Risk Factors Comparison 2024-04-01 to 2023-03-31 Form: 10-K

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

Risks Related to Our Business and Industry Our ~~ProNeura~~ development ~~programs~~ **program** ~~are~~ **is** at **a** very early ~~stages~~ **stage** and will require substantial additional resources that may not be available to us. To date, other than our work on Probuphine in OUD and our work on ~~nalmefene~~ **Nalmefene , which were sold to Fedson in September 2023** , we have conducted only limited research and development activities assessing our **kappa opioid agonist** ~~ProNeura delivery system' s applicability in other potential indications. While the nalmefene~~ program ~~has been funded in large part by NIDA, there is no assurance that NIDA will continue to provide the necessary funding to complete the regulatory approval process for this product candidate~~ . We will also require substantial additional funds to advance our kappa opioid agonist program beyond the proof- of- concept stage and to support further research and development activities, including the anticipated costs of nonclinical studies and clinical trials, regulatory approvals, and eventual commercialization of any therapeutic based on **kappa opioid agonist** ~~our~~ **or other programs** ~~ProNeura platform technology~~ . If we are unable to obtain substantial government grants or enter into third party collaborations to fund our ~~ProNeura~~ programs, we will need to seek additional sources of financing, which may not be available on favorable terms, if at all. If we are unsuccessful in obtaining the requisite funding for our ~~ProNeura~~ programs, we could be forced to discontinue product development. Furthermore, funding arrangements with collaborative partners or others may require us to relinquish rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves or license rights to technologies, product candidates or products on terms that are less favorable to us than might otherwise be available. Our ability to successfully develop any future product candidates ~~based on our ProNeura drug delivery technology~~ is subject to the risks of failure and delay inherent in the development of new pharmaceutical products, including: delays in product development, clinical testing, or manufacturing; unplanned expenditures in product development, clinical testing, or manufacturing; failure to receive regulatory approvals; emergence of superior or equivalent products; inability to manufacture on our own, or through any others, product candidates on a commercial scale; and failure to achieve market acceptance. Because of these risks, our research and development efforts may not result in any commercially viable products and our business, financial condition, and results of operations could be materially harmed. Clinical trials required for new product candidates are expensive and time- consuming, and their outcome is uncertain. Conducting clinical trials is a lengthy, time- consuming, and expensive process. The length of time may vary substantially according to the type, complexity, novelty, and intended use of the product candidate, and often can be several years or more per trial. Delays associated with products for which we are directly conducting clinical trials may cause us to incur additional operating expenses. The commencement and rate of completion of clinical trials may be delayed by many factors, including, for example: ● inability to manufacture sufficient quantities of qualified materials under cGMP for use in clinical trials; ● slower than expected rates of patient recruitment; ● failure to recruit a sufficient number of patients; modification of clinical trial protocols; ● changes in regulatory requirements for clinical trials; ● the lack of effectiveness during clinical trials; ● the emergence of unforeseen safety issues; ● delays, suspension, or termination of the clinical trials due to the institutional review board responsible for overseeing the study at a particular study site; and ● government or regulatory delays or " clinical holds " requiring suspension or termination of the trials. The results from early clinical trials are not necessarily predictive of results obtained in later clinical trials. Accordingly, even if we obtain positive results from early clinical trials, we may not achieve the same success in future clinical trials. Clinical trials may not demonstrate statistically significant safety and effectiveness to obtain the requisite regulatory approvals for product candidates. The failure of clinical trials to demonstrate safety and effectiveness for the desired indications could cause us to abandon a product candidate and could delay development of other product candidates. Any delay in, or termination of, our clinical trials could materially harm our business, financial condition, and results of operations. We face risks associated with third parties conducting preclinical studies and clinical trials of our products. We depend on third- party laboratories and medical institutions to conduct preclinical studies and clinical trials for our products and other third- party organizations to perform data collection and analysis, all of which must maintain both good laboratory and good clinical practices. We also depend upon third party manufacturers for the production of any products we may successfully develop to comply with cGMP of the FDA, which are similarly outside our direct control. If third party laboratories and medical institutions conducting studies of our products fail to maintain both good laboratory and clinical practices, the studies could be delayed or have to be repeated. We face risks associated with product liability lawsuits that could be brought against us. The testing, manufacturing, marketing and sale of human therapeutic products entail an inherent risk of product liability claims. We currently have a limited amount of product liability insurance, which may not be sufficient to cover claims that may be made against us in the event that the use or misuse of our product candidates causes, or merely appears to have caused, personal injury or death. In the event we are forced to expend significant funds on defending product liability actions, and in the event those funds come from operating capital, we will be required to reduce our business activities, which could lead to significant losses. Adequate insurance coverage may not be available in the future on acceptable terms, if at all. If available, we may not be able to maintain any such insurance at sufficient levels of coverage and any such insurance may not provide adequate protection against potential liabilities. Whether or not a product liability insurance policy is obtained or maintained in the future, any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources or destroy the prospects for commercialization of the product which is the subject of any such claim. We may be unable to protect our patents and proprietary rights. Our future success will depend to a significant extent on our ability to: ● obtain and keep patent protection for our products, methods and technologies on a domestic and international basis; ● enforce our patents to prevent

others from using our inventions; ● maintain and prevent others from using our trade secrets; and ● operate and commercialize products without infringing on the patents or proprietary rights of others. We cannot assure you that our patent rights will afford any competitive advantages, and these rights may be challenged or circumvented by third parties. Further, patents may not be issued on any of our pending patent applications in the **United States** ~~U. S.~~ or abroad. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before a potential product can be commercialized, any related patent may expire or remain in existence for only a short period following commercialization, reducing or eliminating any advantage of the patent. If we sue others for infringing our patents, a court may determine that such patents are invalid or unenforceable. Even if the validity of our patent rights is upheld by a court, a court may not prevent the alleged infringement of our patent rights on the grounds that such activity is not covered by our patent claims. In addition, third parties may sue us for infringing their patents. In the event of a successful claim of infringement against us, we may be required to: ● pay substantial damages; ● stop using our technologies and methods; ● stop certain research and development efforts; ● develop non- infringing products or methods; and ● obtain one or more licenses from third parties. If required, we cannot assure you that we will be able to obtain such licenses on acceptable terms, or at all. If we are sued for infringement, we could encounter substantial delays in development, manufacture and commercialization of our product candidates. Any litigation, whether to enforce our patent rights or to defend against allegations that we infringe third party rights, will be costly, time consuming, and may distract management from other important tasks. We also rely in our business on trade secrets, know- how and other proprietary information. We seek to protect this information, in part, through the use of confidentiality agreements with employees, consultants, advisors and others. Nonetheless, we cannot assure you that those agreements will provide adequate protection for our trade secrets, know- how or other proprietary information and prevent their unauthorized use or disclosure. To the extent that consultants, key employees or other third parties apply technological information independently developed by them or by others to our proposed products, disputes may arise as to the proprietary rights to such information, which may not be resolved in our favor. We must comply with extensive government regulations. The research, development, manufacture, labelling, storage, record- keeping, advertising, promotion, import, export, marketing and distribution of pharmaceutical products are subject to an extensive regulatory approval process by the FDA in the **United States** ~~U. S.~~ and comparable health authorities in foreign markets. The process of obtaining required regulatory approvals for drugs is lengthy, expensive and uncertain. Approval policies or regulations may change, and the FDA and foreign authorities have substantial discretion in the pharmaceutical approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed. Regulatory approval may entail limitations on the indicated usage of a drug, which may reduce the drug' s market potential. Even if regulatory clearance is obtained, post- market evaluation of the products, if required, could result in restrictions on a product' s marketing or withdrawal of the product from the market, as well as possible civil and criminal sanctions. Of the large number of drugs in development, only a small percentage successfully complete the regulatory approval process and are commercialized. We face intense competition. With respect to our product development programs, we face competition from numerous companies that currently market, or are developing, products for the treatment of the diseases and disorders we have targeted, many of which have significantly greater research and development capabilities, experience in obtaining regulatory approvals and manufacturing, marketing, financial and managerial resources than we have. We also compete with universities and other research institutions in the development of products, technologies and processes, as well as the recruitment of highly qualified personnel. Our competitors may succeed in developing technologies or products that are more effective than the ones we have under development or that render our proposed products or technologies non- competitive or obsolete. In addition, our competitors may achieve product commercialization or patent protection earlier than we will. We depend on a small number of employees and consultants. We are highly dependent on the services of a limited number of personnel and the loss of one or more of such individuals could substantially impair our ongoing commercialization efforts. We compete in our hiring efforts with other pharmaceutical and biotechnology companies, and it may be difficult and could take an extended period of time because of the limited number of individuals in our industry with the range of skills and experience required and because of our limited resources. In addition, we retain scientific and clinical advisors and consultants to assist us in all aspects of our business. Competition to hire and retain consultants from a limited pool is intense. Further, because these advisors are not our employees, they may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, and typically they will not enter into non- compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. We face potential liability related to the privacy of health information we obtain from clinical trials sponsored by us or our collaborators, from research institutions and our collaborators, and directly from individuals. Numerous federal and state laws, including state security breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, and disclosure of personal information. In addition, most health care providers, including research institutions from which we or our collaborators obtain patient health information, are subject to privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 ~~, or~~ **(“** HIPAA ~~,~~ **”)** as amended by the Health Information Technology for Economic and Clinical Health Act. Although we are not directly subject to HIPAA, we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain or disclose individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. Rising inflation and interest rates could negatively impact our revenues, profitability and borrowing costs. In addition, if our costs increase and we are not able to correspondingly adjust our commercial relationships to account for this increase, our net income would be adversely affected, and the adverse impact may be material. Inflation rates, particularly in the **United States** ~~U. S.~~, have increased recently to levels not seen in years **before retreating in the latter part of 2023** . Increased

inflation may result in decreased demand for our products, increased operating costs (including our labor costs), reduced liquidity, and limitations on our ability to access credit or otherwise raise debt and equity capital. In addition, the United States Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation. Increases in interest rates have had, and could continue to have, a material impact on our borrowing costs. In an inflationary environment, we may be unable to raise the sales prices of our products at or above the rate at which our costs increase, which could reduce our profit margins and have a material adverse effect on our financial results and net income. We also may experience lower than expected sales if there is a decrease in spending on products in our industry in general or a negative reaction to our pricing. A reduction in our revenue would be detrimental to our profitability and financial condition and could also have an adverse impact on our future growth. We face risks related to health epidemics, such as the COVID- 19 global pandemic, that could adversely affect our operations or financial results. The ~~ongoing~~ COVID- 19 pandemic ~~has~~ had ~~and may continue to have~~ a material adverse effect on our business ~~. While the duration of the pandemic~~ and ~~its potential economic impact are difficult to predict, it already has~~ caused significant disruption in the healthcare industry ~~and is likely to have continuing impacts as it continues~~. Although we expect that the primary impacts of the COVID- 19 pandemic are behind us, as we have seen with the spread of the Delta and Omicron variants, the extent to which COVID- 19 continues to impact our business, healthcare systems in general or the global economy as a whole will depend on future developments that are highly uncertain and cannot be predicted and may result in a sustained economic downturn that could affect our ability to access capital on reasonable terms, or at all. We are increasingly dependent on information technology systems, infrastructure and data. Cybersecurity breaches could expose us to liability, damage our reputation, compromise our confidential information or otherwise adversely affect our business. We are increasingly dependent upon information technology systems, infrastructure and data. Our computer systems may be vulnerable to service interruption or destruction, malicious intrusion and random attack. Security breaches pose a risk that sensitive data, including intellectual property, trade secrets or personal information may be exposed to unauthorized persons or to the public. Cyber- attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber- attacks could include the deployment of harmful malware, denial- of service, social engineering and other means to affect service reliability and threaten data confidentiality, integrity and availability. Our key business partners face similar risks, and a security breach of their systems could adversely affect our security posture. While we continue to invest in data protection and information technology, there can be no assurance that our efforts will prevent service interruptions, or identify breaches in our systems, that could adversely affect our business and operations and / or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm. Risks Related to our Common Stock Our share price may be volatile, which could prevent you from being able to sell your shares at or above your purchase price. The market price of shares of our common stock has been and may continue to be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including: ● results of our product development efforts; ● regulatory actions with respect to our products under development or our competitors' products; ● actual or anticipated fluctuations in our financial condition and operating results; ● actual or anticipated fluctuations in our competitors' operating results or growth rate; ● announcements by us, our potential future collaborators or our competitors of significant acquisitions, strategic collaborations, joint ventures, or capital commitments; ● issuance of new or updated research or reports by securities analysts; ● fluctuations in the valuation of companies perceived by investors to be comparable to us; ● inconsistent trading volume levels of our shares; ● additions or departures of key personnel; ● disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; ● announcement or expectation of additional financing efforts; ● sales of our common stock by us, our insiders or our other stockholders; ● market conditions for biopharmaceutical stocks in general; and ● general economic and market conditions. The stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations, may negatively impact the market price of shares of our common stock and could subject us to securities class action litigation. If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline. The trading market for our common stock will depend on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our stock or change their opinion of our stock, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline. Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our ~~board~~ **Board** ~~of directors~~ is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our ~~board~~ **Board** ~~of directors~~. Among other things, these provisions provide that: ● the authorized number of directors can be changed only by resolution of our ~~board~~ **Board** ~~of directors~~; ● our bylaws may be amended or repealed by our ~~board~~ **Board** ~~of directors~~ or our stockholders; ● stockholders may not call special meetings of the stockholders or fill vacancies on the ~~board~~ **Board** ~~of directors~~; ● our ~~board~~ **Board** ~~of directors~~ is authorized to issue, without

stockholder approval, preferred stock, the rights of which will be determined at the discretion of the ~~board~~ **Board** ~~of directors~~ and that, if issued, could operate as a " poison pill " to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that our ~~board~~ **Board** ~~of directors~~ does not approve; ● our stockholders do not have cumulative voting rights, and therefore our stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors; and ● our stockholders must comply with advance notice provisions to bring business before or nominate directors for election at a stockholder meeting. If we cannot continue to satisfy the Nasdaq Capital Market continued listing standards and other Nasdaq rules, our common stock could be delisted, which would harm our business, the trading price of our common stock, our ability to raise additional capital and the liquidity of the market for our common stock. Our Common Stock is currently listed on the Nasdaq Capital Market (" Nasdaq "). The listing standards of Nasdaq require that a company maintain stockholders' equity of at least $ 2. 5 million and a minimum bid price subject to specific requirements of $ 1. 00 per share. There is no assurance that we will be able to maintain compliance with the minimum closing price requirement or the minimum stockholders' equity requirement. Should we fail to comply with the minimum listing standards applicable to issuers listed on Nasdaq, our common stock may be delisted from Nasdaq. If our common stock is delisted, it could reduce the price of our common stock and the levels of liquidity available to our stockholders. If our common stock were to be delisted from Nasdaq and was not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over- the- counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further. ~~Our failure to meet the continued listing requirements of Nasdaq could result in a de- listing of our common stock. At December 31, 2022, our stockholders' equity was below the $ 2, 500, 000 minimum stockholders' equity requirement for continued listing. We have previously received notices of noncompliance due to our failure to maintain the $ 2, 500, 000 minimum stockholders' equity requirement for continued listing. In the past, were able to regain compliance with that requirement through capital raises and our discontinuation of the expenses associated with Probuphine commercial operations. There can be no assurance that we will continue to meet all of the criteria necessary for Nasdaq to allow us to remain listed. In March 2023, we received a letter from the Listing Qualifications staff of The Nasdaq Stock Market, or Nasdaq, notifying us that we were no longer in compliance with the minimum bid price requirement for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550 (a) (2) requires listed companies to maintain a minimum bid price of $ 1. 00 per share. The letter noted that the bid price of our common stock was below $ 1. 00 for the 30- day period ending March 15, 2023. The notification letter had no immediate effect on our listing on the Nasdaq Capital Market. Nasdaq has provided us with 180 days, or until September 12, 2023, to regain compliance with the minimum bid price requirement by having a closing bid price of at least $ 1. 00 per share for a minimum of 10 consecutive business days. In January 2023, we received a notice from Nasdaq, regarding the fact that we had not yet held an annual meeting of shareholders within twelve months of the end of our fiscal year ended December 31, 2021 and we no longer comply with Listing Rules for continued listing. In February 2023, we provided Nasdaq with a plan to regain compliance. If the plan is accepted by Nasdaq, we will have until June 29, 2023 to regain compliance. In May 2022, we received a notice from Nasdaq regarding the fact that the market price of our common stock was below the $ 1. 00 minimum bid price requirement for continued listing. In July 2022, we were able to regain compliance with the minimum bid requirement and remain listed on Nasdaq. If our common stock is delisted from Nasdaq, our common stock would likely then trade only in the over- the- counter market. If our common stock were to trade on the over- the- counter market, selling our common stock could be more difficult because smaller quantities of shares would likely be bought and sold, transactions could be delayed, and we could face significant material adverse consequences, including: a limited availability of market quotations for our securities; reduced liquidity with respect to our securities; a determination that our shares are a " penny stock, " which will require brokers trading in our securities to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our securities; a reduced amount of news and analyst coverage for our company; and a decreased ability to issue additional securities or obtain additional financing in the future. These factors could result in lower prices and larger spreads in the bid and ask prices for our common stock and would substantially impair our ability to raise additional funds and could result in a loss of institutional investor interest and fewer development opportunities for us.~~ In addition to the foregoing, if our common stock is delisted from Nasdaq and it trades on the over- the- counter market, the application of the " penny stock " rules could adversely affect the market price of our common stock and increase the transaction costs to sell those shares. The ~~Securities and Exchange Commission, or~~ SEC ~~,~~ has adopted regulations which generally define a " penny stock " as an equity security that has a market price of less than $ 5. 00 per share, subject to specific exemptions. If our common stock is delisted from Nasdaq and it trades on the over- the- counter market at a price of less than $ 5. 00 per share, our common stock would be considered a penny stock. The SEC' s penny stock rules require a broker- dealer, before a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document that provides information about penny stocks and the risks in the penny stock market. The broker- dealer must also provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker- dealer and the salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer' s account. In addition, the penny stock rules generally require that before a transaction in a penny stock occurs, the broker- dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser' s agreement to the transaction. If applicable in the future, these rules may restrict the ability of brokers- dealers to sell our common stock and may affect the ability of investors to sell their shares, until our common stock no longer is considered a penny stock. Future sales of our common stock, or the perception that future sales may occur, may cause the market price of our common stock to decline, even if our business is doing well. Sales by our stockholders of a substantial number of shares of our common stock in the public market could occur in the future. These sales, or the perception in the

market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. We will seek to raise additional funds and may finance acquisitions or develop strategic relationships by issuing securities that would dilute your ownership. Depending on the terms available to us, if these activities result in significant dilution, it may negatively impact the trading price of our shares of common stock. We have financed our operations, and we expect to continue seeking to finance our operations, acquisitions, if any, and the development of strategic relationships by issuing equity and / or convertible securities, which could significantly reduce the percentage ownership of our existing stockholders. Further, any additional financing that we secure, including any debt financing, may require the granting of rights, preferences or privileges senior to, or pari passu with, those of our common stock. Any issuances by us of equity securities may be at or below the prevailing market price of our common stock and in any event may have a dilutive impact on your ownership interest, which could cause the market price of our common stock to decline. We may also raise additional funds through the incurrence of debt or the issuance or sale of other securities or instruments senior to our shares of common stock. The holders of any securities or instruments we may issue may have rights superior to the rights of our common stockholders. If we experience dilution from the issuance of additional securities and we grant superior rights to new securities over common stockholders, it may negatively impact the trading price of our shares of common stock **,** and you may lose all or part of your investment. ~~One~~ **Certain** of our stockholders **have** ~~, David E. Lazar, has~~ significant voting power over our common stock and may vote ~~his~~ **their** shares in a manner that is not in the best interest of other stockholders. One of our stockholders, **Choong Choon Hau** ~~David E. Lazar~~ , controls approximately ~~24~~ **26** . ~~96~~ **42** % of the voting power represented by our outstanding shares of common stock. ~~He~~ **In addition, The Sire Group Ltd. (“ Sire ”) owns 950, 000 shares of Series AA Convertible Preferred Stock. Each share of Series AA Preferred Stock is convertible into shares of our common stock, subject to ownership limitations set forth in the Certificate of Designations, Preferences and Rights of Series AA Convertible Preferred Stock (the “ Certificate of Designations ”). The Series AA Preferred Stock has certain voting rights set forth in the Certificate of Designations. Such stockholders** may be able to exert significant control over our management and affairs requiring stockholder approval, including approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock. This concentration of ownership may not be in the best interests of all of our stockholders **. We identified a material weakness in our internal control over financial reporting as of December 31, 2023 and this or other material weaknesses could continue to materially impair our ability to report accurate financial information in a timely manner. Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of its disclosure controls and procedures as defined in Rules 13a- 15 (e) and 15d- 15 (e) under the Exchange Act for the year ended December 31, 2023. Based on such evaluation, the principal executive officer and principal financial officer has concluded that our disclosure controls and procedures were not effective as of December 31, 2023 due to the identified material weakness in internal control over financial reporting as discussed below. Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a- 15 (f) and 15d- 15 (f) of the Exchange Act). Our management, under the supervision and with the participation of the principal executive officer and principal financial officer, conducted an assessment of the effectiveness of internal control over financial reporting as of December 31, 2023, based on the framework and criteria established in Internal Control- Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO framework). Based on this assessment, management concluded that, as of December 31, 2023, its internal control over financial reporting was not effective due to the existence of the material weakness described below. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that a reasonable possibility exists that a material misstatement of the annual or interim financial statements would not be prevented or detected on a timely basis. Our management identified a deficiency in our internal control over financial reporting that gave rise to a material weakness. The deficiency primarily related to limited finance and accounting staffing levels not commensurate with our complexity and our financial accounting and reporting requirements. We underwent organizational changes in 2023 and 2022, including multiple reductions in our workforce, and operate with a very lean finance and accounting department. This limited staffing resulted in a lack of resources to fully monitor and operate our internal controls over financial reporting as of December 31, 2023, resulting in a deficiency being discovered during our annual auditing process. Our management continues to evaluate the material weakness discussed above and is implementing its remediation plan as further described in Item 9A below. However, assurance as to when the remediation efforts will be complete cannot be provided and the material weakness cannot be considered remedied until the applicable controls have operated for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. Our management cannot provide assurances that the measures that have been taken to date, and are continuing to be implemented, will be sufficient to remediate the material weakness identified or to avoid potential future material weaknesses. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results in a timely manner or prevent fraud, which would adversely affect investor confidence in our company and harm our business. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations in a timely manner, or at all. Testing by us conducted in connection with Section 404 (a) of the Sarbanes Oxley Act may reveal material weaknesses in our internal controls over financial reporting related to our limited finance, accounting and IT staffing levels. While we are implementing our remediation plan as further described in Item 9A below, we cannot provide assurances that the measures that have been taken to date, and are continuing to be implemented, will be**

sufficient to remediate the material weakness identified or to avoid potential future materials weaknesses. Subsequent testing by our independent registered public accounting firm in connection with Section 404 (b) of the Sarbanes Oxley Act may reveal continued or additional deficiencies in our internal controls over financial reporting that are deemed to be significant deficiencies or material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. We are required to disclose material changes made in our internal controls over financing reporting and procedures on a quarterly basis and our management are required to assess the effectiveness of these controls annually. We are also required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an emerging growth company or a non- accelerated filer, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, for as long as we are a smaller reporting company under the JOBS Act or a non- accelerated filer, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404 (b) of the Sarbanes- Oxley Act. To achieve compliance with Section 404 (a) of the Sarbanes- Oxley Act, we engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to implement our remediation plan, continue to dedicate internal resources, potentially engage additional outside consultants to assess the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively and implement a continuous reporting and improvement process for internal control over financial reporting. We have determined that, as of December 31, 2023, our disclosure controls and procedures were not effective due to the identified material weakness in internal control and financial reporting as described herein. The effectiveness of our internal controls in future periods is subject to the risk that our controls may become further inadequate because of changes in conditions. We may be unable to timely remediate our material weakness and may discover additional weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system' s objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. If we are not able to comply with the requirements of Section 404 of the Sarbanes- Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities including equivalent foreign authorities . We have never paid any cash dividends and have no plans to pay any cash dividends in the future. **Our** ~~Holders of shares of our~~ common ~~stock~~ **stockholders** are entitled to receive such dividends as may be declared by our ~~board~~ **Board** ~~of directors~~ . To date, we have paid no cash dividends on our shares of our preferred or common stock **,** and we do not expect to pay cash dividends in the foreseeable future. In addition, the declaration and payment of cash dividends is restricted under the terms of our existing Loan Agreement. We intend to retain future earnings, if any, to provide funds for operations of our business. Therefore, any return investors in our preferred or common stock may have will be in the form of appreciation, if any, in the market value of their shares of common stock. Item 1B. Unresolved Staff Comments.