Risk Factors Comparison 2024-03-11 to 2023-03-30 Form: 10-K

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Investing in our common stock involves a high degree of risk. These risks include, but are not limited to, those described below, each of which may be relevant to an investment decision. You should carefully consider the risks described below, together with all of the other information in this Annual Report on Form 10- K, including our financial statements and related notes and Item 7. " Management' s Discussion and Analysis of Financial Condition and Results of Operations. " before deciding to invest in our common stock. The realization of any of these risks could have a significant adverse effect on our reputation, business, financial condition, results of operations and growth, and our ability to accomplish our strategic objectives. In that event, the market price of our common stock could decline, and you may lose part or all of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and the market value of our common stock. Summary of Risk Factors Our business and an investment in our company is subject to numerous risks, many of which are discussed in the section entitled " Risk Factors " set forth in this Annual Report on Form 10- K. Some of these risks include: ● We are an early clinical stage pharmaceutical company with a limited operating history. ● We have never generated revenue from operations, are unlikely to generate revenues for several years, and our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern. We may never become profitable or, if we achieve profitability, be able to sustain profitability. ● We need to raise additional capital to fund our operations, which may not be available on acceptable terms, if at all. ● Future sales of shares by existing stockholders or us could cause our stock price to decline. ● The sale of our common stock through our Lincoln Park Purchase Agreement may cause substantial dilution to our existing stockholders, and such sales, or the anticipation of such sales, may cause the price of our common stock to decline. Moreover, the terms of the Lincoln Park Purchase Agreement limit the amount of shares of common stock we may issue to Lincoln Park, which may require us to utilize more costly and time- consuming means of accessing the capital markets, which could materially adversely affect our liquidity and cash position. ● Our independent auditor' s report for the fiscal year ended December 31, ~~2022~~ **2023** includes an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern. ● We have identified material weaknesses in our internal control ~~over financial reporting~~ and if our remediation of such material weaknesses is not effective, or if we fail to develop and maintain an effective system of disclosure controls and internal control ~~over financial reporting~~, our ability to produce timely and accurate financial statements or comply with applicable laws and regulations could be impaired. ● Our research and development are primarily focused on the drug suramin, leaving us subject to the risk of a lack of diversity in the active pharmaceutical ingredients we utilize in our business. We do not know whether we will be successful in our efforts to build a pipeline of product candidates or if we will be able to develop any products of commercial value ~~. ● We currently do not have quantities of suramin sufficient to support all of our clinical trial needs and we will need to manufacture additional suramin in order to satisfy those needs~~. ● We cannot be certain that PAX- 101 or any other product candidates that we may develop or acquire will receive regulatory approval, and without regulatory approval we will not be able to market any of our product candidates. Any delay in the regulatory review or approval of any of our product candidates will materially or adversely harm our business. ● Even if we obtain regulatory approval for our product candidates, if we are unable to successfully commercialize our products, it will limit our ability to generate revenue and will materially adversely affect our business, financial condition and results of operations. ● We have received deficiency letters from Nasdaq relating to non- compliance with Nasdaq' s continued listing requirements. Our common stock could become subject to delisting from Nasdaq if we fail to regain compliance. ● While we believe we may be eligible to receive a tropical disease PRV for the use of PAX- 101 for the treatment of HAT, there is a risk that we will not receive such PRV, which would require us to find alternative sources of funding for our later stage clinical programs. ● It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights. ● PAX- 101 and our other product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts. ● Clinical and preclinical drug development is a lengthy and expensive process with uncertain outcomes that may lead to delayed timelines and increased cost, which may prevent us from being able to complete clinical trials. ● If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our drug candidates. ● We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively. ● Since certain of our directors and officers are employed by and / or consult for other companies, their other activities could compete for time on, or create conflicts of interest with, our activities. ● ~~We face risks related to health pandemics, epidemics and outbreaks, including the COVID- 19 pandemic, which could significantly disrupt our preclinical studies and clinical trials, and therefore our receipt of necessary regulatory approvals could be delayed or prevented. ●~~ Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, could adversely affect our current and projected business operations and our financial condition and results of operations. Risks Related to Our Financial Position and Need for CapitalOur independent auditor' s report for the fiscal year ended December 31, ~~2022~~ **2023** includes an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern. Due to the uncertainty of our ability to meet our current operating and capital expenses, in its report on our audited annual financial statements as of and for the year ended December 31, ~~2022~~ **2023**, our independent auditors included an explanatory paragraph regarding concerns about our ability to continue as a going concern. Recurring losses from operations raise substantial doubt about our ability to continue as a going concern. If we are unable to continue as a going concern, we might have to liquidate our assets and the value we receive for our assets in liquidation or dissolution could be

significantly lower than the values reflected in our financial statements. We are an early clinical stage pharmaceutical company with a limited operating history. We are an early clinical stage pharmaceutical company with a limited operating history. We must complete clinical studies and receive regulatory approval of an NDA before commercial sales of a product can commence. The likelihood of success of our business plan must be considered in light of the problems, substantial expenses, difficulties, complications and delays frequently encountered in connection with developing and expanding early- stage businesses and the regulatory and competitive environment in which we operate. Pharmaceutical product development is a highly speculative undertaking, involves a substantial degree of risk and is a capital- intensive business. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially early- stage clinical pharmaceutical companies such as ours. Potential ~~22investors --~~ **investors** should carefully consider the risks and uncertainties that a company with a limited operating history will face. In particular, potential investors should consider that we cannot assure you that we will be able to, among other things: ● successfully implement or execute our current business plan, and we cannot assure you that our business plan is sound; ● successfully manufacture our clinical products and establish commercial drug supply; ● successfully complete the clinical trials necessary to obtain regulatory approval for the marketing of our drug candidates, including PAX- 101; **23** ● secure, maintain and, as necessary, defend our intellectual property rights; ● secure market exclusivity and / or adequate intellectual property protection for our drug candidates; ● attract and retain an experienced management and advisory team; ● secure acceptance of our drug candidates in the medical community and with third- party payors and consumers; ● launch commercial sales of our drug candidates, whether alone or in collaboration with others; ● raise sufficient funds in the capital markets or otherwise to effectuate our business plan; and ● utilize the funds that we do have and / or raise in this offering or in the future to efficiently execute our business strategy. If we cannot successfully execute any one of the foregoing, our business may fail and your investment will be adversely affected. We have never generated revenue from operations, are unlikely to generate revenues for several years, and our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern. We may never become profitable or, if we achieve profitability, be able to sustain profitability. We have never generated revenue from operations, are unlikely to generate revenues for several years, and are currently operating at a loss and expect our operating costs will increase significantly as we incur further costs related to preclinical development and the clinical trials for our drug candidates. We expect to incur substantial expenses without corresponding revenues unless and until we are able to obtain regulatory approval and successfully commercialize any of our drug candidates. We may never be able to obtain regulatory approval for the marketing of our drug candidates in any indication in the United States or internationally. Even if we are able to commercialize our drug candidates, there can be no assurance that we will generate significant revenues or ever achieve profitability. We have incurred recurring losses since inception and have an accumulated deficit of approximately $ ~~33~~ **52** . ~~7~~ **0** million as of December 31, ~~2022~~ **2023** , which recurring losses have raised substantial doubt regarding our ability to continue as a going concern. We anticipate operating losses to continue for the foreseeable future due to, among other things, costs related to research funding, development of our product candidates and preclinical and clinical programs, regulatory clearances, strategic alliances, the development of our administrative organization, as well as costs to comply with the requirements of being a public company operating in a highly regulated industry. As of December 31, ~~2022~~ **2023** , we had $ ~~1~~ **4** . ~~9~~ **7** million of cash and cash equivalents. Our forecast of the period of time through which our current financial resources will be adequate to support our operations and the costs to support our general and administrative, sales and marketing, research and development activities and costs to comply with the requirements of being a public company operating are forward- looking statements and involve risks and uncertainties. The financial statements do not include any adjustments that might be necessary should we be unable to continue as a going concern. We are uncertain when or if we will be able to achieve or sustain profitability. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable would impair our ability to sustain operations and adversely affect the price of our common stock and our ability to raise capital. ~~23We~~ **We** need to raise additional capital to fund our operations, which may not be available on acceptable terms, if at all. Our ability to continue as a going concern **, maintain our listing on Nasdaq, and continue our operations** is dependent on our ability to raise additional capital and should we be unable to raise sufficient additional capital, we may be required to undertake cost- cutting measures including delaying or discontinuing certain clinical activities. We need to raise significant additional capital to continue to fund the clinical trials for PAX- 101, and our other product candidates. We will likely seek to sell common equity, including pursuant to the Lincoln Park Purchase Agreement (as defined below), preferred equity or convertible debt securities, enter into a credit facility or another form of third- party funding, or seek other debt financing. In addition, the sale of equity and convertible debt securities may result in dilution to our stockholders and certain of those securities may have rights senior to those of our common stock. If we raise additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these securities or other debt could contain covenants that would restrict our operations, fund raising capabilities or otherwise. Any other third- party funding arrangement could require us to relinquish valuable rights. ~~The~~ **24The** source, timing and availability of any future financing will depend principally upon market conditions, and, more specifically, on the progress of our clinical development programs. Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us, among other things, to delay, scale back or eliminate some or all of our planned clinical trials **, development programs or operations** . These factors among others create a substantial doubt about our ability to continue as a going concern. Future sales of shares by existing stockholders or us could cause our stock price to decline. Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. We may issue additional shares of our common stock or securities convertible into our common stock from time to time in connection with a financing, acquisition, investments or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and cause the trading price of our common stock to

decline. Specially, if and when we sell shares of common stock to Lincoln Park pursuant to the Lincoln Park Purchase Agreement, Lincoln Park may resell all, some or none of such shares at any time or from time to time in its discretion, subject to compliance with applicable securities laws. Therefore, sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity- related securities in the future at a time and at prices that it might otherwise wish to effect such sales. ~~In addition, the 2023 Note provides that commencing August 6, 2023, we will pay the outstanding principal amount of the 2023 Note in twelve consecutive monthly payments of $ 306, 666. 66 each. At our option, the monthly payment can be made in cash, shares of our common stock at a price based on 90 % of the 5 lowest VWAPs during the 20 days prior to the payment date, or a combination of cash and stock. If we were to make repayments in common stock or a combination of cash and stock, we would be required to issue a substantial amount of common stock at a discount to the trading price of our common stock.~~ Sales of our common stock may be made by holders of our public float or by holders of restricted securities in compliance with the provisions of Rule 144 of the Securities Act of 1933, or the Securities Act. There were ~~12~~ **7** , ~~035~~ **401** , ~~592~~ **242** shares of common stock outstanding as of December 31, ~~2022~~ **2023** ~~. Of these shares of our common stock~~ , **substantially all of which** ~~1, 545, 454 shares sold in our initial public offering in 2022 and~~ are freely tradable, without restriction, in the public market. We registered up to ~~13~~ **770** , **718** ~~102, 199~~ shares of common stock pursuant to the Lincoln Park Purchase Agreement **, of which 549, 896 remain available,** and, if and when we sell shares to Lincoln Park thereunder, they will be freely tradeable pursuant to such registration statement ~~. We have also agreed with the holder of the 2023 Note to file a registration statement covering any shares we may issue upon conversion of such convertible note, which will also be freely tradeable upon registration and issuance~~ . We have also registered ~~2~~ **98** , **619** ~~500, 000~~ shares of our common stock underlying existing grants or grants that we may issue under our equity compensation plan. Also, in general **,** under Rule 144, a non- affiliated person who has satisfied a six- month holding period in a company registered under the Exchange Act, as amended, may, sell their restricted common stock without volume limitation, so long as the issuer is current with all reports under the Exchange Act in order for there to be adequate common public information. ~~24Affiliated~~ -- **Affiliated** persons may also sell their common shares held for at least six months, but affiliated persons will be required to meet certain other requirements, including manner of sale, notice requirements and volume limitations. Non- affiliated persons who hold their common shares for at least one year will be able to sell their common stock without the need for there to be current public information in the hands of the public. Future sales of shares of our public float or by restricted common stock made in compliance with Rule 144 may have an adverse effect on the then prevailing market price, if any, of our common stock. The sale of our common stock through our Lincoln Park Purchase Agreement ~~and the issuance of common stock pursuant to the 2023 Note~~ may cause substantial dilution to our existing stockholders, and such sales or issuances, or the anticipation of such sales or issuances, may cause the price of our common stock to decline. Moreover, the terms of the Lincoln Park Purchase Agreement limit the amount of shares of common stock we may issue to Lincoln Park, which may require us to utilize more costly and time- consuming means of accessing the capital markets, which could materially adversely affect our liquidity and cash position. On November 17, 2022, we entered into a Purchase Agreement (the " Lincoln Park Purchase Agreement ") with Lincoln Park Capital Fund, LLC (" Lincoln Park "), under which, from time to time, we may cause Lincoln Park to purchase shares of our common stock. Although we have the right to control whether we sell any shares, if at all, under the Lincoln Park Purchase Agreement, and we generally have the right to control the timing and amount of any such sales, we are subject to certain restrictions, including those that limit the number of shares we may sell. **We** ~~In particular, with respect to the Lincoln Park Purchase Agreement, we may not sell more than 2, 354, 717 shares to Lincoln Park, which we refer to as the Exchange Cap, including the 198, 974 shares of our common stock that we issued to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the Lincoln Park Purchase Agreement (the " Commitment Shares "), unless we obtain stockholder approval to issue shares in excess of the Exchange Cap or the average price per share of shares issued to Lincoln Park equals or exceeds $ 1. 55 (which represents the official closing price of our common stock on Nasdaq the day of signing of the Purchase Agreement) and we~~ may not sell shares to Lincoln Park if it would result in Lincoln Park beneficially owning more than 9. 99 % of our then outstanding shares of common stock. Accordingly, we may not be able to utilize the Purchase Agreement to raise additional capital when, or in the amounts, we desire. If we cannot sell the full amount of the shares of common stock that Lincoln Park has committed to purchase because of these limitations, we may be required to utilize more costly and time- consuming means of accessing the capital markets, which could materially adversely affect our liquidity and cash position. ~~The~~ **25The** ~~13~~ **549** , **896** ~~102, 199~~ shares of common stock that ~~may~~ **remain to** be resold into the public markets pursuant to the prospectus that is part of the registration statement on Form S- 1 (File No. 333- 268882) that ~~the Company filed on December 19, 2022, which~~ was declared effective by the SEC ~~on~~ **in** December ~~27,~~ 2022, represents approximately ~~108~~ **7** . ~~9~~ **4** % of the shares of common stock outstanding as of December 31, ~~2022~~ **2023** . While we generally have the right to control the timing and amount of any future sales of our shares to Lincoln Park, additional sales of our common stock, if any, to Lincoln Park will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Lincoln Park all, some or none of the additional shares of our common stock that may be available for us to sell pursuant to the Lincoln Park Purchase Agreement. If and when we do sell shares to Lincoln Park, after Lincoln Park has acquired the shares, Lincoln Park may resell all, some or none of those shares at any time or from time to time in its discretion. Therefore, sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity- related securities in the future at a time and at a price that we might otherwise wish to effect sales. ~~In addition, the 2023 Note provides that commencing August 6, 2023, we will pay the outstanding principal amount of the 2023 Note in twelve consecutive monthly payments of $ 306, 666. 66 each. At our option, the monthly payment can be made in cash, shares of our common stock at a price based on 90 % of the 5 lowest VWAPs during~~

~~the 20 days prior to the payment date, or a combination of cash and stock. If we were to make repayments in common stock or a combination of cash and stock, we would be required to issue a substantial amount of common stock at a discount to the trading price of our common stock. We have also agreed with the holder of the 2023 Note to file a registration statement covering any shares we may issue upon conversion of such convertible note, which will also be freely tradeable upon registration and issuance.~~ Risks Related to Product Development, Regulatory Approval, Manufacturing and CommercializationOur research and development are primarily focused on the drug suramin, leaving us subject to the risk of a lack of diversity in the active pharmaceutical ingredients we utilize in our business. We do not know whether we will be successful in our efforts to build a pipeline of product candidates or if we will be able to develop any products of commercial value. Any product candidates that we develop or acquire may not be effective for the target indications and we may not be successful in using our intellectual property to build a pipeline of product candidates and progress these product candidates through clinical development for the treatment of any medical conditions. Moreover, our business plan currently is focused primarily on the use of the ~~25drug --~~ **drug** suramin, leaving us subject to the risk of a lack of diversity in our product pipeline and the active pharmaceutical ingredients we utilize in our business. Even if we are successful in continuing to build our pipeline, we may not be able to develop or acquire other product candidates that are safe and effective. Our research programs may initially show promise in creating potential product candidates, yet fail to yield viable product candidates for further clinical development for a number of reasons, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. Our research programs to identify new product candidates will require substantial technical, financial and human resources. In addition, we may focus our efforts and resources on one or more potential product candidates that ultimately prove to be unsuccessful in clinical trials testing efficacy and safety. If we are unable to identify suitable additional compounds for preclinical and clinical development, our ability to develop product candidates and obtain product revenues in future periods could be compromised, which could result in significant harm to our financial position and adversely impact our stock price. We cannot be certain that PAX- 101 or any other product candidates that we may develop or acquire will receive regulatory approval, and without regulatory approval we will not be able to market any of our product candidates. Any delay in the regulatory review or approval of any of our product candidates will materially or adversely harm our business. We expect to invest most of our capital in the development of PAX- 101 and PAX- 102. Our ability to generate revenue related to product sales, which we do not expect will occur for at least the next several years, if ever, will depend on the successful development and regulatory approval of one or more of our product candidates. All of our product candidates require regulatory review and approval prior to commercialization. Any delays in the regulatory review or approval of our product candidates would delay market launch, increase our cash requirements and result in additional operating losses. This failure to obtain regulatory approvals would prevent our product candidate from being marketed and would have a material and adverse effect on our business. The process of obtaining FDA and other required regulatory approvals, including foreign approvals, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. Furthermore, this approval process is extremely complex, expensive and uncertain. We may be unable to submit any new drug application, or NDA, in the United States or any marketing approval application in foreign jurisdictions for any of our products. If we submit an NDA including any amended NDA or supplemental NDA, to the FDA seeking marketing approval for any of our product candidates, the FDA must decide whether to accept or reject the submission for filing. We cannot be certain that any of these submissions will be accepted for filing and reviewed by the FDA, or that the marketing approval application submissions to any other regulatory authorities will be accepted for filing and review by those authorities. We cannot be certain that we will be able to respond to any regulatory requests during the review period in a timely manner, or at all, without delaying potential regulatory action. We also cannot be certain that any of our product candidates will receive favorable recommendations from any FDA advisory committee or foreign regulatory bodies or be approved for marketing by the FDA or foreign regulatory authorities. In addition, delays in approvals or rejections of marketing applications may be based upon ~~many~~ **26many** factors, including regulatory requests for additional analyses, reports, data and studies, regulatory questions regarding data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding such product candidates. The results of preclinical studies and clinical trials may not result in the demonstration of safety or efficacy of the products we are developing. Further, the data from these studies are subject to different interpretations, which could delay, limit or prevent regulatory review or approval of any of our product candidates. Furthermore, regulatory attitudes towards the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, policy changes and agency funding, staffing and leadership. We do not know whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects. In addition, the environment in which our regulatory submissions may be reviewed changes over time. For example, average review times at the FDA for NDAs have fluctuated over the last ten years, and we cannot predict the review time for any of our submissions with any regulatory authorities. Review times can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes. Moreover, in light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of the U. S. Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling such as boxed warnings and precautions that further limit use of the drug products, and establishment of Risk Evaluation and Mitigation Strategy (" REMS ") measures that may, for instance, restrict distribution of drug products. Drug safety issues may result in a more cautious approach by the FDA to clinical trials. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion, or require longer or additional ~~26clinical --~~ **clinical** trials that may result in substantial additional expense and a delay or failure in obtaining approval or may result in approval for a more limited indication than originally sought.

Clinical and preclinical drug development is a lengthy and expensive process with uncertain outcomes that may lead to delayed timelines and increased cost, which may prevent us from being able to complete clinical trials. Clinical testing is expensive, can take many years to complete, and its outcome is inherently uncertain. The results of preclinical and clinical studies of our product candidates may not be predictive of the results of later- stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies, and we cannot be certain that we will not face similar setbacks. In addition, there may be third party individuals or groups that publish data from experiments using suramin that may reflect, either positively or negatively, on our clinical development program despite that we have no affiliation with or control over such individuals or groups. For example, we are aware of other suramin- related research that has been conducted in the autism indication at the University of California, San Diego as well as in other unrelated indications within and outside of the United States. Our clinical development programs could be negatively impacted by adverse events reported in such third party studies. With respect to **FXS, FXTAS,** ME / CFS and LCS, no company, to our knowledge, has yet been successful in its efforts to obtain regulatory approval in the United States or Europe of treatment for these conditions. The mechanism of disease for these conditions has not been scientifically confirmed, and as a result, the mechanism of action for PAX- 101 in potentially treating these diseases is unknown. In addition, LCS is potentially a self- resolving disease in some people, as well as a disease that increases and decreases in severity. As such, there may not be sufficient biomarkers or validated behavioral scoring metrics that could be used to support potential approval for PAX- 101 in these diseases, and clinical trials will be difficult to design, conduct and assess. This will make our development and potential approval of PAX- 101 for these indications very difficult, and we may not be successful. We cannot be certain that clinical trials for PAX- 101 or any of our other product candidates will be completed, or completed on schedule, or that any other future clinical trials for PAX- 101 or any of our other product candidates, will begin on time, not need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all, or that any interim analyses with respect to such trials will be completed on schedule or support continued clinical development of the associated product candidate **. In particular, the basis for our submission of an NDA for approval of PAX- 101 in HAT is historical data that is limited and not complete, and FDA may not agree that our study design is adequate or the data sufficient for approval. Because of the difficulties inherent in designing 27clinical trials for a universally fatal disease, we may not be able to provide FDA with additional data (regarding safety and effectiveness) or analyses adequate for approval if requested by the FDA, which could prevent us from ever getting approval for PAX- 101 in HAT** . We could also encounter delays if a clinical trial is suspended or terminated by us upon recommendation of the data monitoring committee for such trial, by the institutional review board (“ IRB ”) of the institutions in which such trials are being conducted, or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, site misconduct or deviations from Good Clinical Practice, major findings from an inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate revenue from the sale of any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval processes, and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may significantly harm our business, financial condition and prospects. If the FDA does not conclude that our product candidates satisfy the requirements for the 505 (b) (2) regulatory approval pathway, or if the requirements for approval of any of our product candidates under Section 505 (b) (2) are not as we expect, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful. We intend to seek FDA approval through the 505 (b) (2) regulatory pathway for each of our product candidates. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch- Waxman Act, added Section 505 (b) (2) to the Federal ~~27Food --~~ **Food** , Drug, and Cosmetic Act, or FDCA. Section 505 (b) (2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant. If the FDA does not allow us to pursue the 505 (b) (2) regulatory pathway for our product candidates as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates would likely substantially increase. Moreover, the inability to pursue the 505 (b) (2) regulatory pathway could result in new competitive products reaching the market faster than our product candidates, which could materially adversely impact our competitive position and prospects. Even if we are permitted to pursue the 505 (b) (2) regulatory pathway for a product candidate, we cannot assure you that we will receive the requisite or timely approvals for commercialization of such product candidate. In addition, notwithstanding the approval of a number of products by the FDA under Section 505 (b) (2) over the last few years, certain competitors and others have objected to the FDA’ s interpretation of Section 505 (b) (2). We expect that our competitors could file citizens’ petitions with the FDA in an attempt to persuade the FDA that our product candidates, or the clinical studies that support their approval, contain deficiencies. If the FDA’ s interpretation of Section 505 (b) (2) is successfully challenged, the FDA may be required to change its Section 505 (b) (2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505 (b) (2). Delays in the commencement, enrollment and completion of our clinical trials could result in increased costs to us and may delay or limit our ability to obtain regulatory approval for PAX- 101 and our other product candidates. Delays in the

commencement, enrollment and completion of clinical trials could increase our product development costs or delay the regulatory approval of our product candidates. The commencement, enrollment and completion of clinical trials can be delayed for a variety of reasons, including: ● the inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; ● the inability to maintain necessary supplies of study drug and comparator to maintain predicted enrollment rates at clinical trial sites; **28** ● regulatory authority objections to commencing a clinical trial; ● the inability to obtain ethics committee or IRB approval to conduct a clinical trial; ● difficulty recruiting and enrolling subjects to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our study and competition from other clinical trial programs for the same indication as our product candidates; ● difficulty obtaining informed consent in some patient populations who may be under 18 years of age and may not have the capacity to consent; ● the inability to retain subjects in clinical trials due to the treatment protocol, personal issues, side effects from the therapy or lack of efficacy; and ● difficulty in importing and exporting clinical trial materials and study samples. We currently do not have quantities of suramin sufficient to support all of our clinical trial needs and we will need to **rely on third- party** ~~manufacture~~ **manufacturers** ~~additional suramin in order~~ to ~~satisfy~~ **meet** ~~those~~ ~~--~~ **the demand** ~~needs. There is no readily available source~~ of **future production** ~~suramin for use in clinical trials in the United States~~. There is currently one manufacturer of suramin, Bayer, which does not manufacture suramin on a regular basis and, when it does, generally only manufactures small quantities in response to outbreaks of HAT. We have engaged two independent contract development manufacturing organizations to develop, validate and scale our supply chain for suramin and the shelf stable drug product that is ultimately distributed to pharmacies. We have completed the necessary steps to begin producing suramin in early 2022 and began the final **stage of the** development phase in ~~April~~ **the first quarter** ~~2022~~ **2024**, including the production and final release testing process, that will produce suramin for both clinical and registrational purposes. However, this ~~28final~~ ~~--~~ **final** development phase is expected to take a significant amount of time ~~,~~ and we cannot conduct our clinical trials until we have sufficient suramin supply. We currently do not expect to have quantities of suramin sufficient to support submission of an NDA for PAX- 101' s East African HAT indication until the fourth quarter of ~~2023~~ **2024**. If our suppliers of active ingredients to manufacture suramin are unable or unwilling to perform for any reason, we may not be able to locate alternative acceptable manufacturers or formulators or enter into favorable agreements with them. Any inability to acquire sufficient quantities of suramin or other active pharmaceutical ingredients we may utilize in a timely manner from third parties could delay clinical trials and prevent us from developing our products in a cost- effective manner or on a timely basis. In addition, manufacturers of our product candidates are subject to current Good Manufacturing Practices (" cGMP ") and similar foreign standards and we would not have control over compliance with these regulations by our manufacturers. If one of our contract manufacturers fails to maintain compliance, the production of our products could be interrupted, resulting in delays and additional costs. In addition, if the facilities of such manufacturers do not pass a pre- approval or post- approval plant inspection, the FDA will not grant approval and may institute restrictions on the marketing or sale of our products. We are reliant on third- party manufacturers and suppliers to meet the demands of our clinical supplies, particularly for suramin. Delays in receipt of materials, scheduling, release, custom' s control, and regulatory compliance issues may adversely impact our ability to initiate, maintain, or complete clinical trials that we are sponsoring. Commercial manufacturing and supply agreements have not been established. Issues arising from scale- up, environmental controls, equipment requirements, or other factors, may have an adverse impact on our ability to manufacture our product candidates. Even if we obtain regulatory approval for our product candidates, if we are unable to successfully commercialize our products, it will limit our ability to generate revenue and will materially adversely affect our business, financial condition and results of operations. Even if we obtain regulatory approval for our product candidates, our long- term viability and growth depend on the successful commercialization of products which lead to revenue and profits. Pharmaceutical product development is an expensive, high risk, lengthy, complicated, resource intensive process. In order to succeed, among other things, we must be able to: ● identify potential drug product candidates; **29** ● design and conduct appropriate laboratory, preclinical and other research; ● submit for and receive regulatory approval to perform clinical studies; ● design and conduct appropriate preclinical and clinical studies according to good laboratory and good clinical practices; ● select and recruit clinical investigators; ● select and recruit subjects for our studies; ● collect, analyze and correctly interpret the data from our studies; ● submit for and receive regulatory approvals for marketing; ● secure market and formulary access from payors; and ● manufacture the drug product candidates according to cGMP. The development program with respect to any given product may take many years and thus delay our ability to generate profits. In addition, potential products that appear promising at early stages of development may fail for a number of reasons, including the possibility that the products may require significant additional testing or turn out to be unsafe, ineffective, too difficult or expensive to develop or manufacture, too difficult to administer, or unstable. Failure to successfully commercialize our products will adversely affect our business, financial condition and results of operations. ~~29The~~ ~~--~~ **The** market for PAX- 101' s lead indication, HAT, is extremely small, as the majority of usage would be in Sub- Saharan Africa. Further, we would likely donate any product for use in this indication to the WHO for use by patients in Africa. If our preclinical and clinical studies do not produce positive results, if our clinical trials are delayed or if serious side effects are identified during such studies or trials, we may experience delays, incur additional costs and ultimately be unable to commercialize our product candidates. Before obtaining regulatory approval for the sale of our product candidates, we must conduct, generally at our own expense, extensive preclinical tests to demonstrate the safety of our product candidates in animals, and clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Preclinical and clinical testing is expensive, difficult to design and implement and can take many years to complete. A failure of one or more of our preclinical studies or clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent our ability to obtain regulatory approval or commercialize our product candidates, including: ● our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical

testing or clinical trials or we may abandon projects that we expect to be promising; ● regulators or ethics committees / IRBs may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site; ● conditions imposed on us by the FDA or any non- U. S. regulatory authority regarding the scope or design of our clinical trials may require us to resubmit our clinical trial protocols to ethics committees / IRBs for re- inspection due to changes in the regulatory environment; ● the number of patients required for our clinical trials may be larger than we anticipate and recruitment of the target population may be more difficult than we anticipate, or participants may drop out of our clinical trials at a higher rate than we anticipate; ● our third- party contractors or clinical investigators may fail to comply with regulatory requirements or fail to meet their contractual obligations to us in a timely manner; **30** ● we might have to suspend or terminate one or more of our clinical trials if we, the regulators or the ethics committees / IRBs determine that the participants are being exposed to unacceptable health risks; ● regulators or ethics committees / IRBs may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; ● the cost of our clinical trials may be greater than we anticipate; ● the supply or quality of our product candidates or other materials necessary to conduct our clinical trials may be insufficient or inadequate or we may not be able to reach agreements on acceptable terms with prospective clinical research organizations; and ● the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics. For example, suramin can cause significant side effects, including nausea, vomiting, diarrhea, abdominal pain, and a feeling of general discomfort. Other side effects include skin sensations such as crawling or tingling sensations, tenderness of the palms and soles, numbness of the extremities, watery eyes, and photophobia. In addition, nephrotoxicity is common, as is peripheral neuropathy when the drug is administered at high doses. ~~30In~~ **In** addition, if we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete our clinical trials or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may: ● be delayed in obtaining, or may not be able to obtain, marketing approval for one or more of our product candidates; ● obtain approval for indications that are not as broad as intended or entirely different than those indications for which we sought approval; ● the product labeling may be very restrictive and lead to limitations in commercial value; or ● have the product removed from the market after obtaining marketing approval. Our product development costs will also increase if we experience delays in testing or approvals. We do not know whether any preclinical tests or clinical trials will be initiated as planned, will need to be restructured or will be completed on schedule, if at all. Significant preclinical or clinical trial delays also could shorten the patent protection period during which we may have the exclusive right to commercialize our product candidates. Such delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products and product candidates. If we cannot enroll enough patients to complete our clinical trials, such failure may adversely affect our business, financial condition and results of operations. The completion rate of clinical studies of our products is dependent on, among other factors, the patient enrollment rate. Patient enrollment is a function of many factors, including: ● securing sufficient numbers of investigators and clinical trial sites; ● investigator identification and recruitment of appropriate patients; ● ethics committees / IRBs and regulatory approvals to initiate study sites; ● patient population size; ● the nature of the protocol to be used in the trial; ● patient availability and proximity to clinical sites; **31** ● the eligibility criteria for the study; ● competition from other companies' clinical studies for the same patient population; and ● the ability to obtain comparator drug / device. We believe our procedures for enrolling patients have been appropriate; however, delays in patient enrollment would increase costs and delay ultimate commercialization and sales, if any, of our products. Such delays could have a material adversely affect our business, financial condition and results of operations. ~~We face risks related to health pandemics, epidemics and outbreaks, including the COVID- 19 pandemic, which could significantly disrupt our preclinical studies and clinical trials, and therefore our receipt of necessary regulatory approvals could be delayed or prevented. We face risks related to health pandemics, epidemics or outbreaks of communicable diseases. For example, the outbreak around the world, including in the U. S., the European Union (the " E. U. ") members, China and many other countries, of the highly transmissible and pathogenic COVID- 19. The outbreak of such communicable diseases could result in a widespread health crisis that could adversely affect general commercial activity and the economies and financial markets of many countries, which in the case of COVID- 19 has 31occurred. In addition, the COVID- 19 pandemic is having a severe effect on the clinical trials of many drug candidates. Some trials have been merely delayed, while others have been cancelled. The extent to which the COVID- 19 pandemic may impact our preclinical and clinical trial operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration and geographic reach of the outbreak, the severity of COVID- 19, and the effectiveness of actions to contain and treat COVID- 19. Although to date our clinical trials have been minimally impacted by the pandemic, the continued spread of COVID- 19 globally could adversely impact our clinical trial operations, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID- 19 if an outbreak occurs in their geography. Disruptions or restrictions on our ability to travel to monitor data from our clinical trials, or to conduct clinical trials, or the ability of patients enrolled in our studies to travel, or the ability of staff at study sites to travel, as well as temporary closures of our facilities or the facilities of our clinical trial partners and their contract manufacturers, would negatively impact our clinical trial activities. In addition, we rely on independent clinical investigators, contract research organizations and other third- party service providers to assist us in managing, monitoring and otherwise carrying out our preclinical studies and clinical trials, including the collection of data from our clinical trials, and the outbreak may affect their ability to devote sufficient time and resources to our programs or to travel to sites to perform work for us. Similarly, our preclinical trials could be delayed and / or disrupted by the COVID- 19 pandemic. As a result, the expected timeline for data readouts of our preclinical studies and clinical trials and certain regulatory filings may be negatively impacted, which would adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses and have a material adverse effect on our business, financial condition and results of operations.~~ If we are not

successful in discovering, developing and commercializing additional product candidates, our ability to expand our business and achieve our strategic objectives would be impaired. Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following: ● the research methodology used may not be successful in identifying potential product candidates; ● we may be unable to identify viable product candidates in our screening campaigns; ● competitors may develop alternatives that render our product candidates obsolete; ● product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights; ● a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria; ● a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; ● a product candidate may not be perceived or accepted as safe and effective by patients, the medical community or third- party payors; and ● the development of resistance to potential product candidates may render them ineffective against target infections with respect to our development program in HAT. If we are unsuccessful in identifying and developing additional product candidates, our potential for growth may be impaired. Even if we receive regulatory approval for PAX- 101 or any other product candidates we may develop or acquire, we still may not be able to successfully commercialize it and the revenue that we generate from its sales, if any, may be limited. If approved for marketing, the commercial success of PAX- 101 or any other product candidates we may develop or acquire will depend upon acceptance by the medical community, including physicians, patients and health care payors. The degree of market acceptance of PAX- 101 or such other product candidate will depend on a number of factors, including: ● demonstration of clinical safety and efficacy of such product candidate; ~~32~~ ● relative convenience and ease of administration; ● the prevalence and severity of any adverse effects as well as the cost and convenience of monitoring and treating them; ● the willingness of physicians to prescribe such product candidate and of the target patient population to try new therapies; ● pricing and cost- effectiveness; **32** ● the inclusion or omission of such product candidate in applicable treatment guidelines; ● the effectiveness of our or any future collaborators' sales and marketing strategies; ● limitations or warnings contained in FDA- approved labeling; ● 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; and ● the willingness of patients to pay out- of- pocket in the absence of third- party coverage or reimbursement. If PAX- 101 or any other product candidates we may develop or acquire is approved, but does not achieve an adequate level of adoption by physicians, health care payors and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third- party payors on the benefits of such product candidate 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 prevent or reduce our ability to commercialize such product candidate 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 render such product candidate not commercially viable. For example, regulatory authorities may approve such product candidate for fewer or more limited indications than we request, may not approve the price we intend to charge for such product candidate, may grant approval contingent on the performance of costly post- marketing clinical trials, or may approve such product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that indication. Further, the FDA may place conditions on approvals including potential requirements or risk management plans and the requirement for a REMS to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; and the FDA will not approve the NDA without an approved REMS. REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of such product candidate. 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 such product candidate. We currently have no sales and marketing organization. If we are unable to establish satisfactory sales and marketing capabilities, we may not successfully commercialize any of our product candidates, if regulatory approval is obtained. At present, we have no sales or marketing personnel. In order to commercialize products that are approved for commercial sales, we must either develop a sales and marketing infrastructure or collaborate with third parties that have such commercial infrastructure. If we elect to develop our own sales and marketing organization, we do not intend to begin to hire sales and marketing personnel until our product candidates are in Phase 3 clinical trials or closer to NDA submission, and we do not intend to establish our own sales organization in the United States until shortly prior to FDA approval of PAX- 101 or any of our other product candidates for neurologic indications. For HAT we do not intend to establish a sales organization as we do not intend to sell PAX- 101 for HAT in any market. We may not be able to establish a direct sales force in a cost- effective manner or realize a positive return on this investment. In addition, we will have to compete with established and well- funded pharmaceutical and biotechnology companies to recruit, hire, train ~~33and~~ -- **and** retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize PAX- 101 or any of our other product candidates in the United States without strategic partners or licensees include: ● our inability to recruit and retain adequate numbers of effective sales and marketing personnel; ● the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our future products; ● the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and ● unforeseen costs and expenses associated with creating an independent sales and marketing organization. ~~If~~ **33If** we are not successful in recruiting sales and marketing personnel or in building a sales and

marketing infrastructure, or if we do not successfully enter into appropriate collaboration arrangements, we will have difficulty successfully commercializing PAX- 101 or any other product candidates we may develop or acquire, which would adversely affect our business, operating results and financial condition. Outside the United States, we may commercialize our product candidates by entering into collaboration agreements with pharmaceutical partners. We may not be able to enter into such agreements on terms acceptable to us or at all. In addition, even if we enter into such relationships, we may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties. Even if we obtain marketing approval for PAX- 101 or any other product candidates that we may develop or acquire, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates 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 future products. Even if we obtain United States regulatory approval of PAX- 101 or any other product candidates that we may develop or acquire, the FDA 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, and post- market surveillance to monitor safety and efficacy. Our future products 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, or cGCPs, for any clinical trials that we conduct post- approval. In addition, manufacturers of drug products and their facilities are subject to continuous review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMPs, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents. With respect to sales and marketing activities by us or any future partner, 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 U. S. 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 U. S. Anti- Kickback Statute, U. S. 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 U. S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U. S. 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 U. S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries. In addition, 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 our product candidates, physicians may nevertheless legally prescribe our products 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, including revocation of its marketing approval. The federal government has levied large civil and criminal fines against companies for alleged ~~34improper --~~ **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 discovers previously unknown problems with a product, 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 or GMP, we may be subject to the following administrative or judicial sanctions: ● restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls; ● issuance of warning letters or untitled letters; ● clinical holds; **34** ● injunctions or the imposition of civil or criminal penalties or monetary fines; ● suspension or withdrawal of regulatory approval; ● suspension of any ongoing clinical trials; ● refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals; ● suspension or imposition of restrictions on operations, including costly new manufacturing requirements; or ● product seizure, 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 PAX- 101 or any of our other 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. Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug 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 our drug candidates, restrict or regulate post- approval activities and affect our ability to profitably sell our drug candidates. 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 our drug candidates, if any, may be. In addition, increased scrutiny by the U. S. 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. In the United States, under the

Medicare Modernization Act (“ MMA ”), Medicare Part D provides coverage to the elderly and disabled for outpatient prescription drugs by approving and subsidizing prescription drug plans offered by private insurers. The MMA also authorizes Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. The Part D plans use their formulary leverage to negotiate rebates and other price concessions from drug manufacturers. Also under the MMA, Medicare Part B provides coverage to the elderly and disabled for physician- administered drugs on the basis of the drug’ s average sales price, a price that is calculated according to regulatory requirements and that the manufacturer reports to Medicare quarterly. Both Congress and the Centers for Medicare & Medicaid Services (“ CMS ”), the agency that administers the Medicare program, from time to time consider legislation, regulations, or other initiatives to reduce drug costs under Medicare Parts B and D. For example, under the 2010 Affordable Care Act, drug manufacturers are required to provide a 50 % discount on prescriptions for branded drugs filled while the beneficiary is in the Medicare Part D coverage gap, also known as the “ donut hole. ” There have been legislative proposals ~~35to~~ **to** repeal the “ non- interference ” provision of the MMA to allow CMS to leverage the Medicare market share to negotiate larger Part D rebates. Further cost reduction efforts could decrease the coverage and price that we receive for our drug candidates and could seriously harm our business. Private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement under the Medicare program may result in a similar reduction in payments from private payors. The 2010 Affordable Care Act is intended to broaden access to health insurance and reduce or constrain the growth of healthcare spending. Further, the Affordable Care Act imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also increased the amount of the rebates drug manufacturers must pay to state Medicaid programs, required that Medicaid rebates be paid on managed Medicaid utilization, and increased the additional rebate on “ line extensions ” (such as extended release formulations) of solid oral dosage forms of branded products. The law also contains substantial provisions affecting fraud and abuse compliance and transparency, which may require us to modify our business practices with healthcare practitioners, and incur substantial costs to ensure compliance. ~~While~~ **35While** we are unable to predict what legislation, if any, may potentially be enacted, to the extent that future changes affect how our product candidates could be paid for and / or reimbursed by the government and private payers, our business could be adversely affected. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011 included, among other things, provisions that have led to 2 % across- the- board reductions in Medicare payment amounts. Several states have adopted or are considering adopting laws that require pharmaceutical companies to provide notice prior to raising prices and to justify price increases. We expect that additional healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability. Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties. Our future profitability will depend, in part, on our ability to commercialize our product candidates in foreign markets for which we intend to rely on collaborations with third parties. If we commercialize PAX- 101 or any other product candidates that we may develop in foreign markets, we would be subject to additional risks and uncertainties, including: ● our customers’ ability to obtain market access and appropriate reimbursement for our product candidates in foreign markets; ● our inability to directly control commercial activities because we are relying on third parties; ● the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements; ● different medical practices and customs in foreign countries affecting acceptance in the marketplace; ● import or export licensing requirements; ● longer accounts receivable collection times; ● longer lead times for shipping; ● language barriers for technical training; ● reduced protection of intellectual property rights in some foreign countries; ● foreign currency exchange rate fluctuations; and ● the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute. ~~36Foreign~~ -- **Foreign** sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs, any of which may adversely affect our results of operations. If we market our product candidates in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties. The FDA enforces laws and regulations which require that the promotion of pharmaceutical products be consistent with the approved prescribing information. While physicians may prescribe an approved product for a so- called “ off label ” use, it is unlawful for a pharmaceutical company to promote its products in a manner that is inconsistent with its approved label and any company which engages in such conduct can subject that company to significant liability. Similarly, industry codes in the E. U. and other foreign jurisdictions prohibit companies from engaging in off- label promotion and regulatory agencies in various countries enforce violations of the code with civil penalties. While we intend to ensure that our promotional materials are consistent with our label, regulatory agencies may disagree with our assessment and may issue untitled letters, warning letters or may institute other civil or criminal enforcement proceedings. In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical ~~industry~~ **36industry** . These laws include the U. S. Anti- Kickback Statute, U. S. False Claims Act and similar state laws. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws. The U. S. Anti- Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve

remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not, in all cases, meet all the criteria for safe harbor protection from anti-kickback liability. Moreover, recent health care reform legislation has strengthened these laws. For example, the Health Care Reform Law, among other things, amends the intent requirement of the U. S. Anti- Kickback Statute and criminal health care fraud statutes; a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Health Care Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the U. S. Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the U. S. False Claims Act. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. Over the past few years, several pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off- label promotion that caused claims to be submitted to Medicare or Medicaid for non- covered, off- label uses; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Most states also have statutes or regulations similar to the U. S. Anti-Kickback Statute and the U. S. False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include substantial civil monetary penalties, exclusion of a manufacturer' s products from reimbursement under government programs, substantial criminal fines and imprisonment. We have been and expect to be significantly dependent on our collaborative agreements for the development of our product candidates, which exposes us to the risk of reliance on the performance of third parties. In conducting our research and development activities, we currently rely, and expect to continue to rely, on collaborative agreements with third parties such as manufacturers, contract research organizations, commercial partners, universities, governmental agencies and not- for- profit organizations for both strategic and financial resources. The loss of, or failure to perform by us or our partners under any applicable agreements or arrangements, or our failure to secure additional agreements for our product candidates, would substantially disrupt or delay our research and development activities, including our in-process and anticipated clinical trials. Any such loss would likely increase our expenses and materially harm our business, financial condition and results of operation. ~~37We~~ **We** expect that we will rely on third parties to conduct clinical trials for our product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize PAX- 101 or any other product candidates that we may develop or acquire and our business could be substantially harmed. We expect to enter into agreements with third- party CROs to conduct and manage our clinical programs. We rely heavily on these parties for execution of clinical studies for PAX- 101 and our other product candidates and can control only certain and very limited aspects of their activities. Nevertheless, we would be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs would not relieve us of our regulatory responsibilities. We and our CROs would be required to comply with cGCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces these cGCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with cGCPs. In addition, our clinical trials must be conducted with products produced under cGMP regulations ~~and~~ **37and** will require a large number of test subjects. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties. As a result, many important aspects of our drug development programs would be outside of our direct control. In addition, the CROs may not perform all of their obligations under their arrangements with us or in compliance with regulatory requirements. If the CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of PAX- 101 or any other product candidates that we may develop or acquire may be delayed or our development program may be materially and irreversibly harmed. We cannot control the amount and timing of resources these CROs would devote to our program or our product candidates. If we are unable to rely on the clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of our clinical trials, which could significantly delay commercialization and require significantly greater expenditures. If any of our relationships with these third- party CROs terminate, we may not be able to enter into arrangements with alternative CROs. As a result of the foregoing, our financial results and the commercial prospects for PAX- 101 and our other product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. Reimbursement decisions by third- party payors may have an adverse effect on pricing and market acceptance of PAX- 101 or any other product candidates that we may develop or acquire. If there is not sufficient reimbursement for our future products, it is less likely that such products will be widely used. Market acceptance and sales of PAX- 101 or any other product candidates for which we obtain regulatory approval will depend on reimbursement policies and may be affected by future healthcare reform measures in both the United States and foreign jurisdictions. Government authorities and third- party payors, such as private health insurers and health maintenance organizations, decide which products they will cover and establish payment levels. In addition, government authorities and these third- party payors are increasingly attempting to contain health care costs by demanding price discounts or rebates and limiting both the types and variety of products that they will cover and the amounts that they will pay for these products. In addition, we might need to

conduct post- marketing studies in order to demonstrate the cost- effectiveness of any future products to such payors' satisfaction. Such studies might require us to commit a significant amount of management time and financial and other resources. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower- cost products that are already reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints and / or imperfections in Medicare or Medicaid data used to calculate these rates. Net prices for products may be reduced by mandatory discounts or rebates required by government health care programs. Such legislation, or similar regulatory changes or relaxation of laws that restrict imports of products from other countries, could reduce the net price we receive for any future marketed products. As a result, our future products might not ultimately be considered cost- effective. We cannot be certain that reimbursement will be available for PAX- 101 or any other product candidates that we develop or acquire. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, any future products. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize PAX- 101 or any other product candidates that we develop or acquire. ~~38Government~~ -- **Government** authorities and third- party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U. S. healthcare industry and elsewhere is cost containment. Government authorities and these third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third- party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop. ~~There~~ **38There** may be significant delays in obtaining reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government- funded and private payors for new products that we develop or acquire could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. While we believe we may be eligible to receive a tropical disease priority review voucher (" PRV ") for the use of PAX- 101 for the treatment of HAT, there is a risk that we will not receive such PRV, which would require us to find alternative sources of funding for our later stage clinical programs. We may be eligible to receive a tropical disease PRV for PAX- 101, as Human African Trypanosomiasis (" HAT ") is defined as a disease qualifying for a tropical disease PRV under Section 524 of the Federal Food, Drug and Cosmetic Act (the " FD & C Act "). The FDA is authorized to award a tropical disease PRV to sponsors of applications for certain products for the prevention or treatment of certain tropical diseases, upon FDA approval of the sponsor' s marketing application. A tropical disease PRV may be used by the sponsor that obtains the tropical disease PRV or may be transferred to another sponsor that may use it to obtain Priority Review for a different application. In order to be eligible for a tropical disease PRV, the application must: (i) be for a tropical disease as defined in Section 524 of the FD & C Act; (ii) be submitted under Section 505 (b) (1) of the FD & C Act or Section 351 of the Public Health Service Act (the " PHSA "); (iii) be for a product that contains no active ingredient that has been approved in any other application submitted under Section 505 (b) (1) of the FD & C Act or Section 351 of the PHSA; and (iv) qualify for Priority Review; (v) contain reports of one or more new clinical investigations (other than bioavailability studies) that are essential to the approval of the application and conducted or sponsored by the sponsor; and (vi) contain the applicant' s attestation that such report (s) were not submitted as part of an application for marketing approval or licensure by a regulatory authority in India, Brazil, Thailand, or any country that is a member of the Pharmaceutical Inspection Convention or the Pharmaceutical Inspection Cooperation Scheme prior to September 27, 2007. A U. S. approval in HAT would potentially qualify us to earn a tropical disease PRV from the FDA, which we intend to monetize to raise funds to support the later stage development and commercialization of PAX- 101 and PAX- 102 in the treatment of ASD, **FXAS, FXTAS,** ME / CFS and LCS, the cost of which is estimated to be between $ 120 million and $ 140 million to gain FDA approval and commercially launch ~~both~~ **all** indications in the United States, depending on the design of required clinical trial protocols. However, there can be no assurance that we will receive approval from the FDA for PAX- 101, and even if PAX- 101 is approved by the FDA, there is a risk that we will not receive a tropical disease PRV. Further, the PRV program has been subject to criticism, including by the FDA, and it is possible that even if we obtain approval for PAX- 101 and qualify for a PRV, the program may no longer be in effect at the time of approval. In addition, although PRVs may be sold or transferred to third parties, there is no guarantee that we will be able to realize any value if we were to sell a PRV. If we are unable to obtain a PRV, or if we are unable to sell our PRV or if the amount we obtain from its sale is insufficient to fund our operations, we may be required to fund the later stage development and commercialization of PAX- 101 and PAX- 102 in the treatment of ASD, ME / CFS and LCS through sales of our equity or

debt securities, through strategic collaborations with third parties or other similar transactions. None of these alternative arrangements may be available to us on commercially reasonable terms, or at all, and if ~~39we~~ **we** are unable to raise funding to further our clinical and commercial development, our business and stock price will be adversely impacted. In addition, we will not be eligible to receive a PRV for PAX- 101 for HAT until we submit our NDA for such indication, and we may experience delays in developing and maintaining an uninterrupted supply chain for suramin, which is necessary to support such submission. Without sufficient suramin supply we would not be eligible to receive a PRV and, if granted, monetize such PRV, which could result in the delays or abandonment of any potential development and commercialization of PAX- 101 and PAX- 102 in the treatment of HAT, ASD, ME / CFS and LCS. If we do not obtain market exclusivity for our certain of our products, including orphan drug exclusivity, our business may be harmed. We may seek exclusivity for certain of our product candidates, including PAX- 101 and PAX- 102. Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan ~~Drug~~ **39Drug** Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals in the United States. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of market exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same disease for seven years. Orphan drug exclusivity may be lost if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug designation must be requested before submitting an application for marketing approval. A company that first obtains FDA approval for a designated orphan drug for the designated rare disease or condition receives orphan drug market exclusivity for that drug for the designated disease for a period of seven years in the United States. This orphan drug exclusivity prevents the FDA from approving another application to market a drug containing the same active moiety for the same orphan indication, except in very limited circumstances, including when the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care within the meaning of FDA regulations and guidance. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Even though we received orphan drug designation for PAX- 101 and may seek orphan drug designation for PAX- 102, we may not be the first to obtain marketing approval for the orphan- designated indication due to the uncertainties associated with developing product candidates. If any of these other pharmaceutical companies obtains approval of an NDA before we are able to receive approval for one or more of our drug candidates with the same active moiety for the same indication, we would be barred from marketing that product in the United States during the seven- year orphan drug exclusivity period, unless we could demonstrate that such drug candidate is clinically superior to the approved products or satisfies one of the other limited exceptions to such orphan drug exclusivity. In addition, even though we received orphan drug designation for PAX- 101 and may seek orphan drug designation for PAX- 102, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition or a drug with the same active moiety can be approved for a different indication. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. In addition, even if we seek orphan drug designation for any of our product candidates or indications, we may never receive such designations or obtain orphan drug exclusivity. Also, overcoming the orphan drug marketing exclusivity is difficult to establish, with limited precedent, and there can be no assurance that the FDA will agree with our position seeking to overcome such marking exclusivity and approve PAX- 101 or PAX- 102 for U. S. market access with orphan drug exclusivity. If we fail to receive such extensions or exclusive rights, our ability to prevent competitors from manufacturing, marketing and selling competing products will be materially impaired, and our results of operations and financial condition may be significantly adversely affected. ~~40Any~~ -- **Any** failure to comply with applicable data protection and privacy laws and regulations could lead to significant penalties against us, and adversely impact our operating results. Under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, (collectively, " HIPAA "), the U. S. Department of Health and Human Services has issued regulations to protect the privacy and security of protected health information used or disclosed by covered entities including certain healthcare providers, health plans and healthcare clearinghouses. HIPAA also regulates standardization of data content, codes and formats used in healthcare transactions and standardization of identifiers for health plans and providers. HIPAA and its regulations, including the final omnibus rule published on January 25, 2013, also imposes certain obligations on the business associates of covered entities that obtain protected health information in providing services to or on behalf of covered entities. In addition to federal privacy regulations, there are a number of state laws governing confidentiality and security of health information that are applicable to our business. In addition to possible federal administrative, civil and criminal penalties for HIPAA violations, state attorneys general are authorized to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney' s fees and costs associated with pursuing federal civil actions. Accordingly, state attorneys general have brought civil actions seeking injunctions and damages resulting from alleged violations of HIPAA' s privacy and security rules. New laws and regulations governing privacy and security may be adopted in the future as well. ~~Because~~ **40Because** of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our current or future business activities, including certain clinical research, sales and marketing practices and the provision of certain items and services to our customers, could be subject to challenge under one or more of such privacy and data security laws. The heightening compliance environment and the need to build and maintain robust and secure systems to comply with different privacy compliance and reporting requirements in multiple jurisdictions could increase the possibility that a healthcare company may fail to comply fully with one or more of these requirements. If our operations are found to be in violation of any of the privacy or data security laws or regulations described above that are

applicable to us, or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal, civil and administrative penalties, damages, fines, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a consent decree or similar agreement to resolve allegations of non- compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any product candidates we may develop, once approved, are sold in a foreign country, we may be subject to similar foreign laws. Risks Relating to Our Intellectual Property RightsWe depend on data licensed to us by third parties, and the loss of access to this data may terminate or delay the further development of our Human African Trypanosomiasis (HAT) NDA filing. Our business relies on the license of data from the Ministry of Health, Republic of Malawi and Lwala Hospital (Soroti, Uganda). The loss of our key data may seriously impair our business and future viability, and could result in delays in developing, introducing or maintaining our product candidates and formulations until equivalent data, if available, is identified, licensed and integrated. In addition, any defects in the data we license could prevent the implementation or impair the functionality of our product candidates or formulation, delay new product or formulation introductions or injure our reputation. It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights. Our commercial success will depend, in part, on maintaining and obtaining patent protection for our technologies, products and processes, successfully defending these patents against third- party challenges and successfully enforcing these patents against third- party competitors. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowable, or whether any claims will be allowed in our pending applications or, the enforceability of our existing and future patents. As part of our intellectual property strategy, we intend to file U. S. nonprovisional, and foreign national and regional stage applications of this PCT application in due course. We also plan to file further patent applications covering our technology and products. We are not aware of any contested proceedings or third- party claims against our pending PCT international patent applications. We cannot predict the outcome of our patent applications related to suramin and its uses, as our pending patent application and future applications may never be approved by United States or foreign patent offices. ~~41The~~ -- **The** degree of our current and future protection for our proprietary rights 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. For example, others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to our development programs, or important to our business. Furthermore, because patent applications are generally not published until 18 months from their earlier priority date, there is always a moving window of uncertainty as to whether third parties currently have any pending patent applications of which we would not be aware. We cannot be certain that any patents or patent application owned by a third- party will not have priority over patents and patent applications filed by us, or that we will not be involved in interference, opposition or invalidity proceedings before United States or foreign patent offices. In addition, even if we are successful in protecting our proprietary rights, generic alternatives to our therapeutic products are, and will likely continue to be, available. We also rely on trade secrets to protect technology, especially in cases when we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we require employees, academic collaborators, consultants and other contractors to enter into confidentiality agreements, we may not be able to adequately 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. If we cannot maintain the confidentiality of our proprietary technology and other confidential information, our ability to receive patent protection and our ability to protect valuable information owned by us may be imperiled. Enforcing a claim that a third- ~~party~~ **41party** entity 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 knowledge, methods and know- how. If we fail to maintain or obtain additional patent protection or trade secret protection for PAX- 101 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. In addition, third parties' patent or trade secret protection could limit or impact our freedom to operate. We may also rely on the trademarks we may develop to distinguish our products from the products of our competitors. We cannot guarantee that any trademark applications filed by us or our business partners will be approved. Third parties may also oppose such trademark applications, or otherwise challenge our use of the trademarks. In the event that the trademarks we use are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to modifying advertising and marketing for our brands. Further, we cannot provide assurance that competitors will not infringe the trademarks we use, or that we will have adequate resources to enforce these trademarks. PAX- 101 and our other product candidates 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. We respect the valid patent rights of third parties of which we are aware. 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 PAX- 101 or any of our other product candidates. 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 PAX- 101 or our other 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: ● result in costly litigation; ● divert the time and attention of our technical personnel and management; ● prevent us from commercializing a product until the asserted patent expires or is held finally invalid or not infringed in a court of law; ● require us to cease or modify our use of the technology and / or develop non- infringing technology; ~~or42~~ **or** ● require us to enter into royalty or licensing agreements. Furthermore, we cannot guarantee that we would be successful in defending against these claims of patent infringement. For example, if we were required to modify our use of the technology or develop an alternative non- infringing technology, we cannot be certain that we would be successful in making the modifications or developing the technology and whether it would be economically feasible or practical to do so. Also, it may not be possible to obtain royalty or licensing agreements on favorable terms or to obtain such agreements at all. Although no third- party has asserted a claim of infringement against us, others may hold proprietary rights that could prevent our product candidates from being marketed. Any patent- related legal action against us claiming damages and seeking to enjoin commercial activities relating to 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 PAX- 101 or any other 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 PAX- 101 or any other product candidates or processes to avoid infringement, if necessary. ~~We~~ **42We** are aware of PCT international patent application PCT / US2018 / 017674, titled " Methods for Autism Spectrum Disorder Pharmacotherapy ", which lists Perfect Daylight Limited and The Regents of the University of California as Applicants, filed on February 9, 2018, published as WO 2018 / 148580 on August 16, 2018, and claiming priority to U. S. provisional patent application no. 62 / 457, 120, filed on February 9, 2017. The patent application describes compositions of antipurinergic agents, such as suramin, and methods of use for treating cognitive developmental disorders and autism spectrum disorder. From publicly available databases, we are aware that a U. S. ~~national phase~~ **nonprovisional patent** application of this PCT patent application, U. S. application Serial No. 16 / 537, 397, was filed in the United States and ~~is currently pending~~ **was subsequently abandoned in favor of U. S. application Serial No. 18 / 323, 375, filed Mary 24, 2023 and U. S. application Serial No. 18 / 414, 171, filed January 16, 2024** . The European equivalent of the application was granted as EP3579836 on December 15, 2021 **and was validated in Belgium** , **France, Germany, Great Britain, and Switzerland** ~~which commenced a 9- month period for public opposition~~ . A Chinese application, CN201880024535. 9, is also pending. **Because** ~~We are also aware of PCT international~~ patent application PCT / US2018 / 017200,..... phase patent applications. Because national phase applications of PCT / US2018 / 017674 are still pending at least in the United States and China, it is not certain if any patents will ultimately issue from these applications nor is it possible to predict the resultant claim scope of any such issued patent. We will continue to monitor the prosecution of these patent applications from publicly available documents. ~~PCT international patent~~ application PCT / US2018 / 017200,titled " Antipurinergic Compounds and Uses thereof," which lists CSP Pharma,Inc.as Applicant,filed on February 7,2018,published as WO 2018 / 148262 on August 16,2018,and claiming priority to U.S.provisional patent application no.62 / 456,438,filed on February 8,2017.The patent application describes compositions and methods for treating neurodevelopmental disorders.The compositions contain an APT,such as suramin,and a carrier formulated for non- intravenous administration.The neurodevelopmental disorders include ASD.From publicly available databases,we are aware that a national phase application of this PCT patent application,U.S.application Serial No.16 / 484,284 was filed in the United States.However,the US Patent Office issued a Notice of Abandonment on August 12,2021 for applicant' s failure to respond to the office action of January 14,2021.No further child applications are listed as pending.We are also aware of PCT international patent application PCT / US2017 / 041932,titled " Diagnostic and Methods of Treatment for Chronic Fatigue Syndrome and Autism Spectrum Disorders," which lists The Regents of the University of California as Applicant,filed on July 13,2017,published as WO 2018 / 013811 on January 18,2018,and claiming priority to U.S.provisional patent application nos.62 / 464,369,filed on February 27,2017 and 62 / 362,564,filed on July 14,2016.The patent application describes biomarkers for diagnosing and predicting the development of chronic fatigue syndrome and methods of treating a mitochondrial disease or disorder,such as ASD,by administering an effective amount of an APT,such as suramin.Publicly available databases show no pending ~~US or~~ national or regional phase patent **applications.Because national phase** As discussed above, our success depends in part on avoiding infringement of the proprietary technologies of others. We are aware of the risks associated with the valid patent rights of third parties, however, identification of these third party proprietary technologies and patent rights is difficult because patent searching is imperfect. Also, because patent applications are maintained in secrecy until publication, we may be unaware of third- party patents that may be infringed by commercialization of PAX- 101 or any of our other product candidates. Based on as yet unforeseen activities associated with the intellectual property of such third parties we may have to make modifications to our development plans, the filing of new patent applications and the prosecution of our patent portfolio, and our business. A number of companies, including several major pharmaceutical companies, have conducted research on APTs and their effect on purinergic receptors and potential therapies which resulted in the filing of many patent applications related to this research. If we were ~~43to~~ **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 United States Patent and Trademark Office, we would have to prove that the claims are unpatentable by a preponderance of the evidence. Moreover, even if we were successful in such an invalidity challenge, the decision could be appealed by the other party to the Court of Appeals for the Federal Circuit, which could involve significant resources to litigate and we cannot predict whether we would prevail on appeal. There is no assurance that a jury and / or court would find in our favor on questions of infringement, validity or enforceability. Accordingly, if patents exist or are in the future granted that conflict with our patents,

and if we face an adverse determination in a judicial or administrative proceeding, or if we are unable to obtain necessary licenses, we could be prevented from developing and commercializing PAX- 101 or another product candidate, which in turn would harm the viability of our company and our business, prospects, financial condition and operating results. ~~We~~ **43We** may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers. As is commonplace in our industry, we employ individuals who were previously employed at other pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject in the future to claims that our employees or prospective employees are subject to a continuing obligation to their former employers (such as non- competition or non- solicitation obligations) or claims that our employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. We may be subject to claims challenging the inventorship of our patents and other intellectual property. Although we are not aware of any asserted third- party claims challenging inventorship of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, strategic partners, commercial counterparties or other third parties associated with us or one of our predecessors in ownership of PAX- 101 have an interest in our patents or other intellectual property as an inventor or co- inventor. While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we cannot fully control the enforcement of these policies by third parties with which we contract, nor can we be certain that assignment agreements between us and our employees, between us and our counterparties, or between our counterparties and their employees or between our predecessors of ownership and their employees and counterparties, will effectively protect our interests as to any party who conceives or develops intellectual property that we regard as our own. Among other issues, the assignment of intellectual property rights may not be self- executing, the assignment agreements may be breached, or we may have disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. As we approach potential commercialization of our product candidates, we will need to more closely analyze the facts that we believe might be used to assert an inventorship claim against us. Determinations like these involve complex sets of facts and the application of sometimes- unsettled patent law, resulting in inherent uncertainties regarding ownership rights. If claims challenging inventorship are made against us, we may need to resort to litigation to resolve those claims. If we fail in defending against any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of valuable intellectual property rights or the right to assert those rights against third- parties marketing competing products. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. There are risks to our intellectual property based on our international business operations. We may face risks to our technology and intellectual property as a result of our conducting business outside of the United States, including as a result of our license of clinical data from the Ministry of Health, Republic of Malawi and Lwala Hospital (Soroti, Uganda), as certain jurisdictions may not have comparable levels of protection of corporate proprietary information and assets such as intellectual property, trademarks, trade secrets, know- how and customer information and records. While these risks are common to many companies, ~~44conducting --~~ **conducting** business in certain foreign jurisdictions, housing technology, data and intellectual property abroad, or licensing technology to or from foreign partners may have more significant exposure. Risks Related to Our Common StockWe have received deficiency letters from Nasdaq relating to non- compliance with Nasdaq' s continued listing requirements. Our common stock could become subject to delisting from Nasdaq if we fail to regain compliance. ~~In~~ **We were notified by the Nasdaq in** December 2022 **that we were not in compliance with the Minimum Market Value Requirement requiring us to maintain a market value of listed securities of a minimum of $ 35. 0 million for a period of 30 consecutive business days, and Nasdaq granted us a period of 180 calendar days, or until June 5, 2023, to regain compliance with the Minimum Market Value Requirement. In June 2023** , we received notice from **the** Nasdaq ~~notifying us~~ **Staff stating** that ~~our~~ **we have not regained compliance with the** ~~minimum~~ **Minimum** ~~market~~ **Market** ~~value~~ **Value Requirement during** ~~of listed securities (" MVLS ") was below~~ the ~~minimum of $ 35 million required for continued~~ **180- day grace period and would be subject to delisting. After a hearing to appeal the Staff' s delisting determination, we were granted an exception to maintain our** listing **on The** Nasdaq **Capital Market notwithstanding** ~~. We been provided an initial period of 180 calendar days, or~~ **our failure** ~~until June 5, 2023, to regain compliance. If compliance in not achieved by June 5, 2023, we expect that Nasdaq would provide written notification that our securities are subject to delisting. We continue to monitor our MVLS and consider our available options~~ to regain compliance with the **Minimum Market Value Requirement. We were required to demonstrate compliance with the alternative criteria set forth in** Nasdaq ~~minimum MVLS requirements~~ **Listing Rule 5550 (b) (1)** , which ~~may include applying for an extension~~ **requires us to maintain stockholders' equity** of ~~the~~ **at least $ 2. 5 million by December 11, 2023. On December 20, 2023, Nasdaq notified us 44that we had demonstrated** compliance ~~period or appealing to~~ **with this criteria and imposed** a **Discretionary Panel Monitor until December 20, 2024. The Discretional Panel Monitor provides that if we fail to maintain compliance with any continued listing requirement, Nasdaq will issue a Delist Determination Letter and schedule a new hearing with the** Nasdaq Hearings Panel ~~. There can be~~ **, and we would** ~~no~~ **not** ~~assurance~~ **be entitled to any grace periods for subsequent noncompliance with listing standards. We expect** that we will **need to raise additional capital on a regular basis to maintain compliance with the stockholders' equity standard, and such financing may be significantly dilutive to our existing shareholders, may not be available on favorable terms or at all and we may not** be able **to maintain our compliance with this standard in the future. On January 12, 2024, we received a notification letter from Nasdaq advising us that for 31 consecutive trading days preceding January 11, 2024, the bid price of our common stock had closed below the $ 1. 00 per share minimum required for continued listing on Nasdaq. As a result of the Nasdaq panel imposing the**

Panel Monitor on the Company until December 20, 2024, we are not eligible for a grace period. We requested a hearing before the Panel which is expected to take place April 2024. This request stays any delisting action in connection with the notice and our common stock continues to be listed on Nasdaq until the Panel renders a decision subsequent to the hearing. At the hearing, we intend to present a plan to regain compliance with the ~~Nasdaq minimum~~ **Minimum** ~~MVLS~~ **Bid Price** ~~requirements~~ **Requirement** ~~or otherwise maintain~~ **and may request that the Panel allow us additional time within which to regain** compliance ~~with~~ **. While we expect to submit a comprehensive plan to regain compliance and a request for 180 days in which to implement the plan,** ~~the~~ **there can be no assurance that the Panel will grant our request for the additional time requested. If we are not granted the request or if we fail to satisfy any** other ~~Nasdaq listing requirements. If we fail to satisfy the~~ continued listing requirements of Nasdaq, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non- compliance with Nasdaq' s listing requirements. The prices of our shares may be volatile, which could subject us to securities class action litigation and prevent you from being able to sell your shares at or above the price at which you purchased them. This price at which you purchased your shares may vary from the market price of our common stock thereafter. You may be unable to sell your shares of common stock at or above the price at which you purchased them. The market price for our common stock may be volatile and subject to wide fluctuations in response to factors including the following: ~~•~~ ● actual or anticipated fluctuations in our quarterly or annual operating results; ~~•~~ ● actual or anticipated changes in the pace of our corporate achievements or our growth rate relative to our competitors; ~~•~~ ● failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public; ~~•~~ ● issuance of new or updated research or reports by securities analysts; ~~•~~ ● share price and volume fluctuations attributable to inconsistent trading volume levels of our shares; ● additions or departures of key management or other 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 debt or equity financing efforts; ~~•~~ ● sales of our common stock by us, our insiders or our other stockholders; ~~•~~ **45** ● general economic, market or political conditions in the United States or elsewhere (including, without limitation, conditions arising out the COVID- 19 pandemic). In particular, the market prices of early clinical- stage companies like ours have been highly volatile due to factors, including, but not limited to any delay or failure in a clinical trial for our product candidates or receive approval from the FDA and other regulatory agents; ● 45 ~~•~~ developments or disputes concerning our product' s intellectual property rights; ~~•~~ ● our or our competitors' technological innovations; ~~•~~ ● fluctuations in the valuation of companies perceived by investors to be comparable to us; ~~•~~ ● announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies or patents; ~~•~~ ● failure to complete significant transactions or collaborate with vendors in manufacturing our product; and ~~•~~ ● proposals for legislation that would place restrictions on the price of medical therapies. ~~Our officers~~ **In addition** , **trading in** ~~directors, and principal stockholder (which is an affiliate of our Executive Chairman) exercise significant control over our company, and will control our company for the foreseeable future, including the outcome of matters requiring stockholder approval. Our officers, directors, entities controlled by our officers and directors, and principal stockholders who beneficially own more than 5 % of~~ our common stock ~~in the aggregate~~ **may be subject to abuse** , **volatility** and **shorting** ~~in particular, TardiMed~~ , which **may have little** ~~is controlled by Michael Derby, our Executive Chairman, and which provides office space and important administrative services~~ to **do** ~~us pursuant to that certain Rent and Administrative Services Agreement that we entered into~~ with **ouroperations** ~~TardiMed in July 2020, which was amended in November 2020, have the ability, acting together, to control the election of our~~ **or** ~~directors and the outcome of corporate actions requiring stockholder approval, such as: (i) a merger or a sale of our company, (ii) a sale of all or substantially all of our assets, and (iii) amendments to our certificate of incorporation, as amended (our " Certificate of Incorporation ") and our amended and restated bylaws (our " Bylaws "). This concentration of voting power and control could have a significant effect in delaying, deferring or preventing an action that might otherwise be beneficial to our other stockholders and be disadvantageous to our stockholders with interests different from those entities and individuals. These individuals also have significant control over our~~ business **prospects** , ~~policies and affairs as officers and directors of our company~~ . If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our common stock, the price of our common stock could decline. The trading market for our common stock relies in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts. The price of our common stock could decline if one or more equity analysts downgrade our common stock or if analysts issue other unfavorable commentary or cease publishing reports about us or our business. We are an " emerging growth company, " and will be able take advantage of reduced disclosure requirements applicable to " emerging growth companies, " which could make our common stock less attractive to investors. We are an " emerging growth company, " as defined in the JOBS Act and, for as long as we continue to be an " emerging growth company, " we intend to take advantage of certain exemptions from various reporting requirements applicable to other public companies but not to " emerging growth companies, " including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an " emerging growth company " for up to five years, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed $ 1. 235 billion, (ii) the date that we become a " large accelerated filer " as defined in Rule 12b- 2 under the Securities Exchange Act of 1934, as amended, which would occur if the market value of our common stock that is held by

non- affiliates exceeds $ 700 million as of the last business day of our most recently completed second fiscal quarter, or (iii) the date on which we have issued more than $ 1 billion in non- convertible debt during the preceding three year period. We intend to take advantage of these reporting exemptions described above until we are no longer an " emerging growth company. " Under the JOBS Act, " emerging growth companies " can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will not be subject to the same new or revised accounting standards as public companies that are not ~~46emerging~~ -- **emerging** growth companies. As a result of this election, our financial statements may not be comparable to those of companies that are not emerging growth companies. We cannot predict if investors will find our common stock less attractive if we choose to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and the price of our common stock may be more volatile. ~~We~~ **46We** incur significant costs and devote substantial management time as a result of operating as a public company, which we expect to increase after we are no longer an " emerging growth company. As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. For example, we are required to comply with certain of the requirements of the Sarbanes- Oxley Act and the Dodd- Frank Wall Street Reform and Consumer Protection Act, as amended, as well as rules and regulations subsequently implemented by the SEC, including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Compliance with these requirements increases our legal and financial compliance costs and makes some activities more time consuming and costly. In addition, our management and other personnel need to divert attention from operational and other business matters to devote substantial time to these public company requirements. In particular, we expect to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes- Oxley Act. In addition, after we no longer qualify as an " emerging growth company, " as defined under the JOBS ACT we expect to incur additional management time and cost to comply with the more stringent reporting requirements applicable to companies that are deemed accelerated filers or large accelerated filers, including complying with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act. We are just beginning the process of compiling the system and processing documentation needed to comply with such requirements. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. In that regard, we currently do not have an internal audit function, and we will need to hire or contract for additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. We cannot predict or estimate the amount of additional costs we may incur as a result of being a public company or the timing of such costs. There may be limitations on the effectiveness of our internal controls, and a failure of our control systems to prevent error or fraud may materially harm our company. Proper systems of internal controls over financial accounting and disclosure controls and procedures are critical to the operation of a public company. We are also at the early stages of establishing, and we may be unable to effectively establish such systems. This would leave us without the ability to reliably assimilate and compile financial information about our company and significantly impair our ability to prevent error and detect fraud, all of which would have a negative impact on our company from many perspectives. Moreover, we do not expect that disclosure controls or internal control over financial reporting, even if established, will prevent all error 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. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Failure of our control systems to prevent error or fraud could materially adversely impact us. We have identified material weaknesses in our internal control ~~over financial reporting~~ and if our remediation of such material weaknesses is not effective, or if we fail to develop and maintain an effective system of disclosure controls and internal control ~~over financial reporting~~ , our ability to produce timely and accurate financial statements or comply with applicable laws and regulations could be impaired. In the course of preparing our financial statements for the ~~year~~ **years** ended December 31, 2020 and **December 31** ~~the nine months ended September 30~~ , ~~2022~~ **2023** , we identified material weaknesses in our internal control ~~over financial reporting~~ relating to the evaluation of complex financial instruments, including earnings per share **. A material weakness is a deficiency, or combination of deficiencies, in internal control, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis** . The material weaknesses have not been remediated as of December 31, ~~2022~~ **2023** ~~. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such 47that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis~~ . Our management has concluded that our control around the ~~interpretation and~~ accounting for certain complex instruments issued by the Company **and earnings per share** was not effectively designed or maintained **, and therefore not accounted for correctly** . ~~We~~ **47We** originally prepared an accounting position paper concluding that our Series Seed Preferred Stock should have been classified as mezzanine equity in accordance with ASC 480. Upon further analysis, it was determined that the Series Seed Preferred Stock should have been recorded as permanent equity because certain redemption provisions are within the Company' s control. Therefore, management has concluded that our controls around the interpretation and accounting for our Series Seed Preferred Stock issued was not effectively designed or maintained. Additionally, the original earnings per share calculation did not correctly classify the shares associated with our SAFE investment and our Series Seed Preferred Stock as a separate class of participating securities. Upon further analysis we determined the controls over the calculation of earnings per share resulted in a material weakness. To remediate the above material weaknesses, we **have** ~~intend to develop~~ **developed** a remediation plan with assistance from our accounting advisors and have dedicated significant resources and efforts to the remediation and improvement of our internal control ~~over financial reporting~~ . While we have processes to identify and appropriately apply

applicable accounting requirements, we plan to enhance our system of evaluating and implementing the complex accounting standards that apply to our financial statements. Our plans at this time include providing enhanced access to accounting literature, research materials and documents, and increased communication among our personnel and third- party professionals with whom we consult regarding complex accounting applications. The elements of our remediation plan can only be accomplished over time, and we can offer no assurance that these initiatives will ultimately have the intended effects. We do not believe that the remediation of these material weaknesses will result in significant incremental cost. However, another significant financial reporting failure or material weakness in internal control ~~over financial reporting~~ could result in substantial cost to remediate and could cause a loss of investor confidence and decline in the market price of our stock **. In addition to the material weaknesses identified above, we also did not design and maintain effective controls over information technology (IT) general controls for information systems that are relevant to the preparation of our financial statements, specifically, with respect to user provisioning and deprovisioning, user access review, passwords, privileged access, cybersecurity, system development lifecycle, and SOC report management review. These IT deficiencies did not result in a misstatement to our financial statements, however, the deficiencies, when aggregated, could impact the effectiveness of IT- dependent controls that could result in misstatements potentially impacting all financial statement accounts and disclosures that would not be prevented or detected. Accordingly, management has determined that these deficiencies in the aggregate constitute a material deficiency. To remediate the above material weaknesses, we have developed a remediation plan with assistance from our IT advisors and have dedicated significant resources and efforts to the remediation and improvement of our internal control** . We cannot assure you, however, that any actions we may take in the future will be sufficient to remediate the control deficiencies that led to our material weaknesses in our internal control ~~over financial reporting~~ or that they will prevent or avoid potential future material weaknesses. Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Further, weaknesses in our disclosure controls and internal control ~~over financial reporting~~ may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Our independent registered public accounting firm is not required to formally attest to the effectiveness of our internal control ~~over financial reporting~~ until after we are no longer an " emerging growth company " as defined in the JOBS Act. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our internal control ~~over financial reporting~~ is documented, designed, or operating. Any failure to implement and maintain effective internal control ~~over financial reporting~~ also could adversely affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control ~~over financial reporting~~ that we will eventually be required to include in our periodic reports that are filed with the Commission. Ineffective disclosure controls and procedures and internal control ~~over financial reporting~~ could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the trading price of our common stock. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on the Nasdaq Capital Market. We have never declared or paid dividends on our common stock, and we do not currently intend to pay dividends on our common stock in the foreseeable future, and consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock. We have never declared or paid cash dividends on our common stock and do not anticipate paying any cash dividends to holders of our common stock in the foreseeable future. Consequently, investors must rely on sales of their common stock after price appreciation, ~~which~~ **48which** may never occur, as the only way to realize any future gains on their investments. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares. ~~48Our~~ -- **Our** operations expose us to litigation, tax, environmental and other legal compliance risks. We are subject to a variety of litigation, tax, environmental, health and safety and other legal compliance risks. These risks include, among other things, possible liability relating to product liability matters, intellectual property rights, contract- related claims, taxes, health and safety liabilities, environmental matters and compliance with U. S. and foreign laws, competition laws and laws governing improper business practices. We may be subject to claims from vendors, licensees, licensors and securityholders (including our current securityholders), including with respect to alleged breaches of agreements, material misstatements in our public filings and other reasons. We could be charged with wrongdoing as a result of such matters. We have not received any notice of any such claims and believe such claims would be without merit and would vigorously defend ourselves, however the risk of such claims is uncertain and there can be no assurance that our Company will not be liable for damages, the amount of which cannot be predicted. Further, in connection with any such claims, a court may grant other remedies that will have a material adverse effect on our Company' s financial condition or results of operations, or that will result in changes to our liquidity or capitalization. Changes in laws or regulations could result in higher expenses and payments, and uncertainty relating to laws or regulations may also affect how we conduct our operations and structure our investments and could limit our ability to enforce our rights. Anti- takeover provisions contained in our Certificate of Incorporation and our Bylaws, as well as provisions of Delaware law, could impair a takeover attempt. Our Certificate of Incorporation, Bylaws and Delaware law contain provisions which could have the effect of rendering more difficult, delaying or preventing an acquisition deemed undesirable by our board of directors. These provisions include: ● classifying our board of directors into three classes; ● authorizing " blank check " preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend, and other rights superior to our common stock; ● limiting the liability of, and providing indemnification to, our directors and officers; ● limiting the ability of our stockholders to call and bring business before special meetings; ● requiring advance notice of stockholder proposals for business to be conducted at meetings of our stockholders and for nominations of candidates for election to our board of directors; ● controlling the procedures for the conduct and scheduling of

board of directors and stockholder meetings; and ● providing our board of directors with the express power to postpone previously scheduled annual meetings and to cancel previously scheduled special meetings. These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation law, which prevents some stockholders holding more than 15 % of our outstanding common stock from engaging in certain business combinations without approval of the holders of substantially all of our outstanding common stock. Any provision of our Certificate of Incorporation, Bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock. 49Our Certificate of Incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees. Our Certificate requires that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will, to the fullest extent permitted by law, be the sole and exclusive forum for each of the following: ● any derivative action or proceeding brought on our behalf; ● any action asserting a claim for breach of any fiduciary duty owed by any director, officer or other employee of ours to the Company or our stockholders, creditors or other constituents; ● any action asserting a claim against us or any director or officer of ours arising pursuant to, or a claim against us or any of our directors or officers, with respect to the interpretation or application of any provision of, the DGCL, our Certificate of Incorporation or Bylaws; or ● any action asserting a claim governed by the internal affairs doctrine; provided, that, if and only if the Court of Chancery of the State of Delaware dismisses any of the foregoing actions for lack of subject matter jurisdiction, any such action or actions may be brought in another state court sitting in the State of DelawareThe exclusive forum provision is limited to the extent permitted by law, and it will not apply to claims arising under the Exchange Act or for any other federal securities laws which provide for exclusive federal jurisdiction, though it may apply to other state and federal law claims including actions arising under the Securities Act (although our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder). However, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our Certificate of Incorporation provides that the Court of Chancery for the State of Delaware will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, there is uncertainty as to whether a court would enforce such a forum selection provision as written in connection with claims arising under the Securities Act. In addition, a stockholder may nevertheless seek to bring such a claim arising under the Securities Act against us, our directors, officers, or other employees in a venue other than the Court of Chancery for the State of Delaware. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our Certificate of Incorporation. Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, this provision may limit or discourage a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition. We note that there is uncertainty as to whether a court would enforce the provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers. General Company- Related RisksSince certain of our directors and officers are employed by and / or consult for other companies, their other activities could compete for time on, or create conflicts of interest with, our activities. Certain of our officers are not required to work exclusively for us. For example, ~~Michael Derby~~ **David W. Hough** , our ~~Executive Chairman of~~ **Chief Medical Officer is** the ~~Board~~ **Chief Medical Officer of Freedom Biosciences** and ~~Zachary Rome~~ **Stephen D. Sheldon** , our **Chief Financial Officer and** Chief Operating Officer ~~and a director, are partners at TardiMed Sciences, LLC (" Tardimed ") and Stephen D. Sheldon, our Chief Financial Officer~~ , is the Chief Executive Officer of Indochina Healthcare Co. Ltd. Pursuant to ~~50the~~ -- **the** agreements we have entered into with ~~these~~ **50these** individuals, ~~Messrs~~ **Messr** . **Hough is** ~~Derby and Rome are~~ obligated to devote only 20 hours per week to activities related to our Company. Therefore, it is possible that a conflict of interest with regard to an officer' s time may arise based on their other employment and / or business operations. As we progress, if the full- time services of these individuals are required and the current directors and officers cannot provide that level of commitment, we will need to identify suitable individuals who can dedicate such time to our Company. We can provide no assurance that we will be able to successfully identify and retain qualified candidates for these positions. We will need to grow the size of our organization, and we may experience difficulties in managing this growth. We have ~~three~~ **six** full- time employees and ~~two~~ **one** part- time ~~employees~~ **employee** . As our development and commercialization plans and strategies develop, we will need to expand the size of our employee base for managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, our management may have to divert a disproportionate amount of its attention away from our day- to- day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize our drug candidates and our ability to compete effectively will depend, in part, on our ability to

effectively manage our future growth. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. In addition, the loss of the services of certain key employees, including Howard J. Weisman, our Chief Executive Officer **and Chairman of the Board** , would adversely impact our business prospects. Our ability to compete in the highly competitive pharmaceuticals industry depends in large part upon our ability to attract highly qualified managerial, scientific and medical personnel. In order to induce valuable employees to remain with us, we intend to provide employees with stock- based compensation that vests over time. The value to employees of stock- based compensation that vests over time will be significantly affected by movements in the price of our common stock that we will not be able to control and may at any time be insufficient to counteract more lucrative offers from other companies. Our management team has expertise in many different aspects of drug development and commercialization. However, we will need to hire additional personnel as we further develop our drug candidates. Competition for skilled personnel in our market is intense and competition for experienced scientists may limit our ability to hire and retain highly qualified personnel on acceptable terms. Despite our efforts to retain valuable employees, members of our management, scientific and medical teams may terminate their employment with us on short notice. We have entered into employment agreements with our executive officers. However, these employment arrangements provide for at- will employment, which means that any of our employees could leave our employment at any time, with or without notice. The loss of the services of any of our executive officers or other key employees could potentially harm our business, operating results or financial condition. In particular, we believe that the loss of the services of Howard J. Weisman, our Chief Executive Officer, would have a material adverse effect on our business. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid- level, and senior managers as well as junior, mid- level, and senior scientific and medical personnel. Other pharmaceutical companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles, and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high- quality candidates than what we have to offer. If we are unable to continue to attract and retain high- quality personnel, the rate and success at which we can develop and commercialize product candidates would be limited. We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively. The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors in a number of jurisdictions, many of which have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than we have. Established competitors may invest heavily to quickly discover and develop novel compounds that could make PAX- 101 or any other product candidates we may develop or acquire obsolete or uneconomical. Any new product that competes with an approved product may need to demonstrate compelling advantages in efficacy, cost, convenience, tolerability and safety to be commercially successful. Other competitive factors, including generic competition, could force us to lower prices or could result in reduced sales. In addition, new products developed by others could emerge as competitors to PAX- 101 or any of our other product candidates. If we are not able 51to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions. We face competition with respect to our current product candidates and we will face competition with respect to any product candidates that we may seek to develop or commercialize in the future. Our current and potential competitors in ASD include CureMark LLC, which is in Phase 3 studies for CM- AT for ASD, Yamo Pharmaceuticals, which is in Phase 2 studies for LI- 79 for ASD, GW Pharmaceuticals, which is in Phase 2 studies for Cannabidivarin for ASD, ~~Zynerba Pharmaceuticals~~ **Harmony Biosciences** , which is in Phase ~~2~~ **3** studies for Cannabidiol (" CBD ") gel for ASD, QBioMed, which is developing a preclinical asset called QBM- 001 for rare pediatric nonverbal autism and Kuzani Therapeutics, Inc., which has announced that it is in clinical development for the treatment of the core symptoms of ASD in children. There are two treatments that have been approved by FDA to treat the non- core symptom of irritability in ASD: Risperdal ® (Risperidone) and Abilify ® (Aripiprazole). Axial Therapeutics is in Phase 2 studies for AB- 2004 for irritability in ASD. For ME / CFS, AIM ImmunoTech has an approval for rintatolimod in Argentina, and is in development for the drug in the US. For LCS, Tonix Pharmaceuticals is in Phase 2 studies for TNX- 102 SL. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our drug candidates. We face a potential risk of product liability as a result of the clinical testing of our drug candidates and will face an even greater risk if we commercialize our drug candidates. For example, we may be sued if any product we develop or acquire or any materials that we use in our products allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. 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. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: ● decreased demand for our drug candidates; ● injury to our reputation; ● withdrawal of clinical trial participants; ● costs to defend the related litigation; ● a diversion of management' s time and our resources; ● substantial monetary awards to trial participants or patients; ● product recalls, withdrawals or labeling, marketing or promotional restrictions; ● the inability to commercialize our drug candidates; and ● a decline in the value of our stock. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop or acquire. We intend to obtain product liability insurance covering our clinical trials. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our

insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. **52** 52We may acquire businesses, assets or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions. We may acquire additional businesses, assets or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new businesses, assets or products we may acquire, and any delay in their integration may delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction. We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively. Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber- attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced a cyber- attack to date, there can be no assurance that we will not experience cyber- attacks in the future, suffer indirect consequences from cyber- attack on a third- party, or fail to anticipate, identify or offset such threats of potential cyber- attacks or security breaches in a timely manner. This is especially so considering the nature of cyber- attack techniques, which change frequently, can be difficult to detect for extended periods of time and often are not recognized until they succeed. System failures, accidents or security breaches could cause interruptions in our operations and could result in a material disruption of our product development and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of product development or clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs and the development of our product candidates could be delayed. Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, could adversely affect our current and projected business operations and our financial condition and results of operations. Actual events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (" SVB ") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (" FDIC ") as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each sent into receivership. The Department of the Treasury, the Federal Reserve and the FDIC released a statement that indicated that all depositors of SVB would have access to all of their funds, including funds held in uninsured deposit accounts, after only one business day of closure. The U. S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $ 25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. There is no guarantee, however, that the U. S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion. We do not hold cash deposits or securities at SVB and have not experienced any adverse impact to our liquidity or to our current and projected business operations, financial condition or results of operations. However, uncertainty remains over liquidity concerns in the broader financial services industry, and our business, our business partners, or industry as a whole may be adversely impacted in ways that we cannot predict at this time. Although we assess our banking relationships as we believe necessary or appropriate, our access to cash in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the financial institutions with which we have banking relationships, and in turn, us. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could also include factors involving financial markets 53