Risk Factors Comparison 2024-04-08 to 2023-04-17 Form: 10-K

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You should carefully consider the risks described below with respect to an investment in our shares. If any of the following risks actually occur, our business, financial condition, operating results or cash provided by operations could be materially harmed. As a result, the trading price of our common stock could decline, and you might lose all or part of your investment. When evaluating an investment in our common stock, you should also refer to the other information in this Form 10- K, including our consolidated financial statements and related notes. Risks Relating to Our Business Generally If we fail to implement our biopharmaceutical business strategy or if our biopharmaceutical business strategy is ineffective, our financial performance could be materially and adversely affected. Our future financial performance and success are dependent in large part upon the effectiveness of our new biopharmaceutical business strategy and our ability to implement our biopharmaceutical business strategy successfully. Implementation of our strategy will require effective management of our operational, financial, and human resources and will place significant demands on those resources. There are risks involved in pursuing our strategy, including those under the caption " Risks Relating to Our Biotechnology Segment ". In addition to the risks set forth elsewhere in this Form 10- K, effectiveness of and the successful implementation of our business strategy could also be affected by a number of factors beyond our control, such as increased competition, legal developments, government regulation, general economic conditions, increased operating costs or expenses, and changes in industry trends. We may decide to alter or discontinue certain aspects of our business strategy at any time. If we are not able to implement our business strategy successfully, our long- term growth and profitability may be adversely affected. Even if we are able to implement some or all of the initiatives of our business strategy successfully, our operating results may not improve and could decline substantially. We have identified and disclosed in this Form 10- K material weaknesses in our internal control over financial reporting. If we are not able to remediate these material weaknesses and maintain an effective system of internal controls, we may not be able to accurately or timely report our financial results, which could cause our stock price to fall or result in our stock being delisted. We need to devote significant resources and time to comply with the requirements of the Sarbanes- Oxley Act of 2002 (" Sarbanes- Oxley ") with respect to internal control over financial reporting. In addition, Section 404 under Sarbanes- Oxley requires that we assess the design and operating effectiveness of our controls over financial reporting, which are necessary for us to provide reliable and accurate financial reports. As reported in Part II – Item 9A, Controls and Procedures, there were material weaknesses in our internal controls over financial reporting at January 1, 2022. Specifically, management noted the following material weaknesses in internal control when conducting their evaluation of internal control as of January 1, 2022: (1) insufficient information technology general controls and segregation of duties. It was noted that people who were negotiating a contract were also involved in approving invoices without proper oversight. Additional controls and procedures are necessary and are being implemented to have checks and balances on significant transactions and governance with those charged with governance authority; (2) inadequate control design or lack of sufficient controls over significant accounting processes; the cutoff and reconciliation procedures were not effective with certain accrued and deferred expenses; (3) insufficient assessment of the impact of potentially significant transactions; and (4) insufficient processes and procedures related to proper recordkeeping of agreements and contracts. In addition, contract- to- invoice reconciliation was not effective with certain transportation service providers. As part of its remediation plan, processes and procedures have been implemented to help ensure accruals and invoices are reviewed for accuracy and properly recorded in the appropriate period. We expect our systems and controls to become increasingly complex to the extent that we integrate acquisitions and **if and** as our business grows. To effectively manage our Company today and this anticipated complexity, we need to remediate these material weaknesses and continue to improve our operational, financial, and management controls and our reporting systems and procedures. Any failure to remediate these material weaknesses and implement required new or improved controls, or difficulties encountered in the implementation or operation of these controls, could harm our operating results or cause us to fail to meet our financial reporting obligations, which could adversely affect our business and jeopardize our listing on the Nasdaq Capital Market, either of which would harm our stock price. Our biotechnology business has a limited operating history Our biotechnology business was started in September 2019 and has a limited operating history. We have not commenced revenue- producing operations. To date, our biotechnology-related operations have consisted of preliminary research and development, and characterization and testing of SR TV1001 (now known as JAN101) and our December 2022 acquisition of Soin Therapeutics and its LDN product (now known as JAN123). Our limited operating history makes it difficult for potential investors to evaluate our technology or the prospective operations of our biotechnology business. You should consider the prospects of our biotechnology business in light of the costs, uncertainties, delays, and difficulties frequently encountered by companies in the early stages of development, especially clinical- stage biopharmaceutical businesses such as ours. Potential investors should carefully consider the risks and uncertainties that a biotechnology business with a limited operating history faces. In particular, potential investors should consider that we may be unable to (i) successfully implement or execute the business plan of our biotechnology business or currently validate that our biotechnology business plan is sound; (ii) successfully complete clinical trials and obtain regulatory approval for the marketing of ~~JAN 101~~ **JAN101 or JAN123** ; (iii) successfully demonstrate a favorable differentiation between ~~JAN 101~~ **JAN101 or JAN123** and the current products on the market; (iv) successfully manufacture our clinical drug product and establish a commercial drug supply; (v) secure market exclusivity and / or adequate intellectual property protection for ~~JAN 101~~ **JAN101 or JAN123** ; and (vi) raise sufficient funds in the capital markets to effectuate our biotechnology business plan, including product and clinical development, regulatory approval, and commercialization for ~~JAN 101~~ **JAN101 or JAN123** . Our

business model is partially dependent on certain patent rights licensed to us from the Licensors (as defined below), and the loss of those license rights would, in all likelihood, cause our business, as presently contemplated, to fail. In November 2019, UABRF, TheraVasc, and the Board of Supervisors of Louisiana State University and Agricultural and Mechanical College, acting on behalf of LSU Health Shreveport, together with UABRF and TheraVasc, **(collectively,** the " Licensors "), granted us an exclusive worldwide, royalty- bearing license to the patent rights for SR TV1001 (now known as JAN101) in the negotiated fields of use. The patent license agreement requires us to pay royalties and milestone payments and conform to a variety of covenants and agreements, and in the event of our breach of the agreement, the Licensors may elect to terminate the agreement. As of the date of this Form 10- K, we believe we are in compliance with the patent license agreement and consider our relationship with the Licensors to be excellent. We will be completely dependent on third parties to manufacture **JAN101** ~~JAN 101,~~ and ~~its~~ **JAN123, and their** commercialization could be halted, delayed, or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of ~~JAN 101~~ **JAN101 or JAN123** , or fail to do so at acceptable quality levels or prices. We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture our drug candidate for use in our clinical trials or for commercial sales, if any. As a result, we will be obligated to rely on contract manufacturers when we conduct clinical trials and if and when our initial or subsequent product candidates are approved for commercialization. In January 2020, we entered into a Master Agreement for Development, Manufacturing and Supply with CoreRx Inc. (" CoreRx "), pursuant to which CoreRx has agreed to provide to us certain product testing, development, and clinical manufacturing services for ~~JAN 101~~ **JAN101. We have not yet entered into any manufacturing agreements for the manufacture of JAN123 and must identify and contract with a company capable of producing sufficient quantities of this product for our clinical trials** . We have not entered into agreements with any contract manufacturers for commercial supply **for either JAN101 or JAN123 and may not be able to engage contract manufacturers for commercial supply of our initial or subsequent product candidates on favorable terms to us, or at all, should the need arise. We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture our drug candidate for use in our clinical trials or for commercial sales, if any. As a result, we will be obligated to rely on contract manufacturers when we conduct clinical trials and if and when our initial or subsequent product candidates are approved for commercialization. In January 2020, we entered into a Master Agreement for Development, Manufacturing and Supply with CoreRx Inc. (" CoreRx "), pursuant to which CoreRx has agreed to provide to us certain product testing, development, and clinical manufacturing services for JAN 101. We have not entered into agreements with any contract manufacturers for commercial supply** and may not be able to engage contract manufacturers for commercial supply of our initial or subsequent product candidates on favorable terms to us, or at all, should the need arise. In a previous clinical trial, the manufacture of JAN101 by a different manufacturing company resulted in a product that demonstrated initial instability that led to the product being out- of- specification. While the FDA allowed the trial to continue, there is no guarantee that, if the product manufactured by CoreRx is similarly unstable, the FDA will allow us to continue to develop that product. Even if the product manufactured by CoreRx is stable, the FDA may require additional studies to confirm the stability of the product, increasing development cost and times. The facilities used by CoreRx to manufacture **JAN101** ~~JAN 101~~ must be approved by the FDA or comparable foreign regulatory authorities. Such approvals are subject to inspections that will be conducted after we submit an NDA to the FDA or their equivalents to other relevant regulatory authorities. We will not control the manufacturing process of ~~JAN 101~~ **JAN101, JAN123** or subsequent product candidates and will be completely dependent on our contract manufacturing partners for compliance with cGMPs, for manufacture of both active drug substances and finished drug products. These cGMP regulations cover all aspects of the manufacturing, testing, quality control, storage, distribution, and record keeping relating to our initial or subsequent product candidates. If our contract manufacturers do not successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we will not be able to secure or maintain regulatory approval for products made at their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our initial or subsequent product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, manufacture, obtain regulatory approval for, or market our initial or subsequent product candidates, if approved. Likewise, we could be negatively impacted if any of our contract manufacturers elect to discontinue their business relationship with us. Our contract manufacturer will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. We will not have control over our contract manufacturer' s compliance with these regulations and standards. Failure by our contract manufacturer to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market ~~JAN 101~~ **JAN101 or JAN123** , delays, suspensions or withdrawals of approvals, inability to supply product, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect our biotechnology business. In addition, we will not have control over the ability of our contract manufacturer to maintain adequate quality control, quality assurance, and qualified personnel. Failure by our contract manufacturer to comply with or maintain any of these standards could adversely affect our ability to develop, manufacture, obtain regulatory approval for or market ~~JAN 101~~ **JAN101 or JAN123** , if approved. Our manufacturer must obtain the API from a third party. A number of groups manufacture our API; however, some of these are manufactured as a food product, and others, while manufactured under GMP, do not have the required Drug Master File on file with the FDA. CoreRx identified an API from Merck KGaA for use in the current production of clinical grade JAN101. At the time of the manufacture of the API, the product met the specifications outlined in both the drug substance monographs for Europe and the US. However, subsequent to the manufacture of the API, the US monograph was changed in the US Pharmacopeia (" USP ") and, while most of the tests conform, Merck KGaA was unable to complete two of the new testing requirements. Although the two tests are not considered safety issues and do not impact the quality of the product, there is no

guarantee the FDA will approve the product for clinical trials if the two tests are not completed, which could delay our ability to start the Phase IIb clinical trial, as planned. Identifying an analytical laboratory to perform the two tasks may be difficult and could require development and validation of the tests, adding both time and costs to us. In addition, there is no guarantee that, once developed, the product will meet the specifications as outlined in the USP. Even if the FDA allows the current product to be used in the Phase IIb clinical trial, there is no guarantee that the FDA will allow further clinical work with the product or commercialization of the product until it is shown to conform to USP standards. We may be required to work with the API manufacturer to file the appropriate documents and there is no guarantee that the FDA will approve the filing. This could necessitate additional funding to hire an API manufacturer and produce the product under GMP with all necessary filings. If, for any reason, these third parties are unable or unwilling to perform, we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for APIs or finished products or should cease doing business with us for any reason, we could experience significant interruptions in the supply of our initial or subsequent product candidates or may not be able to create a supply of any of our ls at all. Were we to encounter manufacturing difficulties, our ability to produce a sufficient supply of any of our product candidates might be negatively affected. Our inability to coordinate the efforts of our third- party manufacturing partners, or the lack of capacity available at our third- party manufacturing partners, could impair our ability to supply any of our product candidates at required levels. Because of the significant regulatory requirements that we would need to satisfy in order to qualify a new bulk drug substance or finished product manufacturer, if we face these or other difficulties with our then- current manufacturing partners, we could experience significant interruptions in the supply of any of our product candidates if we decided to transfer the manufacture of any of our product candidates to one or more alternative manufacturers in an effort to deal with such difficulties. CoreRx currently serves as our sole manufacturer of JAN101. As CoreRx also manufactures other products, there can be no guarantee that CoreRx will have the capacity to manufacture additional clinical product for us in a timely manner, when required, which could lead to significant delays in initiating other clinical studies. CoreRx will unlikely have the capacity to manufacture the amount of product needed, if and when JAN101 is approved for marketing. This would necessitate identifying additional manufacturer (s) who may or may not be able to replicate the manufacturing process developed at CoreRx. In addition, the increase in quantities required for commercialization of the product, if commercialization occurs, could require modifying the manufacturing process to produce larger quantities of tablets more efficiently. Such modifications of the manufacturing process, if even possible, could result in significant delays in the delivery of the product. We will be validating the manufacturing process, with appropriate process parameters and critical process, at CoreRx in ~~2023~~ **2024** . Based on current batch sizes, these validated processes will support the manufacture of approximately 6. 5 million tablets a month. This would allow us to enter the marketplace, but would support sales of only 1- 2 % of the addressable market. There is no guarantee that CoreRx will increase its manufacturing capacity when needed by us; thus, we will likely need to identify another approved manufacturer with increased capacity. In addition, we will need to revalidate the manufacturing process to demonstrate to the FDA the ability to reproducibly manufacture larger batch sizes, which will increase time and costs. If these activities are not carried out in a timely manner, a shortage of product could result following commercial launch, which could significantly affect sales and overall valuation of the Company. Any manufacturing problem or the loss of our contract manufacturer could be disruptive to our operations and result in development delays and lost sales. Additionally, we will rely on third parties to supply the raw materials needed to manufacture our initial or subsequent product candidates. Any such reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability, and quality. Any unanticipated disruption to the operation of one of our contract manufacturers caused by problems with suppliers could delay shipment of any of our product candidates, increase our cost of goods sold and result in lost sales. **Pharmacies may be able to compound LDN in competition with us, but the economic impact may not be material. JAN123 is a biphaisc formulation of LDN being developed for CRPS. However, compounding pharmacies have already sold a non- biphasic LDN for this purpose and for other purposes. The patent JanOne was issued for JAN123, in conjunction with Orphan Drug approval, will provide additional marketing protection for CRPS. Compounding pharmacies are not subject to FDA approval and could compound LDN for their patients. We believe that production and sales by a single compounding pharmacy of a material amount of a compounded product would transform such compounding pharmacy into a pharmaceutical manufacturer, which would then subject it to all of the FDA approval protocols, including cGMP requirements. Thus, compounding pharmacies would not be able to scale their compounding activities for LDN to facilitate their material sales growth of LDN or to become impactful in the marketplace. As disclosed below, we cannot provide assurances with respect to third- party coverage and reimbursement. We believe that persons who purchase LDN from a compounding pharmacy may need to pay out- of- pocket for the product with limited or no insurance coverage.** If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our initial or subsequent product candidates. We will face a potential risk of product liability as a result of the clinical testing of our initial or subsequent product candidates. For example, we may be sued if any product we develop, including **JAN101** ~~JAN 101~~ , **JAN123** or any materials that we use in it, allegedly causes injury or is found to be otherwise unsuitable during product testing and manufacturing. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. In the United States, claims could also be asserted against us 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 initial or subsequent product candidates. Even successful defense of these claims would require us to employ significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may

result in, among other things (i) decreased demand for ~~JAN 101~~ **JAN101, JAN123** or any future products that we may develop; (ii) failure to obtain regulatory approval for our product candidates; (iii) withdrawal of participants in our clinical trials; (iv) substantial monetary awards to trial participants or patients; (v) product recalls or withdrawals or labeling, marketing, or promotional restrictions; and (vi) the inability to commercialize our initial or subsequent product candidates. As of the date of this Form 10- K, we do not carry product liability insurance. The success of our biotechnology business is entirely dependent on our ability to obtain the marketing approval for our product candidates by the FDA and the regulatory authorities in foreign jurisdictions in which we intend to market them, of which there can be no assurance. We are not permitted to market **JAN101** ~~JAN 101~~ or **JAN123** ~~JAN 123~~ as prescription pharmaceutical products in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries. In the United States, the FDA generally requires the completion of clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before an NDA is approved. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are eventually approved for commercialization. As of the date of this Form 10- K, we have not submitted an NDA to the FDA or comparable applications to other regulatory authorities for any subsequent product candidates. Because of the clinical trial history of JAN101, we believe that **JAN101** ~~JAN 101~~ will qualify for FDA approval through the FDA' s 505 (b) (2) regulatory pathway and in corresponding regulatory paths in other foreign jurisdictions. Notwithstanding the use of the FDA' s 505 (b) (2) regulatory pathway, we will be required to conduct Phase IIb and Phase III studies prior to filing for marketing approval of ~~JAN 101~~ **JAN101. The active ingredient in JAN123 is naltrexone, which has been approved for use at much higher doses by the FDA for other indications, thus we believe that JAN123 will also qualify for the 505 (b) (2) regulatory pathway. In addition, the FDA has approved the Orphan Designation for JAN123, which could lead to approval after just two clinical trials. However, based on the strength of the results of the registration trial, the FDA could request additional clinical studies prior to approval** . Our success depends on our receipt of the regulatory approvals described above, and the issuance of such regulatory approvals is uncertain and subject to a number of risks, including the following: (i) the results of toxicology studies may not support the filing of an NDA for **JAN101** ~~JAN 101~~ ; (ii) the FDA may require additional pharmacokinetic studies with JAN101, including studies with food, prior to allowing the Company to conduct Phase IIb and Phase III clinical trials; (iii) the FDA or comparable foreign regulatory authorities or Institutional Review Boards (" IRBs ") may disagree with the design or implementation of our clinical trials; (iv) we may not be able to provide acceptable evidence of **JAN101** ~~JAN 101~~ ' s safety and efficacy; (v) the results of our clinical trials may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA, the EMA, or other regulatory agencies for us to receive marketing approval for **JAN101** ~~JAN 101~~ ; (vi) the dosing of **JAN101** ~~JAN 101~~ in a particular clinical trial may not be at an optimal level; (vii) patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to **JAN101** ~~JAN 101~~ ; (viii) the data collected from clinical trials may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere; (ix) the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third- party manufacturers with which we contract for clinical and commercial supplies; and (x) the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval of **JAN101** ~~JAN 101~~ . The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity, and novelty of the product candidates involved, the jurisdiction in which regulatory approval is sought, and the substantial discretion of the regulatory authorities. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for a submitted product application may cause delays in the approval or rejection of an application. Regulatory approval obtained in one jurisdiction does not necessarily mean that a product candidate will receive regulatory approval in any or all other jurisdictions in which we may seek approval; but, the failure to obtain approval in one jurisdiction may negatively impact our ability to seek approval in a different jurisdiction. Failure to obtain regulatory approval for ~~JAN 101~~ **JAN101 or JAN123** for the foregoing, or any other reasons, will prevent us from commercializing ~~JAN 101~~ **JAN101 or JAN123** , and our ability to generate revenue will be materially impaired. Clinical testing is expensive, is difficult to design and implement, can take many years to complete **,** and is uncertain as to outcome. Our business model depends in part on the successful development, regulatory approval, and commercialization of ~~JAN 101~~ **JAN101 or JAN123** , which may never occur. ~~JAN 101 is~~ **Both JAN101 and JAN123 are** in the early stages of development and, as of the date of this Form 10- K, we have not progressed **JAN101** ~~JAN 101~~ beyond early clinical studies designed only to show safety **, nor has JAN123 been tested in any FDA approved clinical trials** . Three INDs have previously been submitted by previous licensees / assignees of JAN101 and were accepted by the FDA. These INDs were transferred to JanOne in 2020. Even though the INDs were transferred to us, the FDA may still require additional work prior to re- initiation of clinical trials. If we do not obtain such approvals to re- initiate trials as presently planned, the time in which we expect to commence clinical programs for any product candidate will be extended and such extension will increase our expenses, delay our potential receipt of any revenues, and increase our need for additional capital. Moreover, there is no guarantee that we will receive approval to commence human clinical trials or, if we do receive approval, that our clinical trials will be successful or that we will continue clinical development in support of an approval from the FDA or comparable foreign regulatory authorities for any indication. We note that most product candidates never reach the clinical development stage and even those that do commence clinical development have only a small chance of successfully completing clinical development and gaining regulatory approval. Success in early phases of pre- clinical and clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our initial or any

subsequent product candidates. Therefore, our business currently depends entirely on the successful development, regulatory approval, and commercialization of our product candidates, which may never occur. **JAN123 has received Orphan Drug designation from the FDA, allowing for fewer and smaller clinical trials prior to approval. In part, this is due to fewer patients being available for treatment and may lead to delays in recruiting subjects for the trial and therefore delays in reaching the market.** Even if we receive regulatory approval for ~~JAN 101~~ **JAN101 or JAN123** , we may not be able to commercialize it successfully and the revenue that we generate from its sales, if any, may be limited. If approved for marketing, the commercial success of **JAN101** ~~JAN 101~~ will depend upon the product' s acceptance by the medical community, including physicians, patients, and health care payors. The degree of market acceptance for **JAN101** ~~JAN 101~~ will depend on a number of factors, including (i) demonstration of clinical safety and efficacy; (ii) relative convenience, dosing burden, and ease of administration; (iii) the prevalence and severity of any adverse effects; (iv) the willingness of physicians to prescribe **JAN101** ~~JAN 101~~ and the target patient population to try new therapies; (v) efficacy of JAN 101 compared to competing products; (vi) the introduction of any new products that may in the future become available, targeting indications for which **JAN101** ~~JAN 101~~ may be approved; (vii) new procedures or therapies that may reduce the incidences of any of the indications in which **JAN101** ~~JAN 101~~ may show utility; (viii) pricing and cost- effectiveness; (ix) the inclusion or omission of **JAN101** ~~JAN 101~~ in applicable guidelines; (x) the effectiveness of our own or any future collaborators' sales and marketing strategies; (xi) limitations or warnings contained in approved labeling from regulatory authorities; (xii) our ability to obtain and maintain sufficient third- party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers, and other third- party payors or to receive the necessary pricing approvals from government bodies regulating the pricing and usage of therapeutics; and (xiii) the willingness of patients to pay out- of- pocket in the absence of third- party coverage or reimbursement or government pricing approvals. **JAN123 will face al the commercialization factors described above with an additional risk of compounding pharmacies prescribing the product to patients. The active ingredient, naltrexone, is available and has been compounded into LDN formulations similar to JAN123. These compounded LDN formulations have been provided to numerous patients with different forms of pain. While not approved for the treatment of pain and therefore unlikely to be reimbursed, the low cost of the compounded LDN could cause reduce pricing of JAN123. We believe that JAN123 will have advantages over the compounded LDN in terms of reduced side effects, but many patients currently have not had the side effects or accepted these as part of reducing their pain with compounded LDN. JanOne may have to enforce its patents, which could result in lengthy and costly litigation, to prevent compounding pharmacies from selling LDN for indications for which JanOne has received patent protection.** If ~~JAN 101~~ **JAN101 or JAN123** is approved but does not achieve an adequate level of acceptance by physicians, health care payors, and patients, our biotechnology business may not generate sufficient revenue to cover costs. Our efforts to educate the medical community and third- party payors on the benefits of ~~JAN 101~~ **JAN101 or JAN123** may require significant resources and may never be successful. In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize ~~JAN 101~~ **JAN101 or JAN123** successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that renders our product candidate not commercially viable. For example, regulatory authorities may approve our product candidate for fewer or more limited indications than we request, may not approve the price we intend to charge for our product candidate, may grant approval contingent on the performance of costly post- marketing clinical trials, or may approve any of our product candidates with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that indication. Further, the FDA or comparable foreign regulatory authorities may place conditions on approvals or require risk management plans or a REMS to assure the safe use of the drug. Moreover, product approvals may be withdrawn for non- compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of our product candidate. Even if we obtain marketing approval for our product candidate, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidate could be subject to labeling and other restrictions and withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidate. Even if we obtain regulatory approval for our product candidate for an indication, the FDA or foreign equivalent may still impose significant restrictions on its indicated uses or marketing or the conditions of approval, or impose ongoing requirements for potentially costly and time- consuming post- approval studies, including Phase IV clinical trials, and post- market surveillance to monitor safety and efficacy. Our product candidate will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events, and other post-market information. These requirements include registration with the FDA, as well as continued compliance with current good clinical practices regulations for any clinical trials that we conduct post- approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current cGMPs, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents. The FDA has the authority to require a REMS as part of an NDA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe- use criteria or requiring patient testing, monitoring and / or enrollment in a registry. With respect to sales and marketing activities related to our product candidate, advertising and promotional materials must comply with FDA rules in addition to other applicable federal, state **,** and local laws in the United States and similar legal requirements in other countries. In the United States, the distribution of product samples to physicians must comply with the requirements of the United States Prescription

Drug Marketing Act. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the United States Anti- Kickback Statute, United States False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific / educational grant programs. If we participate in the United States Medicaid Drug Rebate Program, the Federal Supply Schedule of the United States Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to United States federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries. In addition, if ~~JAN 101~~ **JAN101 or JAN123** is approved for a particular indication, our product labeling, advertising, and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product' s approved labeling. If we receive marketing approval for ~~JAN 101~~ **JAN101 or JAN123** , physicians may nevertheless legally prescribe our product to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off- label uses, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses, and a company that is found to have improperly promoted off- label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off- label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed. If we or a regulatory agency discover previously unknown problems with one of our product candidates, such as adverse events of unanticipated severity or frequency, problems with the facility where the product is manufactured, or we or our manufacturers fail to comply with applicable regulatory requirements, we may be subject to the following administrative or judicial sanctions: (i) restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls; (ii) issuance of warning letters or untitled letters; (iii) clinical holds; (iv) injunctions or the imposition of civil or criminal penalties or monetary fines; (v) suspension or withdrawal of regulatory approval; (vi) suspension of any ongoing clinical trials; (vii) refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals; (viii) suspension or imposition of restrictions on operations, including costly new manufacturing requirements; or (ix) product seizure or detention or refusal to permit the import or export of product. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue. Adverse regulatory action, whether pre- or post- approval, can also potentially lead to product liability claims and increase our product liability exposure. Obtaining and maintaining regulatory approval of ~~JAN 101~~ **JAN101 or JAN123** in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of ~~JAN 101~~ **JAN101 or JAN123** in other jurisdictions. Obtaining and maintaining regulatory approval of our initial or subsequent product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction; but, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing, and promotion of that product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials, as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our initial or subsequent product candidates and affect the prices we may obtain. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for ~~JAN 101~~ **JAN101 or JAN123** , restrict, or regulate post- approval activities and affect our ability to profitably sell ~~JAN 101~~ **JAN101 or JAN123** . Legislative and regulatory proposals have been made to expand post- approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance, or interpretations will be changed, or what the impact of such changes on the marketing approvals of ~~JAN 101~~ **JAN101 or JAN123** , if any, may be. In addition, increased scrutiny by Congress of the FDA' s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post- marketing testing and other requirements. Any termination or suspension of, or delays in the commencement or completion of, any necessary studies of any of our product candidate for any indications could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects. The commencement and completion of clinical studies can be delayed for a number of reasons, including delays related to: (i) the FDA or a comparable foreign regulatory authority failing to grant permission to proceed and placing the clinical study on hold; (ii) subjects for clinical testing failing to enroll or remain enrolled in our trials at the rate we expect; (iii) a facility manufacturing our initial or subsequent product candidates being ordered by the FDA or other government or regulatory authorities to shut down, temporarily or permanently, due to violations of cGMP requirements or other applicable requirements, or cross- contaminations of the product candidates in the manufacturing process; (iv) any changes to our manufacturing process that may be necessary or desired; (v) subjects choosing an alternative treatment for the indications for which we are developing our initial or subsequent product candidates, or participating in competing clinical studies; (vi) subjects experiencing severe or unexpected drug- related adverse effects; (vii) reports from clinical testing on similar technologies and products raising safety and / or efficacy concerns;

(viii) third- party clinical investigators losing their licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule, or employing methods consistent with the clinical trial protocol, cGMP requirements, or other third parties not performing data collection and analysis in a timely or accurate manner; (ix) inspections of clinical study sites by the FDA, comparable foreign regulatory authorities, or IRBs finding regulatory violations that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study, or that prohibit us from using some or all of the data in support of our marketing applications; (x) third- party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or any of the data produced by such contractors in support of our marketing applications; (xi) one or more IRBs refusing to approve, suspending, or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; (xii) reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; (xiii) deviations of the clinical sites from trial protocols or dropping out of a trial; (xiv) adding new clinical trial sites; (xv) the inability of the CRO to execute any clinical trials for any reason; and (xvi) government or regulatory delays or " clinical holds " requiring suspension or termination of a trial. Product development costs for our initial and any subsequent product candidates will increase if we have delays in testing or approval or if we need to perform more or larger clinical studies than planned. Additionally, changes in regulatory requirements and policies may occur and we may need to amend study protocols to reflect these changes. Amendments may require us to resubmit our study protocols to the FDA, comparable foreign regulatory authorities, and IRBs for reexamination, which may impact the costs, timing, or successful completion of that study. If we experience delays in completion of, or if we, the FDA or other regulatory authorities, the IRB, or other reviewing entities, or any of our clinical study sites suspend or terminate any of our clinical studies of any of our product candidates, their commercial prospects may be materially harmed and our ability to generate product revenues will be delayed. Any delays in completing our clinical trials will increase our costs, slow our development and approval process, and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition, and prospects significantly. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical studies may also ultimately lead to the denial of regulatory approval of one of more of our product candidates. In addition, if one or more clinical studies are delayed, our competitors may be able to bring competing products to market before we do, and the commercial viability of our affected product candidates could be significantly reduced. Third- party coverage and reimbursement and health care cost containment initiatives and treatment guidelines may constrain our future revenues. Our ability to market ~~JAN 101~~ **JAN101 or JAN123** successfully will depend in part on the level of reimbursement that government health administration authorities, private health coverage insurers, and other organizations provide for the cost of ~~JAN 101~~ **JAN101 or JAN123** and related treatments. Countries in which ~~JAN 101~~ **JAN101 or JAN123** is sold through reimbursement schemes under national health insurance programs frequently require that manufacturers and sellers of pharmaceutical products obtain governmental approval of initial prices and any subsequent price increases. In certain countries, including the United States, government- funded and private medical care plans can exert significant indirect pressure on prices. We may not be able to sell ~~JAN 101~~ **JAN101 or JAN123** profitably if adequate prices are not approved or coverage and reimbursement is unavailable or limited in scope. Increasingly, third- party payors attempt to contain health care costs in ways that are likely to impact the development of our product including: (i) failing to approve or challenging the prices charged for health care products; (ii) introducing reimportation schemes from lower priced jurisdictions; (iii) limiting both coverage and the amount of reimbursement for new therapeutic products; (iv) denying or limiting coverage for products that are approved by the regulatory agencies but are considered to be experimental or investigational by third- party payors; and (v) refusing to provide coverage when an approved product is used in a way that has not received regulatory marketing approval. It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights. Our success depends on successfully blocking others from developing and commercializing similar products. As ~~a~~ repurposed ~~drug~~ **drugs** , our ~~API~~ **APIs** ~~has~~ **have** previously been approved for other indications, none of which currently represent a threat to our ~~product~~ **products** , and therefore cannot be protected. We will rely on our method of use and oral formulation patents to protect our ~~product~~ **products** , which may also put our ~~product~~ **products** at risk from companies developing oral formulations using the same API for other indications. Even though our patents provide protection for specific uses, we will not be able to prevent other companies from developing the same ~~API~~ **APIs** for other uses. If a similar dose, formulation **,** and route of administration is developed for another indication by a different company, we cannot guarantee that the product they market for the other indication will not be prescribed off- label by doctors or filled by pharmacists for use in indications our patents cover and that if less expensive, would not negatively affect our sales, if our ~~product~~ **products** ~~is~~ **are** ultimately approved by the FDA **.** The degree of future protection afforded by the patent rights licensed to us is uncertain, because legal means afford only limited protection and may not adequately protect our rights, permit us to gain or keep our competitive advantage, or provide us with any competitive advantage at all. We cannot be certain that any patent application owned by a third party will not have priority over patent applications in which we hold license rights or that we will not be involved in interference, opposition or invalidity proceedings before United States or foreign patent offices. Additionally, if the Licensors were to initiate legal proceedings against a third party to enforce a patent covering **JAN101** ~~JAN 101~~ , the defendant could counterclaim that such patent is invalid and / or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness, or non- enablement. Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the United States Patent and Trademark Office (the " PTO ") or made a misleading statement during

prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include regarding- examination, post- grant review, and equivalent proceedings in foreign jurisdictions, e. g., opposition proceedings. Such proceedings could result in revocation or amendment of the Licensors' patents in such a way that they no longer cover **JAN101** ~~JAN-101~~ or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which the Licensors and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on any of our product candidates. Such a loss of patent protection would have a material adverse impact on our business. In the future, we may rely on know- how and trade secrets to protect technology, especially in cases in which we believe patent protection is not appropriate or obtainable. However, know- how and trade secrets are difficult to protect. While we intend to require employees, academic collaborators, consultants, and other contractors to enter into confidentiality agreements, we may not be able adequately to protect our trade secrets or other proprietary or licensed information. Typically, research collaborators and scientific advisors have rights to publish data and information in which we may have rights. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts are sometimes less willing to protect trade secrets than patents. Moreover, our competitors may independently develop equivalent or better knowledge, methods, and know- how. If we fail to obtain or maintain patent protection or trade secret protection for our product candidates or our technologies, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and attain profitability. It is difficult and costly to block others from developing similar products for other indications, and we cannot ensure that these products will not be less expensive and thus be prescribed off- label by physicians for use in our indications. Our success depends on successfully blocking others from developing and commercializing similar products. As a repurposed ~~drug~~ **drugs** , our ~~API~~ **APIs** ~~has~~ **have** previously been approved for other indications ~~,~~ **and therefore cannot be protected. Although** none of ~~which currently~~ **the approved indications for the API used in JAN101 represent a threat to JAN101, the API used in naltrexone has been formulated by compounding pharmacies to treat the indication JanOne is pursuing and thus** represents a **real** threat **in commercialization of JAN123** ~~to JAN-101, and therefore cannot be protected~~ . We will rely on our method of use and oral formulation patents to protect ~~JAN-101~~ **JAN101 and JAN123** , which may also put ~~JAN-101~~ **JAN101 and JAN123** at risk from companies developing oral formulations using the same API for other indications. Even though our patents provide protection for specific uses, we will not be able to prevent other companies from developing the same API for other uses. If a similar dose, formulation, and route of administration is developed for another indication by a different company, we cannot guarantee that the product they market for the other indication will not be prescribed off- label by doctors or filled by pharmacists for use in indications our patents cover and that if less expensive, would not negatively affect our sales, if ~~JAN-101~~ **JAN101 or JAN123** is ultimately approved by the FDA. ~~JAN-101~~ **JAN101 or JAN123** may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts. Our success depends in part on avoiding infringement of the proprietary technologies of others. The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Identification of third- party patent rights that may be relevant to our proprietary technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases, and the difficulty in assessing the meaning of patent claims. Additionally, because patent applications are maintained in secrecy until the application is published, we may be unaware of third- party patents that may be infringed by commercialization of ~~JAN-101~~ **JAN101, JAN123** or any subsequent product candidate. There may be certain issued patents and patent applications claiming subject matter that we may be required to license in order to research, develop, or commercialize any of our product candidates, and we do not know if such patents and patent applications would be available to license on commercially reasonable terms, or at all. Any claims of patent infringement asserted by third parties would be time- consuming and may: (i) result in costly litigation; (ii) divert the time and attention of our technical personnel and management; (iii) prevent us from commercializing a product candidate until the asserted patent expires or is held finally invalid or not infringed in a court of law; (iv) require us to cease or modify our use of the technology and / or develop non- infringing technology; or (v) require us to enter into royalty or licensing agreements. Third parties may hold proprietary rights that could prevent ~~JAN-101~~ **JAN101 or JAN123** from being marketed. Any patent- related legal action against us claiming damages and seeking to enjoin commercial activities relating to any of our product candidates or our processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market ~~JAN-101~~ **JAN101, JAN123** or any subsequent product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign ~~JAN-101~~ **JAN101, JAN123** or any subsequent product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing ~~JAN-101~~ **JAN101, JAN123** or a subsequent product candidate, which could harm our business, financial condition, and results of operations. We expect that there are other companies, including major pharmaceutical companies, working in the areas competitive to ~~JAN-101~~ **JAN101 or JAN123** that either have resulted, or may result, in the filing of patent applications that may be deemed related to our activities. If we were to challenge the validity of these or any issued United States patent in court, we would need to overcome a statutory presumption of validity that attaches to every issued United States patent. This means that, in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent' s claims. If we were to challenge the validity of these or any issued United States patent in an administrative trial before the Patent Trial and Appeal Board in the PTO, we would have to prove that the claims are unpatentable by a preponderance of the evidence. There is no assurance that a jury and / or court would find in our favor on

questions of infringement, validity, or enforceability. Even if we are successful, litigation could result in substantial costs and be a distraction to management. GENERAL RISK FACTORS ~~Isaac Capital Group, LLC (" ICG ") owns a large percentage of our voting stock, which may allow it to control substantially all matters requiring stockholder approval. Currently, ICG owns approximately 18. 7 % of our outstanding shares of common stock. ICG' s sole member is Jon Isaac, the President and Chief Executive Officer of Live Ventures. Jon Isaac is the son of our Chief Executive Officer Tony Isaac. Because of such ownership and the relationship, ICG may be able significantly, and possibly adversely, to affect our corporate decisions, including the election of the board of directors.~~ The market price of our common stock has been, and may continue to be volatile and fluctuate significantly, which could result in substantial losses for investors and subject us to securities class action litigation. The trading price for our common stock has been, and we expect it to continue to be, volatile. The price at which our common stock trades depends upon a number of factors, including our historical and anticipated operating results, our financial situation, announcements of technological innovations or new products by us, our ability or inability to raise the additional capital we may need and the terms on which we raise it, and general market and economic conditions. Some of these factors are beyond our control. Broad market fluctuations may lower the market price of our common stock and affect the volume of trading in our stock, regardless of our financial condition, results of operations, business or ~~prospect~~ **prospects** . Among the factors that may cause the market price of our common stock to fluctuate are the risks described in this " Risk Factors " section. In addition, the stock markets, in general, The Nasdaq Capital Market and the market for biopharmaceutical companies in particular, may experience a loss of investor confidence. Such loss of investor confidence may result in extreme price and volume fluctuations in our common stock that are unrelated or disproportionate to the operating performance of our business, financial condition or results of operations. These broad market and industry factors may materially harm the market price of our common stock and expose us to securities class action litigation. Such litigation, even if unsuccessful, could be costly to defend and divert management' s attention and resources, which could further materially harm our financial condition and results of operations. ~~We may not be able to maintain compliance with the continued listing requirements of The Nasdaq Global Market. Our common stock is listed on the Nasdaq Global Market. In order to maintain that listing, we must satisfy minimum financial and other requirements including, without limitation, a requirement that our closing bid price be at least $ 1. 00 per share. If we fail to continue to meet all applicable continued listing requirements for The Nasdaq Global Market in the future and Nasdaq determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock, our ability to obtain financing to repay debt, and fund our operations. 51~~