Risk Factors Comparison 2024-03-25 to 2023-03-31 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

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, **2023 and** 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 **our** ~~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~~ **Nasdaq** and the costs of compliance with SEC and ~~NASDAQ~~ **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~~ **changes in** inflation **and** ~~, 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 **and Hamas / Israel** 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 do not currently have $ 2. 5 million or more of stockholders' equity, and as a result, we are not in compliance with the continued listing requirements of the Nasdaq Capital Market and our common stock and public warrants are subject to delisting** ; ● 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 **expected to be** sufficient to fund our planned business operations through **approximately May** ~~the second quarter of 2023~~ **2024** . 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 **, including seeking bankruptcy protection** . 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~~ **rising** interest rates and inflation, as well as global conflicts ~~which~~ **such** as the ongoing conflict between Ukraine and Russia, **and Israel and Hamas** ~~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 **, or may be forced to seek bankruptcy protection** . 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~~ **2023** , we had an accumulated deficit of $ ~~107~~ **127** , ~~408~~ **343** , ~~545~~ **657** and **a** working capital **deficit** of $ ~~3~~ **1** , ~~270~~ **422** , ~~608~~ **710** , and for the year ended December 31, ~~2022~~ **2023** , a net loss of $ ~~38~~ **19** , ~~726~~ **935** , ~~259~~ **112** and cash used in operating activities **for the year ended December 31, 2023,** of $ ~~12~~ **10** , ~~127~~ **922** , ~~585~~ **223** . As of March ~~29~~ **18** , ~~2023~~ **2024** , we had cash on hand of approximately $ ~~2~~ **0** . ~~7~~ **8** million. The accompanying ~~consolidated~~ **Consolidated** ~~financial~~ **Financial statements** ~~Statements~~ have been prepared assuming **we** ~~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 **we** ~~the Company~~ recently raised funds through the sale of equity in July 2022 (**approximately** $ 6. 5 million of gross proceeds) ~~and~~ **,** December 2022 (**approximately** $ 6. 0 million of gross proceeds **), April 2023 (approximately $ 3. 0 million of gross proceeds), August 2023 (approximately $ 3. 0 million) and November 2023 (approximately $ 0. 8 million**), 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~~ **350** , 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~~ **financing** . 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 **. The Consolidated Financial Statements included** ~~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 **United States** ~~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~~ **Consolidated** ~~financial~~ **Financial** ~~statements~~ **Statements included herein** do not include any adjustments relating to the recoverability of assets and classification of liabilities that might be necessary should **we** ~~the Company~~ be unable to continue as a going concern. The ~~consolidated~~ **Consolidated** ~~financial~~ **Financial** ~~statements~~ **Statements** included herein also include a going concern footnote. Additionally, wherever possible, our **board of directors (“** Board of Directors **” or “ Board ”)** 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~~ **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 **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~~ 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. **Our License Agreements with the University of Oxford and other licensors may be terminated in certain circumstances without our consent. All of our License Agreements with the University of Oxford and other licensors remain subject to various conditions and covenants, and provide for certain termination rights to the licensors. Those agreements typically allow termination by the licensor for our failure to pay amounts due timely, our failure to cure a material breach under the terms of the applicable license agreement, and our insolvency. As a result, if we are deemed insolvent, or in the event we seek bankruptcy protection, the licensors of our license agreements may terminate their license agreements with us. In the event such license agreements are terminated, we could lose the right to develop all of our platforms and technologies, may lose any investments made towards developing such platforms and technologies, and may be left without any intellectual property, product pathways, or development opportunities. Such terminations may result in the value of our securities declining in value or becoming worthless, the need for us to change our business plan, and may result in the Company seeking bankruptcy protection.** We **owe a significant amount of money to the University of Oxford, which funds we do not have. The university** may ~~need~~ **take action against us to enforce their rights to payment in the future, which could have a material adverse effect on us and our operations. Due to recent financial constraints, the Company has been unable to timely pay amounts due to the University of Oxford (“ Oxford ”), the licensor of the majority of the Company' s licenses and patents and the Company' s research partner. Oxford alleges that an aggregate of approximately £ 929, 030 is owed from the Company and one of its subsidiaries to**

Oxford under the terms of licenses and agreements with Oxford and related parties. The Company is currently in ongoing discussions with Oxford to reduce that amount and enter into a payment plan with regards to the amounts owed; however, no definitive terms or extensions have been agreed to date. Oxford has also notified the Company that it is not willing to discuss any new projects or arrangements until all outstanding invoices have been paid or a payment plan has been agreed to; has engaged a law firm to seek the collection of the amounts owed, together with interest; and has threatened legal proceedings against us. While we are hopeful that we can come to mutually agreeable terms regarding a settlement, payment plan, and / or extension, with Oxford, we may not have sufficient funds to pay amounts due to Oxford in the near term, if at all, and Oxford may take action against us, including filing legal proceedings against us seeking amounts due and interest, attempting to terminate their relationship with us, and / or filing a wind-up petition against one of the Company' s subsidiaries in the U. K.. If Oxford were to take legal action against us or terminate their relationship with us, we may be forced to scale back our business plan and / or seek bankruptcy protection. We may be subject to litigation and damages for our failure to pay amounts due to Oxford, and may be forced to pay interest and penalties, which funds we do not currently have. We plan to seek to raise ~~additional~~ **funding in the future to support our operations, and to pay amounts due to Oxford, through a combination of equity offerings, debt financing 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** , ~~causing~~ **if accomplished, may result in** dilution to our **then** stockholders **. Additionally** , ~~restricting~~ **in December 2023, we engaged A. G. P. / Alliance Global Partners as financial advisor to explore and evaluate strategic alternatives to enhance shareholder value. Potential strategic alternatives that may be explored** ~~our~~ **or** ~~operations or adversely affecting our ability~~ **evaluated by the Company as part of this process include, but are not limited** to ~~operate our~~ **, an acquisition, merger, reverse merger, other** business **combination, sale of assets, licensing or other strategic transactions involving the Company** . ~~We may~~ **The Company does** not **intend** ~~be able~~ to ~~obtain additional financing on terms favorable to us, if at all, including~~ **discuss or disclose further developments during this process unless and until its Board of Directors** ~~as~~ **has approved** a **specific action or otherwise determined that further disclosure is appropriate. There is no assurance that the strategic review process will** result ~~of macroeconomic conditions such as a severe or prolonged economic downturn. Disruption, uncertainty or volatility~~ in the **approval** ~~capital markets could increase our~~ **or** ~~cost~~ **completion** of capital or limit our ability to raise..... Bank. Although we do not have any ~~accounts at~~ **specific transaction** or **outcome** ~~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. **Our** ~~The Company' s~~ reporting currency is the United States dollar. The functional currency of certain subsidiaries is the Canadian Dollar (" CAD ") or British Pound (**" £ " or** " 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, **2023 and** 2022 ~~and 2021~~ , **we** ~~the Company~~ recorded other comprehensive (loss) ~~income~~ of **($ 15, 816) and** ($ 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 **our** ~~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 **our** ~~the Company' s~~ operations, expenses, access to capital and the market for **our** ~~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 **our** ~~the Company' s~~ funding sources, suppliers and partners. Potential effects include financial instability; inability to obtain credit to finance operations and purchases of **our** ~~the Company' s~~ future planned products; and insolvency. A downturn in the economic environment could also lead to limitations on **our** ~~the Company' s~~ ability to sell equity or issue new debt; reduce liquidity; and result in declines in the fair value of **our** ~~the Company' s~~ financial instruments. These and other economic factors could materially adversely affect **our** ~~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 **and 2023** , 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~~ **During** 2022 ~~has seen~~ **and the early part of 2023, there were** 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 **, and Israel and Hamas, which threatens to spread to other Middle Eastern countries** . 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~~ **Supply** chain constraints and inflationary pressures **have in the past and** may **in the future,** 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 **Israel and Hamas, which began in October 2023 and which threatens to spread to** ~~the~~ **other Middle Eastern countries** ~~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 **us** ~~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, **we are** ~~the Company is~~ no longer the insured under the subject insurance policy, notwithstanding the fact that the fees which **we** ~~the Company seeks~~ **seek** to recover from AmTrust relate to matters occurring prior to the merger. On ~~September 20~~ **April 21** , ~~2022~~ **2023** , **the Court issued an Order Granting in Part and Denying in Part** the Company ~~filed its Answer and Counterclaims against AmTrust for bad faith breach of AmTrust~~ ' s **Motion for Partial Summary Judgment. Specifically, the Court granted summary adjudication in favor of the Company on the following issues: (a) that the Company is, in fact, an insured under both the AmTrust and Freedom** insurance **policies; (b) that certain SEC subpoena related expenses for defendants Dr. Marlene Krauss, the Company' s former Chief Executive Officer and Director, and George Hornig, the former Chairman of the Board, are within the basic scope of** coverage ~~obligations~~ **under both the AmTrust and Freedom insurance policies; and (c) that the Insured vs. Insured exclusion relied upon by AmTrust and Freedom is not applicable** to **bar any such coverage. The Court also found that there were issues of disputed facts as to the Change in Control exclusion contained within the policies, which therefore precluded the Court from granting the remainder of** the Company ~~under the subject directors~~ ' ~~and officers~~ **s requests for summary adjudication as a matter of law. Accordingly, the Court, at this time, denied the Company** ' ~~insurance~~ **s further requests for summary adjudication and deemed that for the time being, the Change in Control issue is to be determined at the time of trial, in order to find that the policies provide (i) coverage for the fees which the Company has advanced and will advance to Dr. Marlene Krauss and George Hornig; (ii) that AmTrust has breached the** policy ~~, and seeking damages~~ **; (iii) that AmTrust must pay such expenses** of ~~at least $ 2 million in compensatory damages, together with applicable punitive damages. In addition,~~ the Company **; and that** ~~brought a Third- Party Complaint against its excess insurance carrier~~ , ~~Freedom Specialty Insurance Company~~ **once the AmTrust policy has been exhausted,** (**iv** ~~" Freedom "~~) ~~seeking declaratory relief~~ that Freedom will ~~also~~ be ~~required~~ **obligated** to ~~honor~~ **pay such expenses of the Company pursuant to** its policy ~~coverage as soon as the amount of AmTrust' s insurance coverage obligations to the Company have been exhausted~~ . On ~~October 25~~ **August 4** , ~~2022~~ **2023** , **the Court granted** ~~AmTrust filed its Answer to~~ the Company' s ~~Counterclaims and~~ **request to file a second motion for partial summary judgment in this case** , **this one being** on ~~October 27, 2022, Freedom filed its Answer to~~ the ~~Third- Party~~ **issue of whether AmTrust should be required to advance to the** ~~Complaint~~ -- **Company** ~~. On November 22, 2022,~~ the **defense costs being incurred by Dr. Marlene Krauss and George Hornig during the pendency of the case. The** Company filed ~~a~~ **such** Motion for **Partial** Summary **Judgment,** ~~Adjudication against both AmTrust~~ and **it has now been** ~~Freedom. The Motion was~~ fully briefed ~~and a~~ **by the parties. The** hearing **for such motion** was held on ~~March 9~~ **January 11** , ~~2023~~ **2024** ~~. The Court~~ **, however the Judge** took the matter under submission and has not yet issued ~~a ruling~~ **any decision on the Motion. The parties have commenced written discovery proceedings against each other, and it is anticipated that depositions will also occur. The Company intends to continue to vigorously pursue this matter in order to establish the Company' s entitlement to full payment by both AmTrust and Freedom of the subject advancement expenses of the Company** . While the Company **continues to** ~~believes~~ **believe** it has a strong case against **both** AmTrust **and Freedom and believes the Court ruling in its favor in regards to the matters discussed above is a significant positive outcome for the Company** , 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 **us** ~~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~~ **our** financial statements for the year ended December 31, 2022 **and since such date** 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~~ **the Company has been in discussions with** an alternative supplier of the anti- TNF biosimilar drug ~~, and we~~ **which has expressed interest in proceeding. We** may **ultimately** 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 **provided in section 505 (b) (2) of the FDC Act** . **A Section 505 (b) (2)** NDA **is in contrast to an NDA under section 505 (b) (1) of the FDC Act, which is commonly known as a Full NDA because it requires the applicant to undertake all of the nonclinical and clinical investigations necessary for the approval of the application. In contrast, a Section 505 (b) (2) NDA application is one for which one or more of the investigations relied on by the applicant for approval were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.** 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~~ **a Full** 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 **the** 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~~ **lack of qualified employees and consultants** , ~~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~~ **previously** 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~~ **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 **the section entitled** " **Item 1.** Business " **in this Report** 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 **and our partner' s** operations are subject to risks associated with ongoing and potential future global conflicts ~~.~~ ~~Currently~~ , **including specifically** ~~there~~ -- **the** ~~is~~ **operations of Yissum, our research partner. In February 2022,** an ~~ongoing~~ **armed** conflict ~~involving~~ **escalated between** Russia and Ukraine **. The sanctions announced by the United States** and ~~the~~ **other** ~~war between the two~~ countries ~~continues~~ **against Russia and Belarus following Russia' s invasion of Ukraine** to ~~evolve as~~ **date include restrictions on selling or importing goods, services, or technology in or from affected regions and travel bans and asset freezes impacting connected individuals and political,** military ~~activity proceeds~~ **, business,** and ~~additional~~ **financial organizations in Russia and Belarus. The United States and other countries could impose wider** sanctions **and take other actions should the conflict further escalate. Separately, in October 2023, Israel and certain Iranian- backed Palestinian forces began an armed conflict in Israel, the Gaza Strip, and surrounding areas, which threatens to spread to other Middle Eastern countries including Lebanon and Iran. These wars** 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~~ **these** ~~conflict~~ **conflicts** currently ~~has~~ **have** 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 **. Additionally, we currently have agreements and relationships in place with Yissum Research Development Company of the Hebrew University of Jerusalem, Ltd. (" Yissum "), located in Israel, and Yissum' s operations may be materially affected by the ongoing war in Israel, which may delay, prevent, or materially increase the cost of the ongoing services Yissum is required to provide to the Company** . 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 **Hamas / Israel** ~~conflict~~ **conflicts** 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 **. We may enter into strategic transactions in the future which may result in a material change in our operations and / or a change of control. In December 2023, we engaged A. G. P. / Alliance Global Partners as financial advisor to explore and evaluate strategic alternatives to enhance shareholder value. Potential strategic alternatives that may be explored or evaluated by the Company as part of this process include, but are not limited to, an acquisition, merger, reverse merger, other business combination, sale of assets, licensing or other strategic transactions involving the Company. The Company does not intend to discuss or disclose further developments during this process unless and until its Board of Directors has approved a specific action or otherwise determined that further disclosure is appropriate. There is no assurance that the strategic review process will result in the approval or completion of any specific transaction or outcome. The Board of Directors and management team are committed to acting in the best interests of the Company, its stockholders and its stakeholders. There is no deadline or definitive timetable set for completion of the strategic alternatives review process and there can be no assurance that this process will result in the Company pursuing a transaction or any other strategic outcome. As a result of the above, in the future, we may enter into transactions with parties seeking to merge and / or acquire us and / or our operations. While we have not entered into any agreements or understandings with any such parties to date, in the event that we do enter into such a transaction or transactions in the future, new shares of common stock or preferred stock could be issued resulting in substantial dilution to our then current stockholders and / or a change of control. As a result, our new majority stockholders may change the composition of our Board of Directors and may replace our current management. Any future transaction may also result in a change in our business focus. We have not entered into any agreements relating to any strategic transaction involving the Company as of the date of this Report and may not enter into such agreements in the future. Any future**

strategic transaction involving the Company or its operations may have a material effect on our operations, cash flows, results of operations, prospects, plan of operations, the listing of our common stock on Nasdaq, our officers, directors and majority stockholder (s), and the value of our securities . 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~~ **our** 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~~ **our** 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~~ **our** 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, **pandemics or epidemics may impact patient ability and willingness to travel to clinical trial sites as a result of quarantines and** ~~the~~ **other** ~~ongoing~~ **restrictions, which may negatively impact enrollment in our clinical trials, for example, our trials have in the past had difficulty recruiting a sufficient number of patients due to the** 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 **ACA** ~~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 **, have not received approval for any products, and have not marketed any approved product** . 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 **the** 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 **United States** ~~U. S.~~, the ~~EU~~ **European Union** 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 **with certain universities** and any that we may enter into in the future **with other partners** may not be successful, which could adversely affect our ability to develop and commercialize our future product candidates. We are **seeking** ~~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~~ **our** 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 **on** 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. 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 **the website** worldpoplulationreview. com, at least ~~39~~ **38** 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. **We** ~~The Company reviews~~ **review** 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. **We** ~~The Company reviews~~

review 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. **Our** ~~The Company' s~~ publicly **-** traded stock closed at $ ~~78~~ **1, 482** . 00 per share as of December 31, 2021; during 2022, the market value of **our** ~~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 **our** ~~the Company' s~~ publicly **-** traded stock fell to $ ~~51~~ **984** . ~~80~~ **20** , $ ~~16~~ **322** . ~~96~~ **24** , $ ~~13~~ **252** . ~~30~~ **70** and $ ~~3~~ **64** . ~~39~~ **41** , per share, respectively, and as such, **we** ~~the Company~~ elected to conduct a quantitative analysis of goodwill to assess for impairment as of September 30, 2022 and December 31, 2022. **We** ~~The Company~~ determined the fair market value of ~~its~~ **our** 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, **we** ~~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 **we** ~~the Company becomes~~ **become** 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 **we are** ~~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, **we** ~~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~~ **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 ~~values~~ **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~~ , **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~~ **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~~ **As of September 30, 2023, the carrying amount of the IP R & D** ~~Assets~~ **assets** ~~and~~ **on the balance sheet was $ 9, 063, 000 (which consists of a balance related to the Company' s 180 LP subsidiary); the Company typically assesses asset** ~~Impairment~~ **impairment** ~~of Long- lived Assets " in~~ **on an annual basis unless a triggering event or** ~~the~~ **other** ~~consolidated~~ **facts or circumstances indicate that an evaluation should be performed at an earlier date. At the end of the third quarter of 2023, the Company assessed general economic conditions, industry and market considerations, the Company' s** financial ~~statements~~ **performance and all relevant legal, regulatory, and political factors that might indicate the possibility of impairment and** ~~included~~ **concluded** ~~herein beginning~~ **that, when these factors were collectively evaluated, it was likely that the asset was impaired. The Company recorded a loss in the amount of $ 9, 063, 000, which appeared as a loss** on ~~page F- 1,~~ **impairment to IP R & D assets on the income statement** for **the three and nine months ended September 30** ~~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~~ **2023. As of December 31, 2023, the balance of the IP R & D assets** on the **balance sheet is $ 0** ~~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 **in the past, and may in the future,** ~~identified~~ **identify** 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~~ **A material weakness is a deficiency** , ~~including our~~ **or a combination** ~~principal financial officer, conducted an evaluation~~ of **deficiencies, in** ~~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 **our** ~~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 **we are** ~~the Company is~~ committed to remediating ~~its~~ **our** 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~~ **Nasdaq** , we could face severe consequences from those authorities. **Any** ~~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 **would** ~~have taken and plan to~~ take in the future will remediate ~~the material weakness identified or that~~ any additional material weaknesses **which could be identified,** 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~~ **Nasdaq** , as applicable, or other regulatory authorities. In addition, even if we ~~are~~ **would be** 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 **our** ~~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 **closing** ~~sale~~ **sales** prices of our common stock ranged from a post- split adjusted high of $ ~~80~~ **1, 482. 04 per share to a low of $ 23. 56 per share and during fiscal 2023, the closing sales prices of our common stock ranged from a high of $ 100** . 70 per share ~~(on January 5, 2022)~~ to a low of $ ~~1~~ **3** . ~~18~~ **21** per share ~~(on December 23, 2022)~~ . During this time, we **do not believe that 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 **us** ~~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~~ **The exercise of our** outstanding options and warrants **, and the sale of common stock upon exercise thereof,** may adversely affect the trading price of our securities. As of ~~December 31~~ **March 20** , ~~2022~~ **2024** , we had (i) outstanding stock options to purchase an aggregate of ~~162~~ **17** , ~~956~~ **788** shares of common stock at a weighted average exercise price of $ ~~84. 63~~ **633 . 95** per share; **and** (ii) outstanding warrants to purchase ~~3~~ **983** , **473** ~~435, 728~~ shares of common stock at a weighted average exercise price of $ ~~33~~ **83** . ~~94~~ **97** per share **(when not including the 275, 205 pre- funded warrants)** . 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~~ **seven hundred sixtieth** of one share of common stock at an exercise price of $ 5. 75 per 1 / ~~40th~~ **760th** of one share ($ ~~230~~ **4, 370** . 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~~ **760** . As a result, the Public Warrants may not have any significant value. Additionally, warrant holders not holding at least ~~40~~ **760** 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~~ **760** Public Warrants or a number of Public Warrants not evenly divisible by ~~40~~ **760** will not receive any common stock upon the exercise of Public ~~Warrant~~ **Warrants** , 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 **and cause significant dilution to existing stockholders** . 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 **immediate** resale in the public market, including (a) options to purchase ~~162~~ **17** , ~~956~~ **788** shares of common stock with a weighted average exercise price of $ ~~84. 63~~ **633 . 95** per share; and (b) warrants to purchase ~~3~~ **987** , **473** ~~435, 728~~ shares of common stock with a weighted average exercise price of $ ~~33~~ **83** . ~~94~~ **97** per share **(such amount does not include 257, 205 pre- funded warrants which were outstanding as of December 31, 2023, all of which have been exercised as of March 7, 2024)** . 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 **. The exercise of outstanding convertible securities will also cause significant dilution to existing stockholders and will likely cause the per- share value of our common stock to decline, possibly significantly** . 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~~ **certain outstanding** warrants ~~granted in July 2022~~ could discourage an acquisition of us by a third party. ~~Certain provisions~~ **Provisions** of **certain outstanding** ~~the common stock~~ warrants ~~granted by us in July 2022~~ could make it more difficult or expensive for a third party to acquire us. **Certain outstanding** ~~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 **each of** the **outstanding** ~~common stock~~ warrants **issued** ~~. Further, the common stock warrants granted by us~~ in **connection with the** July 2022 **Offering, the December 2022 Offering, the April 2023 Offering and August 2023 Offering (each as defined and / or discussed herein), and the outstanding December 2023 Pre- Funded Warrants and December 2023 Common Warrants, respectively. Further, such outstanding warrants** 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~~ **the applicable** 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. **However** ~~As of March 28~~, ~~2023,~~ **as of** ~~there~~ -- **the date of this Report, our public float was less than $ 75 million, and under SEC regulations for so long as our public float remains less than $ 75 million, the amount we can raise through primary public offerings of securities in any twelve- month period using our shelf registration statement on Form S- 3** is **limited to** an aggregate of ~~over~~ **one- third of our public float. At such time as our public float again exceeds** $ **75** ~~6. 0~~ million ~~in~~ **, the number of** securities ~~which are eligible for sale in the public markets from time to time~~ **we may sell under a Form S- 3 registration statement will no longer be limited by such rules** . 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 **us** ~~the Company~~ and **our** ~~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 **us** ~~the Company~~ and **our** ~~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 **we** ~~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 **Second** 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 **Second** 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~~ **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 **a** 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 **Second** 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 **us** ~~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~~ **us or** ~~or~~ **our** ~~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 **our** ~~the~~

~~Company' s~~ stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with ~~the Company~~ **us or** ~~or~~ **our** ~~the Company' s~~ directors or officers, which may discourage such lawsuits against **us** ~~the Company~~ and **our** ~~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 **us** ~~the Company~~ or any of ~~its~~ **our** officers or directors, or any of their respective affiliates, and that **we** ~~the Company renounces~~ **renounce** any expectancy that any of ~~the~~ **our** directors or officers ~~of the Company~~ will offer any such corporate opportunity of which he or she may become aware to **us** ~~the Company~~, except that the doctrine of corporate opportunity shall apply with respect to any of ~~the~~ **our** 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~~ **our** director or officer ~~of the Company~~, (ii) that is one **we are** ~~the Company is~~ legally and contractually permitted to undertake and would otherwise be reasonable for **us** ~~the Company~~ to pursue, and (iii) to the extent the director or officer is permitted to refer such opportunity to **us** ~~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** ~~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** ~~NASDAQ Capital Market~~ corporate governance requirements, including requirements under the Sarbanes- Oxley Act of 2002 and other rules implemented by the SEC and **Nasdaq** ~~The NASDAQ Capital Market~~. The rules of **Nasdaq** ~~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~~ **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~~ **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~~ **are** not ~~been~~ in compliance ~~in the past~~ with the continued listing standards of ~~NASDAQ and~~ **Nasdaq,** may not be able to comply with ~~NASDAQ~~ **Nasdaq** ' s continued listing standards in the future **, and as a result our common stock and warrants may be delisted from Nasdaq** . Our common stock and **Public** ~~warrants~~ **Warrants** trade on **Nasdaq** ~~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 **Nasdaq** ~~The NASDAQ Capital Market~~ for any period of time by perpetually satisfying ~~NASDAQ~~ **Nasdaq** ' s continued listing requirements. ~~While we are currently~~ **On September 7, 2023, the Company received written notice from the Listing Qualifications Department of The Nasdaq Stock Market LLC (" Nasdaq ") notifying the Company that it is not** in compliance with ~~NASDAQ~~ **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 July 26, 2023 to September 6, 2023, the Company no longer meets the minimum bid price requirement. The notification letter stated that the Company has 180 calendar days or until March 5, 2024, 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. If the Company does not regain compliance by March 5, 2024, an additional 180 days may be granted to regain compliance, so long as the Company meets The Nasdaq Capital Market initial listing criteria (except for the bid price requirement) and notifies Nasdaq in writing of its intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. If the Company does not qualify for the second compliance period or fails to regain compliance during the second 180- day period, the Company' s common stock will be subject to delisting, at which point the Company would have an opportunity to appeal the delisting determination to a Hearings Panel. The Company intends to monitor the closing bid price of its common stock and may, if appropriate, consider implementing available options to regain compliance with the minimum bid price requirement under the Nasdaq Listing Rules, including affecting a reverse stock split. The Company held a special stockholders' meeting on February 16, 2024, to seek approval, for among other things, an amendment to our 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, by a ratio of between one- for- four to one- for- forty, 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 February 16, 2025. On February 16, 2024, the Company' s Board of Directors authorized a reverse stock split of our issued and outstanding shares of common stock in the amount of one- for- nineteen, which was effective on February 28, 2024. On March 13, 2024, the Company received a letter from Nasdaq notifying the Company that it has regained full compliance with the minimum bid price for continued listing on Nasdaq, pursuant to Nasdaq Listing Rule 5550 (a) (2), because Nasdaq has determined that for 10 consecutive business days, the closing bid price of the Company' s common stock was at or above $ 1. 00 per share. On October 11, 2023, the Company received written notice from Nasdaq notifying the Company that it was not in compliance with the shareholder approval requirements set forth in Nasdaq Listing Rule 5635 (d), which require prior shareholder approval for transactions, other than public offerings, involving the issuance of 20 % or more of the pre- transaction shares outstanding at less than the applicable Minimum Price (as defined in Listing Rule 5635 (d) (1) (A)). The Staff' s determination under Listing Rule 5635 (d) relates to the offering and issuance by the Company of an aggregate of: (i) 35, 102 shares of the Company' s common stock, at a price of $ 12. 35 per share, (ii) pre- funded warrants to purchase up to 207, 814 shares of common stock, at a price of $ 12. 3481 per pre- funded warrant and (iii) warrants to purchase up to 242, 915 shares of common stock. The offering price per share and associated common warrant was $ 12. 35 and the offering price per pre- funded warrant and associated common warrant was $ 12. 3481. The Staff determined that the offering was not a " public offering " for the purposes of Nasdaq' s shareholder approval rules due to the type of offering, a best efforts offering pursuant to a placement agency agreement, and the fact that one investor purchased 98 % of the offering. As a result, because the offering represented greater than 20 % of the common stock outstanding and was priced below the Minimum Price, the Staff determined that the Company was required to obtain prior shareholder approval under Listing Rule 5635 (d). The October 11, 2023 letter provided the Company 45 days to submit a plan to regain compliance. The plan of compliance was subsequently submitted by the Company to Nasdaq on November 9, 2023, and on November 14, 2023, Nasdaq granted the Company an extension, until December 15, 2023, to complete certain transactions set forth in the plan of compliance, in order to remedy its prior violation of Nasdaq rules as described in the October 11, 2023 letter from Nasdaq. The Company undertook several transactions in November and December 2023, including amending the terms of the warrants discussed above, to not be exercisable until the Company' s stockholders approve such issuance in accordance with the Nasdaq Listing Rules, in order to regain compliance with Listing Rule 5635 (d) (1) (A)). As a result of those transactions, on December 14, 2023, Nasdaq provided the Company written notice that the Company has complied with the terms of the prior extension; that the Company complies with Listing Rule 5635 (d) (1) (A)); and that the matter is now closed. On November 15, 2023, the Company received a letter from Nasdaq notifying the Company that it was not in compliance with the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550 (b) (1) (the " Rule ") requires companies listed on the Nasdaq Capital Market to maintain stockholders' equity of at least $ 2, 500, 000. In the Company' s Quarterly Report on Form 10- Q for the quarter ended September 30, 2023, the Company reported a stockholders' deficit of ($ 149, 327), which is below the minimum stockholders' equity required for continued listing pursuant to the Rule. Additionally, the Company does not meet the alternative Nasdaq** continued listing standards ~~, we have in~~ **under Nasdaq Listing Rules. Nasdaq provided** the ~~past been out of~~ **Company until January 2, 2024 to submit to Nasdaq a plan to regain compliance. We submitted the plan to**

regain compliance in a timely manner, and on January 11, 2024, Nasdaq advised the Company that it has determined to grant the Company an extension to regain compliance with ~~such~~ **the Rule. The terms of the extension are as follows: on or before May 13, 2024, the Company must complete certain transactions described in greater detail in the compliance plan, contemplated to result in the Company increasing its stockholders' equity to more than $ 2. 5 million, and opt for one of the two following alternatives to evidence compliance with the Rule: Alternative 1: The Company must furnish to the SEC and Nasdaq a publicly available report (e. g., a Form 8- K) including: 1. A disclosure of the Staff' s deficiency letter and the specific deficiency (ies) cited; 2. A description of the completed transaction or event that enabled the Company to satisfy the stockholders' equity requirement for** continued listing ~~standards~~ **;** and **3. An affirmative statement that, as of the date of the report, the Company believes it has regained compliance with the stockholders' equity requirement based upon the specific transaction** ~~our~~ **or** ~~failure~~ **event referenced in Step 2; or Alternative 2: The Company must furnish** to **the SEC and Nasdaq a publicly available report including: 1. Steps 1 & 2 set forth above; 2. A balance sheet no older than 60 days with pro forma adjustments for any significant transactions or event occurring on or before the report date; and 3. That the Company believes it satisfies the stockholders' equity requirement as of the report date. The pro forma balance sheet must evidence compliance with the stockholders' equity requirement. Additionally, in either case the Company is required to disclose that Nasdaq will** continue to ~~meet~~ **monitor the Company' s ongoing compliance with the stockholders' equity requirement and, if at the time of its next periodic report the Company does not evidence compliance, that it may be subject to delisting. Regardless of which alternative the Company chooses, if the Company fails to evidence compliance upon filing its next periodic report with the SEC following the end of such compliance period (i. e., its Quarterly Report for the Quarter ended June 30, 2024), the Company may be subject to delisting. In the event the Company does not satisfy** these ~~requirements~~ **terms, Nasdaq will provide written notification that its securities will be delisted. At that time, the Company** may **appeal Nasdaq' s determination to a Hearings Panel. The Company is currently evaluating various courses of action to regain compliance and is hopeful that it can regain compliance with Nasdaq' s minimum stockholders' equity standard within the compliance period. However, there can be no assurance that the Company will be able to complete the transactions contemplated in the compliance plan, which the Company expects will allow it to regain compliance with the Rule, or that such transactions will** result in ~~our securities being delisted from NASDAQ~~ **the Company regaining compliance with the Rule, within the compliance period granted by Nasdaq, if at all** . **Among the** ~~Conditions~~ **conditions** required for continued listing on The ~~NASDAQ~~ **Nasdaq** Capital Market ~~include requiring that we~~ **, Nasdaq requires us to** 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 **. As of December 31** , ~~having~~ **2023 and September 30, 2023, our stockholders' equity was below $ 2. 5 million and we did not otherwise meet the net income requirements described above, and as such, we are not currently in compliance with Nasdaq' s continue listing standards relating to minimum stockholders' equity. If we fail to timely remedy our compliance with such applicable requirement, our common stock and Public Warrants may be delisted. Our failure to meet Nasdaq' s continued listing requirements for the reasons above, or any other reason, may result in our securities being delisted from Nasdaq. Additional conditions required for continued listing on Nasdaq include requiring that we have** a majority of independent directors, a **two- person compensation committee and a** three ~~-~~ member audit committee (**each** consisting of all independent directors) ~~, and maintaining a bid price above $ 1~~ . **As a result** ~~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~~ **our common** ~~maintain a~~ stock ~~price above $ 1. 00. If we fail to comply with NASDAQ rules~~ and **Public Warrants** ~~requirements, our stock~~ may be delisted **from Nasdaq** . ~~In addition, even~~ **Even** if we demonstrate compliance with the requirements ~~above~~ **of Nasdaq** , we will have to continue to meet other objective and subjective listing requirements to continue to be listed on The ~~NASDAQ~~ **Nasdaq** Capital Market. Delisting from The ~~NASDAQ~~ **Nasdaq** Capital Market could make trading our common stock and **Public** ~~/ or warrants~~ **Warrants** more difficult for investors, potentially leading to declines in our share price and liquidity. Without a ~~NASDAQ~~ **Nasdaq** Capital Market listing, stockholders may have a difficult time getting a quote for the sale or purchase of our **common** stock **and Public Warrants** , the sale or purchase of our **common** stock **and Public Warrants** would likely be made more difficult **,** and the trading volume and liquidity of our **common** stock **and Public Warrants** could decline. Delisting from The ~~NASDAQ~~ **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 **Public** ~~/ or warrants~~ **Warrants** and the ability of our stockholders **and warrant holders** to sell our common stock and **Public** ~~/ or warrants~~ **Warrants** in the secondary market. If our common stock and **Public** ~~/ or warrants~~ **Warrants** are delisted by ~~NASDAQ~~ **Nasdaq** , our common stock and **Public** ~~/ or warrants~~ **Warrants** may be eligible to trade on an over- the- counter quotation system, such as the OTCQB Market **or the OTC Pink market** , where an investor may find it more difficult to sell our **common** stock **and Public Warrants** or obtain accurate quotations as to the market value of our common stock and **Public** ~~/ or warrants~~ **Warrants** . In the event our common stock and **Public** ~~/ or warrants~~ **Warrants** ~~are~~ **is** delisted from The ~~NASDAQ~~ **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~~ **our** ~~board~~ **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 **of the Company** . 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~~ **our** 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~~ **our** 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~~ **for research and** development ~~of our products and services~~, **and general corporate purposes** ~~product purchases in our wholesale distribution division~~, **including** the **potential expenses related** ~~expansion of our marketing, or the support of operations~~ to ~~educate our customers~~ **completing a reverse merger and legal expenses**. 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~~ **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~~ **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~~ **Board** of ~~directors~~ **Directors** has authority, without action or vote of the stockholders, but subject to ~~NASDAQ~~ **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 **under, and incorporated by reference** in **,** " **Item 3. Legal Proceedings** ~~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~~ **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 " **Item 10.** Directors, **Executive** 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 **the accounting principles generally accepted in the United States of America (“** 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. ~~105~~