Risk Factors Comparison 2023-12-08 to 2022-12-05 Form: 10-K

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Our business is subject to a number of risks of which you should be aware before making an investment decision. The following summary highlights some of the risks you should consider with respect to our business and prospects. This summary is not complete and the risks summarized below are not the only risks we face. For a more complete understanding of the risks related to our business and an investment in our common stock, we encourage you to read and consider the more detailed discussion of these highlighted risks, which discussion immediately follows this summary. A summary of the material risks that may affect our business, operating results and financial condition include, but are not necessarily limited to, those relating to: Risks Related to the Regulation and Commercialization of Our Products and Drug Candidates ? We have limited experience in obtaining regulatory approval or emergency use authorization for a drug. ? We could experience delays in our planned clinical trials. ? Our clinical trials may be suspended or discontinued. ? We **could experience delays or unanticipated costs in connection with our planned Phase 2b clinical trial of enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP- 1 RA who are at- risk for developing muscle atrophy and muscle weakness if the FDA does not accept our trial design.** ? **We** may be subject to risks relating to collaboration with third parties. ? We intend to rely on CROs to conduct our research and development activities. ? We expect to rely on third party manufacturers for our drug candidates and we rely on third party manufacturers for our marketed products. ? Disruptions to or significantly increased costs associated with transportation and other distribution channels for our products may adversely affect our margins and profitability. ? Changes in law could have a negative ~~effect~~ **impact** on the approval of our drug candidates. ? We may fail or elect not to commercialize our drug candidates or our approved or authorized products. ? ~~Due to the COVID- 19 pandemic, we may find it difficult to effectively recruit new clinical trial patients in a timely manner and to partner with clinical trial investigators and sites, which could delay or prevent us from proceeding with, or otherwise adversely affect, clinical trials of our drug candidates.~~ ? ~~Disruptions at the FDA caused by the COVID- 19 pandemic could delay or prevent new drugs from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent the FDA from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.~~ ? ~~Our pursuit~~ **development and commercialization** of ~~a COVID- 19 treatment candidate is still at the investigational stage. We may be unable to produce a drug that successfully treats the COVID- 19 virus in a timely manner, if at all.~~ ? ~~Government entities may take actions that directly or indirectly have the effect of limiting opportunities for~~ sabizabulin as a ~~COVID- 19 treatment.~~ ? ~~We may be unable to obtain an emergency use authorization from the FDA to market sabizabulin as a potential~~ treatment for **ARDS will depend on** ~~COVID- 19 in the United States in a timely manner, if at all, or our from any other regulatory authority for any other region or country.~~ ? ~~We may be unable to obtain emergency authorizations or approvals from regulatory authorities in foreign countries to market sabizabulin as a potential treatment for COVID- 19 in a timely manner, if at all.~~ ? ~~If we are unable to manufacture sabizabulin as a COVID- 19 treatment in sufficient quantities, at sufficient yields or are unable to obtain regulatory approvals for a manufacturing facility for sabizabulin, we may experience delays in product development, regulatory approval and commercial distribution.~~ ? ~~We may face competition in connection with sabizabulin for a COVID- 19 treatment, if authorized.~~ ? ~~Our~~ ability to ~~produce a treatment for the COVID- 19 virus may be curtailed by government actions or interventions, which may be more likely during a global health crisis such as COVID- 19.~~ ? ~~We may need to seek and~~ secure significant funding through ~~financings~~ **government grants, pharmaceutical company partnerships** or ~~from other~~ **similar external** sources ~~to effectively commercialize sabizabulin as a treatment for COVID- 19~~. ? We are subject to extensive and costly governmental regulation, including healthcare reform measures that may negatively impact sales of FC2 ~~, ENTADFI and, if an EUA is obtained, sabizabulin as a treatment for COVID- 19~~. ? We could experience misconduct by our employees. ? Coverage and reimbursement may not be available for our products. ? We may not be able to gain ~~or~~ **and** retain market acceptance for our drug candidates. ? Our drug products may be subject to governmental pricing controls. ? Third parties may obtain FDA regulatory exclusivity to our detriment. Risks Related to Our Financial Position and Need for Capital ? We have incurred net losses in recent fiscal years and expect to continue to incur losses for the foreseeable future. ? **Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in this Annual Report on Form 10- K for the fiscal year ended September 30, 2023.** ? **We will need to raise** ~~Additional~~ **additional capital to fund our operations in the future. If we are unsuccessful in attracting new capital, we may not be able to continue operations or may be forced to sell assets to do so. Alternatively, capital may not be available to us on favorable terms, or if at all. If available,** financing **terms** may ~~be~~ **lead to significant dilution of our stockholders' equity.** ? **The amount of additional financing that we will** ~~needed~~ -- **need** to support our development and commercialization activities **is uncertain** . ? **We may not receive any** ~~COVID- 19 and its impact on the economic environment and capital markets could adversely affect our access to capital when needed.~~ ? ~~If we fail to obtain~~ additional **payments from BWV in connection** ~~capital, we may need to reduce the scope of our development or commercialization programs or we could be forced to share our rights to technologies~~ with ~~third parties on terms that~~ **the sale of our ENTADFI assets and** may not ~~be favorable to us~~ **receive any value for the shares of BWV Series A Preferred Stock we hold** . Risks Related to Our Business ? ~~The COVID- 19 pandemic has disrupted, and may continue to disrupt, our operations and the operations of our suppliers and customers.~~ ? Our FC2 business may be affected by contracting risks with government and other international health agencies. ? The FDA issued a final order reclassifying female condoms as Class II medical devices, which

may result in increased competition for FC2 in the U. S. market. ? We may experience competition, especially for ~~sabizabulin~~ **enobosarm** as a treatment for **metabolic diseases** ~~COVID- 19~~, if **approved** ~~authorized, ENTADFI~~, and FC2 **. ? Our net revenues from sales of FC2 may not return to past levels**. ? We may not be able to successfully implement our strategy to grow sales of FC2 ~~or ENTADFI~~ in the U. S. market **through** ~~or~~ **our own portal** ~~, if authorized, sabizabulin in the U. S. or any foreign market. ? We may not be able to sustain price levels for FC2 in the U. S. market~~. ? An inability to identify or complete future acquisitions could adversely affect our future growth. ? We may experience difficulties in integrating strategic acquisitions. ? We ~~depend on~~ **may be subject** ~~two~~ **to claims** ~~major customers for~~ **or** ~~a significant portion~~ **investigations relating to The Pill Club' s business practices with respect to sales** of **FC2. ? It is unlikely that we will collect any amount of** our ~~net revenues~~ **accounts receivable with The Pill Club. ? We are subject to potential liability relating to a dispute with a supplier**. ? Since we sell FC2 in foreign markets, we are subject to international business risks that could adversely affect our operating results. ? Increases in the cost of raw materials, labor, and other costs used to manufacture FC2 could increase our cost of sales and reduce our gross margins. ? Currency exchange rate fluctuations could increase our expenses. ? We rely on a single facility to manufacture FC2, which subjects us to the risk of supply disruptions. ? **We may incur costs or experience supply interruptions relating to our need to transition the supply of the nitrile polymer for FC2. ?** Uncertainty and adverse changes in the general economic conditions may negatively affect our business. ? Material adverse or unforeseen legal judgments, fines, penalties, or settlements could have an adverse impact on our profits and cash flows. ? **We have been named a defendant in stockholder class actions. These, and potential similar or related lawsuits or investigations, could result in substantial legal fees, fines, penalties or damages and may divert management' s time and attention from our business. ?** Our business and operations would suffer if we sustain cyber- attacks or other privacy or data security incidents that result in security breaches. ? Any failure to comply with the FCPA and similar anti- bribery laws in non- U. S. jurisdiction could materially adversely affect our business and result in civil and / or criminal sanctions. ? We will need to increase the size and complexity of our organization in the future, and we may experience difficulties in executing our growth strategy and managing any growth. ? Uncertainties in the interpretation and application of tax rules in the various jurisdictions in which we operate could materially affect our deferred tax assets, tax obligations and effective tax rate. ? Our effective tax rate may be negatively impacted if we are unable to realize deferred tax assets or by future changes to tax laws in jurisdictions in which we operate. ? Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. Risks Relating to Our Intellectual Property ? We may be unable to protect the proprietary nature of the intellectual property covering our products. ? Our or our licensors' patents may expire or be invalidated, found to be unenforceable, narrowed or otherwise limited or our or our licensors' patent applications may not result in issued patents or may result in patents with narrow, overbroad, or unenforceable claims. ? We **may not have sufficient intellectual property protection for enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving GLP- 1 RA who are at- risk for developing muscle atrophy and muscle weakness. ? We** are dependent in part on some license relationships. ? We may face claims that our intellectual property infringes on the intellectual property rights of third parties. If we infringe intellectual property rights of third parties, it may increase our costs or prevent us from being able to commercialize our product candidates. ? We ~~must submit patent certifications in connection with the 505 (b) (2) FDA regulatory pathway. ? We~~ may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of our competitors. ? We may need to file lawsuits or take other actions to protect or enforce our intellectual property rights. ? We may fail to protect the confidentiality of commercially sensitive information. Risks Related to Ownership of Our Common Stock ? Ownership in our common stock is highly concentrated and your ability to influence corporate matters may be limited as a result. ? **Our common stock may be subject to delisting from the Nasdaq Capital Market if our common stock has a closing bid price of less than $ 1. 00 per share. ?** We incurred ~~a charge~~ **charges** to earnings in fiscal 2020 **and in fiscal 2023** resulting from the APP Acquisition, and additional charges to earnings resulting from the APP Acquisition in the future may cause our operating results to suffer. ? ~~If we fail~~ **The restatement of our prior quarterly financial statements may affect stockholder and investor confidence in us or harm our reputation, and may subject us** to ~~maintain effective~~ **additional risks and uncertainties, including increased costs and the increased possibility of legal proceedings and regulatory inquiries, sanctions or investigations. ? We identified a material weakness in** internal control over financial reporting, **and determined that they resulted in our internal control over financial reporting and disclosure controls and procedures not being effective, as of September 30, 2023. If we are not able to remediate this material weakness,** ~~our~~ **or** ~~ability~~ **we identify additional deficiencies in the future or otherwise fail** to ~~produce accurate~~ **maintain an effective system of internal controls, including disclosure controls and procedures, this could result in material misstatements of our** financial statements or ~~comply with applicable regulations could be impaired~~ **cause us to fail to meet our reporting obligations**. ? We are a " smaller reporting company " and will be able to avail ourselves of reduced disclosure requirements applicable to smaller reporting companies, which could make our common stock less attractive to investors. ? There are provisions in our charter documents, Wisconsin law and our residual royalty agreement that might prevent or delay a change in control of our company. ? The trading price of our common stock has been volatile, and investors in our common stock may experience substantial losses ~~. ? If our stock price declines, our common stock may be subject to delisting from the NASDAQ Capital Market~~. ? A substantial number of shares may be sold in the market, which may depress the market price for our common stock. ? Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be our shareholders' sole source of gain. Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with all of the other information included in this Annual Report and our other SEC filings, in considering our business and prospects. The risks described below are not the only risks we face. Additional risks that we do not yet know of or that we currently think are immaterial may also impair our business operations. If any of the events or circumstances described in the following risks occurs, our business, financial condition, results of operations or prospects could

be materially adversely affected. In such cases, the trading price of our common stock could decline. Risks Related to the Regulation and Commercialization of Our Products and Drug Candidates We have limited experience in obtaining regulatory approval or emergency use authorization for a drug. We have only obtained regulatory approval for one ~~of our drugs~~ **drug** ~~under development~~, ENTADFI (tadalafil and finasteride) capsules, for oral use **, which we sold to BWV in April 2023** . We have never obtained an EUA in the U. S. or in any other jurisdiction. It is possible that the FDA or other regulatory authorities may refuse to accept any or all of our ~~EUAs or~~ planned NDAs for substantive review or may conclude, after review of our data, that our applications are insufficient to obtain regulatory authorization or approval of any of our drug candidates ~~, including sabizabulin for the treatment of certain hospitalized COVID- 19 patients~~ . The FDA may also require that we conduct additional clinical or manufacturing validation studies, which may be costly and time- consuming, and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA required studies, approval of any NDA or authorization of any EUA application ~~, including that for sabizabulin,~~ that we submit may be significantly delayed, possibly for years, or may require us to expend more resources than we have available or can secure. Any delay or inability in obtaining regulatory approvals would delay or prevent us from commercializing our drug candidates, generating revenue from these proposed products and achieving and sustaining profitability. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve any NDA or any EUA ~~, including that for sabizabulin,~~ we submit ~~. In addition, if the requirements for approval of any of our drug candidates under Section 505 (b) (2) are not as we expect, it will likely take significantly longer, cost significantly more and be significantly more complicated to gain FDA approval for these drug candidates, and in any case may not be successful~~ . If any of these outcomes occur, we may be forced to abandon our planned NDAs or EUAs ~~, including that for sabizabulin,~~ for one or more of our drug candidates, which would materially adversely affect our business. Clinical trials involve a lengthy and expensive process with an uncertain outcome and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any time during the clinical trial process as a result of inadequate performance of a drug, inadequate adherence by patients or investigators to clinical trial protocols or other factors. New drugs in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through earlier clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials as a result of a lack of efficacy or adverse safety profiles, despite promising results in earlier trials. Our future clinical trials may not be successful or may be more expensive or time- consuming than we currently expect. If clinical trials for any of our drug candidates fail to demonstrate safety or efficacy to the satisfaction of the FDA, the FDA will not approve that drug and we would not be able to commercialize it, which will have a material adverse effect on our business, financial condition, results of operations and prospects. We could experience delays in our planned clinical trials. We may experience delays in any of the clinical trials that will be required to be conducted for our drug candidates. Our planned clinical trials might not begin on time; may be interrupted, delayed, suspended, or terminated once commenced; might need to be redesigned; might not enroll a sufficient number of patients; or might not be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including the following: ? delays in obtaining regulatory approval to commence a trial; ? imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities; ? imposition of a clinical hold because of safety or efficacy concerns by the FDA, a DSMB or IDMC, a clinical trial site' s IRB or us; ? delays in reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical trial sites; ? delays in obtaining required IRB approval at each site; ? delays in identifying, recruiting and training suitable clinical investigators; ? delays in recruiting suitable patients to participate in a trial; ? delays in having patients complete participation in a trial or return for post- treatment follow- up; ? clinical sites dropping out of a trial to the detriment of enrollment; ? time required to add new sites; ? delays in obtaining sufficient supplies of clinical trial materials, including suitable active pharmaceutical ingredients; ? delays resulting from negative or equivocal findings of DSMB or IDMC for a trial; or ? delays resulting from shutdowns or quarantines or staffing shortages relating to **a pandemic** ~~COVID- 19~~ or other reasons. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, **a** ~~the ongoing COVID- 19~~ pandemic, competing clinical trials, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Any of these delays in completing our clinical trials could increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue as to the affected drug candidate. Our clinical trials may be suspended or discontinued. Before we can obtain regulatory approval for the commercial sale of our drug candidates, we may be required to complete preclinical development with respect to such drug candidates and / or extensive clinical trials in humans to demonstrate the safety and efficacy of the drug candidates. To date, regulatory approval has not been obtained for any of our drug candidates. Unfavorable results from preclinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated. In addition, we may report top- line data from time to time, which is based on a preliminary analysis of key efficacy and safety data. Such top- line data may be subject to change following a more comprehensive review of the data related to the applicable clinical trial. If we delay or abandon our development efforts related to any of our drug candidates, we would experience potentially significant delays in, or be required to abandon, development of that drug candidate. If we delay or abandon our development efforts related to any of our drug candidates, our business, financial condition, results of operations and prospects may be materially adversely affected. Our clinical trials may be suspended or terminated at any time for a number of reasons. A clinical trial may be suspended or terminated by us, our collaborators, the FDA or other regulatory authorities because of a failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols,

presentation of unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using the investigational drug, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial or negative or equivocal findings of the DSMB, IDMC or the IRB for a clinical trial. An IRB may also suspend or terminate our clinical trials for failure to protect patient safety or patient rights. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe the clinical trials are not being conducted in accordance with applicable regulatory requirements or present an unacceptable safety risk to participants. If we elect or are forced to suspend or terminate any clinical trial of any drug candidate we are developing, the commercial prospects of such drug candidate will be harmed and our ability to generate revenue from such drug candidate will be delayed or eliminated. Any of these occurrences may materially harm our business, financial condition, results of operations and prospects **. We could experience delays or unanticipated costs in connection with our planned Phase 2b clinical trial of enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP- 1 RA who are at- risk for developing muscle atrophy and muscle weakness if the FDA does not accept our trial design. We intend to submit an IND for enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP- 1 RA who are at- risk for developing muscle atrophy and muscle weakness in the fourth quarter of 2023. Subject to receiving clearance of our IND, we plan to conduct a Phase 2b multicenter, double- blind, placebo- controlled, randomized, dose- finding clinical trial designed to evaluate the safety and efficacy of enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP- 1 RA who are at- risk for developing muscle atrophy and muscle weakness, with the first data from the trial expected in the second half of 2024. Upon the review of our IND and clinical trial design, the FDA may require that we conduct preclinical studies or additional or earlier clinical trials or that we conduct larger and more expensive clinical trials than the planned Phase 2b clinical trial we have described in this report. FDA may also disagree with the indication we have proposed and require us to more clearly define or otherwise alter the condition we are seeking to treat. Any delays of or unanticipated changes to the planned Phase 2b clinical trial may increase our costs, slow down our product development and approval process and jeopardize our ability to develop enobosarm for and ultimately generate revenue from enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP- 1 RA who are at- risk for developing muscle atrophy and muscle weakness, which may cause a change in our development strategy. Additional costs may also require us to raise additional capital, which may not be available when needed or on terms acceptable to us. As a result, we may be forced to abandon our development of enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP- 1 RA who are at- risk for developing muscle atrophy and muscle weakness. There can be no assurances that the FDA will accept our proposed trial design, that we will be able to cost- effectively continue development of enobosarm, or that enobosarm will receive FDA approval or be commercialized, for any application** . We may be subject to risks relating to collaboration with third parties. As part of our business strategy, we may enter into collaboration arrangements with strategic partners to develop and commercialize our drug candidates or to develop companion diagnostics for our drug candidates. For our collaboration efforts to be successful, we must identify partners whose competencies complement our competencies. We may be unsuccessful in entering into collaboration agreements with acceptable partners or negotiating favorable terms in these agreements. Also, we may be unsuccessful in integrating the resources and capabilities of these collaborators with our own. In addition, we may face a disadvantage in seeking to enter into or negotiating collaborations with potential partners because other potential collaborators may have greater management and financial resources than we do. Our collaborators may prove difficult to work with or less skilled than originally expected or may require more time to achieve the planned goals of any such collaboration, if they are achieved at all. For companion diagnostics, any such collaborator may be unsuccessful in obtaining regulatory approval for the planned diagnostic and, even if approved, may not be successful in commercializing the diagnostic or achieving widespread adoption of the diagnostic by physicians. If we are unsuccessful in our collaborative efforts, our ability to develop and market drug candidates could be severely limited. We intend to rely on CROs to conduct our research and development activities. We do not have the resources to independently conduct research and development activities. Therefore, we intend to and do rely on CROs to conduct research and development activities for our drug candidates and for the execution of our clinical studies. Although we will control only certain aspects of our CROs' activities, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We cannot be sure that the CROs will conduct the research properly in a timely manner or on a cost- effective basis, or that the results will be reproducible. We and our CROs are required to comply with the FDA' s cGCPs, which are regulations and guidelines enforced by the FDA for all of our drug products in clinical development. The FDA enforces these cGCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable or invalid and the FDA may require us to perform additional clinical trials before approving our drug candidates. In addition, to evaluate the safety and effectiveness compared to placebo of our drug candidates to a statistically significant degree, our clinical trials will require an adequately large number of test subjects. Any clinical trial that a CRO conducts abroad on our behalf is subject to similar regulation. Accordingly, if our CROs fail to comply with these regulations or recruit a sufficient number of patients, we may be required to repeat clinical trials, which would delay the regulatory approval process. In addition, we will not employ the personnel of our CROs, and, except for remedies available to us under our agreements with such organizations, we cannot control whether or not they will devote sufficient time and resources to our research and development and our clinical studies. Our CROs may also have relationships with other commercial entities, including one or more of our competitors, for

which they may also be conducting clinical studies or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised because of the failure to adhere to our clinical protocols or regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates that we seeks to develop. As a result, our financial results and the commercial prospects for our drug candidates that we seek to develop would be harmed, our costs could increase and our ability to generate revenue from such drug candidates could be delayed or ended. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or entering into new relationships with CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially affect our ability to meet our desired clinical development timelines and can increase our costs significantly. We may encounter challenges or delays in entering into or maintaining these relationships, and any such delays or challenges may have a material adverse impact on our business, financial condition, results of operations and prospects. We expect to rely on third party manufacturers for our drug candidates and we rely on third party manufacturers for our marketed products. For the foreseeable future, we expect to and do rely on third- party manufacturers and other third parties to produce, package and store sufficient quantities of drug candidates for use in our clinical trials ~~and, in the case of ENTADFI and sabizabulin, if authorized, sufficient to meet demand~~ . These drug candidates and products are complicated and expensive to manufacture. If our third- party manufacturers fail to deliver our drug candidates for clinical use on a timely basis, with sufficient quality, and at commercially reasonable prices, we may be required to delay or suspend clinical trials or otherwise discontinue development and production of our drug candidates. While we may be able to identify replacement third- party manufacturers or develop our own manufacturing capabilities for these drug candidates or products, this process would likely cause a delay in the availability of our drug candidates or products and an increase in costs. In addition, third- party manufacturers may have a limited number of facilities in which our drug candidates or products can be produced, and any interruption of the operation of those facilities due to events such as equipment malfunction or failure or damage to the facility by natural disasters could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in available drug candidates or products. In addition, regulatory requirements could pose barriers to the manufacture of our drug candidates or marketed products. Third- party manufacturers are required to comply with the FDA **'** **'** s cGMPs. As a result, the facilities used by any manufacturers of our drug candidates and marketed products must maintain a compliance status acceptable to the FDA. Holders of NDAs, or other forms of FDA approvals or clearances, or those distributing a regulated product under their own name, are responsible for manufacturing even though that manufacturing is conducted by a third- party contract manufacturing organization (CMO). Our third- party manufacturers will be required to produce our drug candidates and marketed products under FDA cGMPs in order to meet acceptable standards. Our third- party manufacturers may not perform their obligations under their agreements with us or may discontinue their business before the time required by us to gain approval for or commercialize our drug candidates. In addition, our manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. Failure by any of our manufacturers to comply with applicable cGMPs could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply, recalls, withdrawals, issuance of safety alerts and criminal prosecutions, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Finally, we also could experience manufacturing delays if our CMOs give greater priority to the supply of other products over our products or otherwise do not satisfactorily perform according to the terms of their agreements with us. If any supplier for our drug candidates or marketed products experiences any significant difficulties in its manufacturing processes, does not comply with the terms of the agreement between us or does not devote sufficient time, energy and care to providing our manufacturing needs, we could experience significant interruptions in the supply of our drug candidates or marketed products, which could impair our ability to supply our drug candidates at the levels required for our clinical trials or commercialization and prevent or delay their successful development and commercialization. Disruptions to or significantly increased costs associated with transportation and other distribution channels for our products may adversely affect our margins and profitability. We expect to rely on the uninterrupted and efficient operation of third- party logistics companies to transport and deliver our products, including ~~sabizabulin, if authorized, ENTADFI and~~ FC2. These third- party logistics companies may experience disruptions to the transportation channels used to distribute our products, including disruptions caused by ~~the COVID- 19 pandemic~~ **pandemics** , increased airport and shipping port congestion, a lack of transportation capacity, increased fuel expenses, and a shortage of manpower or capital or due to other business interruptions. Disruptions to the transportation channels experienced by our third- party logistics companies may result in increased costs, including the additional use of airfreight to meet demand. Disruptions to this business model or our relationship with the third party if, for example, performance fails to meet our expectations, could harm our business. Changes in law could have a negative impact on the approval of our drug candidates. The FDA has established regulations, guidelines and policies to govern the drug development and approval process, as have foreign regulatory authorities. Any change in regulatory requirements resulting from the adoption of new legislation, regulations or policies may require us to amend existing clinical trial protocols or add new clinical trials to comply with these changes. Such amendments to existing protocols or clinical trial applications or the need for new ones, may significantly and adversely affect the cost, timing and completion of the clinical trials for our drug candidates. In addition, the FDA' s policies may change and additional government regulations may be issued that could prevent, limit or delay regulatory approval of our drug candidates, or impose more stringent product labeling and post- marketing testing and other requirements. The political environment in the U. S. could result in significant changes in, and uncertainty with respect to, legislation, regulation and government policy that could

significantly impact our business and the health care industry. While it is not possible to predict whether and when any such changes will occur, specific proposals that have been discussed or implemented which could have a material impact on us include, but are not limited to, potential changes to the ACA, recently issued regulations offering employers religious and moral exemptions from the ACA' s requirement to provide insurance covering birth control, and the enactment of the 21st Century Cures Act. If we are slow or unable to adapt to any such changes, our business, prospects and ability to achieve or sustain profitability would be adversely affected. We may fail or elect not to commercialize our drug candidates or our approved or authorized products. We cannot be sure that, if our clinical trials for any of our drug candidates are successfully completed, we will be able to submit an NDA to the FDA or that any NDA we submit will be approved by the FDA in a timely manner, if at all, or that the submission of any NDA is commercially feasible. Similar risks apply to ~~our~~ Emergency Use Authorization applications in the U. S. and other jurisdictions ~~for sabizabulin for certain hospitalized COVID- 19 patients~~ . After completing clinical trials for a drug candidate in humans, a drug dossier is prepared and submitted to the FDA as an NDA, and includes all preclinical studies and clinical trial data relevant to the safety and effectiveness of the product at the suggested dose and duration of use for the proposed indication as well as manufacturing information, in order to allow the FDA to review such drug dossier and to consider a drug candidate for approval for commercialization in the United States. If we are unable to submit an NDA with respect to any of our current drug candidates, if any NDA we submit is not approved by the FDA, or we elect not to file an NDA, or if we are unable to obtain any required state and local distribution licenses or similar authorizations, we will be unable to commercialize that product. The FDA can and does reject NDAs and require additional clinical trials, even when drug candidates achieve favorable results in Phase 3 clinical trials. ~~Similarly, we may not successfully commercialize our approved or authorized product, ENTADFI, or we may not receive authorization to commercialize sabizabulin. We or our collaboration partners in any potential commercial marketing efforts of ENTADFI or sabizabulin, if authorized, may not be successful in achieving widespread patient or physician awareness or acceptance of these products. Also, we may be subject to pricing pressures from competitive products or from governmental or commercial payors or regulatory bodies that could make it difficult or impossible for us to commercialize ENTADFI or sabizabulin, if authorized, successfully. Any failure to commercialize our marketed drugs could have a material adverse effect on our revenue and our business.~~ If we fail to commercialize any of these drug candidates, or approved or authorized products, our business, financial condition, results of operations and prospects may be materially adversely affected and our reputation in the industry and in the investment community would likely be damaged. ~~Due to the COVID- 19 pandemic, we may find it difficult to effectively recruit new clinical trial patients in a timely manner and to partner with clinical trial investigators and sites, which could delay or prevent us from proceeding with, or otherwise adversely affect, clinical trials of our drug candidates. Identifying and qualifying patients to participate in, and partnering with investigators and sites to run, clinical trials of our drug candidates is critical to the timely completion of our clinical trials. Patients may be unwilling to participate in our clinical trials because of the ongoing COVID- 19 pandemic. The severe burden on healthcare systems caused by the COVID- 19 pandemic has also impaired the ability of many research sites to start new clinical trials or to enroll new patients in clinical trials. The imposed mandatory sheltering in place and social distancing restrictions may delay the recruitment of patients and impede their ability to effectively participate in such trials. Significant fees may also be owed to contract research organizations associated with starting and stopping clinical trials, typically more so than delaying the start of a clinical trial. There is a risk that changing circumstances relating to the COVID- 19 pandemic may not allow our healthcare clinical trial investigators, their healthcare facilities or other necessary parties to continue to participate in our clinical trials through completion or may delay the initiation of planned clinical trials. Any delays related to clinical trials could result in increased costs, delays in advancing our drug candidates, delays in testing the effectiveness of our drug candidates or termination of the clinical trials altogether. Disruptions at the FDA caused by the COVID- 19 pandemic could delay or prevent new drugs from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent the FDA from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. Disruptions at the FDA caused by the COVID- 19 pandemic may slow the time necessary for new drugs to be reviewed and / or approved, which would adversely affect our business. In response to the COVID- 19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products through April 2020. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. The FDA has also prioritized the review of submissions relating to COVID- 19. The FDA may adopt other restrictions or policy measures in response to the COVID- 19 pandemic or issue guidance materially affecting the conduct of clinical trials. If global health concerns continue to prevent the FDA from conducting its regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Our pursuit of a COVID- 19 treatment candidate is still at the investigational stage. We may be unable to produce a drug that successfully treats the virus in a timely manner, if at all. We filed an application for an Emergency Use Authorization for sabizabulin for the treatment of hospitalized COVID- 19 patients with moderate or severe risk of ARDS in June 2022 after announcing positive interim phase 3 clinical data. The FDA has not yet authorized, and may never authorize, our EUA for sabizabulin or the FDA may require additional studies as a condition of any authorization that we do not believe are commercially reasonable to undertake which may lead to FDA refusal of our EUA. Similarly, we have filed applications for emergency use or other similar expedited regulatory pathways in certain jurisdictions outside the U. S., including the United Kingdom, the European Union, Australia, Switzerland, South Korea, and Canada, and similar risks apply to those applications. Moreover, any authorization by the FDA or any other regulatory authority may have significant restrictions or conditions that hamper our ability to effectively market sabizabulin or any such authorization may come late enough in the COVID- 19 pandemic that our ability to market sabizabulin effectively or for a sufficient period of time may be negatively affected.~~ Our development ~~of a COVID- 19 treatment is still at the investigational stages,~~ and ~~we may be unable to produce a drug that~~

successfully treats the virus in a timely manner, if at all. We are also committing financial resources and personnel to the development of a COVID- 19 treatment which may cause delays in or otherwise negatively impact our other development programs, despite uncertainties surrounding the longevity and extent of coronavirus as a global health concern. We have expended considerable resources in scaling- up manufacturing of sabizabulin so that we might be ready to meet potential demand in the U. S. and elsewhere around the world, if sabizabulin receives any authorization, but, if we do not receive any authorization, we may have to write- off stock of sabizabulin if we are not able to redirect it before applicable expiration dates. In addition, if we do not receive any such authorization, we may have to unwind certain business arrangements into which we have entered in building up our commercialization infrastructure and such efforts may result in significant contractual, severance, or other costs. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate or against which our treatment, if developed, may not be partially or fully effective or by drug products to treat COVID- 19 being developed by other companies that receive approval. In addition, conducting a clinical trial of a COVID- 19 treatment is challenging in the current environment due to a number of factors, including a large number of competitive clinical trials seeking to enroll COVID- 19 patients, the high workload of hospital staff, and the difficulty of enrolling patients in intensive care or similar environments. These challenges may delay any clinical trial, increase its costs or otherwise adversely affect any such clinical trial. Government entities may take actions that directly or indirectly have the effect of limiting opportunities for sabizabulin as a COVID- 19 treatment. Various government entities, including the U. S. government, are offering incentives, grants and contracts to encourage additional investment by commercial organizations into preventative and therapeutic agents against COVID- 19, which may have the effect of increasing the number of competitors and / or providing advantages to competitors. Accordingly, there can be no assurance that we will be able to successfully establish a competitive market share if we develop a COVID- 19 treatment. COVID- 19 treatments may also be subject to government pricing controls, which could adversely affect the profitability of any COVID- 19 treatment we are able to develop and commercialize. We may be unable to obtain an emergency use authorization from the FDA to market sabizabulin as a potential treatment for **ARDS** COVID- 19 in the United States in a timely manner, if at all, or from any other regulatory authority for any other region or country. In response to the global outbreak of COVID- 19, we have been pursuing the development of sabizabulin as a treatment for COVID- 19. Our ability to commercialize sabizabulin as a treatment for COVID- 19 will depend on regulatory approval in the United States and other jurisdictions. In the United States, we initially plan to use the FDA' s EUA process, and on June 7, 2022, the Company submitted a request for an EUA. EUA is a form of temporary marketing authorization that the FDA may grant to an investigational drug at times when the Secretary of Health and Human Services has declared a public health emergency to exist. This declaration was made by the Secretary of Health and Human Services in March 2020 in relation to the COVID- 19 pandemic. In order to grant an EUA, the FDA must determine that an investigational drug is likely safe and likely effective in treating the disease that is the subject of the public health emergency. Although the EUA process is designed to enable more expeditious marketing of a drug in response to a public health emergency, FDA review of an EUA application may take longer than expected and may result in the FDA requesting additional data or other information that may have the effect of delaying the EUA, and any agreements or positions taken by the FDA in a pre- EUA meeting does not bind the FDA or prevent it from later taking a different position, asking for more data, or delaying or denying the application. The FDA may decline to grant an EUA if it concludes that an investigational drug is not safe or effective. If any such issues arise in connection with our submission of an EUA for sabizabulin, our ability to market sabizabulin as a COVID- 19 treatment may delayed or dependent on a more time- consuming regulatory approval process, which may have a material adverse effect on our business. If we are granted an EUA by the FDA for sabizabulin, we would be able to distribute sabizabulin under the conditions set forth in the EUA prior to FDA approval. Furthermore, the FDA may revoke (or refuse to grant) an EUA where it is determined that the underlying health emergency no longer exists or warrants such authorization, and we cannot predict how long, if ever, an EUA would remain in place. Such revocation could adversely impact our business in a variety of ways, including if sabizabulin is not yet approved by the FDA and if we and our manufacturing partners have invested in the supply chain to provide sabizabulin under an EUA. Similar risks apply to all of our efforts to obtain emergency authorization or other similar expedited regulatory authorization in other countries around the world, including the United Kingdom, the European Union, Australia, Switzerland, South Korea, and Canada. We may be unable to obtain emergency authorizations or approvals from regulatory authorities in foreign countries to market sabizabulin as a potential treatment for COVID- 19 in a timely manner, if at all. Similar to the regulatory challenges we face for an EUA or approval of sabizabulin for the treatment of COVID- 19 in the United States, we will not be able to market sabizabulin for the treatment of COVID- 19 in any foreign jurisdiction without an applicable authorization or approval in any such foreign jurisdiction. We have never received any such authorization or approval for any of our drug candidates from any foreign regulatory authority and, even if such an authorization or approval is granted, we have no experience marketing a drug outside the United States. Like any EUA or approval in the United States, any authorization or approval outside the United States may be subject to various conditions required by any such foreign regulatory authority. There can be no assurances of the timing of receipt of any such foreign authorization or approval or whether we will receive any such foreign authorization or approval at all and, if we do receive any such authorization or approval, whether we will be able to market sabizabulin on favorable economic terms. We lack experience in scaling- up and commercializing a drug product. We are working toward the large- scale technical development, manufacturing scale- up and larger scale deployment of sabizabulin as a COVID- 19 treatment. To support the scale- up, we have expended and will need to continue to expend significant resources and capital. In connection with this process, we may seek to enter into a collaboration or other arrangement with a larger organization, although we may be unable to enter into such arrangements on favorable terms, or at all, or may decide to proceed with development and commercialization on our own. In that case, we will need to expend significant resources to commercialize sabizabulin, which may require additional financial resources. In addition, since the path to licensure or emergency approval of any COVID- 19 treatment remains uncertain, we

~~may have a widely used drug in circulation in the United States or another country prior to our receipt of marketing approval. Unexpected safety issues, including any that we have not yet observed in our clinical trials for sabizabulin, could lead to significant reputational damage for us and our drug development program going forward and other issues, including delays in our other programs, the need for re- design of our clinical trials and the need for significant additional financial resources. If we are unable to manufacture sabizabulin as a COVID- 19 treatment in sufficient quantities, at sufficient yields or are unable to obtain regulatory approvals for a manufacturing facility for sabizabulin, we may experience delays in product development, regulatory approval and commercial distribution. If we are authorized to market sabizabulin as a COVID- 19 treatment, its commercialization will require access to facilities to manufacture sabizabulin at sufficient yields and at commercial scale. We have no experience in manufacturing any of our drug candidates in the volumes that would be necessary to support commercial sales. Efforts to establish these capabilities may not meet initial expectations as to scheduling, scale- up, reproducibility, yield, purity, cost, potency or quality. In addition, other companies, many with substantial resources, may compete with us for access to materials needed to manufacture sabizabulin. Manufacturing sabizabulin as a COVID- 19 treatment will involve a complicated process with which we have limited experience. We are dependent on third- party organizations to conduct our manufacturing activities. If third- party manufacturing organizations are unable to manufacture sabizabulin in commercial quantities and at sufficient yields, then we will need to identify and reach supply arrangements with additional third parties. Third- party manufacturers must also be inspected by the FDA as part of the FDA' s review of our marketing application. Sabizabulin may be in competition with other products for access to these facilities and may be subject to delays in manufacturing if third parties give other products higher priority. We may not be able to enter into any necessary additional third- party manufacturing arrangements on acceptable terms, or on a timely basis. In addition, we have to enter into technical transfer agreements and share our know- how with the third- party manufacturers, which can be time- consuming and may result in delays. Any delay in the manufacture or delivery of sabizabulin could adversely affect our ability to sell sabizabulin as a COVID- 19 treatment, if approved. Our reliance on third- party manufacturers may adversely affect our operations or result in unforeseen delays or other problems beyond our control. Because of contractual restraints and the limited number of third- party manufacturers with the expertise, required regulatory approvals and facilities to manufacture sabizabulin on a commercial scale, replacement of a manufacturer may be expensive and time- consuming and may cause interruptions in the production of sabizabulin. A third- party manufacturer may also encounter difficulties in production. These problems may include: ? difficulties with production costs, scale up and yields; ? availability of raw materials and supplies; ? quality control and assurance; ? shortages of qualified personnel; ? compliance with strictly enforced federal, state and foreign regulations that vary in each country where products might be sold; and ? lack of capital funding. As a result, any delay or interruption could have a material adverse effect on our business, financial condition, or results of operations. We may face competition in connection with sabizabulin for a COVID- 19 treatment, if authorized. Another party may be successful in producing a more efficacious, an earlier- stage, or a less expensive treatment for COVID- 19 which may also lead to the diversion of governmental and quasi- governmental funding as well as government or commercial payor reimbursements away from us and toward other companies. In particular, given the widespread media attention on the current COVID- 19 pandemic, there are efforts by public and private entities to develop COVID- 19 treatments. Those other entities may develop COVID- 19 treatments that, as compared to sabizabulin, are more effective, become the standard of care, have broader market acceptance, are safer or have fewer or less severe side effects, are more convenient, are developed at a lower cost or earlier, or may be more successfully commercialized. Many of these other organizations are much larger than we are and have access to larger pools of capital and broader manufacturing infrastructure. Larger pharmaceutical and biotechnology companies have extensive experience in clinical testing and obtaining regulatory approval for their products, and may have the resources to heavily invest to accelerate discovery and development of their vaccine candidates. Our business could be materially and adversely affected if competitors develop and commercialize one or more COVID- 19 treatments before we can complete development and seek approval for sabizabulin. Our ability to produce a treatment for the COVID- 19 virus may be curtailed by government actions or interventions, which may be more likely during a global health crisis such as COVID- 19. Given the significant global impact of the COVID- 19 pandemic, it is possible that one or more government entities may take actions that directly or indirectly have the effect of diminishing some of our rights or opportunities with respect to sabizabulin and the economic value of a COVID- 19 treatment to us could be limited. Governments and other health authorities may also focus on vaccines rather than treatment options such as sabizabulin in addressing the COVID- 19 pandemic, which may reduce funding and other market opportunities for sabizabulin. We also intend to seek to enter into contracts with foreign health authorities to supply sabizabulin, which will depend on spending and political priorities, the availability of alternative treatment options, and the continuation of the COVID- 19 as a public health emergency. Government entities may also impose restrictions or limitations on our third- party service providers and may require us to obtain alternative sources for sabizabulin. If we are unable to timely enter into alternative arrangements, or if such alternative arrangements are not available on satisfactory terms, we will experience delays in the development or production of our sabizabulin, increased expenses, and delays in potential distribution or commercialization of sabizabulin, if authorized. We may need to seek and~~ secure significant funding through **government grants, pharmaceutical company partnerships or similar external sources. We currently plan to prioritize the use of our internal cash and the net proceeds of any future** financings **to the development of enobosarm, with a primary near- term focus on funding a Phase 2b clinical trial designed to evaluate the safety and efficacy of enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP- 1 RA who are at- risk ~~or~~ for ~~from other~~ developing muscle atrophy and muscle weakness, and to seek external funding through government grants, pharmaceutical company partnerships or similar** sources to **advance ~~effectively commercialize~~** sabizabulin as a treatment for ~~COVID~~ **viral** ~~-~~ ~~19~~ **induced ARDS** . ~~We~~ **Such funding may not be available on a timely basis or at all, which may cause a significant delay in or the suspension of our development of sabizabulin as a treatment for viral- induced ARDS.**

Government funding for private sector research and development activities can be difficult to obtain and may contain limitations on its use. For example, in October 2023, we were notified that we were not selected for participation in the planned Phase 2 ARDS clinical trial to be sponsored by BARDA. There are ~~currently advancing~~ **also uncertainties regarding** our **ability** ~~pipeline of prostate and breast cancer drug candidates and are conducting multiple clinical studies, and we plan~~ to **obtain funding through partnerships** ~~initiate additional studies in infectious diseases. Discovering development candidates and developing investigational medicines is expensive, and we expect to continue to spend substantial amounts to (i) perform basic research, perform preclinical studies, and conduct clinical trials of our current and future programs, (ii) continue to develop and expand our platform and infrastructure and supply preclinical studies and clinical trials~~ with **pharmaceutical companies, including significant competition in seeking** appropriate **partners** ~~grade materials (including cGMP materials), (iii) seek regulatory approvals for our investigational medicines,~~ and **the possibility that potential partners may not view** ~~(iv) launch and commercialize any products for which we receive regulatory approval, including building our own commercial sales, marketing, and distribution organization. Furthermore, our ongoing work on~~ sabizabulin ~~will require significant additional investment during 2023 and beyond. As of September 30, 2022, we had approximately $ 80. 2 million in cash and cash equivalents. We expect that our existing cash and cash equivalents will be sufficient to fund our current planned operations through at least the next twelve months. However, our operating plan may change~~ as **having the requisite potential** ~~a result of many factors currently unknown~~ to **demonstrate safety and efficacy** ~~us, including with respect to our~~ **or adequate intellectual property protection** ~~development, manufacturing, ability to obtain authorization to distribute, and commercialization of sabizabulin for COVID- 19 and availability and conditions of advanced purchase agreements, if any, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, structured financings, government or other third- party funding, sales of assets, marketing and distribution arrangements, other collaborations and licensing arrangements, or a combination of these approaches. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Our spending will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with discovery of development candidates and development of our investigational medicines are highly uncertain, we are unable to estimate the actual funds we will require for development, marketing, and commercialization activities~~ . We are subject to extensive and costly governmental regulation, including healthcare reform measures that may negatively impact sales of FC2 ~~, ENTADFI and, if an EUA is obtained, sabizabulin as a treatment for COVID- 19~~ . Our marketed ~~products~~ **product** , ~~ENTADFI and~~ FC2, and our drug candidates ~~, including sabizabulin as a treatment for COVID- 19,~~ are subject to extensive and rigorous domestic government regulation, including regulation by the FDA, the FTC, the Centers for Medicare & Medicaid Services (CMS), other divisions of the U. S. Department of Health and Human Services, including its Office of Inspector General, the U. S. Department of Justice, the Departments of Defense and Veterans Affairs, to the extent our products are paid for directly or indirectly by those departments, state and local governments and their respective foreign equivalents. The FDA regulates the research, development, preclinical and clinical testing, manufacture, safety, effectiveness, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import and export of pharmaceutical products and medical devices under various regulatory provisions. The Office of Prescription Drug Promotion (OPDP) division of the FDA also regulates the advertising, marketing, and promotion of the Company' s products. Many states and local governments require distribution licenses or similar authorizations to sell products in their jurisdictions. Any of our products that are tested or marketed outside the U. S. are also subject to extensive regulation by foreign governments, whether or not we have obtained FDA approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding U. S. regulation. The ACA mandates coverage of FC2 by U. S. health insurance plans. The ACA is periodically subject to legal challenges and a continuing political effort to limit its scope or even potentially repeal it. We do not expect any imminent such modifications or repeal under the Biden Administration, but we can offer no assurance that the political situation regarding the ACA will not change in ways in the future that could have a material adverse effect on our ability to commercialize FC2 as a prescription product in the U. S. Specific to the contraception coverage mandate, ACA regulations provide exemptions from this requirement for qualifying religious employers and individuals and non- governmental entities that object to providing the coverage on the basis of sincerely held religious beliefs. The Trump administration issued two interim final regulations in October 2017 expanding the exemptions to those entities objecting to the requirement on the basis of religious and moral convictions, which were finalized in November 2018. Federal court judges in Pennsylvania and California separately blocked enforcements of these exemption regulations, with appellate courts upholding the decisions. On July 8, 2020, the Supreme Court reversed the lower courts' rulings, allowing the rules to go into effect. Even though the U. S. Department of Labor issued a statement on January 10, 2022, reminding plans and issuers subject to these requirements of their responsibility to fully comply with the requirements under PHS Act section 2713 and the HRSA Guidelines, challenges or future regulatory efforts to erode the contraception mandate may persist. If successful, such challenges may adversely impact sales of FC2 in states that do not separately provide for reimbursement of FC2. Medical devices such as FC2 are cleared or approved for one or more specific intended uses and performance claims that must be adequately substantiated. Promoting a device for an off- label use or making misleading or unsubstantiated claims could result in government enforcement action. Any changes to the device, including labeling, post- clearance or approval must be assessed to determine if a new clearance or approval is required. Furthermore, the facility in which we manufacture FC2 is subject to periodic inspection by the FDA and other federal, state and foreign government authorities, which require manufacturers of medical devices to adhere to certain regulations, including the FDA' s Quality System Regulation, which requires, among other things, periodic audits, design controls, quality control testing and documentation procedures, as well as complaint evaluations and investigation. The FDA also requires the reporting of certain adverse events and product malfunctions and may require the reporting of recalls or other correction or removals of devices in commercial distribution. Issues identified through such

inspections and reports may result in FDA enforcement action. Moreover, issues identified through such inspections and reports may require significant resources to resolve. The FDA may inspect our facilities periodically to determine compliance with provisions of the FDC Act and FDA regulations. The FDA also requires the reporting of certain adverse events and product malfunctions and may require the reporting of recalls or other field safety corrective actions. Issues identified through such inspections and reports may result in FDA enforcement action. Moreover, issues identified through such inspections and reports may require significant resources to resolve. Failure to comply with applicable laws and regulations could lead to the following actions: ? partial suspension or total shutdown of manufacturing; ? product shortages; ? delays in product manufacturing; ? FDA warning letters or other notifications of violations of law; ? fines or civil penalties; ? delays in or restrictions on obtaining new regulatory clearances or approvals; ? withdrawal or suspension of required clearances, approvals or licenses; ? product seizures or recalls; ? injunctions; ? criminal prosecution; ? advisories or other field actions; ? operating restrictions, including the inability to market a product in certain state or local jurisdictions; and ? prohibitions against exporting of products to, or importing products from, countries outside the U. S. Any of these actions could have a material adverse effect on our business. Any of our products that are tested or marketed abroad are also subject to extensive regulation by foreign governments, whether or not we have obtained FDA approval for a given product and its uses. Such foreign regulation may be equally or more burdensome than U. S. regulation. We are subject to additional health care regulation and enforcement by the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include the following: ? the federal Anti- Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order, or recommendation of, any good or service for which payment may be made under government health care programs such as the Medicare and Medicaid programs; ? the federal False Claims Act that prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government health care programs that are false or fraudulent; ? federal criminal laws that prohibit executing a scheme to defraud any health care benefit program or making false statements relating to health care matters; and ? state law equivalents of each of the above federal laws, such as anti- kickback and false claims laws that may apply to items or services reimbursed by any third- party payor, including commercial insurers. In addition, there has been a recent trend of increased federal and state regulation of payments made by drug and device manufacturers to health care practitioners. Some states, such as California, Connecticut, Massachusetts and Nevada, mandate implementation of corporate compliance programs, while other state laws prohibit, or require tracking and reporting of, certain gifts, compensation and other remuneration to physicians and other health care practitioners. In recent years, a number of states, including California, Minnesota, Oregon, Texas and Washington, have enacted laws requiring manufacturers to submit reports on drugs whose list price has increased by more than a certain percentage during a specified period and / or new drugs that are being launched at a price exceeding a specified amount. Among other things, the reports must explain the justifications for the price or price increase. The scope and enforcement of these laws is uncertain and subject to change in the current environment of health care reform, especially in light of the lack of applicable precedent and regulations. We cannot predict the impact on our business of any changes in these laws. Federal or state regulatory authorities may challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time- consuming. We could experience misconduct by our employees. We will be exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, marketing and promotional laws, rules, and policies, to provide accurate information to the FDA, to comply with federal and state health care fraud and abuse laws and regulations, to comply with anti- corruption laws, including the FCPA, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and prevent employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. Coverage and reimbursement may not be available for our products. Market acceptance and sales for our marketed ~~products~~ **product**, ~~including ENTADFI and~~ FC2, and drug candidates ~~, including sabizabulin as a treatment for COVID- 19,~~ will depend on coverage and reimbursement policies and may be affected by health care reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which products they will pay for and establish reimbursement levels. We cannot be sure that coverage and reimbursement will be available for our drug candidates, if approved. We also cannot be sure that the amount of reimbursement available, if any, will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our drug candidates. We may not be able to gain and retain market acceptance for our drug candidates. Physicians may not prescribe our drug candidates, if approved by the appropriate regulatory authorities for marketing and sale, which would prevent any such drug candidate from generating revenue. Market acceptance of our marketed ~~products~~ **product**, ~~including sabizabulin, ENTADFI, and~~ FC2, and drug candidates by physicians, patients and payors, will depend on a number of factors, many of which are beyond our control, including the following: ? the clinical indications for which our drug

candidates are approved, if at all; ? acceptance by physicians and payors of each product as safe and effective treatment; ? the cost of treatment in relation to alternative treatments; ? the relative convenience and ease of administration of our products in the treatment of the conditions for which they are intended; ? the availability and efficacy of competitive drugs; ? the effectiveness of our sales and marketing efforts; ? the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations; ? the availability of coverage and adequate reimbursement by third parties, such as insurance companies and other health care payors, or by government health care programs, including Medicare and Medicaid; ? limitations or warnings contained in a product' s FDA or other applicable regulatory agency' s approved labeling; and ? prevalence and severity of adverse side effects. Even if the medical community accepts that our drug candidates are safe and efficacious for their approved indications, physicians may not immediately be receptive to the use or may be slow to adopt such products as an accepted treatment for the conditions for which they are intended. Without head- to- head comparative data, we will also not be able to promote our products as being superior to competing products. If our drug candidates, if approved, do not achieve an adequate level of acceptance by physicians and payors, we may not generate sufficient or any revenue from these products. In addition, our efforts to educate the medical community and third- party payors on the benefits of our products may require significant resources and may never be successful. In addition, even if our drug candidates achieve market acceptance, we may not be able to maintain that market acceptance over time if: ? new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete; ? unforeseen complications arise with respect to use of our products; or ? sufficient third- party insurance coverage or reimbursement does not remain available. Our drug products may be subject to governmental pricing controls. In many foreign markets, including the countries in the EU, pricing of pharmaceutical products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental pricing controls. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our likelihood of launching a product and on the profitability of any marketed product. Third parties may obtain FDA regulatory exclusivity to our detriment. We plan to seek to obtain market exclusivity for our drug candidates and any other drug candidates we develop in the future. To the extent that patent protection is not available or has expired, FDA marketing exclusivity may be the only available form of exclusivity available for these proposed products. Marketing exclusivity can delay the submission or the approval of certain marketing applications. Potentially competitive products may also seek marketing exclusivity and may be in various stages of development, including some more advanced than our drug candidates. We cannot predict with certainty the timing of FDA approval or whether FDA approval will be granted, nor can we predict with certainty the timing of FDA approval for competing products or whether such approval will be granted. It is possible that competing products may obtain FDA approval with marketing exclusivity before we do, which could delay our ability to submit a marketing application or obtain necessary regulatory approvals, result in lost market opportunities with respect to our drug candidates and materially adversely affect our business, financial condition and results of operations. Risks Related to Our Financial Position and Need for Capital We have incurred net losses in recent fiscal years and expect to continue to incur losses for the foreseeable future. We incurred **a** net loss of $ ~~83~~ **93** . ~~8~~ **1** million during the year ended September 30, ~~2022~~ **2023** . Pharmaceutical product development is a speculative undertaking, involves a substantial degree of risk and is a capital- intensive business. We expect to incur significant expenses until we are able to obtain regulatory approval and subsequently sell one or more of our drug candidates under development in significant quantities, which may not happen. We expect to devote most of our financial resources to research and development, including our non- clinical development activities and clinical trials. Our drug candidates will require the completion of regulatory review, significant marketing efforts and substantial investment before they can provide us with any revenue. We are uncertain when or if we will be able to achieve or sustain profitability. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable would impair our ability to sustain operations and adversely affect the price of our common stock and our ability to raise capital. **Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in this Annual Report on Form 10- K for the fiscal year ended September 30, 2023. The report from our independent registered public accounting firm for the year ended September 30, 2023, includes an explanatory paragraph stating that our losses from operations and required additional funding to finance our operations raise substantial doubt about our ability to continue as a going concern for a period of one year after the date the financial statements are issued. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or a part of their investment. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all. There can be no assurance that the current operating plan will be achieved in the time frame anticipated by us, or that our cash resources will fund our operating plan for the period anticipated by the Company or that additional funding will be available on terms acceptable to us, or at all. We will need to raise additional capital to fund our operations in the future. If we are unsuccessful in attracting new capital, we may not be able to continue operations or may be forced to sell assets to do so. Alternatively, capital may not be available to us on favorable terms, or if at all. If available, financing terms may lead to significant dilution of our stockholders' equity. We are not profitable and have had negative cash flow from operations. We will need large amounts of capital to support our development and commercialization efforts for our drug candidates, including the Phase 2b clinical trial to evaluate the efficacy and the safety of enobosarm in preventing**

significant muscle wasting in obese patients receiving a GLP- 1 therapeutic to treat obesity. Our existing cash and cash equivalents as of the date of this report may not be sufficient to fund our working capital needs and operating expenses. To obtain the capital necessary to fund our operations, we expect to finance our cash needs through public or private equity offerings, debt financing and / or other capital sources. Additional **capital may not be available at such times or amounts as needed by us. Even if capital is available, it might be available only on unfavorable terms. Any additional equity or convertible debt** financing ~~may~~ **into which we enter could** be **dilutive to our existing stockholders. Any future debt financing into which we enter may impose covenants upon us that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, we may need to relinquish rights to our technologies or our products or grant licenses on terms that are not favorable to us. If access to sufficient capital is not available as and when** needed **, our business will be materially impaired, and we may be required to cease operations, curtail one or more product development or commercialization programs, scale back or eliminate the development of business opportunities, or significantly reduce expenses, sell assets, seek a merger or joint venture partner, file for protection from creditors or liquidate all of our assets. Any of these factors could harm our operating results. The amount of additional financing that we will need** to support our development and commercialization activities **is uncertain** . We expect to incur significant expenditures over the next several years to support our preclinical and clinical development activities, particularly with respect to clinical trials for certain of our drug candidates and to commence the commercialization of our drug candidates. This may require us to obtain additional financing for our business until revenues from our current commercial operations independently fund our drug development programs. We may also need to obtain additional financing to complete the development of any additional drug candidates we might acquire or to pay other operating expenses ~~. Additional financing may not be available on terms acceptable to us. If we are unable to obtain needed financing on acceptable terms, we may not be able to implement our business plan, which could have a material adverse effect on our business, financial condition, results of operations and prospects. If we raise additional funds through the sale of equity, convertible debt or other equity- linked securities, our shareholders' ownership will be diluted. We may issue securities that have rights, preferences and privileges senior to our common stock~~ . Our future capital requirements will depend upon a number of factors, including: ? the size, complexity, results and timing of our development programs and clinical trials; ? our ability to successfully commercialize our drug candidates, if approved; ? our ability to obtain sufficient supply of the compounds necessary for our drug candidates at a reasonable cost; ? the time and cost involved in obtaining regulatory approvals; ? the time and cost involved in developing any required companion diagnostics for any of our product candidates, including enobosarm; ? the terms and timing of any potential future collaborations, licensing or other arrangements we may establish; ? cash requirements of any future acquisitions, in- licenses or the development of other drug candidates; ? our receipt of funds from other potential sources, including cash flow from licenses and sales, and payments on outstanding receivables; ? the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims; ? the costs involved in manufacturing and commercializing our drug candidates; ? the amount of sales or other revenues from drug candidates that we may commercialize, if any, including the selling prices for such drug candidates and the availability of adequate third- party coverage and reimbursement; ? regulatory changes; ? changes to federal, state or local health care or prescription drug programs; ? market and economic conditions; and ? competing technological and market developments. These factors could result in variations from currently projected operating and liquidity requirements. ~~COVID- 19~~ **We may not receive any additional payments from BWV in connection with the sale of our ENTADFI assets** and ~~its impact~~ **may not receive any value for the shares of BWV Series A Preferred Stock we hold. In April 2023, we sold our ENTADFI assets to BWV and** on ~~the economic environment~~ **September 29, 2023, we entered into** ~~and~~ **an amendment** ~~capital markets could adversely affect our access~~ to ~~capital when needed. We expect to incur significant expenditures over~~ the ~~next several~~ **BWV Asset Purchase Agreement which provided that the promissory note for the $ 4 million installment of the purchase price due September 30, 2023 was deemed paid and fully satisfied upon (1) the payment to us of the sum of $ 1. 0 million in immediately available funds on September 29, 2023, and (2) the issuance to us by October 3, 2023 of 3, 000 shares of BWV Series A Preferred Stock. The BWV Series A Preferred Stock may not be converted into shares of BWV common stock until one** ~~years~~ **year** ~~to support our preclinical and clinical development activities~~ **after issuance. Although BWV' s common stock is currently traded on the Nasdaq Capital Market** , ~~particularly~~ **there is limited trading volume and we do not have any registration rights** with respect to **the shares** ~~clinical trials for certain~~ of ~~our drug candidates~~ **BWV common stock issuable upon conversion of the BWV Series A Preferred Stock, which means that any sales by us of those shares may be subject to volume and other limitations pursuant to Rule 144 under the Securities Act of 1933, as amended. Under the BWV Asset Purchase Agreement, BWV is obligated to pay** ~~and~~ **an** ~~to commence the commercialization of~~ **additional $ 10 million in installments in** our ~~drug candidates~~ **fiscal year 2024 pursuant to unsecured promissory notes, plus up to** ~~and~~ **an** ~~to commercialize our marketed products. Market volatility resulting~~ **additional $ 80 million in milestone payments based on BWV' s net sales** from **ENTADFI business after closing. There is uncertainty** ~~the COVID- 19 pandemic or other factors could adversely affect our ability to access capital~~ as **to whether** and when **we will receive any future installment payments** ~~needed and could also adversely affect the terms~~ of **purchase price or** ~~a financing. If~~ sales ~~of FC2 decline~~ **milestone payments under the BWV Asset Purchase Agreement** , **and there** ~~sales of ENTADFI are lower than expected, or sabizabulin~~ is **a risk** ~~not authorized for sale due, in any case, to the current economic environment, supply constraints or other issues, we may need additional financing to make up for reduced expected cash flows from these products. If adequate funds are not available on commercially acceptable terms when needed, we may be forced to delay, reduce or terminate some~~ of **a** ~~our research and development~~

activities or we may be unable to take advantage of future **default by BWV** business opportunities. If we fail to obtain additional capital, we may need to reduce the scope of our development or commercialization programs or we could be forced to share our rights to technologies with third parties on terms that may not be favorable to us. We may need large amounts of capital to support our development and commercialization efforts for our drug candidates. If we are unable to secure sufficient capital to fund our operations as needed, we will not be able to continue these efforts and we might have to enter into strategic collaborations that could require us to share commercial rights to one or more of our drug candidates with third parties in ways that **performing its payment obligations, and** we currently do not intend or **have a security interest in any of BWV' s assets and accordingly would be an unsecured creditor in the event that BWV defaulted. We received payment of $ 1. 0 million** on terms that may **September 29, 2023. There can be** not **no** be favorable **assurance as** to **(1) whether and when** us. We may also need to raise additional funds if we choose **will receive the future installment payments of purchase price or sales milestone payments under the BWV Asset Purchase Agreement, (2) the ability of BWV** to expand more rapidly than we presently anticipate **obtain the requisite approval of its shareholders** or **for the conversion of all the shares of BWV Series A Preferred Stock, and (3) whether and when** we encounter **will be able to receive** any **cash proceeds from the BWV Series A Preferred Stock** unforeseen events that affect our current business plan. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms and not enter into strategic collaborations, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts . Risks Related to Our Business The COVID- 19 pandemic has disrupted, and may continue to disrupt, our operations and the operations of our suppliers and customers. In December 2019, a novel strain of coronavirus was reported to have emerged in Wuhan, China. COVID- 19, the disease caused by the coronavirus, has since spread to over 100 countries, including every state in the United States. On March 11, 2020, the World Health Organization declared COVID- 19 a pandemic, and on March 13, 2020, the United States declared a national emergency with respect to the COVID- 19 outbreak. The outbreak and government measures, which in the U. S. have been largely left to individual states with varying approaches, including orders to close businesses considered non- essential and orders for quarantining, taken in response have had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. We have also adopted various recommended policies and procedures applicable to office- based employees, including certain work from home measures, to protect the health and safety of our employees. If COVID- 19 continues to spread and to affect economic activity in the United States and other markets in which we conduct business, we may experience disruptions that could severely impact our business, including: ? if our Malaysian manufacturing facility is closed again our ability to supply product to our customers could be disrupted; ? we may encounter labor or raw material shortages, transportation delays or other issues at our Malaysian manufacturing facility or to our various customers; ? our personnel may not be able to travel between our facilities in the United States, the United Kingdom and Malaysia, which may impact our ability to effectively oversee our international operations; ? customer demand for FC2 may be adversely affected, including with respect to FC2 in the U. S. prescription market if insurance coverage is affected by job losses and in the global public health sector if governments delay future tenders or reduce spending on female condoms due to financial strains or changed spending priorities caused by the COVID- 19 pandemic; ? our customers, including in the global public health sector, may reduce or delay orders or delay paying their accounts receivable balances due to liquidity issues, spending priorities or other issues related to the COVID- 19 pandemic, including government- imposed closures or operating reductions; ? there may be limitations in employee resources, potentially including key executives, because of sickness of employees or their families or the desire of employees to avoid contact; ? we may face delays in receiving approval from the FDA or other applicable regulatory authorities in connection with our clinical trials; ? there may be delays or difficulties in enrolling patients in our clinical trials or in recruiting clinical site investigators and staff; ? there may be delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including delays or interruptions in manufacturing and interruption in shipping; ? there may be changes in local regulations as part of a response to the COVID- 19 outbreak which may require us to change the ways in which our clinical trials are conducted, to incur unexpected costs, or to discontinue the clinical trials altogether; ? healthcare resources may be diverted away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials; ? key clinical trial activities may be interrupted, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or the clinical research organizations or clinical trial sites' own risks related to the COVID- 19 outbreak, which could affect the integrity of clinical data or the conduct of the trial; ? participants enrolled in our clinical trials could acquire COVID- 19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events; ? necessary interactions with local regulators, ethics committees and other important agencies and contractors may be delayed due to limitations in employee resources or forced furlough of government employees; and ? the FDA may refuse to accept data from clinical trials in affected geographies. Significant uncertainty remains as to the potential impact of the COVID- 19 pandemic on our operations, and on the global economy. It is currently not possible to predict how long the pandemic will last or the time that it will take for economic activity to return to prior levels. We do not yet know the full extent of any impact on our business or our operations, and it is possible that its effect on our business and operations will significantly worsen in the future. Our FC2 business may be affected by contracting risks with government and other international health agencies. Large international agencies and government health agencies which purchase and distribute FC2 for use in family planning and HIV / AIDS prevention programs have historically purchased significant quantities of FC2. Sales to such agencies may be subject to government contracting risks, including the appropriations process and funding priorities, potential bureaucratic delays in awarding contracts under governmental tenders, process errors, politics or other pressures, and the risk

that contracts may be subject to cancellation, delay, or restructuring. A governmental tender award indicates acceptance of the bidder' s price rather than an order or guarantee of the purchase of any minimum number of units. Many governmental tenders are stated to be " up to " the maximum number of units, which gives the applicable government agency discretion to purchase less than the full maximum tender amount. As a result, government agencies may order and purchase fewer units than the full maximum tender amount and there are no guarantees as to the timing or amount of actual orders or shipments under government tenders. Orders received may vary from the amount of the tender award based on a number of factors, including vendor supply capacity, quality inspections, and changes in demand. These contracting risks may cause significant quarter- to- quarter variations in our operating results and could adversely affect our net revenues and profitability. Budget issues, spending cuts, and global health spending priorities affecting government health agencies may also adversely affect demand for FC2 and our net revenues. The FDA issued a final order reclassifying female condoms as Class II medical devices, which may result in increased competition for FC2 in the U. S. market. On September 21, 2018, the FDA issued a final order reclassifying female condoms from Class III to Class II medical devices, renaming them " single- use internal condoms " and requiring new devices in this category to submit a 510 (k) premarket notification and comply with various " special controls. " Special controls are a battery of product clinical testing which includes, but is not limited to, determining product effectiveness against pregnancy and against infection transmission, and product tolerability. While FC2 is the only currently available female condom approved for marketing by the FDA in the U. S., this reclassification by the FDA may reduce the barriers for other types of female condoms to enter the U. S. market. If other female condoms enter the U. S. market, we may face increased competition in the U. S., which may put downward pressure on pricing for FC2 and adversely affect sales of FC2 in the U. S. We may experience competition, especially for ~~sabizabulin~~ **enobosarm** as a treatment for **metabolic diseases** ~~COVID- 19~~, if **approved** ~~authorized, ENTADFI~~, and FC2. We are engaged in the marketing and development of products in industries, including the pharmaceutical industry, that are highly competitive. The pharmaceutical industry is also characterized by extensive research and rapid technological progress. Potential competitors with respect to our drug candidates in North America, Europe and elsewhere include major pharmaceutical companies, specialty pharmaceutical companies and biotechnology firms, universities and other research institutions and government agencies. Many of our competitors have substantially greater research and development and regulatory capabilities and experience, and substantially greater management, manufacturing, distribution, marketing and financial resources, than we have. We may be unable to compete successfully against current and future competitors, and competitive pressures could have a negative effect on our net revenues and profit margins **. The market for treatments relating to obesity, including treatments relating to muscle atrophy and muscle weakness in patients receiving a GLP- 1 RA, is highly competitive and includes major pharmaceutical companies. Such competitors may have substantially greater research and development and regulatory capabilities and experience, and substantially greater management, manufacturing, distribution, marketing and financial resources, than we have. We may be unable to compete successfully against current and future competitors, and competitive pressures could have a negative effect on our net revenues and profit margins. In addition, if we believe that a competitor' s development activities infringe on our intellectual property rights relating to enobosarm, we may lack the resources to file infringement claims, which can be expensive and time- consuming** . Other parties have developed and marketed female condoms, although only two such products presently have WHO pre- qualification and none of these female condoms have been approved for market by the FDA. FDA market approval is required to sell female condoms in the U. S., and WHO pre- qualification is required to sell female condoms to U. N. agencies. The FDA' s reclassification of female condoms from Class III to Class II medical devices may reduce the barriers for other types of female condoms to enter the U. S. market. FC2 has also been competing with other female condoms in markets that do not require either FDA market approval or WHO prequalification. There are other ~~polyethurane~~ -- **polyurethane** brands from China ~~(Ormelle, Sensitex)~~ that have CE- certification. We have experienced increasing competition in the global public health sector, and competitors received part of the last three South African tenders and the latest Brazilian tender. Increasing competition in FC2' s markets has put pressure on pricing for FC2 and adversely affected sales of FC2, and some customers, particularly in the global public health sector, may prioritize price over other features where FC2 may have an advantage. It is also possible that other companies will develop a female condom, and such companies could have greater financial resources and customer contacts than us. In addition, other contraceptive and HIV- prevention and treatment methods compete with FC2 for funding and attention in the global public health sector. ~~Other parties~~ **Our net revenues from sales of FC2 may not return to past levels. Net revenues from sales of FC2** have ~~developed~~ **declined significantly in recent periods, particularly in the U. S. prescription channel. Although we are working to restore ordering** and **utilization patterns in future periods, net revenues from sales of FC2 may not return to past levels. Ordering patterns may not rebound or may continue to decline if our distribution partners in the telehealth sector encounter issues, we or our distribution partners are not able or willing to spend sufficient amounts to** ~~marketed~~ -- **market** ~~drugs~~ **and promote FC2, or underlying demand** for **FC2 decreases** ~~prevention and treatment of COVID- 19~~. ~~Many of these parties are substantially~~ **In particular, sales to our** ~~larger~~ **largest telehealth customer,** ~~than us and are substantially better capitalized and have more resources and commercialization resources than us. These~~ -- **The Pill Club,** ~~parties may also have better relationships with government and commercial payors. Other parties have developed and marketed drugs for BPH that~~ have been **eliminated due** ~~accepted by the physician, patient and payor communities. Many of these other products have also reached the point where they are now generic drugs, which means that they are sold at a very low price, a price which ENTADFI may not be able~~ to **The Pill Club** ~~meet which could limit ENTADFI~~ ' s **recent Chapter 11 bankruptcy filing** ~~reach into the physician, patient~~ and **the termination** ~~payor communities, including government payors. We may not be able to successfully implement our strategy to grow sales~~ of ~~FC2 or~~ **our contract** ~~ENTADFI in the U. S. market or, if authorized, sabizabulin in the U. S. or any foreign market. In 2017, we implemented a strategy to grow sales for FC2 in the U. S. market, focusing on prescription sales because FC2 is currently reimbursable by prescription under the ACA. As part of this growth strategy, we have developed relationships~~ with **The Pill**

Club ~~distributors and telemedicine providers in the U. S. It is difficult to predict the degree of market acceptance and consumer demand we may achieve for FC2 in the U. S., and we may ultimately not be able to achieve or sustain significant sales growth in the U. S. market. Our prescription sales in the U. S. may also be adversely affected by regulations offering employers religious and moral exemptions from the ACA' s requirement to provide insurance covering birth control~~ . In addition, ~~while~~ we **may lack resources to increase** ~~experienced fast growth in prescription sales of~~ FC2 ~~through fiscal 2021 largely through a small number~~ **marketing efforts by an amount sufficient to grow revenues and drive awareness** of ~~current~~ **our independent, FC2- dedicated direct to patient** telemedicine ~~providers, prescription sales of FC2 to those current telemedicine providers declined significantly in fiscal 2022. We may not be able to return to sales growth in fiscal 2023 as our current customers may not resume past ordering patterns~~ and **pharmacy services portal** ~~we may not be able to add additional telemedicine providers~~ . Any failure to ~~achieve and~~ **attain or** sustain sales growth for FC2 in the U. S. market may have a material adverse effect on our results of operations **. We may not be able to successfully implement our strategy to grow sales of FC2 in the U. S. market through our own portal** . We are currently working to establish our own dedicated direct to patient telemedicine and pharmacy services portal to continue to drive sales growth for FC2. We have never developed a telemedicine platform before. The cost and regulatory complexity required for launching this platform, including costs with collaborators who are helping us develop the platform, who will help us in our efforts to market the platform and FC2 and who will provide telehealth physician consultations, may outweigh any increased sales resulting from this effort. Similarly, any subsidies that we may offer to patients may be disallowed by regulators at any time. Any of these risks could harm patient acceptance of the platform and our ability to continue to grow FC2 sales ~~. If authorized, we may not be successful in commercializing sabizabulin for the treatment of certain hospitalized COVID- 19 patients due to our inexperience in launching an in- patient drug, reluctance of physicians to treat patients with sabizabulin, reluctance of hospital formulary committees or pharmacy managers to add sabizabulin to their formulary protocols, our inability to achieve pricing for sabizabulin at a price that we believe is commercially reasonable or that recognized the value of sabizabulin, our inability to replicate the clinical trial results of sabizabulin in the post- authorization setting, unforeseen adverse events from treatment with sabizabulin or any other reason. In addition, we may fail to comply with the complex and broad set of laws, rules and regulations in the U. S. and in other countries or regions that govern the manufacture, promotion, pricing, and reimbursement of drugs like sabizabulin. Any of these risks could negatively affect our ability to establish sabizabulin as a viable treatment for certain COVID- 19 patients or our ability to grow sales of sabizabulin, if authorized. We may not be able to expand sales of ENTADFI through partnering with telemedicine or other partners or through our own commercialization efforts. We may not be able to command a price with private and government payors for ENTADFI that would justify our devotion of significant resources to attempting to grow sales of ENTADFI. We may not be able to compete efficiently or effectively in a mature BPH market which is heavily generic. Failure to grow sales of ENTADFI would have a negative effect on our revenue and future plans. We may not be able to sustain price levels for FC2 in the U. S. market. Price levels for sales of FC2 in a developed country such as the U. S. are typically higher than for sales to less developed countries in the global public health sector. Over time, due to increased competition or other factors, including any changes to and validity of ACA, we may experience price erosion in the U. S. market. Negative pressure on our price levels for U. S. sales may have a material adverse effect on our net revenues and gross margin in the U. S. market~~ . An inability to identify or complete future acquisitions could adversely affect our future growth. We intend to pursue acquisitions of new products, technologies, and / or businesses that enable us to leverage our competitive strengths. While we continue to evaluate potential acquisitions, we may not be able to identify and successfully negotiate suitable acquisitions, obtain financing for future acquisitions on satisfactory terms, obtain regulatory approval for acquisitions where required, or otherwise complete acquisitions in the future. An inability to identify or complete future acquisitions could limit our future growth. Similarly, any use of our equity or a convertible debt security in any acquisition would be dilutive to our stockholders and may affect the market price of our shares. We may experience difficulties in integrating strategic acquisitions. The integration of acquired companies and their operations into our operations involves a number of risks, including: ? the acquired business may experience losses that could adversely affect our profitability; ? unanticipated costs relating to the integration of acquired businesses may increase our expenses; ? possible failure to accomplish the strategic objectives for an acquisition; ? the loss of key personnel of the acquired business; ? difficulties in achieving planned cost- savings and synergies may increase our expenses or decrease our net revenues; ? diversion of management' s attention could impair their ability to effectively manage our business operations; ? the acquired business may require significant expenditures for product development or regulatory approvals; ? the acquired business may lack adequate internal controls or have other issues with its financial systems; ? there may be regulatory compliance or other issues relating to the business practices of an acquired business; ? we may record goodwill and nonamortizable intangible assets that are subject to impairment testing on a regular basis and potential impairment charges and we may also incur amortization expenses related to intangible assets; and ? unanticipated management or operational problems or liabilities may adversely affect our profitability and financial condition. Additionally, we may borrow funds or issue equity to finance strategic acquisitions. Debt leverage resulting from future acquisitions could adversely affect our operating margins and limit our ability to capitalize on future business opportunities. Such borrowings may also be subject to fluctuations in interest rates. Equity issuances may dilute our existing shareholders and adversely affect the market price of our shares. We ~~depend on~~ **may be subject** ~~two~~ **to** ~~major~~ **claims or investigations relating to The Pill Club' s business practices with respect to sales of FC2. The Pill Club was one of our largest** customers **, accounting** for **44 %** ~~a significant portion~~ of our net revenues ~~. The Company' s two largest customers~~ in fiscal 2022 ~~accounted~~ **and 43 % of our net revenues in fiscal 2021. On February 7, 2023, the California Attorney General announced a settlement with The Pill Club over a number of alleged improper actions by The Pill Club, including alleged overbilling** for ~~73 % of~~ **FC2. Although we were not involved in** the ~~Company~~ **business practices that were the subject of the California Attorney General** ' s ~~net revenues. An adverse change in~~ **allegations, it is possible that the California Attorney General** ~~our~~ **or**

~~relationship~~ **another governmental authority may investigate or assert claims against us in connection** with **The Pill Club' s practices with respect to sales of FC2. Any such claims** ~~our~~ **or investigations** ~~largest customers~~ could have a material adverse effect on our **reputation** ~~net revenues and profitability. Also~~ , **business** ~~as we saw in fiscal 2022~~ , **results of operations** ~~adverse events at,~~ and **financial condition. Any such claims** ~~purchasing decisions by, these two customers can have a material adverse effect on our~~ **or investigations** ~~net revenues. In addition~~ , **regardless** ~~we may have a concentration~~ of **the outcome, would be costly and time- consuming. It is unlikely that we will collect any amount of our** accounts receivable with **The Pill Club. We have a concentration of accounts receivable at The Pill Club, with $ 3. 9 million of accounts receivable as of June 30, 2023. On April 18, 2023, The Pill Club filed for Chapter 11 bankruptcy and its assets were sold in June 2023 to satisfy a secured creditor. Our claims against The Pill Club for these receivables have been filed with The Pill Club bankruptcy estate and we will continue to pursue payment for as much of the receivables as possible but based on the amount of the claims of other unsecured creditors and the limited assets remaining in The Pill Club bankruptcy estate it is unlikely that we will recover any of these receivables. We have recorded a provision for credit losses of $ 3. 9 million due to The Pill Club' s Chapter 11 bankruptcy filing in April 2023. We are subject to potential liability relating to a dispute with a supplier. A supplier has claimed that we owe approximately $ 10 million for products and services relating to our efforts to commercialize sabizabulin under an EUA. We dispute the amount owed, but there can be no assurance as to how this matter will be resolved. While we have reserved for the full amount of the claim, any resolution of this matter may result in a significant cash obligation. In addition, this matter may become subject to litigation, which would force us to expend significant resources in the defense of such an action, and we may not prevail. Monitoring and defending against any such legal action may be time- consuming for management and may detract from our ability to fully focus our internal resources on our business activities. If we are required to pay all or substantially all of the amount claimed by our supplier with immediate effect, we may need to raise additional capital, curtail** one or more ~~of~~ **product development** ~~our~~ **or** ~~largest customers~~ **commercialization programs** , **scale back** ~~and a delay in payment by a large customer could have a material adverse effect on our~~ **or** ~~cash flows and~~ **eliminate the development of business opportunities, or significantly reduce expenses, sell assets, seek a merger or joint venture partner, file for protection from creditors or** ~~liquidity~~ **liquidate all of our assets** . Since we sell FC2 in foreign markets, we are subject to international business risks that could adversely affect our operating results. Our international operations subject us to risks, including: ? economic and political instability; ? currency fluctuations; ? global pandemics, as governments reallocate their health or development budgets to other health areas; ? changes in international regulatory requirements, import duties, or export restrictions, including limitations on the repatriation of earnings; ? disruptions and price increases in the global transportation network, such as work stoppages, strikes or shutdowns of ports of entry or such other transportation sources, or delays or difficulties in products clearing customs; ? difficulties in staffing and managing foreign operations; ? greater difficulty in collecting accounts receivable and longer collection periods; ? the uncertainty of protection for intellectual property in some countries; ? multiple, conflicting and changing laws and regulations such as privacy regulations, including GDPR, tax laws, export and import restrictions, employment laws, immigration laws, labor laws, regulatory requirements and other governmental approvals, permits and licenses; ? complications in complying with trade and foreign tax laws and greater risk of a failure of foreign employees, distributors or other agents to comply with both U. S. and foreign laws, including antitrust regulations, the FCPA and other anti- bribery or corruption laws, and trade regulations; ? price controls and other restrictions on foreign currency; and ? difficulties in our ability to enforce legal rights and remedies. Any of these risks might disrupt the supply of our products, increase our expenses or decrease our net revenues. The cost of compliance with trade and foreign tax laws increases our expenses, and actual or alleged violations of such laws could result in enforcement actions or financial penalties that could result in substantial costs. Increases in the cost of raw materials, labor, and other costs used to manufacture FC2 could increase our cost of sales and reduce our gross margins. We may experience increased costs of raw materials, including the nitrile polymer used in FC2, and increased labor costs. We may not be able to pass along such cost increases to our customers. As a result, an increase in the cost of raw materials, labor or other costs associated with manufacturing FC2 could increase our cost of sales and reduce our gross margins. We have seen a global shortage of a key ingredient used to manufacture FC2 lubricant, which may give future pricing pressure and stock availability. Strategic supply stocks have been ordered to mitigate this risk, but our supply may not be sufficient to meet demand for FC2 globally or in any particular market. Currency exchange rate fluctuations could increase our expenses. Because we manufacture FC2 in a leased facility located in Malaysia, a portion of our operating costs are denominated in a foreign currency. While a material portion of our future sales of FC2 are likely to be in foreign markets, all sales of FC2 are denominated in U. S. dollars. Manufacturing costs are subject to normal currency risks associated with fluctuations in the exchange rate of the Malaysian ringgit (MYR) relative to the U. S. dollar. Historically, we have not hedged our foreign currency risk. We rely on a single facility to manufacture FC2, which subjects us to the risk of supply disruptions. We manufacture FC2 in a single leased facility located in Malaysia. Difficulties encountered by this facility, such as fire, accident, natural disaster, labor disruptions, or an outbreak of a contagious disease, ~~including COVID- 19,~~ could halt or disrupt production at the facility, delay the completion of orders, or cause the cancellation of orders. Any of these risks could increase our expenses or reduce our net revenues **. We may incur costs or experience supply interruptions relating to our need to transition the supply of the nitrile polymer for FC2. We have relied on a sole supplier for the principal raw material for FC2. The supplier has indicated that it intends to close the facility where our specialty grade of nitrile is currently manufactured at the end of the current calendar year. We intend to move to an alternative grade of nitrile, which will require us to incur costs to formulate and test the alternative grade and seek FDA approval of the alternative grade. We are not certain of the amount of time or costs involved in this transition. In addition, the supplier has stated that it will assist in providing continuity of supply while we transfer to the standardized grade of nitrile and has confirmed that it will utilize another production facility that it controls to produce the current specialty grade.**

Appropriate plant trials and testing have been conducted to show the new facility is capable of supplying our current nitrile grade . Uncertainty and adverse changes in the general economic conditions may negatively affect our business. If general economic conditions, including continued or worsening inflation or supply chain challenges, recessionary pressures, rising interest rates, labor shortages, and rising unemployment, in the U. S. and other global markets in which we operate decline, or if consumers fear that economic conditions will decline, consumers may reduce expenditures for products such as our existing and potential products. Adverse changes may occur as a result of adverse global or regional economic conditions, fluctuating oil prices, supply chain problems, inflation, political instability, declining consumer confidence, a ~~continuation or worsening of the COVID- 19 pandemic or another~~ pandemic, unemployment, fluctuations in stock markets, contraction of credit availability, or other factors affecting economic conditions generally. These changes may negatively affect the sales of our existing or development of future products, increase the cost, and decrease the availability of financing, or increase costs associated with producing and distributing our products and potential drug candidates. In addition, a substantial portion of the sales of FC2 are made in the public market to government agencies, including USAID and other government agencies around the world. Worsening economic conditions as well as budget deficits and austerity measures may cause pressures on government budgets and result in a reduction in quantities or prices for purchases of FC2 by governmental agencies. Sales of FC2 fluctuate, which causes our operating results to vary from quarter- to- quarter. Sales of FC2 fluctuate based upon demand from our commercial partners and the public health sector and the nature of government procurement processes. Historically, our net revenues and profitability have varied from quarter – to- quarter due to such buying patterns. Quarterly variations in operating results may cause us to fail to meet market expectations for our operating results and may tend to depress our stock price during such quarters. Material adverse or unforeseen legal judgments, fines, penalties, or settlements could have an adverse impact on our profits and cash flows. We may, from time to time, become a party to legal proceedings incidental to our business, including, but not limited to, alleged claims relating to product liability, environmental compliance, patent infringement, commercial disputes, securities laws, antitrust and competition laws, regulatory or administrative actions, corporate matters and employment matters. The current and future use of our drug candidates by us and potential collaborators in clinical trials, and the sale of any approved products in the future, may expose us to product liability claims. We will face an inherent risk of product liability claims as a result of the clinical testing of our drug candidates and will face an even greater risk if we obtain FDA approval and commercialize our drug candidates in the U. S. or other additional jurisdictions or if we engage in the clinical testing of proposed new products or commercialize any additional products. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our existing products or drug candidates, if approved. Regardless of the merits or eventual outcome, product liability claims may result in any of the following: ? the inability to commercialize our drug candidates; ? difficulty recruiting subjects for clinical trials or withdrawal of these subjects before a trial is completed; ? labeling, marketing, or promotional restrictions; ? product recalls or withdrawals; ? decreased demand for our products or products that we may develop in the future; ? loss of revenue; ? injury to reputation; ? initiation of investigations by regulators; ? costs to defend the related litigation; ? substantial monetary awards to trial participants or patients; and ? a decline in the value of our shares. Litigation could require us to record reserves or make payments which could adversely affect our profits and cash flows. Even the successful defense of legal proceedings may cause us to incur substantial legal costs, may divert management' s attention and resources away from our business, may prevent us or our partners from achieving or maintaining market acceptance of the affected product and may substantially increase the costs of commercializing our future products and impair the ability to generate revenues from the commercialization of these products either by us or by our strategic alliance partners. We currently maintain limited general commercial liability insurance coverage. However, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or for liabilities in excess of our insurance limits, our assets may not be sufficient to cover such claims and our business operations could be impaired **. We have been named a defendant in stockholder class actions. These, and potential similar or related lawsuits or investigations, could result in substantial legal fees, fines, penalties or damages and may divert management' s time and attention from our business. On December 5, 2022, a putative securities class action complaint was filed in federal district court for the Southern District of Florida against us certain of our current officers and directors. The amended complaint alleges that certain public statements about sabizabulin as a treatment for COVID- 19 between March 1, 2021 and March 2, 2023 violated Sections 10 (b) and 20 (a) of the Securities Exchange Act of 1934 and Rule 10b- 5 promulgated thereunder, and seeks monetary damages. We and certain of our offices and directors are also parties to four derivative actions asserting state law claims primarily in connection with the issues and claims asserted in the securities class action. These legal proceedings and any other similar or related legal proceedings are subject to inherent uncertainties, and the actual costs to be incurred relating to these matters will depend upon many unknown factors. The outcome of these legal proceedings is uncertain, and we could be forced to expend significant resources in the defense of these actions, and we may not prevail. Although we have insurance coverage for these actions, we have a $ 5 million retention amount, which means that we are responsible for the first $ 5 million of costs or damages relating to these actions, and as a result must pay for any defense costs ourselves up to such retention amount before any insurance coverage will apply. Monitoring and defending against legal actions is time- consuming for management and detracts from our ability to fully focus our internal resources on our business activities. In addition, we may incur substantial legal fees and costs in connection with these matters. We are also generally obligated, to the extent permitted by law, to indemnify our current and former directors and officers who are named as defendants in these and similar actions. We are not currently able to estimate**

the possible cost to us from these matters, as these actions are currently at an early stage and we cannot be certain how long it may take to resolve these matters or the possible amount of any damages that we may be required to pay. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages. Decisions adverse to our interests in these actions could result in the payment of substantial damages, and could have a material adverse effect on our cash flow, results of operations and financial position. These and additional legal proceedings may also increase the costs of, or result in adverse changes in, our director and officer insurance coverage, and if we are unable in the future to obtain an acceptable level of director and officer insurance coverage we may face challenges in recruiting or retaining qualified independent directors or officers . Our business and operations would suffer if we sustain cyber- attacks or other privacy or data security incidents that result in security breaches. Our information technology may be subject to cyber- attacks, security breaches or computer hacking. Experienced computer programmers and hackers may be able to penetrate our security controls and misappropriate or compromise sensitive personal, proprietary or confidential information, create system disruptions or cause shutdowns. They also may be able to develop and deploy malicious software programs that attack our systems or otherwise exploit any security vulnerabilities. Our systems and the data stored on those systems may also be vulnerable to security incidents or security attacks, acts of vandalism or theft, misplaced or lost data, human errors, or other similar events that could negatively affect our systems and our data, as well as the data of our business partners. Further, third parties, such as hosted solution providers, that provide services to us, could also be a source of security risk in the event of a failure of their own security systems and infrastructure. The costs to eliminate or address the foregoing security threats and vulnerabilities before or after a cyber- incident could be significant. Our remediation efforts may not be successful and could result in interruptions, delays or cessation of service, and loss of existing or potential suppliers or customers. In addition, breaches of our security measures and the unauthorized dissemination of sensitive personal, proprietary or confidential information about us, our business partners, participants in our clinical trials or other third parties could expose us to significant potential liability and reputational harm. In addition, the loss of clinical trial data from completed or ongoing or planned clinical trials as a result of a data security incident or other systems failure could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. As threats related to cyber- attacks develop and grow, we may also find it necessary to make additional investments to protect our data and infrastructure, which may impact our profitability. As a global enterprise, we could also be negatively impacted by existing and proposed laws and regulations, as well as government policies and practices related to cybersecurity, data privacy, data localization and data protection such as GDPR and the California Consumer Privacy Act. Any failure to comply with the FCPA and similar anti- bribery laws in non- U. S. jurisdiction could materially adversely affect our business and result in civil and / or criminal sanctions. The FCPA and similar anti- bribery laws in non- U. S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to non- U. S. government officials for the purpose of obtaining or retaining business. Because of the importance of the global public health sector for sales of FC2, many of our customer relationships outside of the U. S. are with governmental entities and are therefore potentially subject to such laws. Global enforcement of anti- corruption laws has increased substantially in recent years, with more frequent voluntary self- disclosures by companies, aggressive investigations and enforcement proceedings by U. S. and non- U. S. governmental agencies, and assessment of significant fines and penalties against companies and individuals. Our international operations create the risk of unauthorized payments or offers of payments by one of our employees, consultants, sales agents, or distributors, because these parties are not always subject to our control. Any alleged or actual violations of these regulations may subject us to government scrutiny, severe criminal or civil sanctions and other liabilities, including exclusion from government contracting, and could disrupt our business, and result in a material adverse effect on our reputation, results of operations and financial condition. We will need to increase the size and complexity of our organization in the future, and we may experience difficulties in executing our growth strategy and managing any growth. Our management, personnel, systems and facilities currently in place may not be adequate to support our business plan and future growth. We will need to further expand our scientific, sales and marketing, managerial, operational, financial and other resources to support our planned research, development and commercialization activities. Our need to manage our operations, growth and various projects effectively requires that we: ? 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 for our drug candidates effectively and in a cost- effective manner; ? manage our relationship with our partners related to the commercialization of our drug candidates; ? manage our clinical trials effectively; ? manage our internal manufacturing operations effectively and in a cost- effective manner while increasing production capabilities for our current drug candidates to commercial levels; and ? manage our development efforts effectively while carrying out our contractual obligations to partners and other third parties. In addition, historically, we have utilized and continue to utilize the services of part- time outside consultants to perform a number of tasks for us, including tasks related to preclinical and clinical testing. Our growth strategy may also entail expanding our use of consultants to implement these and other tasks going forward. Because we rely on consultants for certain functions of our business, we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. There can be no assurance that we will be able to manage our existing consultants or find other competent outside consultants, as needed, on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our use of consultants, we might be unable to implement successfully the tasks necessary to execute effectively on our planned research, development and commercialization activities and, accordingly, might not achieve our research, development and commercialization goals. Uncertainties in the interpretation and application of tax rules in the various jurisdictions in which we operate could materially affect our deferred tax assets, tax obligations and effective tax rate. We are subject to a variety of taxes and tax collection and remittance obligations in the U. S. and foreign jurisdictions. Additionally, at any point in time, we may be under examination for value added, sales- based, payroll, product,

import or other non- income taxes. We may recognize additional tax expense, be subject to additional tax liabilities, incur losses and penalties, due to changes in laws, regulations, administrative practices, principles, assessments by authorities and interpretations related to tax, including tax rules in various jurisdictions. We compute our income tax provision based on enacted tax rates in the countries in which we operate. As tax rates vary among countries, a change in earnings attributable to the various jurisdictions in which we operate could result in an unfavorable change in our overall tax provision. Changes in enacted tax rates and the assumptions and estimates we have made, as well as actions we may take, could result in a write down of deferred tax assets or otherwise materially affect our tax obligations or effective tax rate, which could negatively affect our financial condition and results of operations. Our effective tax rate may be negatively impacted if we are unable to realize deferred tax assets or by future changes to tax laws in jurisdictions in which we operate. We are subject to income taxes in the U. S., the U. K. and other global jurisdictions. Our effective tax rate could be adversely affected by changes in the valuation of deferred tax assets and liabilities. We recognize deferred tax assets and liabilities based on the differences between the consolidated financial statement carrying amounts and the tax basis of assets and liabilities. Significant judgment is required in determining our provision for income taxes. We regularly review our deferred tax assets for recoverability and establish a valuation allowance if it is more likely than not that some portion or all of a deferred tax asset will not be realized. If we are unable to generate sufficient future taxable income, if there is a material change in the actual effective tax rates, or if there is a change to the time period within which the underlying temporary differences become taxable or deductible, we could be required to increase our valuation allowance against our deferred tax assets, which could result in a material increase in our effective tax rate. Changes in tax laws or tax rulings could have a material impact on our effective tax rate. Jurisdictions in which we operate, including the U. S. and the UK, may consider changes to existing tax laws. Such changes could increase our tax obligations in those countries where we do business. Any changes in the taxation of our activities in such jurisdictions may result in a material increase in our effective tax rate. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. As of September 30, ~~2022~~ **2023**, we had federal and state net operating loss carryforwards of approximately $ ~~112~~ **140**. 5 million and $ ~~50~~ **62**. ~~9~~ **4** million, respectively, of which $ 29. 7 million and $ ~~28~~ **35**. ~~4~~ **2** million, respectively, if not utilized to offset taxable income in future periods, will begin to expire in ~~2023~~ **2024** and will completely expire in ~~2042~~ **2043**. Under the Internal Revenue Code of 1986, as amended (the " Code ") and the regulations promulgated thereunder, including, without limitation, the consolidated income tax return regulations, various corporate ownership changes could limit our ability to use our net operating loss carryforwards and other tax attributes to offset our income. An " ownership change " (generally a 50 % change in equity ownership over a three- year period) under Section 382 of the Code could limit our ability to offset, post- change, our U. S. federal taxable income. Section 382 of the Code imposes an annual limitation on the amount of post- ownership change taxable income a corporation may offset with pre- ownership change net operating loss carryforwards and certain recognized built- in losses. Risks Relating to Our Intellectual Property We may be unable to protect the proprietary nature of the intellectual property covering our products. Our commercial success depends in part on our ability to obtain and maintain intellectual property rights to our products, drug candidates and technology as well as successfully defending these rights against third party challenges. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and profitability. The patent positions of pharmaceutical products are highly uncertain. The legal principles applicable to patents are in transition due to changing court precedent and legislative action and we cannot be certain that the historical legal standards surrounding questions of validity will continue to be applied or that current defenses relating to issued patents in these fields will be sufficient in the future. Changes in patent laws in the United States, such as the America Invents Act of 2011, may affect the scope, strength and enforceability of our patent rights or the nature of proceedings that may be brought by us related to our patent rights. In addition, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States and we may encounter significant problems in protecting our proprietary rights in these countries. We are limited in protecting our proprietary rights from unauthorized use by third parties by the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. These risks include the possibility of the following: ? the patent applications that we have filed may fail to result in issued patents in the United States or in foreign countries; ? patents issued or licensed to us or our partners may be challenged or discovered to have been issued on the basis of insufficient, incomplete or incorrect information, and thus held to be invalid or unenforceable; ? the scope of any patent protection may be too narrow to exclude competitors from developing or designing around these patents; ? we or our licensor was not the first to make the invention covered by an issued patent or pending patent application; ? we or our licensor was not the first inventor to file a patent application for the technology in the United States or was not the first to file a patent application directed to the technology abroad; ? we may fail to comply with procedural, documentary, fee payment and other similar provisions during the patent application process, which can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights; ? future drug candidates or our proprietary technologies may not be patentable or legal decisions may limit patent- eligible subject matter; ? others may claim rights or ownership with regard to patents and other proprietary rights that we hold or license; ? delays in development, testing, clinical trials and regulatory review may reduce the period of time during which we could market our drug candidates under patent protection; ? we may fail to timely apply for patents on our technologies or products; and ? inability to control patent prosecution, maintenance, or enforcement of any in- licensed intellectual property. We cannot predict whether third parties will assert these claims against us or our strategic partners or against the licensors of technology licensed to us, or whether those claims will harm our business. In addition, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. If we or our partners were to face infringement claims or challenges by third parties relating to our drug candidates, an adverse outcome could subject us to significant liabilities to such third parties and force us or our partners to curtail or cease the development of some or all of our drug candidates, which could adversely affect our business, financial condition, results of operations and prospects. Our or

our licensors' patents may expire or be invalidated, found to be unenforceable, narrowed or otherwise limited or our or our licensors' patent applications may not result in issued patents or may result in patents with narrow, overbroad, or unenforceable claims. Our commercial success will depend in part on obtaining and maintaining patent and trade secret protection for our drug candidates, as well as the methods for treating patients in the prescribed indications using these drug candidates. We will be able to protect our drug candidates and the methods for treating patients in the indications using these drug candidates from unauthorized use by third parties only to the extent that we or our licensors own or control such valid and enforceable patents or trade secrets. Even if our drug candidates and the methods for treating patients for prescribed indications using these drug candidates are covered by valid and enforceable patents and have claims with sufficient scope, disclosure and support in the specification, the patents will provide protection only for a limited amount of time. Our and our licensor' s ability to obtain patents can be highly uncertain and involve complex and in some cases unsettled legal issues and factual questions. Furthermore, different countries have different procedures for obtaining patents, and patents issued in different countries provide different degrees of protection against the use of a patented invention by others. Therefore, if the issuance to us or our licensor, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims in, or the written description or enablement in, a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection. While we will apply for patents covering our technologies and products, as we deem appropriate, many third parties may already have filed patent applications or have received patents in our areas of product development. These entities' applications, patents and other intellectual property rights may conflict with our patent applications or other intellectual property rights and could prevent us from obtaining patents, could call into question the validity of any of our patents, if issued, or could otherwise adversely affect our ability to develop, manufacture, commercialize or market our products. In addition, if third parties file patent applications which include claims covering any technology to which we have rights, we may have to participate in interference, derivation or other proceedings with the USPTO, or foreign patent regulatory authorities to determine our rights in the technology, which may be time- consuming and expensive. Moreover, issued patents may be challenged in the courts or in post- grant proceedings at the USPTO, or in similar proceedings in foreign countries. These proceedings may result in loss of patent claims or adverse changes to the scope of the claims. If we or our licensors or strategic partners fail to obtain and maintain patent protection for our products, or our proprietary technologies and their uses, companies may be dissuaded from collaborating with us. In such event, our ability to commercialize our drug candidates or future drug candidates, if approved, may be threatened, we could lose our competitive advantage and the competition we face could increase, all of which could adversely affect our business, financial condition, results of operations and prospects. In addition, mechanisms exist in much of the world permitting some form of challenge by generic drug marketers to patents prior to, or immediately following, the expiration of any regulatory exclusivity, and generic companies are increasingly employing aggressive strategies, such as " at risk " launches and compulsory licensing to challenge relevant patent rights. Our business also may rely on unpatented proprietary technology, know- how, and trade secrets. If the confidentiality of this intellectual property is breached, it could adversely impact our business. We **may not have sufficient intellectual property protection for enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving GLP- 1 RA who are at- risk for developing muscle atrophy and muscle weakness. The value of enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP- 1 RA who are at- risk for developing muscle atrophy and muscle weakness will depend in part on our ability to obtain and maintain intellectual property rights to this drug candidate as well as successfully defend these rights against third party challenges. We have existing composition of matter and polymorph composition of matter issued patents with the last patent terms expiring in 2028 and 2029 as well as a pending provisional patent method of use application related to the use of enobosarm in weight management, with the longest patent term, if issued, being for the method of use application which would expire in 2044, if issued. This method of use patent application may fail to result in an issued patent, may be challenged, or may result in patent protection that may be too narrow to exclude competitors from developing or designing around any issued patent. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and profitability. We** are dependent in part on some license relationships. We have acquired by license intellectual property and technology relating to our sabizabulin and enobosarm drug candidates and might enter into additional licenses in the future. Licenses to which we are a party contain, and we expect that any future licenses will contain, provisions requiring up- front, milestone and royalty payments to licensors. If we fail to comply with these obligations or other obligations to a licensor, that licensor might have the right to terminate the license on relatively short notice, in which event we would not be able to commercialize the drug candidates that were covered by the license. Also, the milestone and other payments associated with these licenses will make it less profitable for us to develop our drug candidates. We may face claims that our intellectual property infringes on the intellectual property rights of third parties. If we infringe intellectual property rights of third parties, it may increase our costs or prevent us from being able to commercialize our product candidates. Our success depends, in part, on not infringing the patents and proprietary rights of other parties and not breaching any license, collaboration or other agreements we enter into with regard to our technologies and products. Numerous United States and foreign issued patents and pending patent applications owned by others also exist in the therapeutic areas in, and for the therapeutic targets for, which we intend to develop drugs. Patent applications are confidential when filed and remain confidential until publication, approximately 18 months after initial filing, while some patent applications remain unpublished until issuance. As such, there may be other third- party patents and pending applications of which we will be unaware with

claims directed towards composition of matter, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our products or drug candidates. Therefore, we cannot know with certainty the nature or existence of every third- party patent filing. We cannot be sure that we or our partners will be free to manufacture or market our drug candidates as planned or that us or our licensors' and partners' patents will not be opposed or litigated by third parties. If any third- party patent was held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture or methods of treatment related to the use or manufacture of any of our drug candidates, the holders of any such patent may be able to block our ability to develop and commercialize the applicable drug candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. We may not be able to obtain a license to such patent on favorable terms or at all. Failure to obtain such license may have a material adverse effect on our business. There is a risk that we are infringing the proprietary rights of third parties because numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields that are the focus of our development and manufacturing efforts. Others might have been the first to make the inventions covered by each of our or our licensor' s pending patent applications and issued patents and / or might have been the first to file patent applications for these inventions. In addition, because patent applications take many months to publish and patent applications can take many years to issue, there may be currently pending applications, unknown to us or our licensor, which may later result in issued patents that cover the production, manufacture, synthesis, commercialization, formulation or use of our product candidates. In addition, the production, manufacture, synthesis, commercialization, formulation or use of our product candidates may infringe existing patents of which we are not aware. Defending ourselves against third- party claims, including litigation in particular, would be costly and time consuming and would divert management' s attention from our business, which could lead to delays in our development or commercialization efforts. If third parties are successful in their claims, we might have to pay substantial damages or take other actions that are adverse to our business. There is a substantial amount of litigation involving intellectual property in the pharmaceutical industry. If a third party asserts that we infringe its patents or other proprietary rights, we could face a number of risks that could adversely affect our business, financial condition, results of operations and prospects, including the following: ? infringement and other intellectual property claims would be costly and time- consuming to defend, whether or not we are ultimately successful, and could delay the regulatory approval process, consume our capital and divert management' s attention from our business; ? we may have to pay substantial damages for past infringement if a court determines that our products or technologies infringe a competitor' s patent or other proprietary rights; ? a court may prohibit us from selling or licensing our technologies or future products unless a third party licenses its patents or other proprietary rights to us on commercially reasonable terms, which it is not required to do; ? if a license is available from a third party, we may have to pay substantial royalties or lump sum payments or grant cross licenses to our patents or other proprietary rights to obtain that license; or ? we may need to redesign our products so they do not infringe, which may not be possible or may require substantial monetary expenditures and time. We cannot predict whether third parties will assert these claims against us or our strategic partners or against the licensors of technology or other intellectual property licensed to us, or whether those claims will harm our business. In addition, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. If we or our partners were to face infringement claims or challenges by third parties relating to our drug candidates, an adverse outcome could subject us to significant liabilities to such third parties and force us or our partners to curtail or cease the development of some or all of our drug candidates, which could adversely affect our business, financial condition, results of operations and prospects. We ~~must submit patent certifications in connection with the 505 (b) (2) FDA regulatory pathway. We intend to submit NDAs for certain of our drug candidates under Section 505 (b) (2) of the FDCA, which was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch- Waxman Act. Section 505 (b) (2) permits the filing of an NDA when at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. To the extent that a Section 505 (b) (2) NDA relies on clinical trials conducted for a previously approved drug product or the FDA' s prior findings of safety and effectiveness for a previously approved drug product, the Section 505 (b) (2) applicant must submit patent certifications in its Section 505 (b) (2) NDA with respect to any patents for the approved product on which the application relies that are listed in the FDA' s publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book. Specifically, the applicant must certify for each listed patent that (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is not sought until after patent expiration; or (iv) the listed patent is invalid, unenforceable or will not be infringed by the proposed new product. A certification that the new product will not infringe the previously approved product' s listed patent or that such patent is invalid or unenforceable is known as a Paragraph IV certification. If the Section 505 (b) (2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the owner of the referenced NDA for the previously approved product and relevant patent holders within 20 days after the Section 505 (b) (2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement suit against the Section 505 (b) (2) applicant. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification prevents the FDA from approving the application until the earlier of 30 months from the date of the lawsuit, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the applicant. The court also has the ability to shorten or lengthen the 30- month period if either party is found not to be reasonably cooperating in expediting the litigation. Thus, the Section 505 (b) (2) applicant may invest a significant amount of time and expense in the development of its product only to be subject to significant delay and patent litigation before its product may be commercialized. Alternatively, if the NDA or relevant patent holder does not file a patent infringement lawsuit within the specified 45- day period, the FDA may approve the Section 505 (b) (2) application at any time. If we cannot certify that all of the patents listed in the Orange Book for the approved products~~

~~referenced in the NDAs for each of our drug candidates have expired, we will be compelled to include a Paragraph IV certification in the NDA for such drug candidate. Our inability to certify that all of the patents listed in the FDA' s Orange Book for approved products referenced in the NDAs for each of our drug candidates could have a serious and significant adverse effect on the timing for obtaining approval of our drug candidates. We~~ may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of our competitors. As is common in the pharmaceutical industry, we will employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Such claims may lead to material costs for us, or an inability to protect or use valuable intellectual property rights, which could adversely affect our business, financial condition, results of operations and prospects. We may need to file lawsuits or take other actions to protect or enforce our intellectual property rights. We may be subject to competition from third parties with products in the same class of products as our drug candidates or products with the same active pharmaceutical ingredients as our drug candidates in those jurisdictions in which we have no patent protection. Even if patents are issued to us or our licensor regarding our drug candidates or methods of using them, those patents can be challenged by our competitors who can argue such patents are invalid or unenforceable, lack of utility, lack sufficient written description or enablement, or that the claims of the issued patents should be limited or narrowly construed. Patents also will not protect our product candidates if competitors devise ways of making or using these product candidates without legally infringing our patents. The Federal Food, Drug, and Cosmetic Act and FDA regulations and policies create a regulatory environment that encourages companies to challenge branded drug patents or to create non- infringing versions of a patented product in order to facilitate the approval of abbreviated new drug applications for generic substitutes. These same types of incentives encourage competitors to submit new drug applications that rely on literature and clinical data not prepared for or by the drug sponsor, providing another less burdensome pathway to approval. Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. Moreover, we may not have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, 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. In addition, in an infringement proceeding, a court may decide that one of our patents or one of our licensor' s patents is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents, or those of our licensors, do not cover the technology in question or on other grounds. An adverse result in any litigation or defense proceedings could put one or more of our patents, or those of our licensors, at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications, or those of our licensors, at risk of not issuing. Moreover, we may not be able to prevent, alone or with our licensors, misappropriation of our proprietary rights, particularly in countries in which the laws may not protect those rights as fully as in the United States or in those countries in which we do not file national phase patent applications. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. The occurrence of any of the above could adversely affect our business, financial condition, results of operations and prospects. We may fail to protect the confidentiality of commercially sensitive information. We also rely on trade secrets to protect our technology, especially where we do not believe that patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time- consuming, and the outcome is unpredictable. Moreover, our competitors may independently develop equivalent knowledge, methods and know- how. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position. Risks Related to Ownership of Our Common Stock Ownership in our common stock is highly concentrated and your ability to influence corporate matters may be limited as a result. As of ~~November 30~~ **December 5**, ~~2022~~ **2023**, our executive officers and directors collectively beneficially owned approximately ~~23~~ **21**. ~~9~~ **7** % of the outstanding shares of our common stock, including approximately ~~11~~ **10**. ~~2~~ **0** % beneficially owned by Mitchell Steiner, M. D., our Chairman, President and Chief Executive Officer, and ~~10~~ **9**. ~~7~~ **4** % beneficially owned by Harry Fisch, M. D., our Vice Chairman and Chief Corporate Officer. These shareholders may have the ability to exert significant influence over the outcome of shareholder votes, including votes concerning director elections, amendments to our Amended and Restated Articles of Incorporation and other significant corporate transactions. In addition, this concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders. The interests of such stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders. **Our common stock may be subject to delisting from the Nasdaq Capital Market if our common stock has a closing bid price of less than $ 1. 00 per share. If the closing bid price of our common stock is less than $ 1. 00 per share for 30 consecutive trading days, we may receive a letter from the staff of The Nasdaq Stock Market LLC stating that our common stock will be delisted unless we are able to regain compliance with the Nasdaq Listing Rule requiring that we maintain a closing bid price for our common stock of at least $ 1. 00 per share. Although we have not had such a period of 30 consecutive trading days with the closing bid price of our common stock below $ 1. 00 per share, our common stock**

has had a closing bid price below $ 1. 00 for a number of recent days. If our stock price continues to trade below $ 1. 00 per share, it may in the future be subject to delisting. If Nasdaq delists our shares of common stock or warrants from trading on its exchange for failure to meet Nasdaq' s listing standards, we and our stockholders could face significant material adverse consequences including: ? a limited availability of market quotations for our shares; ? reduced liquidity for our shares; ? a determination that our common stock is a " penny stock " which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our shares; ? a limited amount of news and analyst coverage; and ? a decreased ability to issue additional securities or obtain additional financing in the future. We incurred ~~a charge~~ **charges** to earnings in fiscal 2020 **and in fiscal 2023** resulting from the APP Acquisition, and additional charges to earnings resulting from the APP Acquisition in the future may cause our operating results to suffer. Under the acquisition method of accounting in accordance with ASC 805, Business Combinations, we allocated the total purchase price of the APP Acquisition to APP' s net tangible assets and intangible assets based on their respective fair values as of the date of the APP Acquisition and recorded the excess of the purchase price over those fair values as goodwill. Management' s estimates of the fair value of such assets was based upon assumptions that they believed to be reasonable but that will be inherently uncertain. ~~The following~~ **Impairment of goodwill, among other** factors ~~, among others~~, could result in material charges that would cause our financial results to be negatively impacted: ~~? impairment~~ **The restatement** of ~~intangible assets~~ **our prior quarterly financial statements may affect stockholder and investor confidence in us or harm our reputation, and may subject us to additional risks and uncertainties** , including ~~in~~ **increased costs and the increased possibility of legal proceedings and regulatory inquiries, sanctions or investigations. Subsequent to the filing of our Form 10** - ~~process research and development~~ **Q for the quarter ended June 30, 2023 on August 10, 2023** (~~IPR & D~~ **the " Original Form 10- Q "**) ~~:~~**, we reached a determination to restate certain financial information** and ~~? impairment of goodwill. Considering~~ **related footnote disclosures in our previously issued consolidated financial statements in** the ~~high~~ **Original Form 10** - **Q** ~~risk nature of research and development and the industry' s success rate of bringing developmental compounds to market, charges relating to impairment of acquired IPR & D are likely to occur in future periods~~. **As a result** ~~For example, during the fourth quarter~~ of ~~fiscal 2020, we recognized $ 14. 1 million of impairment charges related to~~ the ~~IPR & D acquired~~ **restatement, we have incurred, and may continue to incur, unanticipated costs for accounting and legal fees** in connection with ~~the APP Acquisition~~, ~~which~~ **or related to, such restatement. In addition, such restatement could subject us to a number of additional risks and uncertainties, including the** increased **possibility of legal proceedings and inquiries, sanctions** ~~our~~ - **or investigations by** ~~net loss and net loss per share for fiscal 2020. If there are additional impairment charges in the future, they~~ - **the SEC** ~~would also be accounted for~~ - **or** ~~as expenses that would decrease net income~~ **other regulatory authorities. Any of the foregoing may adversely affect our reputation, the accuracy** and ~~earnings per share~~ **timing of our financial reporting,** ~~for~~ - **or** ~~the periods~~ **our business, results of operations, liquidity and financial condition, or cause stockholders, investors, members and customers to lose confidence** in ~~which those~~ -- **the** ~~adjustments are made. If we fail~~ **accuracy and completeness of our financial reports or cause the market price of our common stock** to ~~maintain effective~~ **decline. We identified a material weakness in** internal control over financial reporting, **and determined** ~~our ability to produce accurate financial statements or comply with applicable regulations could be impaired. Pursuant to Section 404 of the Sarbanes- Oxley Act, our management is required annually to deliver a report~~ that ~~assesses the~~ **they** ~~effectiveness of~~ **resulted in** our internal control over financial reporting ~~. However~~ **and disclosure controls and procedures not being effective** , ~~for~~ as ~~long~~ **of September 30, 2023. If we are not able to remediate this material weakness, or we identify additional deficiencies in the future or otherwise fail to maintain an effective system of internal controls, including disclosure controls and procedures, this could result in material misstatements of our financial statements or cause us to fail to meet our reporting obligations. SEC rules define a material weakness** as ~~we remain~~ a **deficiency** ~~" non- accelerated filer " under the rules of the SEC~~, ~~our~~ - **or a combination** ~~independent registered public accounting firm is not required to deliver an annual attestation report on the effectiveness~~ of ~~our~~ **control deficiencies, in** internal control over financial reporting **such that there is a reasonable possibility that a material misstatement of a registrant' s financial statements will not be prevented or detected on a timely basis** . We ~~will cease~~ **are required** to ~~be a non- accelerated filer if (a) the aggregate market value of our outstanding common stock held by non- affiliates as of the last business day of our most recently completed second fiscal quarter is $ 75 million or more and we reported annual~~ **annually provide management' s** ~~net revenues of greater than $ 100 million for our most recently completed fiscal year or (b) the aggregate market value of our outstanding common stock held by non- affiliates as of the last business day of our most recently completed second fiscal quarter is $ 700 million or more, regardless of annual net revenues. If we cease to be a non- accelerated filer, we would again be subject to the requirement for an annual~~ attestation ~~report by our independent registered public accounting firm~~ on ~~the effectiveness of our~~ internal control over financial reporting. **We** ~~If we~~ are ~~unable~~ **also required** to ~~maintain effective~~ **disclose significant changes made to our internal control procedures on a quarterly basis and any material weaknesses identified by our management in our** internal control over financial reporting **during the course of related assessments. Subsequent to the filing of the Original Form 10- Q, in connection with the restatement, management identified a material weakness in the Company' s internal control over financial reporting related to its controls over applying technical accounting guidance to nonrecurring events and transactions, specific to the evaluation of information that was known or knowable at the time of the transaction or event. Management determined that such material weakness resulted in the Company' s internal control over financial reporting and disclosure controls and procedures not being effective** as ~~required by Section 404~~ of **September 30** ~~the Sarbanes- Oxley Act~~, ~~we may not be able~~ **2023. Effective internal controls are necessary for us** to ~~produce accurate~~ **provide reliable** financial statements ~~,~~and **prevent or detect fraud. The material weakness in internal control over financial reporting described above, any new deficiencies identified in the future or any deficiencies in our disclosure controls and procedures, if not timely remediated, could limit our ability to**

prevent or detect a misstatement of our accounts or disclosures that could result in a material misstatement of our annual or interim financial statements. We are in the process of implementing a remediation plan to remediate the material weakness we identified, which is designed to improve our internal control over financial reporting. We can provide no assurance that the measures we have taken to- date and any actions that we may take in the future will be sufficient to remediate this control deficiency, or that such remediation measures will be effective at preventing or avoiding potential future significant deficiencies or material weaknesses in our internal controls. If we identify any new deficiencies in the future or are not able to successfully remediate the material weakness we have identified and related deficiencies in our disclosure controls and procedures, the accuracy and timing of our financial reporting may be adversely affected, investors may ~~therefore~~ lose confidence in **the accuracy and completeness of** our ~~operating results~~ **financial reports** , **the market price of** our **common** stock ~~price~~ could decline ~~and~~ , we ~~may~~ **could** be subject to **sanctions or investigations by the SEC, or other regulatory authorities, and we may not be able to source external financing for our capital needs on acceptable terms or at all. Each of the foregoing items could adversely affect our business, results of operations, financial condition, and the market price and volatility of our common stock. In addition, we have expended, and expect to continue to expend, significant resources, including accounting- related costs and significant management oversight, in order to assess, implement, maintain, remediate and improve the effectiveness of our internal control over financial reporting and our general control environment. In addition, as a result of the material weakness described above and other matters raised or that may in the future be raised by the SEC, we face the potential for** litigation or ~~regulatory enforcement actions~~ **other disputes which may include, among others, claims invoking the federal and state securities laws, contractual claims or other claims arising from the deficiencies in our internal control over financial reporting described above, the preparation of our financial statements and the restatement described above. Any such litigation or dispute, whether successful or not, could have a material adverse effect on our business, results of operations, liquidity and financial condition** . We are a " smaller reporting company " and will be able to avail ourselves of reduced disclosure requirements applicable to smaller reporting companies, which could make our common stock less attractive to investors. We are a " smaller reporting company, " as defined in the Securities Exchange Act of 1934, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not " smaller reporting companies, " including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer a " smaller reporting company. " We will remain a " smaller reporting company " until (a) the aggregate market value of our outstanding common stock held by non- affiliates as of the last business day of our most recently completed second fiscal quarter is $ 250 million or more and we reported annual net revenues as of our most recently completed fiscal year is $ 100 million or more, or (b) the aggregate market value of our outstanding common stock held by non- affiliates as of the last business day of our most recently completed second fiscal quarter is $ 700 million or more, regardless of annual revenue. There are provisions in our charter documents, Wisconsin law and our residual royalty agreement that might prevent or delay a change in control of our company. We are subject to a number of provisions in our charter documents, Wisconsin law and our residual royalty agreement with SWK Funding LLC that may discourage, delay, or prevent a merger or acquisition that a shareholder may consider favorable. These provisions include the following: ? the authority provided to our Board of Directors in our Amended and Restated Articles of Incorporation to issue preferred stock without further action by our shareholders; ? the provision under Wisconsin law that permits shareholders to act by written consent only if such consent is unanimous; ? the provision under Wisconsin law that requires for a corporation such as us, that was formed before January 1, 1973, the affirmative vote of the holders of at least two- thirds of the outstanding shares of our voting stock to approve an amendment to our articles of incorporation, a merger submitted to a vote of our shareholders, or a sale of substantially all of our assets; ? advance notice procedures for nominations of candidates for election as directors and for shareholder proposals to be considered at shareholders' meetings; ? the Wisconsin control share acquisition statute and Wisconsin' s " fair price " and " business combination " provisions which limit the ability of an acquiring person to engage in certain transactions or to exercise the full voting power of acquired shares under certain circumstances; and ? our residual royalty agreement with SWK Funding LLC requires a mandatory prepayment upon a change of control of Veru or a sale of our FC2 business. The trading price of our common stock has been volatile, and investors in our common stock may experience substantial losses. The trading price of our common stock has been volatile and may continue to be volatile. The trading price of our common stock could decline or fluctuate in response to a variety of factors, including: ? our failure to meet market expectations for our performance; ? the timing of announcements by us or our competitors concerning significant product developments, acquisitions, or financial performance; ? adverse results or delays in our clinical trials for our drug candidates; ? changes in laws or regulations applicable to our business; ~~? competition from new products that may emerge; ? actual or anticipated fluctuations in our financial condition or operating results; ? substantial sales of our common stock; ? issuance of new or updated research reports from securities analysts; ? announcement or expectation of additional debt or equity financing efforts; ? additions or departures of key personnel; ? general stock market conditions; 63~~