for additional one year periods after the Initial Term (each an "Automatic Renewal Term" and the Initial Term together with all Automatic Renewal Terms, if any, the "Term"), subject to the Renewal Requirements (described below), in the event that neither party provided the other written notice of their intent not to automatically extend the term of the agreement at least 30 days prior to the end of the Initial Term or any Automatic Renewal Term. The Term can only be extended for an Automatic Renewal Term, provided that (i) Dr. Steinman is re-elected to the Board of Directors (the "Board") at the Annual Meeting of Stockholders of the Company immediately preceding the date that such Automatic Renewal Term begins; (ii) the Board affirms his appointment as Co-Chairman for the applicable Automatic Renewal Term (or fails to appoint someone else as Co-Chairman prior to such applicable Automatic Renewal Term) and (iii) Dr. Steinman is continuing in his role of having the responsibility for the scientific development for the Company's á7nAChR platform (the "Renewal Requirements"). The Consulting Agreement also expires immediately upon the earlier of: (i) the date upon which Dr. Steinman no longer serves as Co-Chairman and no longer has primary scientific responsibility for our á7nAChR platform; and (ii) any earlier date requested by either (1) the Company (as evidenced by a vote of a majority of the Board (excluding Dr. Steinman) at a meeting of the Board), or (2) Dr. Steinman (as evidenced by written notice from Dr. Steinman to the Board). Additionally, the Company may terminate the Consulting Agreement immediately and without prior notice if Dr. Steinman is unable or refuses to perform the Services, and either party may terminate the Consulting Agreement immediately and without prior notice if the other party is in breach of any material provision of the Consulting Agreement.

The Company agreed to pay Dr. Steinman $225,000 per year during the term of the agreement, along with a one-time payment of $43,750, representing the difference between his old compensation and new compensation, dating back to April 1, 2021. Pursuant to the Consulting Agreement, Dr. Steinman agreed to not compete against the Company, unless approved in writing by the Board of Directors, during the term of the agreement, and also agreed to certain customary confidentiality provisions and assignment of inventions requirements. The Consulting Agreement also has a 12-month non-solicitation prohibition following its termination.

Employment Agreement of Chief Executive Officer

On February 25, 2021, the Company entered into an amended agreement with Dr. James Woody, the Chief Executive Officer of the Company (the "CEO") (the "A&R Agreement"), dated February 24, 2021, and effective November 6, 2020, which replaced the CEO's prior agreement with the Company. Pursuant to the A&R Agreement, the CEO agreed to serve as an officer of the Company for a term of three years, which is automatically renewable thereafter for additional one-year periods, unless either party provides the other at least 90 days written notice of their intent to not renew the agreement. The CEO's annual base salary under the agreement will initially be $450,000 per year, with automatic increases of 5% per annum.

As additional consideration for the CEO agreeing to enter into the agreement, the Company awarded him options to purchase 70,000 shares of the Company's common stock, which have a term of 10 years, and an exercise price of $88.60 per share (the closing sales price on the date the board of directors approved the grant (February 26, 2021)). The options as subject to the Company's 2020 Omnibus Incentive Plan and vest at the rate of (a) 1/5th of such options on the grant date; and (b) 4/5th of such options vesting ratably on a monthly basis over the following 36 months on the last day of each calendar month; provided, however, that such options vest immediately upon the CEO's death or disability, termination without cause or a termination by the CEO for good reason (as defined in the agreement), a change in control of the Company or upon a sale of the Company.

The CEO is also eligible to receive an annual bonus, with a target bonus equal to 45% of his then-current base salary, based upon the Company's achievement of performance and management objectives as set and approved by the Board of Directors and/or Compensation Committee in consultation with the CEO. At the CEO's option, the annual bonus can be paid in cash or the equivalent value of the Company's common stock or a combination. The Board of Directors, as recommended by the Compensation Committee, may also award the CEO bonuses from time to time (in stock, options, cash, or other forms of consideration) in its discretion. Under the A&R Agreement, the CEO is also eligible to participate in any stock option plans and receive other equity awards, as determined by the Board of Directors from time to time. As of December 31, 2022 and 2021, the Company had accrued bonus balances of $313,875 and $205,500, respectively, payable to the CEO.

The A&R agreement can be terminated any time by the Company for cause (subject to the cure provisions of the agreement), or without cause (with 60 days prior written notice to the CEO), by the CEO for good reason (as described in the agreement, and subject to the cure provisions of the agreement), or by the CEO without good reason. The agreement also expires automatically at the end of the initial term or any renewal term if either party provides notice of non-renewal as discussed above.

In the event the A&R Agreement is terminated without cause by the Company, or by the CEO for good reason, the Company agreed to pay him the lesser of 18 months of salary or the remaining term of the agreement, the payment of any accrued bonus from the prior year, his pro rata portion of any current year's bonus and health insurance premiums for the same period that he is to receive severance payments (as discussed above).

The A&R Agreement contains standard and customary invention assignment, indemnification, confidentiality and non-solicitation provisions, which remain in effect for a period of 24 months following the termination of his agreement.

On April 27, 2022, the Company entered into an Amendment to the Employment Agreement, whereby the Company will provide a 3% increase in salary and a 20% accrual of salary, until such time as the Board of Directors determines that the Funding Determination Date has occurred.

Employment Agreement of Chief Financial Officer

On February 25, 2021, the Company entered into an Employment Agreement (the "CFO Agreement") dated February 24, 2021, and effective November 6, 2020, with the Company's Interim Chief Financial Officer, Ozan Pamir. Pursuant to the agreement, the CFO agreed to serve as the Interim Chief Financial Officer ("CFO") of the Company for an initial salary of $300,000 per year, subject to increase to a mutually determined amount upon the closing of a new financing as well as annual increases.

As additional consideration for the CFO agreeing to enter into the agreement, the Company awarded him options to purchase 9,000 shares of the Company's common stock, which have a term of 10 years, and an exercise price of $88.60 per share (the closing sales price on the date the board of directors approved the grant (February 26, 2021)). The options are subject to the Company's 2020 Omnibus Incentive Plan and vest at the rate of (a) 1/5th of such options upon the grant date; and (b) 4/5th of such options vesting ratably on a monthly basis over the following 36 months on the last day of each calendar month; provided, however, that such options vest immediately upon the CFO's death or disability, termination without cause or a termination by the CFO for good reason (as defined in the agreement), a change in control of the Company or upon a sale of the Company.

Under the agreement, the CFO is eligible to receive an annual bonus, in a targeted amount of 30% of his then salary, based upon the Company's achievement of performance and management objectives as set and approved by the CEO, in consultation with the CFO. The bonus amount is subject to adjustment. The Board of Directors, as recommended by the Compensation Committee of the Company (and/or the Compensation Committee), may also award the CFO bonuses from time to time (in stock, options, cash, or other forms of consideration) in its discretion. Under the CFO Agreement, the CFO is also eligible to participate in any stock option plans and receive other equity awards, as determined by the Board of Directors from time to time. As of December 30, 2022 and 2021, the Company had accrued bonus balances of $139,500 and $90,000, respectively, payable to the CFO.

The agreement can be terminated any time by the Company with or without cause with 60 days prior written notice and may be terminated by the CFO at any time with 60 days prior written notice. The agreement may also be terminated by the Company with six days' notice in the event the agreement is terminated for cause under certain circumstances. Upon the termination of the CFO's agreement by the Company without cause or by the CFO for good reason, the Company agreed to pay him three months of severance pay.

The agreement contains standard and customary invention assignment, indemnification, confidentiality and non-solicitation provisions, which remain in effect for a period of 24 months following the termination of his agreement.

Employment Agreement of Chief Operating Officer/Chief Business Officer

On October 29, 2021, the Company entered into an Employment Agreement (the "COO/CBO Agreement") dated October 27, 2021, and effective November 1, 2021, with Quan Vu. Pursuant to the agreement, Mr. Vu agreed to serve as the Chief Operating Officer/Chief Business Officer ("COO/CBO") of the Company for an initial salary of $390,000 per year, subject to a $10,000 increase upon completion of a $50 Million financing and a yearly increase of five percent (5%) on each start-day anniversary.

As additional consideration for the COO/CBO agreeing to enter into the agreement, the Company awarded him options to purchase 13,750 shares of the Company's common stock, which have a term of 10 years, and an exercise price of $79.00 per share. The options are subject to the Company's 2020 Omnibus Incentive Plan and vest ratably on a monthly basis over the following 48 months on the last day of each calendar month; provided, however, that such options vest immediately upon the COO/CBO death or disability, termination without cause or a termination by the COO/CBO for good reason (as defined in the agreement), a change in control of the Company or upon a sale of the Company.

Under the agreement, the COO/CBO is eligible to receive an annual bonus, in a targeted amount of 50% of his then salary, based upon the Company's achievement of performance and management objectives as set and approved by the CEO, in consultation with the CFO. The annual bonus shall be paid on or before March 31 of the year following the year in which the bonus is earned. At the choice of the Executive, the annual bonus can be paid in cash or the equivalent value of the Company's common stock or a combination of both. For calendar 2021, such Bonus payment, if any, will be prorated for approximately 2 months after the Start Date. The CEO, as approved by the Compensation Committee, may also award the Executive a bonus from time to time (in stock, options, cash, or other forms of consideration) in his discretion.

The agreement can be terminated any time by the Company with or without cause with 30 days prior written notice and may be terminated by the COO/CBO at any time with 30 days prior written notice. The agreement may also be terminated by the Company with ten days' notice in the event the agreement is terminated for cause under certain circumstances. Upon the termination of the COO/CBO's agreement by the Company without cause or by the COO/CBO for good reason, the Company agreed to pay him twelve months of severance pay, except if Executive separates from the Company prior to a one-year anniversary.

The agreement contains standard and customary invention assignment, indemnification, confidentiality and non-solicitation provisions, which remain in effect for a period of 24 months following the termination of his agreement.

On April 27, 2022, the Company entered into an Amendment to the Employment Agreement, whereby the Company will provide a 3% increase in salary and a 20% accrual of salary, until such time as the Board of Directors determines that the Funding Determination Date has occurred. As of December 31, 2022, the Company had an accrued bonus balance of $221,000 payable to the COO/CBO. In January 2023, Mr. Vu's services with the Company and the agreement were terminated. See Note 15 – Subsequent Events for additional information.

NOTE 12 - STOCKHOLDERS' EQUITY

Reverse Stock-Split during 2022

On December 15, 2022, at a Special Meeting of the Stockholders of 180 Life Sciences Corp., the stockholders of the Company approved an amendment to the Company's Second Amended and Restated Certificate of Incorporation, as amended, to effect a reverse stock split of our issued and outstanding shares of our common stock, par value $0.0001 per share, by a ratio of between one-for-four to one-for-twenty, inclusive, with the exact ratio to be set at a whole number to be determined by our Board of Directors or a duly authorized committee thereof in its discretion, at any time after approval of the amendment and prior to December 15, 2023 (the "Stockholder Authority"). On December 15, 2022, the Company's Board of Directors (the "Board"), with the Stockholder Authority, approved an amendment to our Second Amended and Restated Certificate of Incorporation to affect a reverse stock split of our common stock at a ratio of 1-for-20 (the "Reverse Stock Split"). Pursuant to the Certificate of Amendment filed to affect the Reverse Stock Split, the Reverse Stock Split was effective on December 19, 2022 and the shares of the Company's common stock began trading on the NASDAQ Capital Market ("NASDAQ") on a post-split basis on December 19, 2022, with new CUSIP number: 68236V203. No change was made to the trading symbol for the Company's shares of common stock or public warrants, "ATNF" and "ATNFW", respectively, in connection with the Reverse Stock Split.

Because the Certificate of Amendment did not reduce the number of authorized shares of common stock, the effect of the Reverse Stock Split was to increase the number of shares of common stock available for issuance relative to the number of shares issued and outstanding. The Reverse Stock Split did not alter the par value of the common stock or modify any voting rights or other terms of the common stock. Any fractional shares remaining after the Reverse Stock Split will be rounded up to the nearest whole share.

With regards to the Company's 2020 Omnibus Incentive Plan and the 2022 Omnibus Incentive Plan, the Company's Compensation Committee and Board deem it in the best interests of the Company and its stockholders to (i) adjust the number of shares of Company common stock available for issuance under the Incentive Plans downward by a factor of 20 (with any fractional shares rounded down to the nearest whole share); (ii) reduce the number of shares of common stock issuable upon each outstanding option to purchase shares of common stock of the Company, and all other outstanding awards, by a factor of 20 (with any fractional shares rounded down to the nearest whole share); and (iii) adjust the exercise price of any outstanding options to purchase shares of common stock previously granted under the Incentive Plans up by a factor of 20 (rounded up to the nearest whole cent), in each case to adjust equitably for the Exchange Ratio of the Reverse Stock Split, which such adjustments effective automatically upon effectiveness of the Reverse Stock Split. The effects of the one-for-twenty reverse stock split have been retroactively reflected throughout the financial statements and notes to the financial statements.

Preferred Stock

Pursuant to the Company's Second Amended and Restated Certificate of Incorporation filed on November 6, 2020, the Company has 5,000,000 preferred shares authorized at a par value of $0.0001 per share, of which 1,000,000 shares are designated as Series A Convertible Preferred Stock ("Series A Preferred"), 1 share is designated as the Class K Special Voting Share and 1 share is designated as the Class C Special Voting Share. The Class K Special Voting Share and the Class C Special Voting Share are together, the "Special Voting Shares" (see Item 5 – Special Voting Shares). As of December 31, 2022, there is no Series A Preferred issued or outstanding; there is one Class K Special Voting Share and one Class C special Voting Share issued and outstanding.

Common Stock

The Company is authorized to issue 100,000,000 shares of the Company's common stock with a par value of $0.0001 per share. Holders of the Company's shares of the Company's common stock are entitled to one vote for each share.

Sale of Common Stock and Warrants in the February 2021 Private Offering

On February 19, 2021, the Company entered into a Securities Purchase Agreement with certain purchasers (the "Purchasers"), pursuant to which the Company agreed to sell an aggregate of 128,200 shares of common stock (the "PIPE Shares") and warrants to purchase up to an aggregate of 128,200 shares of common stock (the "PIPE Warrants"), at a combined purchase price of $91.00 per share and PIPE Warrant (the "Offering"). Aggregate gross proceeds from the offering were approximately $11.7 million. Net proceeds to the Company from the offering, after deducting the placement agent fees and estimated offering expenses payable by the Company, were approximately $10.7 million.

The PIPE Warrants have an exercise price equal to $100.00 per share, were immediately exercisable and are subject to customary anti-dilution adjustments for stock splits or dividends or other similar transactions. However, the exercise price of the PIPE Warrants will not be subject to adjustment as a result of subsequent equity issuances at effective prices lower than the then-current exercise price. The PIPE Warrants are exercisable for 5 years following the closing date. The PIPE Warrants are subject to a provision prohibiting the exercise of such PIPE Warrants to the extent that, after giving effect to such exercise, the holder of such PIPE Warrant (together with the holder's affiliates, and any other persons acting as a group together with the holder or any of the holder's affiliates), would beneficially own in excess of 4.99% of the Company's outstanding common stock (which may be increased to 9.99% on a holder by holder basis, with 61 days prior written consent of the applicable holder). The PIPE Warrants were determined to be liability-classified (see Note 8, Derivative Liabilities). Of the $968,930 of placement agent fees and offering expenses, $364,812 was allocated to the PIPE Shares and $604,118 was allocated to the PIPE Warrant. Because the PIPE Warrants are liability classified, the $604,118 allocated to the warrants was immediately expensed.

In connection with the offering, the Company also entered into a Registration Rights Agreement, dated as of February 23, 2021, with the Purchasers (the "Registration Rights Agreement"). Pursuant to the Registration Rights Agreement, the Company agreed to file a registration statement with the SEC on or prior to April 24, 2021 to register the resale of the PIPE Shares and the shares of common stock issuable upon exercise of the PIPE Warrants (the "PIPE Warrant Shares"), and to cause such registration statement to be declared effective on or prior to June 23, 2021 (or, in the event of a "full review" by the SEC, August 22, 2021). The Company was in default of the terms of the Registration Rights Agreement as the registration statement to register the PIPE Shares and PIPE Warrant Shares was not filed by April 24, 2021; provided that such registration statement has since been filed. As a result of this default, the Company was required to pay damages to the Purchasers in the aggregate amount of $174,993 each month, up to a maximum of $583,310. The Company incurred $524,979 of damages during the year ended December 31, 2021, which amount was paid, and such registration statement was subsequently filed and declared effective, and as a result the Company is no longer in default.

Bridge Note Conversions

During the first quarter of 2021, certain noteholders elected to convert bridge notes with an aggregate principal balance of $365,750 and an aggregate accrued interest balance of $66,633 into an aggregate of 7,920 shares of the Company's common stock at a conversion price of $54.60 per share, pursuant to the terms of such notes (see Note 10 - Convertible Notes Payable).

Convertible Note Conversions

During the first quarter of 2021, certain noteholders elected to convert certain convertible notes payable with an aggregate principal balance of $1,234,333 and an aggregate accrued interest balance of $105,850 into an aggregate of 23,357 shares of the Company's common stock at conversion prices ranging from $49.00-$65.80 per share, pursuant to the terms of such notes (see Note 10 - Convertible Notes Payable).

EarlyBird Settlement

On April 23, 2021, the Company settled the amounts due pursuant to a certain finder agreement entered into with EarlyBird Capital, Inc. ("EarlyBird") on October 17, 2017 (the "Finder Agreement"). The Company's Board of Directors determined it was in the best interests to settle all claims which had been made or could be made with respect to the Finder Agreement and entered into a settlement agreement (the "Settlement Agreement"). Pursuant to the Settlement Agreement, the Company paid EarlyBird a cash payment of $275,000 and issued 11,250 shares of the Company's restricted common stock with a grant date value of $1,973,250 to EarlyBird, in full satisfaction of accounts payable in the amount of $1,750,000. The Company recorded a loss of $223,250 in connection with the Settlement Agreement, which is included in (loss) gain on settlement of liabilities in the accompanying consolidated statements of operations.

Sale of Common Stock and Warrants in the August 2021 Offering

On August 23, 2021, the Company entered into a Securities Purchase Agreement with certain purchasers, pursuant to which the Company agreed to sell an aggregate of 125,000 shares of common stock and warrants to purchase up to an aggregate of 125,000 shares of common stock (the "August 2021 PIPE Warrants"), at a combined purchase price of $120.00 per share and August 2021 PIPE Warrant (the "August 2021 Offering"). Aggregate gross proceeds from the August 2021 Offering were approximately $15,000,000. Net proceeds to the Company from the August 2021 Offering, after deducting the placement agent fees and estimated offering expenses payable by the Company, were approximately $13.9 million.

The August 2021 PIPE Warrants have an exercise price equal to $150.00 per share, are immediately exercisable and are subject to customary anti-dilution adjustments for stock splits or dividends or other similar transactions. However, the exercise price of the August 2021 PIPE Warrants will not be subject to adjustment as a result of subsequent equity issuances at effective prices lower than the then-current exercise price. The August 2021 PIPE Warrants are exercisable for 5 years following the closing date. The August 2021 PIPE Warrants are subject to a provision prohibiting the exercise of such August 2021 PIPE Warrants to the extent that, after giving effect to such exercise, the holder of such August 2021 PIPE Warrant (together with the holder's affiliates, and any other persons acting as a group together with the holder or any of the holder's affiliates), would beneficially own in excess of 4.99% of the Company's outstanding common stock (which may be increased to 9.99% on a holder by holder basis, with 61 days prior written consent of the applicable holder). Although the PIPE Warrants have a tender offer provision, the August 2021 PIPE Warrants were determined to be equity-classified because they met the limited exception in the case of a change-in-control. Because the August 2021 PIPE Warrants are equity-classified, the $1,120,000 of placement agent fees and offering expenses were fully accounted for as a reduction of additional paid in capital.

In connection with the August 2021 Offering, the Company also entered into a Registration Rights Agreement, dated as of August 23, 2021, with the purchasers (the "August 2021 Registration Rights Agreement"). Pursuant to the August 2021 Registration Rights Agreement, the Company agreed to file a registration statement with the SEC on or prior to September 12, 2021 to register the resale of the shares and the shares of common stock issuable upon exercise of the August 2021 PIPE Warrants (the "Warrant Shares") sold in the August 2021 Offering, and to cause such registration statement to be declared effective on or prior to October 22, 2021 (or, in the event of a "full review" by the SEC, November 21, 2021). The registration statement was filed on August 31, 2021 and the SEC declared it effective on September 9, 2021, prior to the deadline set forth in the August 2021 Registration Rights Agreement.

Exchanges of Related Party Loans and Convertible Notes

On September 30, 2021, Dr. Lawrence Steinman and Sir Marc Feldmann, Ph.D., each of whom serve as Co-Executive Chairmen of the Company's Board of Directors, agreed with the Company to convert amounts owed under outstanding loans with an aggregate principal balance of $693,371 and an aggregate accrued interest balance of $157,741 into an aggregate of 7,093 shares of the Company's common stock at the conversion price of $120.00 per share, pursuant to the terms of the agreement, which conversion rate was above the closing consolidated bid price of the Company's common stock on the date the binding agreement was entered into (see Note 9 - Loans Payable and Note 10 - Convertible Notes Payable for more information).

Alpha Capital Settlement

During the third quarter of 2021, the Company issued 7,500 shares of common stock and warrants to purchase 1,250 shares in connection with a settlement entered into with Alpha Capital (see Note 10 - Convertible Notes Payable).

Common Stock Issued for Services during 2021

During the year ended December 31, 2021, the Company issued an aggregate of 15,878 shares of the Company's common stock, respectively, as compensation to consultants, directors, and officers, with an aggregate issuance date fair value of $1,785,366, respectively, which was charged immediately to the consolidated statement of operations for the year ended December 31, 2021.

July 2022 Offering

On July 17, 2022, the Company entered into a Securities Purchase Agreement with certain purchasers, pursuant to which the Company agreed to sell an aggregate of 175,000 shares of common stock, pre-funded warrants to purchase up to an aggregate of 131,604 shares of common stock ("July 2022 Pre-Funded Warrants"), and common stock warrants to purchase up to an aggregate of 306,604 shares of common stock (the "July 2022 Common Warrants"), at a combined purchase price of $21.20 per share and warrant (the "July 2022 Offering"). Aggregate gross proceeds from the July 2022 Offering were $6,499,737. The July 2022 Offering closed on July 20, 2022.

The July 2022 Pre-Funded Warrants have an exercise price equal to $0.0001, are immediately exercisable and are subject to customary anti-dilution adjustments for stock splits or dividends or other similar transactions. The exercise price of the July 2022 Pre-Funded Warrants will not be subject to adjustment as a result of subsequent equity issuances at effective prices lower than the then-current exercise price. The July 2022 Pre-Funded Warrants are exercisable until they are exercised in full. The July 2022 Pre-Funded Warrants are subject to a provision prohibiting the exercise of such July 2022 Pre-Funded Warrants to the extent that, after giving effect to such exercise, the holder of such July 2022 Pre-Funded Warrants (together with the holder's affiliates, and any other persons acting as a group together with the holder or any of the holder's affiliates), would beneficially own in excess of 9.99% of the Company's outstanding common stock (which may be increased or decreased, with 61 days prior written notice by the holder). Although the July 2022 Pre-Funded Warrants have a tender offer provision, the July 2022 Pre-Funded Warrants were determined to be equity-classified because they met the limited exception in the case of a change-in-control. Because the July 2022 Pre-Funded Warrants are equity-classified, the placement agent fees and offering expenses will be accounted for as a reduction of additional paid in capital.

The July 2022 Common Warrants have an exercise price equal to $21.20 per share, are exercisable 6 months following the closing of the July 2022 Offering (the "Initial Exercise Date") and are subject to customary anti-dilution adjustments for stock splits or dividends or other similar transactions. The exercise price of the July 2022 Common Warrants will not be subject to adjustment as a result of subsequent equity issuances at effective prices lower than the then-current exercise price. The July 2022 Common Warrants are exercisable for 5 years following the Initial Exercise Date. The July 2022 Common Warrants are subject to a provision prohibiting the exercise of such July 2022 Common Warrants to the extent that, after giving effect to such exercise, the holder of such July 2022 Common Warrants (together with the holder's affiliates, and any other persons acting as a group together with the holder or any of the holder's affiliates), would beneficially own in excess of 4.99% of the Company's outstanding common stock (which may be increased or decreased, with 61 days prior written notice by the holder). Although the July 2022 Common Warrants have a tender offer provision, the July 2022 Common Warrants were determined to be equity-classified because they met the limited exception in the case of a change-in-control. Because the July 2022 Common Warrants are equity-classified, the placement agent fees and offering expenses will be accounted for as a reduction of additional paid in capital.

As of December 31, 2022, all 131,604 of the July 2022 Pre-Funded Warrants have been exercised for a value of $263; there are no unexercised July 2022 Pre-Funded Warrants remaining as of the end of the year. No July 2022 Common Warrants have been exercised as of December 31, 2022.

December 2022 Offering

On December 20, 2022, the Company entered into a Securities Purchase Agreement with certain purchasers, pursuant to which the Company agreed to sell an aggregate of 215,000 shares of common stock, pre-funded warrants to purchase up to an aggregate of 1,499,286 shares of common stock ("December 2022 Pre-Funded Warrants"), and common stock warrants to purchase up to an aggregate of 2,571,429 shares of common stock (the "December 2022 Common Warrants"), at a combined purchase price of $3.50 per share and warrant (the "December 2022 Offering"). Aggregate gross proceeds from the December 2022 Offering were approximately $6,000,000, and the December 2022 Offering closed on December 22, 2022.

The December 2022 Pre-Funded Warrants have an exercise price equal to $0.0001, are immediately exercisable and are subject to customary anti-dilution adjustments for stock splits or dividends or other similar transactions. The exercise price of the December 2022 Pre-Funded Warrants will not be subject to adjustment as a result of subsequent equity issuances at effective prices lower than the then-current exercise price. The December 2022 Pre-Funded Warrants are exercisable until they are exercised in full. The December 2022 Pre-Funded Warrants are subject to a provision prohibiting the exercise of such December 2022 Pre-Funded Warrants to the extent that, after giving effect to such exercise, the holder of such December 2022 Pre-Funded Warrants (together with the holder's affiliates, and any other persons acting as a group together with the holder or any of the holder's affiliates), would beneficially own in excess of 4.99% of the Company's outstanding common stock (which may be increased or decreased, with 61 days prior written notice by the holder). Although the December 2022 Pre-Funded Warrants have a tender offer provision, the December 2022 Pre-Funded Warrants were determined to be equity-classified because they met the limited exception in the case of a change-in-control. Because the December 2022 Pre-Funded Warrants are equity-classified, the placement agent fees and offering expenses will be accounted for as a reduction of additional paid in capital.

The December 2022 Common Warrants have an exercise price equal to $3.50 per share, are exercisable 6 months following the closing of the December 2022 Offering (the "Initial Exercise Date") (see Note 15 – Subsequent Events, "*Amendment to Common Warrant Agreement for the December 2022 Offering"*) and are subject to customary anti-dilution adjustments for stock splits or dividends or other similar transactions. The exercise price of the December 2022 Common Warrants will not be subject to adjustment as a result of subsequent equity issuances at effective prices lower than the then-current exercise price. The December 2022 Common Warrants are exercisable for 5 years following the Initial Exercise Date. The December 2022 Common Warrants are subject to a provision prohibiting the exercise of such December 2022 Common Warrants to the extent that, after giving effect to such exercise, the holder of such December 2022 Common Warrants (together with the holder's affiliates, and any other persons acting as a group together with the holder or any of the holder's affiliates), would beneficially own in excess of 4.99% of the Company's outstanding common stock (which may be increased or decreased, with 61 days prior written notice by the holder). Although the December 2022 Common Warrants have a tender offer provision, the December 2022 Common Warrants were determined to be equity-classified because they met the limited exception in the case of a change-in-control. Because the December 2022 Common Warrants are equity-classified, the placement agent fees and offering expenses will be accounted for as a reduction of additional paid in capital.

As of December 31, 2022, all 1,499,286 of the December 2022 Pre-Funded Warrants have been exercised for a value of $150; there are no unexercised December 2022 Pre-Funded Warrants remaining as of the end of the year. No December 2022 Common Warrants have been exercised as of December 31, 2022.

Common Stock Issued for Services during 2022

During the year ended December 31, 2022, the Company issued an aggregate of 14,026 of immediately vested shares of the Company's common stock as compensation to consultants, directors, and officers, with an aggregate issuance date fair value of $331,591, which was charged immediately to the consolidated statement of operations for the year ended December 31, 2022.

Restricted Stock Shares Issued during 2022

During the year ended December 31, 2022, the Company issued 600 restricted shares of the Company's common stock, or Restricted Stock Shares as compensation to consultants with an issuance date fair value $48,600, or $81.00 per share. Per the two-year consulting agreement, the Restricted Stock Shares are issued at the beginning of the contract term and annually and vest monthly over a period of 24 months. The Company recognized stock-based compensation expense related to the amortization of the Restricted Stock Shares of $26,325 for the year ended December 31, 2022.

Below is a table summarizing the Restricted Stock Shares granted and outstanding as of and for the year ended December 31, 2022:

	Unvested Restricted Stock	Weighted Average Grant Date FV Price
Unvested as of January 1, 2022	-	$ -
Granted	600	81.00
Vested	325	81.00
Unvested as of December 31, 2022	275	81.00
Total unrecognized expense remaining	$ 22,275	
Weighted-average years expected to be recognized over	1.0	-

Special Voting Shares

The Special Voting Shares were issued to the former shareholders of CBR Pharma and Katexco in connection with the reorganization of 180 prior to the Business Combination. The Special Voting Shares are exchangeable by the holder for shares of the Company's common stock and vote together as a single class with the Company's common stockholders. Special Voting Shares are not entitled to receive any dividend of distributions.

During the year ended December 31, 2022, no shares were issued upon the exchange of common stock equivalents associated with the Special Voting Shares.

During the year ended December 31, 2021, 73,224 shares were issued upon the exchange of common stock equivalents associated with the Special Voting Shares.

The following table summarizes the Special Voting Shares activity during the years ended December 31, 2022 and 2021:

Balance, January 1, 2021	73,488
Shares issued	-
Shares exchanged	(73,224)
Balance, December 31, 2021	264
Shares issued	-
Shares exchanged	-
Balance, December 31, 2022	264

Stock Options

A summary of the option activity during the years ended December 31, 2022 and 2021 is present below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Term (in Years)	Intrinsic Value
Outstanding, January 1, 2021	2,500	49.80	9.92	-
Granted	134,550	96.34	-	-
Exercised	-	-	-	-
Expired	-	-	-	-
Forfeited	-	-	-	-
Outstanding, December 31, 2021	137,050	95.49	9.41	3,525
Granted	25,906	27.20	-	-
Exercised	-	-	-	-
Expired	-	-	-	-
Forfeited	-	-	-	-
Outstanding, December 31, 2022	162,956	84.63	8.60	$ -
Exercisable, December 31, 2022	93,336	83.47	8.50	$ -

A summary of outstanding and exercisable stock options as of December 31, 2022 is presented below:

Stock Options Outstanding		Stock Options Exercisable	
Exercise Price	Number of Shares	Weighted Average Remaining Life in Years	Number of Shares
$ 49.80	2,500	7.9	2,500
$ 88.60	79,000	8.2	54,422
$ 151.20	21,800	8.6	7,721
$ 79.00	33,750	8.9	17,318
$ 27.20	25,906	9.4	11,375
	162,956	8.5	93,337

On February 26, 2021, the Company issued ten-year options to purchase an aggregate of 79,000 shares of the Company's common stock to two officers of the Company, pursuant to the 2020 Omnibus Incentive Plan. The options have an exercise price of $88.60 per share and vest at the rate of 20% on the date of grant and the remaining 80% on a monthly basis thereafter over the following 36 months. The options had a grant date fair value of $4,810,527, which will be recognized over the vesting term.

On August 4, 2021, the Company granted ten-year options for the purchase of an aggregate of 21,800 shares of common stock at an exercise price of $151.20 per share, to six independent directors of the Company, pursuant to the 2020 Omnibus Incentive Plan. The options had an aggregate grant date value of $2,180,375, and vest monthly over four years.

On December 8, 2021, the Company granted ten-year options for the purchase of an aggregate of 33,750 shares of common stock at an exercise price of $79.00 per share to six officers of the Company, pursuant to the 2020 Omnibus Incentive Plan. The options had an aggregate grant date value of $2,077,953 and vest at various periods over four years.

The assumptions used in the Black-Scholes valuation method for these options which were issued in 2021 were as follows:

Risk free interest rate	0.75% - 0.99%
Expected term (years)	5.62 - 6.01
Expected volatility	84% - 98.5%
Expected dividends	0%

These assumptions listed above for 2021and below for 2022 were derived using i) the risk free interest rate published by the federal reserve on the date of grant, ii) the expected term used is the average of the contractual term plus the weighted average vesting term, iii) the volatility was derived using rates from third-party valuation reports of other financial instruments for the applicable quarter and iv) the expected dividends rate used is taken from the applicable option award agreement.

On May 19, 2022, the Company granted ten-year options for the purchase of an aggregate of 5,700 shares of common stock at an exercise price of $27.20 per share to six officers of the Company, pursuant to the 2022 Omnibus Incentive Plan. The options had an aggregate grant date value of $115,936.

On May 19, 2022, the Company also granted ten-year options for the purchase of 6,707 shares and 13,500 shares of common stock at an exercise price of $27.20 per share to two individuals (one a director and the other, a consultant), respectively, pursuant to the 2022 Omnibus Incentive Plan; the 6,707 shares had a grant date value of $130,000 and vested immediately, while the 13,500 shares had a grant date value of $261,704 and vest depending on the achievement of certain milestones.

The assumptions used in the Black-Scholes valuation method for these options which were issued in 2022 were as follows:

Risk free interest rate	2.88%
Expected term (years)	5.00 – 5.77
Expected volatility	91.0%
Expected dividends	0%

The Company recognized stock-based compensation expense of $2,607,501 and $2,852,309 for the years ended December 31, 2022 and 2021, respectively, related to the amortization of stock options. The expense is included within general and administrative expenses or research and development expenses on the consolidated statements of operations. As of December 31, 2021, there was $4,202,495 of unrecognized stock-based compensation expense that will be recognized over the weighted average remaining vesting period of 2.19 years.

NASDAQ Compliance

On September 30, 2022, we received written notice (the "Notification Letter") from the Listing Qualifications Department of The NASDAQ Stock Market LLC ("NASDAQ") notifying the Company that it is not in compliance with the minimum bid price requirements set forth in NASDAQ Listing Rule 5550(a)(2) for continued listing on The NASDAQ Capital Market. NASDAQ Listing Rule 5550(a)(2) requires listed securities to maintain a minimum bid price of $1.00 per share, and Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum bid price requirement exists if the deficiency continues for a period of thirty (30) consecutive business days. Based on the closing bid price of the Company's common stock for the thirty (30) consecutive business days from August 18, 2022 to September 29, 2022, the Company no longer meets the minimum bid price requirement. The Notification Letter stated that the Company has 180 calendar days or until March 29, 2023, to regain compliance with NASDAQ Listing Rule 5550(a)(2). To regain compliance, the bid price of the Company's common stock must have a closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days. The Company implemented a reverse stock-split in December 2022 to assist in regaining compliance with NASDAQ standards. On January 4, 2023, NASDAQ notified the Company that it had regained full compliance with the minimum bid price for continued listing on the NASDAQ pursuant to NASDAQ Listing Rule 5550(a)(2).

NOTE 13 - INCOME TAXES

The Company is subject to federal and state/provincial income taxes in the United States, Canada, and the United Kingdom and each legal entity files on a non-consolidated basis. The benefit of the pre-reorganization net operating losses of 180 LP were passed through to its owners.

The losses before income taxes consist of the following domestic and international components:

	For the Years Ended December 31,	
	2022	**2022**
Domestic	$ (37,727,021)	$ (15,078,170)
International	(1,941,987)	(5,269,682)
	$ (39,669,008)	$ (20,347,852)

The provision for income taxes consists of the following benefits (provisions):

	For the Years Ended December 31,	
	2022	**2021**
Deferred tax benefits:		
Domestic:		
Federal	$ 4,057,936	$ 1,503,577
State	1,343,123	499,136
International	353,038	547,944
	5,754,097	2,550,657
Change in valuation allowance	(4,811,348)	(2,527,453)
Net income tax benefit	$ 942,749	$ 23,204

Certain deferred tax liabilities are denominated in currencies other than the US dollar and are subject to foreign currency translation adjustments. The provision for income taxes differs from the United States Federal statutory rate as follows:

	For the Years Ended December 31,	
	2022	2021
US Federal statutory rate	21.0%	21.0%
Difference between domestic and foreign federal rates	(0.1)%	(0.5)%
State and provincial taxes, net of federal benefits	6.6%	5.2%
Permanent differences:		
Goodwill impairment	(23.7)%	-
Stock-based compensation	-	(5.8)%
Change in the fair value of derivatives and accrued issuable equity	10.7%	(6.4)%
Other	-	(0.8)%
Change in valuation allowance	(12.1)%	(12.4)%
Effective income tax rate	2.4%	0.3%

Deferred tax assets and liabilities consist of the following:

	As of December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 13,399,384	$ 9,395,986
Amortization	165,476	-
Accrued compensation not currently deductible	343,787	169,222
Stock compensation	1,588,866	-
Accrued interest	150,502	146,636
Other	8,125	(1)
	15,656,140	9,711,843
Deferred tax liabilities:		
Difference between book and tax basis related to:		
Technology license	(368,587)	(375,671)
Acquired in-process research and development	(2,332,618)	(3,267,854)
Other	(555,880)	(639,726)
	(3,257,085)	(4,283,251)
Deferred tax assets and liabilities	12,399,055	5,428,592
Valuation allowance	(15,016,414)	(9,072,118)
Deferred tax assets and liabilities, net	$ (2,617,359)	$ (3,643,526)

The change in the valuation reserve for deferred tax assets consists of the following:

	For the Years Ended December 31,	
	2022	2021
Beginning of period	$ (9,072,118)	$ (9,709,220)
Change in valuation pursuant to the tax provision	(4,811,348)	(2,527,453)
True-up to a prior year's tax return	(1,132,948)	3,164,555
End of period	$ (15,016,414)	$ (9,072,118)

As of December 31, 2022, the Company had net operating loss ("NOL") carryforwards that may be available to offset future taxable income in various jurisdictions as follows:

- Approximately $32,400,000 of domestic federal and state NOLs. The federal NOLs have no expiration date and are subject to 80% of taxable income; the state NOLs will begin to expire in 2039;
- Approximately $8,100,000 each of Canadian federal and provincial NOLs. Those NOLs will begin to expire in 2038; and
- Approximately $10,600,000 of United Kingdom federal NOLs. Those NOLs have no expiration date.

The utilization of the domestic NOLs to offset future taxable income may be subject to annual limitations under Section 382 of the Internal Revenue Code and similar state statutes as a result of ownership changes.

The Company has assessed the likelihood that deferred tax assets will be realized in accordance with the provisions of ASC 740 *Income Taxes* ("ASC 740"). ASC 740 requires that such a review considers all available positive and negative evidence, including the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies. ASC 740 requires that a valuation allowance be established when it is "more likely than not" that all, or a portion of, deferred tax assets will not be realized. After the performance of such reviews as of December 31, 2022 and 2021, management believes that uncertainty exists with respect to future realization of its deferred tax assets and has, therefore, established a full valuation allowance. The Company recorded increases in the valuation allowance of $4,811,348 and $2,527,453 in connection with the tax provisions for the years ended December 31, 2022 and 2021, respectively.

Management has evaluated and concluded that there were no material uncertain tax positions requiring recognition in the Company's consolidated financial statements as of December 31, 2022 and 2021. The Company does not expect any significant changes in its unrecognized tax benefits within twelve months of the reporting date.

No tax audits were commenced or were in process during the years ended December 31, 2022 and 2021 nor were any tax related interest or penalties incurred during those periods. The Company's tax returns filed in the United States, Canada, and the United Kingdom since inception remain subject to examination.

NOTE 14 - RELATED PARTIES

Accrued Expenses - Related Parties

Accrued expenses - related parties was $188,159 as of December 31, 2022 and consists of interest accrued on loans and convertible notes due to certain officers and directors of the Company, as well as deferred compensation for certain executives. Accrued expenses - related parties was $18,370 as of December 31, 2021 and consists of interest accrued on loans and convertible notes due to certain officers and directors of the Company.

Loans Payable - Related Parties

Loans payable - related parties consists of $0 and $81,277 as of December 31, 2022 and 2021, respectively. See Note 9 - Loans Payable for more information.

Research and Development Expenses - Related Parties

Research and Development Expenses – Related Parties of $240,731 and $2,947,536 during the years ended December 31, 2022 and 2021, respectively, is related to consulting and professional fees paid to current or former officers, directors or greater than 10% investors, or affiliates thereof.

General and Administrative Expenses - Related Parties

General and Administrative Expenses – Related Parties during the years ended December 31, 2022 and 2021, were $5,612 and $462,580, respectively. Of the expenses incurred during 2022, these primarily relate to professional fees paid to current or former officers, directors or greater than 10% investors, or affiliates thereof. Of the expenses incurred during 2021, approximately $338,000 represents bad debt expense incurred in connection with a receivable from related parties, and approximately $124,000 represents professional fees paid to current or former officers, directors or greater than 10% investors, or affiliates thereof.

Interest Expense - Related Parties

During the year ended December 31, 2022, the Company recorded $1,508 of interest income – related parties, which related to interest expense on loans with officers and directors of the Company.

During the year ended December 31, 2021, the Company recorded $50,255 of interest expense – related parties, of which $11,380 related to the convertible notes with officers and directors of the Company and $38,875 related to interest expense on loans with officers, directors and a greater than 10% investor of the Company.

NOTE 15 - SUBSEQUENT EVENTS

The Company has evaluated events and transactions subsequent to December 31, 2022 through the date the financial statements were issued. Except for the following, there are no subsequent events identified that would require disclosure in the financial statements.

Compliance Notification from NASDAQ

On January 4, 2023, NASDAQ notified the Company that it had regained full compliance with the minimum bid price for continued listing on the Nasdaq pursuant to Nasdaq Listing Rule 5550(a)(2) (see Note 12 for further information.

Amendment to Common Warrant Agreement for the December 2022 Offering

On January 12, 2023, the Company entered into an Amendment to the Common Stock Purchase Warrant Agreement dated December 22, 2022, whereby the holder was issued warrants to purchase up to 2,571,429 shares of common stock at an exercise price of $3.50 per share. Per the Warrant Agreement, the initial exercise date was June 22, 2023; per the Amendment, the exercise date was changed to January 12, 2023.

Kinexum Agreement

On January 13, 2023, the Company entered into an agreement with Kinexum, which agreed to provide assistance to the Company in connection with the Conditional Marketing Authorization (CMA) and Marketing Approval Application (MAA) which the Company expects to submit to the UK Medicines and Healthcare products Regulatory Agency (MHRA) in connection with the Company's planned use of adalimumab to treat progressive early-stage Dupuytren's disease. Including the costs associated with the Kinexum contract, the Company anticipates that it will spend approximately $900,000 to $1,000,000, cumulative in the three quarters ending September 30, 2023 for activities associated with the MHRA filing and other regulatory preparation.

Quan Vu Separation

Effective January 15, 2023, the Company and Quan Vu (the Company's former Chief Operating Officer/Chief Business Officer) mutually agreed to terminate Vu's employment with 180LS. In accordance with the termination, the parties entered into a separation agreement, whereby the Company agreed to pay Vu an agreed-upon severance payment including accrued back-pay, agreed-upon health insurance expenses and accrued paid time-off for a total amount of $407,135.

Glenn Larsen Consulting Agreements

On February 22, 2023, the Company entered into a consulting agreement with Glenn Larsen to provide consulting services; in consideration for the services provided, the Company agrees to compensate Mr. Larsen in the amount of $10,000 per month; the amounts owed may be settled in cash or shares of the Company's common stock (which will be subject to the Company's 2022 Omnibus Incentive Plan ("Plan") or another approved equity compensation plan) or a combination of both at the option of Mr. Larsen. No shares may be issued and cash will be the default payment method for fees until an increase in shares available in the Plan is approved and any issuance is conditioned upon the Company having sufficient shares in the Plan to be issued. Mr. Larsen is also eligible to participate in the Company's stock option plan, subject to approval from the Board of Directors. The initial term of the agreement is for three years from the effective date of the contract and shall automatically extend for additional one-year periods.

Exhibit 4.6

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

General

180 Life Sciences Corp., *formerly* KBL Merger Corp. IV (the "Company" or "we") is incorporated in the state of Delaware. The rights of our stockholders are generally governed by Delaware law, our amended and restated Certificate of Incorporation and our Bylaws (each as amended and restated in effect as of the date hereof).

This exhibit describes the general terms of the following two classes of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock, par value $0.0001 per share and warrants exercisable for one-fortieth of one share of our common stock.

This exhibit is a summary and is not intended to be a complete description of the rights and preferences of such securities. The terms of these securities may also be affected by the Delaware General Corporation Law ("DGCL"). Our amended and restated Certificate of Incorporation and Bylaws are incorporated by reference or filed as an exhibit to the Annual Report on Form 10-K of which this exhibit is a part, and amendments or restatements of each will be filed with the Securities and Exchange Commission ("SEC") in future periodic or current reports in accordance with the rules of the SEC. The summary below is qualified in its entirety by reference to our amended and restated Certificate of Incorporation and Bylaws, which are filed as exhibits to our Annual Report on Form 10-K of which this exhibit is a part.

Authorized Capitalization

The total number of authorized shares of our common stock is 100,000,000 shares, $0.0001 par value per share. The total number of "blank check" authorized shares of our preferred stock is 5,000,000 shares, $0.0001 par value per share. There are no shares of preferred stock currently outstanding.

The terms of our preferred stock are not included herein as such preferred stock is not registered under Section 12 of the Exchange Act.

Common Stock

Voting Rights. Each share of our common stock is entitled to one vote on all stockholder matters. Shares of our common stock do not possess any cumulative voting rights.

Except for the election of directors, if a quorum is present, an action on a matter is approved if it receives the affirmative vote of the holders of a majority of the voting power of the shares of capital stock present in person or represented by proxy at the meeting and entitled to vote on the matter, unless otherwise required by applicable law, Delaware law, our Certificate of Incorporation, as amended or Bylaws, as amended. The election of directors will be determined by a plurality of the votes cast in respect of the shares present in person or represented by proxy at the meeting and entitled to vote, meaning that the nominees with the greatest number of votes cast, even if less than a majority, will be elected. The rights, preferences and privileges of holders of common stock are subject to, and may be impacted by, the rights of the holders of shares of any series of preferred stock that we have designated, or may designate and issue in the future.

Our board of directors is divided into two classes, each of which will generally serve for a term of two years with only one class of directors being elected in each year. There is no cumulative voting with respect to the election of directors, with the result that the holders of more than 50% of the shares voted for the election of directors can elect all of the directors.

Dividend Rights. Each share of our common stock is entitled to equal dividends and distributions per share with respect to the common stock when, as and if declared by our Board of Directors, subject to any preferential or other rights of any outstanding preferred stock.

Liquidation and Dissolution Rights. Upon liquidation, dissolution or winding up, our common stock will be entitled to receive pro rata on a share-for-share basis, the assets available for distribution to the stockholders after payment of liabilities and payment of preferential and other amounts, if any, payable on any outstanding preferred stock.

Fully Paid Status. All outstanding shares of the Company's common stock are validly issued, fully paid and non-assessable.

Listing. Our common stock is listed and traded on the NASDAQ Capital Market under the symbol "ATNF".

Other Matters. No holder of any shares of our common stock has a preemptive right to subscribe for any of our securities, nor are any shares of our common stock subject to redemption or convertible into other securities.

Dividends

We have not paid any cash dividends on our common stock to date and do not intend to pay cash dividends prior to the completion of a business combination. The payment of cash dividends in the future will be dependent upon our revenues and earnings, if any, capital requirements and general financial condition subsequent to completion of a business combination. The payment of any cash dividends subsequent to a business combination will be within the discretion of our board of directors at such time. In addition, our board of directors is not currently contemplating and does not anticipate declaring any stock dividends in the foreseeable future. Further, if we incur any indebtedness, our ability to declare dividends may be limited by restrictive covenants we may agree to in connection therewith.

Warrants

Each warrant entitles the registered holder to purchase one-fortieth of one share of our common stock at a price of $5.75 per $1/40^{th}$ of one share or $230 per whole share, subject to adjustment as discussed below, at any time commencing on December 6, 2020 (30 days after our initial business combination) and ending on November 6, 2025 (five years after our initial business combination), at 5:00 p.m., New York City time, or earlier upon redemption or liquidation. If a warrant holder holds 40 warrants, such warrants will be exercisable for one share of our common stock. No fractional shares will be issued upon exercise of the warrants and warrants must be exercised for whole shares only.

We will not be obligated to deliver any shares of common stock pursuant to the exercise of a warrant and will have no obligation to settle such warrant exercise unless a registration statement under the Securities Act with respect to the shares of common stock underlying the warrants is then effective and a prospectus relating thereto is current, subject to our satisfying our obligations described below with respect to registration. No warrant will be exercisable for cash or on a cashless basis, and we will not be obligated to issue any shares to holders seeking to exercise their warrants, unless the issuance of the shares upon such exercise is registered or qualified under the securities laws of the state of the exercising holder, unless an exemption is available. In the event that the conditions in the two immediately preceding sentences are not satisfied with respect to a warrant, the holder of such warrant will not be entitled to exercise such warrant and such warrant may have no value and expire worthless. In no event will we be required to net cash settle any warrant. In the event that a registration statement is not effective for the exercised warrants, the purchaser of a unit containing such warrant will have paid the full purchase price for the unit solely for the share of common stock underlying such unit.

We agreed that as soon as practicable, but in no event later than thirty (30) days, after the closing of our initial Business Combination (which closing date was November 6, 2020), we would use our best efforts to file with the SEC a registration statement for the registration, under the Securities Act, of the shares of common stock issuable upon exercise of the warrants, which registration statement was filed with the SEC on July 20, 2021, and declared effective by the SEC on July 27, 2021.

Notwithstanding the above, if our common stock is at the time of any exercise of a warrant not listed on a national securities exchange such that it satisfies the definition of a "covered security" under Section 18(b)(1) of the Securities Act, we may, at our option, require holders of public warrants who exercise their warrants to do so on a "cashless basis" in accordance with Section 3(a)(9) of the Securities Act and, in the event we so elect, we will not be required to file or maintain in effect a registration statement or register or qualify the shares under blue sky laws, and in the event we do not so elect, we will use our best efforts to register or qualify the shares under the blue sky laws of the state of residence in those states in which the warrants were initially offered by us in our initial public offering.

Once the warrants become exercisable, we may call the warrants for redemption:

- in whole and not in part;
- at a price of $0.01 per warrant;
- upon not less than 30 days' prior written notice of redemption (the "30-day redemption period") to each warrant holder; and
- if, and only if, the reported last sale price of the common stock equals or exceeds $230.00 per share for any 20 trading days within a 30-trading day period ending on the third trading day prior to the date we send to the notice of redemption to the warrant holders.

If and when the warrants become redeemable by us, we may not exercise our redemption right if the issuance of shares of common stock upon exercise of the warrants is not exempt from registration or qualification under applicable state blue sky laws or we are unable to affect such registration or qualification. We will use our best efforts to register or qualify the shares of common stock under the blue-sky laws of the state of residence in those states in which the warrants were initially offered by us in our initial public offering.

We have established the last of the redemption criterion discussed above to prevent a redemption call unless there is at the time of the call a significant premium to the warrant exercise price. If the foregoing conditions are satisfied and we issue a notice of redemption of the warrants, each warrant holder will be entitled to exercise his, her or its warrant prior to the scheduled redemption date. However, the price of the common stock may fall below the $720.00 redemption trigger price as well as the $230.00 warrant exercise price (for whole shares) after the redemption notice is issued.

If we call the warrants for redemption as described above, our management will have the option to require any holder that wishes to exercise his, her or its warrant to do so on a "cashless basis." If our management takes advantage of this option, all holders of warrants would pay the exercise price by surrendering their warrants for that number of shares of common stock equal to the quotient obtained by dividing (x) the product of the number of shares of common stock underlying the warrants, multiplied by the difference between the exercise price of the warrants and the "fair market value" by (y) the fair market value. The "fair market value" shall mean the average reported last sale price of the common stock for the 10 trading days ending on the third trading day prior to the date on which the notice of redemption is sent to the holders of warrants. If our management takes advantage of this option, the notice of redemption will contain the information necessary to calculate the number of shares of common stock to be received upon exercise of the warrants, including the "fair market value" in such case. Requiring a cashless exercise in this manner would reduce the number of shares to be issued and thereby lessen the dilutive effect of a warrant redemption.

If the number of outstanding shares of common stock is increased by a stock dividend payable in shares of common stock, or by a split-up of shares of common stock or other similar event, then, on the effective date of such stock dividend, split-up or similar event, the number of shares of common stock issuable on exercise of each warrant will be increased in proportion to such increase in the outstanding shares of common stock. A rights offering to holders of common stock entitling holders to purchase shares of common stock at a price less than the fair market value will be deemed a stock dividend of a number of shares of common stock equal to the product of (i) the number of shares of common stock actually sold in such rights offering (or issuable under any other equity securities sold in such rights offering that are convertible into or exercisable for common stock) multiplied by (ii) one (1) minus the quotient of (x) the price per share of common stock paid in such rights offering divided by (y) the fair market value. For these purposes (i) if the rights offering is for securities convertible into or exercisable for common stock, in determining the price payable for common stock, there will be taken into account any consideration received for such rights, as well as any additional amount payable upon exercise or conversion and (ii) fair market value means the volume weighted average price of common stock as reported during the ten (10) trading day period ending on the trading day prior to the first date on which the shares of common stock trade on the applicable exchange or in the applicable market, regular way, without the right to receive such rights.

In addition, if we, at any time while the warrants are outstanding and unexpired, pay a dividend or make a distribution in cash, securities or other assets to the holders of common stock on account of such shares of common stock (or other shares of our capital stock into which the warrants are convertible), other than (a) as described above, (b) certain ordinary cash dividends, (c) to satisfy the redemption rights of the holders of common stock in connection with a proposed initial business combination, (d) as a result of the repurchase of shares of common stock by us if the proposed initial business combination is presented to our stockholders for approval, or (e) in connection with the redemption of our public shares upon our failure to complete our initial business combination, then the warrant exercise price will be decreased, effective immediately after the effective date of such event, by the amount of cash and/or the fair market value of any securities or other assets paid on each share of common stock in respect of such event.

If the number of outstanding shares of our common stock is decreased by a consolidation, combination, reverse stock split or reclassification of shares of common stock or other similar event, then, on the effective date of such consolidation, combination, reverse stock split, reclassification or similar event, the number of shares of common stock issuable on exercise of each warrant will be decreased in proportion to such decrease in outstanding shares of common stock.

Whenever the number of shares of common stock purchasable upon the exercise of the warrants is adjusted, as described above, the warrant exercise price will be adjusted by multiplying the warrant exercise price immediately prior to such adjustment by a fraction (x) the numerator of which will be the number of shares of common stock purchasable upon the exercise of the warrants immediately prior to such adjustment, and (y) the denominator of which will be the number of shares of common stock so purchasable immediately thereafter.

In case of any reclassification or reorganization of the outstanding shares of common stock (other than those described above or that solely affects the par value of such shares of common stock), or in the case of any merger or consolidation of us with or into another corporation (other than a consolidation or merger in which we are the continuing corporation and that does not result in any reclassification or reorganization of our outstanding shares of common stock), or in the case of any sale or conveyance to another corporation or entity of the assets or other property of us as an entirety or substantially as an entirety in connection with which we are dissolved, the holders of the warrants will thereafter have the right to purchase and receive, upon the basis and upon the terms and conditions specified in the warrants and in lieu of the shares of our common stock immediately theretofore purchasable and receivable upon the exercise of the rights represented thereby, the kind and amount of shares of stock or other securities or property (including cash) receivable upon such reclassification, reorganization, merger or consolidation, or upon a dissolution following any such sale or transfer, that the holder of the warrants would have received if such holder had exercised their warrants immediately prior to such event. However, if such holders were entitled to exercise a right of election as to the kind or amount of securities, cash or other assets receivable upon such consolidation or merger, then the kind and amount of securities, cash or other assets for which each warrant will become exercisable will be deemed to be the weighted average of the kind and amount received per share by such holders in such consolidation or merger that affirmatively make such election, and if a tender, exchange or redemption offer has been made to and accepted by such holders (other than a tender, exchange or redemption offer made by us in connection with redemption rights held by our stockholders as provided for in the our amended and restated Certificate of Incorporation or as a result of the repurchase of shares of common stock by us if a proposed initial business combination is presented to the stockholders of the Company for approval) under circumstances in which, upon completion of such tender or exchange offer, the maker thereof, together with members of any group (within the meaning of Rule 13d-5(b)(1) under the Exchange Act) of which such maker is a part, and together with any affiliate or associate of such maker (within the meaning of Rule 12b-2 under the Exchange Act) and any members of any such group of which any such affiliate or associate is a part, own beneficially (within the meaning of Rule 13d-3 under the Exchange Act) more than 50% of the outstanding shares of common stock, the holder of a warrant will be entitled to receive the highest amount of cash, securities or other property to which such holder would actually have been entitled as a stockholder if such warrant holder had exercised the warrant prior to the expiration of such tender or exchange offer, accepted such offer and all of the common stock held by such holder had been purchased pursuant to such tender or exchange offer, subject to adjustments (from and after the consummation of such tender or exchange offer) as nearly equivalent as possible to the adjustments provided for in the warrant agreement. Additionally, if less than 70% of the consideration receivable by the holders of common stock in such a transaction is payable in the form of common stock in the successor entity that is listed for trading on a national securities exchange or is quoted in an established over-the-counter market, or is to be so listed for trading or quoted immediately following such event, and if the registered holder of the warrant properly exercises the warrant within thirty days following public disclosure of such transaction, the warrant exercise price will be reduced as specified in the warrant agreement based on the per share consideration minus Black-Scholes Warrant Value (as defined in the warrant agreement) of the warrant in order to determine and realize the option value component of the warrant. This formula is to compensate the warrant holder for the loss of the option value portion of the warrant value due to the requirement that the warrant holder exercise the warrant within 30 days of the event. The Black-Scholes model is an accepted pricing model for estimating fair market value where no quoted market price for an instrument is available.

The warrants were issued in registered form under a warrant agreement between Continental Stock Transfer & Trust Company, as warrant agent, and us. You should review a copy of the warrant agreement, which is filed as (or incorporated by reference as) an exhibit to our Annual Report on Form 10-K of which this exhibit is a part, for a complete description of the terms and conditions applicable to the warrants. The warrant agreement provides that the terms of the warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision, but requires the approval by the holders of at least 65% of the then outstanding public warrants to make any change that adversely affects the interests of the registered holders of public warrants.

The warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the warrant agent, with the exercise form on the reverse side of the warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price (or on a cashless basis, if applicable), by certified or official bank check payable to us, for the number of warrants being exercised. The warrant holders do not have the rights or privileges of holders of common stock and any voting rights until they exercise their warrants and receive shares of common stock. After the issuance of shares of common stock upon exercise of the warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

Warrants may be exercised only for a whole number of shares of common stock. No fractional shares will be issued upon exercise of the warrants. If, upon exercise of the warrants, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, round down to the nearest whole number the number of shares of common stock to be issued to the warrant holder. As a result, warrant holders not holding multiples of 40 warrants must sell any odd number of warrants in order to obtain full value from the fractional interest that will not be issued.

Listing of Securities

The warrants are listed on The NASDAQ Stock Market under the symbol "ATNFW".

Anti-Takeover Effects Under Section 203 of Delaware General Corporation Law

We are subject to Section 203 of Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the Board of Directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85 percent of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) 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 an exchange offer; or

- on or after such date, the business combination is approved by our Board of Directors and authorized at an annual or a special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3 percent of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines "business combination" to include the following:

- any merger or consolidation involving the corporation or any direct or indirect majority owned subsidiary of the corporation and the interested stockholder or any other corporation, partnership, unincorporated association, or other entity if the merger or consolidation is caused by the interested stockholder and as a result of such merger or consolidation the transaction is not excepted as described above;

- any sale, transfer, pledge, or other disposition (in one transaction or a series) of 10% or more of the assets of the corporation involving the interested stockholder;

- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or

- the receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges, or other financial benefits by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or a person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15 percent or more of the outstanding voting stock of the corporation.

A Delaware corporation may "opt out" of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or bylaws resulting from a stockholders' amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Anti-Takeover Effects Under our Certificate of Incorporation and Bylaws

Exclusive forum for certain lawsuits

Our amended and restated Certificate of Incorporation requires, to the fullest extent permitted by law, that derivative actions brought in our name, actions against directors, officers and employees for breach of fiduciary duty and other similar actions may be brought only in the Court of Chancery in the State of Delaware and, if brought outside of Delaware, the stockholder bringing such suit will be deemed to have consented to service of process on such stockholder's counsel. Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, the provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may have the effect of discouraging lawsuits against our directors and officers.

Notwithstanding the foregoing, in the event the Court of Chancery in the State of Delaware lacks subject matter jurisdiction over any such action or proceeding, the sole and exclusive forum for such action or proceeding will be another court in the State of Delaware, or if no court in the State of Delaware has jurisdiction, the federal district court for the District of Delaware, in each such case, unless the Court of Chancery (or such other state or federal court located within the State of Delaware, as applicable) has dismissed a prior action by the same plaintiff asserting the same claims because such court lacked personal jurisdiction over an indispensable party named as a defendant therein. To the fullest extent permitted by law, the forum selection provision discussed above will apply to derivative actions or proceedings brought on our behalf and arising under the Securities Act or the Exchange Act, although our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. There is uncertainty as to whether a court would enforce such provision in connection with any such derivative action or proceeding arising under the Securities Act or the Exchange Act, and it is possible that a court could find the forum selection provision to be inapplicable or unenforceable in such a case.

Special meeting of stockholders

Our Bylaws provide that special meetings of our stockholders may be called only by a majority vote of our board of directors, by our Chief Executive Officer or by our Chairman.

Advance notice requirements for stockholder proposals and director nominations

Our Bylaws provide that stockholders seeking to bring business before our annual meeting of stockholders, or to nominate candidates for election as directors at our annual meeting of stockholders, must provide timely notice of their intent in writing. Separately, pursuant to Rule 14a-8 of the Exchange Act, proposals seeking inclusion in our annual proxy statement must comply with the notice periods contained therein. Our Bylaws also specify certain requirements as to the form and content of a stockholders' meeting. These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders and may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.

Director terms and removal of directors

Pursuant to our amended and restated Certificate of Incorporation, our Board of Directors is a classified Board of Directors, as a result of which our Board of Directors is divided into two classes, with each class serving for staggered two-year terms and directors can only be removed for 'cause'.

Action by written consent

Our amended and restated Certificate of Incorporation prohibits stockholder action via any written consent to action without meeting.

Vacancies on the Board of Directors

Our amended and restated Certificate of Incorporation and Bylaws provide that, subject to the rights of the holders of any outstanding series of preferred stock and unless otherwise required by law or resolution of our board of directors, vacancies on the board of directors arising through death, resignation, retirement, disqualification or removal, an increase in the number of directors or otherwise may be filled by a majority of the directors then in office, though less than a quorum.

No cumulative voting

Our amended and restated Certificate of Incorporation and Bylaws do not permit cumulative voting in the election of directors. Cumulative voting allows a stockholder to vote a portion or all of its shares for one or more candidates for seats on the board of directors. Without cumulative voting, a minority stockholder may not be able to gain as many seats on our board of directors as the stockholder would be able to gain if cumulative voting were permitted. The absence of cumulative voting makes it more difficult for a minority stockholder to gain a seat on our board of directors to influence our board's decision regarding a takeover.

Exhibit 10.59

FIRST AMENDMENT TO
SEPARATION AND RELEASE AGREEMENT

This First Amendment to Separation and Release Agreement (this "**Agreement**"), dated March 29, 2023 and effective January 18, 2023 (the "**Effective Date**"), amends that certain Separation and Release Agreement dated January 18, 2023 (the "**Separation and Release Agreement**"), by and between Quan Vu, an individual ("**Vu**") and 180 Life Sciences Corp., a Delaware corporation ("**180 Life**") (collectively referred to as the "Parties" or individually referred to as a "**Party**"). Certain capitalized terms used below but not otherwise defined shall have the meanings given to such terms in the Separation and Release Agreement.

WHEREAS, after the Separation and Release Agreement was executed, the Parties discovered that the Separation and Release Agreement contained certain an error in that it provided for Vu to be paid certain amounts as a bonus for fiscal 2021, even though the Board of Directors of 180 Life has to date not approved bonuses for 2021; and

WHEREAS, the Parties desire to amend the Separation and Release Agreement on the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the premises and the mutual covenants, agreements, and considerations herein contained, and other good and valuable consideration, which consideration each of the Parties hereby acknowledge and confirm the receipt and sufficiency thereof, the Parties hereto agree as follows:

1. **Amendment to Separation and Release Agreement**. Effective as of the Effective Date, Section 1 of the Separation and Release Agreement is amended and restated to read as follows:

"1. Severance Payment. Subject to Vu's compliance with the terms and conditions of this Agreement and Release, 180 Life agrees to (a) pay Vu $297,440, less all applicable withholdings and required deductions and (b) reimburse up to $1,100 a month for eight months for Vu's health insurance expenses, whether under COBRA or otherwise (collectively, (a) and (b), the "**Severance Payment**"). The Severance Payment (except for the amounts payable pursuant to (b) which shall be paid by the 15th day of each calendar month during the applicable eight-month period) shall be paid within 30 days of the Separation Date (the "**Payment Date**"). In addition to the Severance Payment, by the Payment Date, 180 Life shall pay Vu $73,645 for accrued backpay and $36,050 for accrued paid time off. Vu agrees that the Severance Payment to be paid under this Agreement and Release is due solely from 180 Life and represents consideration which would not otherwise be due to Vu. Further, 180 Life agrees not to oppose Vu's application for unemployment insurance compensation benefits."

2. **Effect of Agreement**. Upon the effectiveness of this Agreement, each reference in the Separation and Release Agreement to "Agreement," "hereunder," "hereof," "herein" or words of like import shall mean and be a reference to such Separation and Release Agreement as modified or amended hereby.

3. **Separation and Release Agreement to Continue in Full Force and Effect**. Except as specifically modified or amended herein, the Separation and Release Agreement and the terms and conditions thereof shall remain in full force and effect.

4. **Counterparts and Signatures**. This Agreement and any signed agreement or instrument entered into in connection with this Agreement, and any amendments hereto or thereto, may be executed in one or more counterparts, all of which shall constitute one and the same instrument. Any such counterpart, to the extent delivered by means of a facsimile machine or by .pdf, .tif, .gif, .jpeg or similar attachment to electronic mail (any such delivery, an "**Electronic Delivery**") shall be treated in all manner and respects as an original executed counterpart and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. No Party shall raise the use of Electronic Delivery to deliver a signature or the fact that any signature or agreement or instrument was transmitted or communicated through the use of Electronic Delivery as a defense to the formation of a contract, and each such Party forever waives any such defense, except to the extent such defense relates to lack of authenticity.

[Remainder of page left intentionally blank. Signature page follows.]

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed and delivered as of the date set forth on the first page hereof to be effective as of the Effective Date.

Quan Vu

Signature: /s/ Quan Vu

180 Life Sciences Corp.

Signature: /s/ James N. Woody

Printed Name: James N. Woody

Title: CEO

Exhibit 21.1

Direct and Indirect Subsidiaries of 180 Life Sciences Corp.*

LIST OF SUBSIDIARIES

Name	Jurisdiction of Incorporation
180 Life Corp.	Delaware
Katexco Callco ULC	British Columbia
CannBioRex Callco ULC	British Columbia
180 Therapeutics LP	Delaware
Katexco Purchaseco ULC	British Columbia
CannBioRex Purchaseco ULC	British Columbia
Katexco Pharmaceuticals Corp.	British Columbia
CannBioRex Pharmaceuticals Corp.	British Columbia
Katexco Pharmaceuticals Corp.	California
CannBioRex Pharma Limited	United Kingdom

* Pursuant to Item 601(b)(21)(ii) of Regulation S-K, the names of other subsidiaries of 180 Life Sciences Corp. are omitted because, considered in the aggregate, they would not constitute a significant subsidiary as of the end of the year covered by this report. Inclusion in this list is not, however, a representation that the listed subsidiary is a "significant subsidiary."

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of 180 Life Sciences Corp. (the 'Company') on Form S-3 (File No. 333-265416), Post-Effective Amendment No.2 to Registration Statement on Form S-1 on Form S-3 (File No. 333-259209) and Form S-8 (File Nos. 333-259918 and 333-266716) of our report dated March 31, 2023, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to our audits of the consolidated financial statements of 180 Life Sciences Corp. as of December 31, 2022 and 2021 and for each of the two years in the period ended December 31, 2022, which report is included in this Annual Report on Form 10-K of the Company for the year ended December 31,2022.

/s/ Marcum LLP

Marcum LLP
San Francisco, CA

March 31, 2023

Exhibit 31.1

Certification of Chief Executive Officer

I, James N. Woody, M.D., Ph.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of 180 Life Sciences Corp. (the "registrant");

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)), and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: March 31, 2023

/s/ James N. Woody, M.D., Ph.D.

James N. Woody, M.D., Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Chief Financial Officer

I, Ozan Pamir, certify that:

1. I have reviewed this Annual Report on Form 10-K of 180 Life Sciences Corp. (the "registrant");

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)), and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: March 31, 2023

/s/ Ozan Pamir

Ozan Pamir
Interim Chief Financial Officer
(Principal Financial/Accounting Officer)

Exhibit 32.1

Certification of Chief Executive Officer
Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of
The Sarbanes-Oxley Act of 2002

I, James N. Woody, M.D., Ph.D., certify, as of the date hereof, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of 180 Life Sciences Corp. on Form 10-K for the fiscal year ended December 31, 2022 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Form 10-K fairly presents in all material respects the financial condition and results of operations of 180 Life Sciences Corp. at the dates and for the periods indicated.

Dated: March 31, 2023

/s/ James N. Woody, M.D., Ph.D.
James N. Woody, M.D., Ph.D.
Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to 180 Life Sciences Corp. and will be retained by 180 Life Sciences Corp. and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

Certification of Chief Financial Officer
Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of
The Sarbanes-Oxley Act of 2002

I, Ozan Pamir, certify, as of the date hereof, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of 180 Life Sciences Corp. on Form 10-K for the fiscal year ended December 31, 2022 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Form 10-K fairly presents in all material respects the financial condition and results of operations of 180 Life Sciences Corp. at the dates and for the periods indicated.

Dated: March 31, 2023

/s/ Ozan Pamir
Ozan Pamir
Interim Chief Financial Officer
(Principal Financial/Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to 180 Life Sciences Corp. and will be retained by 180 Life Sciences Corp. and furnished to the Securities and Exchange Commission or its staff upon request.