Risk Factors Comparison 2025-03-31 to 2024-04-01 Form: 10-K

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You should carefully consider the following risk factors together with the other information contained in this Annual Report, including our financial statements, the related notes and " Management' s Discussion and Analysis of Financial Condition and Results of Operations " appearing in this **Annual** ~~report~~ **Report** . The occurrence of any of the following risks, or of additional risks and uncertainties not presently known to us or that we currently believe to be immaterial, could materially and adversely affect our business and our financial condition and results of operations. In this event, the market price of our securities could decline and your investment could be lost. You should understand that it is not possible to predict or identify all such risks. Consequently, you should not consider the following to be a complete discussion of all potential risks or uncertainties. Summary of Principal Risk Factors ● Our product development efforts may not....., drug manufacturing and nonclinical activities. ● Our recurring operating losses, negative cash flows from operations, and accumulated deficit raise substantial doubt about our ability to continue as a going concern absent obtaining adequate new financings. ● The report of our independent registered accounting firm on our audited financial statements for the fiscal year ended December 31, ~~2023~~ **2024** contains an explanatory paragraph relating to our ability to continue as a going concern **. ● We have identified material weaknesses in our internal control over financial reporting; 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** . ● We need to obtain additional funding to continue as a going concern; if we are unable to meet our needs for additional funding in the future, we will be required to limit, scale back or cease operations. ● ~~We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future. ● We currently have no source of product revenue and may never become profitable. ● We need to obtain substantial additional funding to further develop our products in future clinical trials and through regulatory processes; if we are unable to meet our needs for additional funding in the future, we will be required to limit, scale back or cease operations. ●~~ Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. ● ~~Adverse~~ **Our product** ~~developments~~ **development efforts** may not be successful.● Our future success is dependent primarily on the regulatory approval and commercialization of our product candidates.● The results of preclinical testing or earlier clinical studies are not necessarily predictive of future results.Any product candidate we advance into clinical trials may not have favorable results in later- stage clinical trials or receive regulatory approval.● Clinical drug development involves a lengthy and expensive process with an uncertain outcome.● Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval,limit the commercial profile of an approved label,or result in significant negative consequences following any marketing approval.● Failure to follow the FDA' s applicable regulatory requirements may result in enforcement action.● Changes in product candidate manufacturing or formulation may result in additional costs or delay.● Healthcare legislation,including potentially unfavorable pricing regulations or other healthcare reform initiatives,may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and ~~affect the affecting --- following any marketing approval.● Failure to follow the FDA' s applicable regulatory requirements may result in enforcement action.● Changes in product candidate manufacturing or formulation may result in additional costs or delay.● Healthcare legislation,including potentially unfavorable pricing regulations or other healthcare reform initiatives,may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and~~ affect the prices we may obtain.● Our employees may engage in misconduct or other improper activities,including noncompliance with regulatory standards and requirements,which could cause significant liability for us and harm our reputation.● We face substantial competition,which may result in others discovering,developing or commercializing products before or more successfully than we do.● If we breach our license agreements or fail to negotiate new agreements pertaining to our product candidates,we could lose the ability to continue the development and potential commercialization of these product candidates.● Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.● **There is no guarantee that the Merger will increase stockholder value,and stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger,including the issuance of our common stock upon conversion of the shares of Series C Preferred issued in the Merger and the concurrent financing.● We expect to incur substantial expenses related to the integration of Trawsfynydd.●** We may engage in future business combinations or collaborations that could disrupt our business,cause dilution to our stockholders and harm our ~~financial condition and operating~~ financial ~~institutions, companies in the financial services industry~~ **condition and operating results. ● We depend on information technology and computer systems to operate** ~~or~~ **our business; our business and operations would suffer in** the ~~financial services industry generally~~ **event of any failures or interruptions of our computer system** , such as ~~actual events~~ **a data breach** or ~~concerns involving liquidity~~ **cybersecurity incident. ● Climate change** , ~~defaults~~ **environmental** , **social and governance and sustainability initiatives may result in regulatory** or ~~non- performance~~ **structural industry changes that** could **require significant operational changes and expenditures, reduce demand for the Company' s products and** adversely affect our **business, financial condition, and results of** operations **. 33 ● Business disruptions could seriously harm our future revenues** and ~~liquidity~~ **financial condition and increase our costs and expenses. ● Our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel. ● Our business, financial condition and results of operations could be materially adversely affected by any negative impact on the global economy and capital**

markets resulting from international conflicts, international trade disputes and geopolitical tensions . ● Changes in United States and China relations, as well as relations with other countries, and / or regulations may adversely impact our business, our operating results, our ability to raise capital and the market price of our shares **. ● We currently conduct clinical trials, and may in the future choose to conduct additional clinical trials, of our product candidates in sites outside the US, and the FDA may not accept data from trials conducted in foreign locations. ● Disruptions at the FDA and foreign regulatory authorities caused by funding shortages, staffing limitations or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business** . ● We rely on third parties to conduct our preclinical and clinical trials. 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 our product candidates. ● If we lose our relationships with CROs, our drug development efforts could be delayed. ● We have limited experience manufacturing our product candidates on a large clinical or commercial scale and have no manufacturing facility. We are dependent on third- party manufacturers for the manufacture of our product candidates for clinical trials as well as on third parties for our supply chain, and if we experience problems with any third parties, the manufacturing of our product candidates or products could be delayed. ● We **have entered into certain related party transactions and may continue to rely on related parties for certain development and support activities. ● We** could be required to incur significant expenses to perfect our intellectual property rights, and our intellectual property rights may be inadequate to protect our competitive position. If we are unable to protect our intellectual property rights, our competitive position could be harmed. ● We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful. ● Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could harm our business. ● We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. ● ~~We may not comply~~ **If we are unable to maintain compliance** with the ~~Nasdaq~~ continued listing requirements ~~. If we are unable to comply with the continued listing requirements~~ of the Nasdaq Capital Market, our ~~Common~~ **common** ~~Stock~~ **stock** could be delisted, which could affect our ~~Common~~ **common** ~~Stock~~ **stock** ' s market price and liquidity and reduce our ability to raise capital. ~~31~~ ● Our share price and the liquidity of our stock may be volatile and result in substantial losses to our stockholders. ● We may be subject to securities litigation, which is expensive and could divert management attention. ● Some provisions of our charter documents and Delaware law may have anti- takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. Risks Related to Our Financial Position and Capital NeedsOur recurring operating losses, negative cash flows from operations, and accumulated deficit raise substantial doubt about our ability to continue as a going concern absent obtaining adequate new financings. ~~Management~~ **34Management** has concluded that substantial doubt exists about our ability to continue as a going concern for the next twelve months from the date of the financial statements included in this Annual Report ~~on Form 10- K~~ . As of December 31, ~~2023~~ **2024** , we had cash and cash equivalents of $ ~~20~~ **21** . ~~8~~ **3** million and current liabilities of $ ~~9~~ **11** . ~~2~~ **5** million. ~~We believe that~~ **Based on current projections,** we ~~have sufficient resources available to support our development activities and business operations and satisfy our obligations into the third quarter of 2024. We~~ do not have sufficient cash and cash equivalents as of the date of this Annual Report ~~on Form 10- K~~ to support our operations for **more than one year** ~~at least the 12 months~~ following the date that the financial statements are issued. We will require substantial additional financing to fund our ongoing clinical trials and operations, and to continue to execute our strategy. To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, we plan to explore various dilutive and non- dilutive opportunities, including equity financings, strategic alliances, business development and / or combinations, and other transactions. The future success of the Company is dependent upon our ability to obtain additional funding. There can be no assurance, however, that we will be successful in obtaining such funding in sufficient amounts, on terms acceptable to us, or at all. The failure to obtain sufficient capital on acceptable terms when needed would have a material adverse effect on our business, results of operations, and financial condition. Accordingly, we have concluded that substantial doubt exists with respect to our ability to continue as a going concern within one year after the date that these financial statements are issued. The report of our independent registered accounting firm on our audited financial statements for the fiscal year ended December 31, ~~2023~~ **2024** contains an explanatory paragraph relating to our ability to continue as a going concern. The auditor' s opinion on our audited financial statements for the year ended December 31, ~~2023~~ **2024** includes an explanatory paragraph stating that we have incurred recurring losses from operations that raise substantial doubt about our ability to continue as a going concern for the next twelve months from the date of the financial statements included in this Annual Report ~~on Form 10- K~~ . While we believe that we will be able to raise the capital we need to continue our operations, there can be no assurances that we will be successful in these efforts or will be able to resolve our liquidity issues or eliminate our operating losses. If we are unable to obtain sufficient funding, we would need to significantly reduce our operating plans and curtail some or all of our development efforts. Accordingly, our business, prospects, financial condition, and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all. We need to obtain additional funding to **execute our business plans** ~~continue as a going concern~~ ; if we are unable to meet our needs for additional funding in the future, we will be required to limit, scale back or cease operations. ~~Our consolidated financial statements for the year ended December 31, 2023 have been prepared assuming we will continue to operate as a going concern. However, due to our ongoing operating losses and our accumulated deficit, management has concluded that there is substantial doubt about our ability to continue as a going concern for the next twelve months from the date of the financial statements included in this Annual Report~~

~~on Form 10- K. Because we continue to experience net operating losses, our ability to continue as a going concern is subject to our ability to 32successfully raise sufficient additional capital, through future financings or through strategic and collaborative arrangements. If we are unable to obtain additional funding, we may not be able to continue as a going concern.~~ We do not **currently** have the funding resources necessary to carry out all of our proposed operating activities. We will need to obtain additional financing in the future in order to fully fund **tivoxavir marboxil, ratutrelvir,** narazaciclib, rigosertib or any other product candidates through the regulatory approval process. Accordingly, we may **be required to** delay or pause our planned clinical trials ~~,~~ until we secure adequate additional funding. If we seek to proceed with a clinical trial without additional funding, we may receive questions or comments from the FDA, fail to obtain IRB approval, or find it more difficult to enroll patients in the trial. We have scaled down our operations in order to reduce spending on general and administrative functions, research and development, and other clinical trials, but by themselves, those measures may not be sufficient to address our funding needs. Our future capital requirements will depend on many factors, including: ● timing and success of our clinical trials; ● continued progress of **,** and increased spending related to **,** our research and development activities; ● conditions in the capital markets and the biopharmaceutical industry, particularly with respect to raising capital or entering into strategic arrangements; **35** ● progress with preclinical experiments and clinical trials, including regulatory approvals necessary for advancement and continuation of our development programs; ● changes in regulatory requirements and guidance of the FDA and other regulatory authorities, which may require additional clinical trials to evaluate safety and / or efficacy, and thus have significant impacts on our timelines, cost projections, and financial requirements; ● ongoing general and administrative expenses related to our reporting obligations under the Exchange Act; ● cost, timing, and results of regulatory reviews and approvals; ● costs of any legal proceedings, claims, lawsuits and investigations; ● success, timing, and financial consequences of any existing or future collaborative, licensing and other arrangements that we may establish, including potential granting of licenses to one or more of our programs in various territories, or otherwise monetizing one or more of our programs; ● cost of filing, prosecuting, defending and enforcing any patent **●** claims and other intellectual property rights; ● costs of commercializing any of our product candidates; ● technological and market developments; ● compliance with Nasdaq' s continued listing requirements; ● cost of manufacturing development; and ● timing and volume of sales of products for which we obtain marketing approval. These factors could result in variations from our projected operating and liquidity requirements. Additional funds may not be available when needed, or, if available, we may not be able to obtain such funds on terms acceptable to us. If adequate funds are unavailable, we may be required, among other things, to: ~~33 ●~~ delay, reduce the scope of or eliminate one or more of our research or development programs; ● license rights to technologies, product candidates or products at an earlier stage or for indications or territories than otherwise would be desirable, or on terms that are less favorable to us than might otherwise be available; ● obtain funds through arrangements that may require us to relinquish rights to product candidates or products that we would otherwise seek to develop or commercialize by ourselves; or ● further reduce or cease operations. We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future. We are a clinical- stage biopharmaceutical company. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate could fail to gain regulatory approval or become commercially viable. We do not have any products approved by regulatory authorities for marketing and have not generated any revenue from product sales to date, and we continue to ~~incur~~ **36incur** significant research, development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in every reporting period since our inception in 1998. For the years ended December 31, **2024, and** 2023 ~~, and 2022~~ , we reported net losses of $ **166. 5 million and $** 18. 9 ~~million and $ 19. 0~~ million, respectively, and we had an accumulated deficit of $ ~~482~~ **649** . ~~6~~ **2** million ~~at~~ **as of** December 31, ~~2023~~ **2024** . We expect to continue to incur significant expenses and operating losses for the foreseeable future. These losses may increase as we continue the research and development of, and seek regulatory approvals for, our product candidates, and potentially begin to commercialize any products that may achieve regulatory approval. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If any of our product candidates fail in clinical trials or do not gain regulatory approval, or if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. We **are obligated to develop and maintain proper and effective internal control over financial reporting. 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 addition, the presence of material weaknesses increases the risk of material misstatement of the consolidated financial statements. We are a public company and are required, pursuant to Section 404 (a) of the Sarbanes- Oxley Act, to furnish a report by management on, among other things, the effectiveness of its internal control over financial reporting on our annual report on Form 10- K. Effective internal control over financial reporting is necessary for reliable financial reports and, together with adequate disclosure controls and procedures, such internal controls are designed to prevent fraud. Undetected material weaknesses in internal controls could lead to financial statement restatements and require us to incur the expense of remediation. We are required to disclose changes made in internal control and procedures on a quarterly basis. As discussed elsewhere in this Annual Report, we completed the Merger in April 2024. Prior to the Merger, Trawsfynydd was a private company and, therefore, its controls were not required to be designed or maintained in accordance with Rules 13a- 15 and 15d- 15 under the Exchange Act. The design and implementation of internal control over financial reporting post- Merger has required, and will continue to require, significant time and resources from management and other personnel. Although we had internal controls in place prior to the Merger, and our management has determined in recent years that such internal controls over financial reporting were effective, during its assessment of our internal controls over financial reporting as**

of December 31, 2024 it was determined that our controls were not effectively updated and implemented to reflect the changes in processes and staffing during the period between completion of the Merger and December 31, 2024. Additionally, it was determined that there was an inadequate segregation of duties over the preparation, review and posting of manual journal entries, which is the result of not having a sufficient risk assessment process in place post-Merger to identify and analyze risk of misstatement due to fraud and / or error. In connection with the audit of our financial statements for the year ended December 31, 2024, we identified material weaknesses in our internal control over financial reporting, which relate to the determinations of management discussed above. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Although we intend to update our controls and implement additional controls, no assurance can be provided that we will be able to remediate the material weaknesses identified on a timely basis, or at all. If we are unable to remedy our material weaknesses, or if we generally fail to establish and maintain effective internal controls appropriate for a public company, we may be unable to produce timely and accurate financial statements, and we may continue to conclude that our internal control over financial reporting is not effective, which could adversely impact our investors' confidence and our stock price. 37We currently have no source of product revenue and may never become profitable. To date, we have not generated any revenues from commercial product sales. Our ability to generate revenue from product sales and achieve profitability will depend upon our ability to successfully commercialize products, including any of our current product candidates, or other product candidates that we may in- license or acquire in the future. Even if we are able to successfully achieve regulatory approval for these product candidates, we do not know when any of these products will generate revenue from product sales for us, if at all. In addition, because of the numerous risks and uncertainties associated with product development, including that our product candidates may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. Even if we are able to complete the development and regulatory process for any product candidates, we anticipate incurring significant costs associated with commercializing these products. **Additionally,** ~~Even~~ **even** if we are able to generate revenues from the sale of our products, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or suspend our operations. Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. Until we can generate substantial revenue from product sales, if ever, we expect to continue to seek additional capital through a combination of private and public equity offerings, debt financings, strategic collaborations and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or ~~34convertible~~ -- **convertible** debt securities, the ownership interests of existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include restrictive covenants limiting our ability to take important actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic collaborations and alliances or licensing arrangements with third parties, which may include existing collaboration partners, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates or formulations that we would otherwise prefer to develop and market ourselves. ~~Adverse developments affecting~~ **We maintain our cash at** financial institutions, ~~companies~~ **often** in **balances** ~~the financial services industry or the financial services industry generally, such as actual events or concerns involving liquidity, defaults or non- performance, could adversely affect our operations and liquidity. Actual events involving limited liquidity, defaults, non- performance or other adverse developments~~ that ~~affect financial~~ **exceed federally insured limits. The majority of our cash is held in accounts at U. S. banking** institutions ~~or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market- wide liquidity problems~~ . **Cash held in depository accounts may exceed** ~~For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed~~ the Federal Deposit Insurance Corporation **(" ,** ~~or the~~ FDIC **") standard deposit insurance limit of $ 250 , 000. If such banking institutions were to fail, such** as ~~receiver~~ **Silicon Valley Bank when the FDIC took control in March 2023 , we could lose all or a portion of those amounts held in excess of such insured amounts. In the future, our access to our cash in amounts adequate to finance our operations could be significantly impaired if the financial institutions with which we have arrangements encounter liquidity constraints or failures. Any future limitation on timely access to our funds or any material loss that we may experience in the future could have a material adverse effect on our financial condition** and ~~created~~ **could materially impact our ability to pay our operating expenses or make other payments. We are currently operating in a period of economic** uncertainty and **capital markets disruption, which has been significantly impacted by geopolitical instability and the ongoing military conflicts between Russia and Ukraine and Israel and Hamas. Our business, financial condition and results of operations could be materially adversely affected by any negative impact on the global economy and capital markets resulting from the conflict in Ukraine and the Middle East and / or geopolitical tensions. U. S. and global markets are experiencing volatility and disruption, and the global economy has been, and may continue to be, negatively impacted by Russia' s ongoing military conflict with Ukraine. As a result of Russia' s invasion of Ukraine in February 2022, the U. S., the European Union, the United Kingdom, other G7 countries, as well as various 38other countries, have imposed substantial financial and economic sanctions on certain industry sectors and parties in Russia. Broad restrictions on**

exports to Russia have also been imposed. These measures include: (i) comprehensive financial sanctions against major Russian banks; (ii) additional designations of Russian individuals with significant business interests and government connections; (iii) designations of individuals and entities involved in Russian military activities; and (iv) enhanced export controls and trade sanctions limiting Russia' s ability to import various goods. Russian military actions and the resulting sanctions could continue to adversely affect the global economy and financial markets and lead to instability and lack of liquidity ~~concerns~~ **in capital markets, potentially making it more difficult** for us **to obtain additional funds. Addition , in October 2023, Hamas militants and members of certain other organizations infiltrated Israel' s southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Shortly thereafter, Israel' s security cabinet declared war against Hamas and launched an aerial bombardment of various targets within the Gaza Strip. It is possible that other countries and / or regional organizations will join the hostilities as well, including without limitation Hezbollah in Lebanon, and Palestinian military organizations in the West Bank, resulting in further expansion of the conflict. The conflict between Israel and Hamas is ongoing, and the length and impact of the ongoing military conflict is highly unpredictable. Although our business has not been materially impacted by the ongoing military conflicts between Russia and Ukraine or Israel and Hamas or geopolitical tensions to date, it is impossible to predict the extent to which our operations, or those of our suppliers and manufacturers, will be impacted in the short and long term, or the ways in which the conflict may impact our business. The extent and duration of the conflicts in Ukraine and the Middle East, geopolitical tensions, sanctions and resulting market disruptions are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described herein. International trade disputes could result in tariffs and other protectionist measures that could have a material adverse effect on our business, financial condition and results of operations. In recent years, including after the most recent presidential election, the U. S. has instituted or proposed changes in trade policies that include the negotiation or termination of trade agreements, the imposition of higher tariffs on imports into the U. S., economic sanctions on individuals, corporations or countries, and other government regulations affecting trade between the U. S. and other countries where we conduct our business, in particular China, Mexico and Canada. A number of other nations have proposed or instituted similar measures directed** at **trade with the United States in response. As a result of these developments, there may be greater restrictions and economic disincentives on international trade** that **could adversely affect our business. Additionally, tariffs could increase our costs, which could have a negative impact on our financial condition and results of operations. As additional trade-related policies are instituted, we may need to modify our business operations to comply and adapt to such developments, which may be** time ~~,~~ **- consuming** and **expensive** ~~in the broader financial services industry remain. There is no guarantee that a similar event will not occur again and that our liquidity will not be adversely affected~~ . Changes in United States and China relations, as well as relations with other countries, and / or regulations may adversely impact our business, our operating results, our ability to raise capital and the market price of our shares. The US government, including the SEC, has made statements and taken certain actions that led to changes to US and international relations, and will impact companies with connections to the United States or China, including imposing several rounds of tariffs affecting certain products manufactured in China, imposing certain sanctions and restrictions in relation to China and issuing statements indicating enhanced review of companies with significant China- based operations. It is unknown whether and to what extent new legislation, executive orders, tariffs, laws or regulations will be adopted, or the effect that any such actions would have on companies with significant connections to the U. S. or to China, our industry or on us. Any unfavorable government policies on cross- border relations and / or international trade, including increased scrutiny on companies with significant China- based operations, capital controls or tariffs, may affect our ability to raise capital and the market price of our shares. If any new legislation, executive orders, tariffs, laws and / or regulations are implemented, if existing trade agreements are renegotiated or if the U. S. or Chinese governments take retaliatory actions due to the recent U. S.- China ~~tension~~ **39tension** , such changes could have an adverse effect on our business, financial condition and results of operations, our ability to raise capital and the market price of our shares. We may be adversely affected by the effects of inflation. Inflation has the potential to adversely affect our liquidity, business, financial condition and results of operations by increasing our overall cost structure. The existence of inflation in the economy has resulted in, and may continue to result in, higher interest rates and capital costs, supply shortages, increased costs of labor, components, manufacturing and shipping, as well as weakening exchange rates and other similar effects. As a result of inflation, we have experienced and may continue to experience cost increases. Although we may take measures to mitigate the effects of inflation, if these measures are not effective, our business, financial condition, results of operations and liquidity could ~~35be~~ **be** materially adversely affected. Even if such measures are effective, there could be a difference between the timing of when these beneficial actions impact our results of operations and when the costs of inflation are incurred. Risks Related to Our Business and IndustryOur product development efforts may not be successful. Clinical and non- clinical development is expensive, time-consuming, and uncertain as to the outcome. The focus of our development efforts is currently on **tivoxavir marboxil and ratutrelvir, while we consider strategic options for** narazaciclib and ~~oral~~ rigosertib. Although ~~,~~ we believe that there are opportunities for us to develop ~~narazaciclib,~~ our **drug candidates** ~~novel multi kinase inhibitor targeting CDK4 / 6 as well as other tyrosine kinases,~~ in **various** indications ~~such as endometrial cancer, metastatic breast cancer, mantle cell lymphoma and multiple myeloma, and oral rigosertib in RAS mutated cancers~~ , clinical drug development is expensive, can take many years to complete, and its outcome is inherently uncertain. Even if our clinical development programs are successful, we may not be able to successfully commercialize any product. There can be no assurance that our focus on **tivoxavir marboxil and ratutrelvir and the strategic options available for** narazaciclib and ~~oral~~ rigosertib will be successful, and that we will be able to successfully develop a product candidate or, even if we do, that we will be able to successfully commercialize such candidate. Our future success is dependent primarily on the regulatory approval and commercialization of our product candidates. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate

with substantial evidence gathered in preclinical and well- controlled clinical studies and, with respect to approval in the United States, to the satisfaction of the FDA, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. A failure of one or more preclinical tests or clinical trials can occur at any stage of testing. Changes to product candidates may also impact their performance in subsequent studies. If we are unable to obtain regulatory approval or designations we may seek, such as orphan designation, for our product candidates in one or more jurisdictions, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of our product candidates. The results of preclinical testing or earlier clinical studies are not necessarily predictive of future results. Any product candidate we advance into clinical trials may not have favorable results in later- stage clinical trials or receive regulatory approval. Encouraging results in preclinical testing and earlier clinical studies do not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of an investigational drug. Additionally, mechanisms of action, studies in small or single patient populations, and interim study results may not be predictive of later stage studies. The development of a product **candidate** for one indication may further impact its development for other indications. ~~By example, our phase III study of intravenous rigosertib for HR MDS did not meet its primary endpoints. It is possible that this may impact how regulators or others view the development of rigosertib for alternative indications and via different methods of administration.~~ If **our** ~~later- stage~~ clinical trials do not produce favorable results **for our product candidates** , our ability to achieve regulatory approval for any of our product candidates may be adversely impacted. ~~Clinical~~ **40Clinical** drug development involves a lengthy and expensive process with an uncertain outcome. We may experience delays in our ongoing or future clinical trials **,** and we do not know whether planned clinical trials will begin or enroll subjects on time, need to be redesigned or be completed on schedule, if at all. Regulatory authorities may also find that our development programs do not support product approval. There can be no assurance that the FDA, an IRB, or a comparable foreign regulatory authority will permit our clinical trials to commence and will not put clinical trials of any of our product candidates on clinical hold in the future. Study results may also cause us to ~~36discontinue~~ -- **discontinue** trials. Clinical trials may be delayed, suspended or prematurely terminated and development programs may not be successful for a variety of reasons, including: ● delay or failure in reaching identifying, contracting with, and retaining contract research organizations ~~, or~~ **(“** CROs ~~,~~ **”)** and clinical trial sites; ● delay or failure in recruiting and enrolling suitable subjects to participate in a trial and / or retaining subjects; ● failure to follow the study procedures or applicable regulatory requirements; ● change in standards of care **,** which may necessitate the modification of our clinical trials or the conduct of new trials; ● negative or ambiguous study results; ● manufacturing or product quality issues; ● the need to conduct additional development work, including clinical trials; ● unanticipated clinical trial costs or insufficient funding, including paying substantial application user fees; ● changes in governmental laws, regulations, policies, or administrative actions; and ● regulatory authority disagreements regarding the design or implementation of our clinical trials. If we experience delays in the completion or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from 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 process and jeopardize our ability to commence product sales and generate revenues. In addition, many of the factors that could cause a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any marketing approval. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. As a result of undesirable side effects or safety or toxicity issues that we may experience in our clinical trials, we may not receive approval to market any product candidates, which could prevent us from ever generating revenues or achieving profitability. Results of our trials could reveal an unacceptably high severity and prevalence of side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development or deny approval of our product candidates for any or all targeted ~~indications~~ **41indications** . These side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. They could also result in restrictive labeling for any approved products. Failure to follow the FDA’ s applicable regulatory requirements may result in enforcement action. If we or our third- party contractors are not able to follow the FDA’ s or comparable foreign regulatory authorities’ regulatory requirements, we or they may face enforcement actions that may materially harm our business, including, but not limited to: ~~37~~ ● warning letters, untitled letters, cyber letters or otherwise unacceptable inspectional findings; ● injunctions, penalties, fines, restitution, consent decrees, corporate integrity agreements, suspension or debarment; ● suspension or termination of any ongoing clinical studies, imposition of a clinical hold, or regulatory authority refusal to approve pending marketing applications; ● modification of promotional materials or labeling, provision of corrective information, imposition of post- market requirements including the need for additional testing; ● restrictions on operations, product seizure or detention, refusal to permit the import or export of products, or product recalls; or ● adverse publicity. Changes in product candidate manufacturing or formulation may result in additional costs or delay. As product candidates are developed through preclinical studies to later- stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. During the course of a development program, sponsors may also change the contract manufacturers used to produce the product candidates. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of clinical trials. Such changes may also require additional testing, notification to, or approval from the FDA or comparable foreign regulatory authority. This could delay completion of clinical trials; require the conduct of bridging clinical trials or

studies, or the repetition of one or more clinical trials; increase clinical trial costs; delay approval of our product candidates; and jeopardize our ability to commence product sales and generate revenue. **42We currently conduct clinical trials, and may in the future choose to conduct additional clinical trials, of our product candidates in sites outside the US, and the FDA may not accept data from trials conducted in foreign locations. We currently conduct, and expect in the future to conduct, clinical trials outside the US for our product candidates. The acceptance of study data from clinical trials conducted outside the US or another jurisdiction by the FDA or comparable foreign regulatory authorities may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the US, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the US population and US medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on- site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on- site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, if the study was not otherwise subject to an IND, the FDA will not accept the data as support for an application for marketing approval unless the study was conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the US or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction. In addition, there are risks inherent in conducting clinical trials in multiple jurisdictions, inside and outside of the US, such as: ● regulatory and administrative requirements of the jurisdiction where the trial is conducted that could burden or limit our ability to conduct our clinical trials; ● foreign exchange fluctuations; ● manufacturing, customs, shipment and storage requirements for clinical trial materials and supplies as well as shipment and storage of biological samples; ● cultural differences in medical practice and clinical research; and ● the risk that the patient populations in such trials are not considered representative as compared to the patient population in the target markets where approval is being sought. Disruptions at the FDA and foreign regulatory authorities caused by funding shortages, staffing limitations or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business. The ability of the FDA and foreign regulatory authorities to review or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA' s or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA' s or foreign regulatory authorities' ability to perform routine functions including a rapid substantial influx of applications from numerous sponsors, as occurred with COVID- 19. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, the US government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. 43Separately, in response to the COVID- 19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. If a prolonged government shutdown occurs, or funding shortages, staffing limitations, or renewed global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities on a timely basis, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.** Healthcare legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain. The regulations that govern, among other things, marketing approvals, coverage, pricing and reimbursement for new drug products vary widely from country to country and our ability to commercialize any products will depend, in part, on the extent to which coverage and adequate reimbursement for our products is available. In the United States and some foreign jurisdictions, including the European Union, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities, limit coverage and reimbursement or restrict the prices we may charge including through payments of increased manufacturer rebates and penalties, and affect our ability to successfully sell any product candidates for which we obtain marketing approval. Furthermore, in the United States private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates. These and any additional healthcare reform measures in the United States, the European Union and other potentially significant markets could further constrain our business or limit the amounts that governments will pay for healthcare products and services, which could result in additional pricing pressures. **Certain** ~~States~~ **states** , in the US, have also enacted laws requiring pharmaceutical companies to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, cap or regulate price increases, negotiate or pay increased supplemental rebates and /

or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing specified physician prescribing data to pharmaceutical companies for use in sales and marketing, and to prohibit other specified sales and marketing practices. ~~38Some --~~ **Some** countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates even if our product candidates obtain marketing approval. We cannot be sure that timely coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of coverage and reimbursement will be. Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation. We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA, Centers for Medicare & Medicaid Services, or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, comply with the FDA' s laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of ~~conduct~~ **44conduct** for our directors, officers and employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions. We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do. The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any product candidate that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of certain disease indications for which we are developing our product candidates. For example, large pharmaceutical **companies such as Roche, GSK and BioCryst Partners successfully market the commercialized anti- influenza drugs neuraminidase inhibitors oseltamivir phosphate (Tamiflu), zanamivir (Relenza), and peramivir (Rapivab) anti- influenza drugs, respectively. Additionally, Roche' s antiviral, baloxavir marboxil (Xofluza), a CEN inhibitor, is also approved for the treatment of influenza. Gilead, Pfizer and Merck have commercialized drugs for the management of COVID- 19 in certain populations, including remdesivir and, nirmatrelvir ritonavir, or molnupiravir, respectively. Furthermore, other** companies such as Pfizer, Novartis, Eli Lilly successfully market commercialized CDK 4 / 6 inhibitors palbociclib, ribociclib and abemaciclib and have done so for a number of years. More recently, G1 Therapeutics secured FDA approval of the CDK 4 / 6 triaciclib for the prevention of myelosuppression following chemotherapy. The approved **antiviral drugs baloxavir marboxil, oseltamivir and** CDK 4 / 6 inhibitor drugs palbociclib, ribociclib and abemaciclib are well established therapies or products and are widely accepted by physicians, patients and third- party payors. By the time ~~narazaciclib~~ **our drug candidates are** possibly ~~is~~ approved in the future, insurers and other third- party payors may also encourage the use of generic products. This may make it difficult for us to achieve market acceptance at desired levels in a timely manner to ensure viability of our business. More established companies may have a competitive advantage over us due to their greater size, cash flows and institutional experience. Compared to us, many of our competitors may have significantly greater financial, technical and human resources. ~~39If~~ **If** we breach our license agreements or fail to negotiate new agreements pertaining to our product candidates, we could lose the ability to continue the development and potential commercialization of these product candidates. If we fail to meet our obligations under our current license agreements or if we fail to negotiate future license agreements, our rights under the licenses could be terminated, and upon the effective date of such termination, our right to use the licensed technology would terminate. While we would expect to exercise all rights and remedies available to us, including attempting to cure any breach by us, and otherwise seek to preserve our rights under the patents and other technology licensed to us, we may not be able to do so in a timely manner, at an acceptable cost or at all. Any uncured, material breach under the license agreement could result in our loss of exclusive rights and may lead to a complete termination of our product development and any commercialization efforts for the applicable product candidates. ~~Product~~ **45Product** liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop. We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by subjects enrolled in our clinical trials, and patients, healthcare providers or others using, administering or selling our products in third party studies, expanded access programs, or commercially, if we receive product approval. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, the clinical development and commercialization of our product candidates could be adversely affected or terminated, and we could incur substantial liabilities. We may engage in future business combinations or collaborations that

could disrupt our business, cause dilution to our stockholders and harm our financial condition and operating results. While we currently have no specific plans to acquire any other specific business, we may, in the future, make acquisitions of, or investments in, or otherwise engage in business combinations or collaborations with companies that we believe have products or capabilities that are a strategic or commercial fit with our current product candidates and business or otherwise offer opportunities for our company. In connection with these acquisitions or investments, we may: issue stock that would dilute our existing stockholders' percentage of ownership; incur debt and assume liabilities; and incur amortization expenses related to intangible assets or incur large and immediate write- offs. We may not be able to complete any future business combination or collaborations on favorable terms, if at all. If we do complete a business combination or collaboration, we cannot assure you that it will ultimately strengthen our competitive position or that it will be viewed positively by customers, financial markets or investors. Furthermore, future business combinations could pose numerous additional risks to our operations, including, but not limited to problems integrating the businesses, products or technologies, increases to our expenses, the failure to discover undisclosed liabilities of an acquired asset or transaction partner, diversion of management' s attention from their day- to- day responsibilities, and harm to our operating results or financial condition. We may not be able to complete any collaboration or business combination or effectively integrate the operations, products or personnel gained through any such business combination. We depend on information technology and computer systems to operate our business; our business and operations would suffer in the event of any failures or interruptions of our computer system, such as a data breach or cybersecurity incident. Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. Cybersecurity attacks are evolving and include, but are not limited to, malicious software, attempts to gain unauthorized access to data and other electronic security breaches that could lead to disruptions in systems, misappropriation of our confidential or otherwise protected information, and corruption of data. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development ~~40programs~~ -- **programs** . For example, the loss of clinical trial data from completed, ongoing or planned clinical trials 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 results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability or damage to our reputation, and the further development of our product candidates could be delayed. Likewise, data privacy or security breaches by employees or others may pose a risk that sensitive data, including our intellectual property, trade secrets or personal information of our employees, patients or other business partners, may be exposed to unauthorized persons or to the public. There can be no assurance that our efforts, or the efforts of our partners and vendors, will prevent service interruptions, or identify breaches in our systems, that could adversely affect our business and operations and / or result in the loss of critical or sensitive information, which could ~~result~~ **46result** in financial, legal, business or reputational harm to us. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other related breaches. Climate change, environmental, social and governance and sustainability initiatives may result in regulatory or structural industry changes that could require significant operational changes and expenditures, reduce demand for the Company' s products and adversely affect our business, financial condition, and results of operations. Climate change, environmental, social and governance (**"** ESG **"**) and sustainability are a growing global movement. Continuing political and social attention to these issues has resulted in both existing and pending international agreements and national, regional and local legislation, regulatory measures, reporting obligations and policy changes. Also, there is increasing societal pressure in some of the areas where we operate, to limit greenhouse gas emissions as well as other global initiatives. These agreements and measures may require, or could result in future legislation, regulatory measures or policy changes that would require operational changes or increase expenses. Furthermore, increasing attention to climate change, ESG and sustainability has resulted in governmental investigations, and public and private litigation, which could increase our costs or otherwise adversely affect our business or results of operations. In addition, organizations that provide information to investors on corporate governance and related matters have developed ratings processes for evaluating companies on their approach to ESG matters. Such ratings are used by some investors to inform their investment and voting decisions. Unfavorable ESG ratings may lead to increased negative investor sentiment toward us, which could have a negative impact on the price of our securities and our access to and costs of capital. Any or all of these ESG and sustainability initiatives may result in significant operational changes and expenditures, cause us reputational harm, and could materially adversely affect our business, financial condition, and results of operations. Business disruptions could seriously harm our future revenues and financial condition and increase our costs and expenses. Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self- insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third- party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of product candidates could be disrupted if the operations of these suppliers are affected by a man- made or natural disaster or other business interruption. The ultimate impact on us, our significant suppliers and our general infrastructure of being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster. Our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel. ~~41We~~ **We** are highly dependent upon **members of our executive management team** ~~Steven Fruchtman, M. D., President~~ and **other employees. As discussed elsewhere in this Annual Report, Nora Brennan was appointed to serve as our Interim Chief Financial Officer in February 2025 and Iain Dukes, our Executive Chairman, will step in to serve as our Interim** Chief Executive Officer, **effective as of close of business on** ~~Mark~~

~~Guerin, C. P. A., Chief Operating and Chief Financial Officer, and Victor Moyo, M. D., Chief Medical Officer, and our other~~ -- **the date of this Annual Report, in connection with Dr. Cautreels' retirement from such role. Both Ms. Brennan and Dr. Dukes have provided services to the Company prior to these changes, which we believe will help minimize the transition period inherent in changes to** executive ~~officers~~ **management; however, no assurances can be provided** . Although we have employment agreements with **our executive officers** ~~the persons named above~~ , these agreements are at- will and do not prevent such persons from terminating their employment with us at any time. We do not maintain" key person" insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. ~~The~~ **47The widespread outbreak of a communicable disease, such as the** recent COVID- 19 pandemic ~~, or the widespread outbreak of any other communicable disease~~ , could adversely impact our business, including our clinical trials, drug manufacturing and nonclinical activities. We face risks related to epidemics and other outbreaks of communicable diseases, such as the recent COVID- 19 pandemic, which could adversely impact our business, including our clinical trials and clinical trial operations. These potential disruptions may include but are not limited to delays or difficulties in clinical site initiation and patient recruitment, patient withdrawals, postponement of planned clinical or preclinical studies, redirection of site resources from studies, study modification, suspension, or termination, the introduction of remote study procedures and modified informed consent procedures, study site changes, direct delivery of investigational products to patient homes requiring state licensing, study deviations or noncompliance, diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials, delays in receiving approval from local regulatory authorities to initiate our planned clinical trials, delays in obtaining supplies of our product candidate or other materials that may be necessary for the conduct of our development program, delays in obtaining necessary inspections from the FDA or other regulatory authorities, changing laws and regulations, and changes or delays in site monitoring. The foregoing may require that we consult with relevant review and ethics committees, IRBs, and the FDA **or foreign regulatory authorities** . The foregoing may also impact the integrity of our study data, which may not become evident until later in our development programs. The effects of a health crisis may also increase the need for clinical trial patient monitoring and regulatory reporting of adverse effects **. Risk Factors Relating to the MergerThere is no guarantee that the Merger will increase stockholder value. As discussed elsewhere in this Annual Report, in April 2024, we merged with Trawsfynydd. We cannot guarantee that implementing the Merger and related transactions will not impair stockholder value or otherwise adversely affect our business. The Merger continues to pose integration challenges between our businesses and management teams, which could result in management and business disruptions, any of which could harm our results of operation, business prospects, and impair the value of the Merger to our stockholders. Stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger, including the issuance of our common stock upon conversion of all outstanding shares of our Series C Preferred issued in the Merger and Financing. If we are unable to realize the full strategic and financial benefits currently anticipated from the Merger, stockholders will have experienced substantial dilution of their ownership interests without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent we are able to realize only part of the strategic and financial benefits currently anticipated from the Merger. The failure to successfully integrate the businesses of Onconova and Trawsfynydd in the expected timeframe would adversely affect Traws Pharma' s future results. Our ability to successfully integrate the operations of Onconova and Trawsfynydd will depend, in part, on our ability to realize the anticipated benefits from the Merger. If we are not able to achieve these objectives within the anticipated time frame, or at all, the anticipated benefits of the Merger may not be realized fully, or at all, or may take longer to realize than expected, and the value of our common shares may be adversely affected. In addition, the integration of the Company' s and Trawsfynydd' s respective businesses has been, and will likely continue to be, a time- consuming and expensive process. Proper planning and effective and timely implementation will be critical to avoid any significant disruption to Traws Pharma' s operations. It is possible that the continuing integration process could result in the loss of key employees, the disruption of our ongoing business or the identification of inconsistencies in standards, controls, procedures and policies that adversely affect our ability to maintain relationships with suppliers, distributors, creditors, lessors, clinical trial investigators or managers or to achieve the anticipated benefits of the Merger. Delays encountered in the integration process could have a material adverse effect on Traws Pharma' s revenues, expenses, operating results and financial condition, including the value of its common shares. 48Our future results will suffer if we do not effectively manage our expanded operations. As a result of the Merger, we have become a more diversified company and our business has become more complex. There can be no assurance that we will effectively manage the increased complexity without experiencing operating inefficiencies or control deficiencies. Significant management time and effort is required to effectively manage our increased complexity and our failure to successfully do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects. We expect to incur substantial expenses related to the integration of Trawsfynydd. We have incurred, and expect to continue to incur, substantial expenses in connection with the Merger and the integration of Trawsfynydd. There are a large number of processes, policies, procedures, operations, technologies and systems that must be integrated, including purchasing, accounting and finance, billing, payroll, research and development, marketing and benefits. Both the Company and Trawsfynydd incurred significant transaction expenses in connection with the drafting and negotiation of the Merger Agreement, the Stock Purchase Agreement and the related ancillary agreements and significant severance expenses in connection with the reduction of employees in April 2024. While we have assumed that a certain level of expenses will be incurred, there are many factors beyond our control that could affect the total amount or the timing of the integration expenses. Moreover, many of the expenses that will be incurred are, by their nature, difficult to estimate accurately. These integration expenses likely will result in our taking significant charges**

against earnings following the completion of the Merger, and the amount and timing of such charges are uncertain at present . Risks Related to Our Dependence on Third PartiesWe rely on third parties to conduct our preclinical and clinical trials. 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 our product candidates. We have relied upon and plan to continue to rely upon third- party CROs to monitor and manage data for our ongoing preclinical and clinical programs, as well as clinical trial sites for the conduct of our clinical trials. There is no guarantee that we will be able to maintain the relationships with these third parties, that we will be able to enter into additional relationships, or that we will be able to find replacement sites or CROs should any of our agreements terminate. We rely on these parties for execution of our preclinical and clinical trials, and we control only some aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and sites does not relieve us of our regulatory responsibilities. We also rely on third parties to assist in conducting our preclinical studies in accordance with Good Laboratory Practices ~~, or~~ **(“** GLP ~~,~~ **”)** and the Animal Welfare Act requirements. We, our clinical trial sites, and our CROs are required to comply with federal regulations and current GCPs, which are international standards meant to protect the rights and health of patients that are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area **, the Australian Human Research Ethics Committee** and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our sites or CROs fail to comply with applicable GCPs, 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 or they may also face regulatory enforcement. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. Failure to comply with these regulations may require us to repeat preclinical and clinical trials, which would delay the regulatory approval process. We may also face liability ~~42and~~ -- **and** / or regulatory enforcement action should any of the third parties that we rely upon fail to comply with legal and / or regulatory requirements. Our CROs and the employees at clinical sites are not our employees, and except for remedies available to us under our agreements with such CROs and sites, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. If CROs or sites do not successfully carry out their ~~contractual~~ **49contractual** duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Moreover, while we are required to monitor the activities of third parties providing services on our behalf, there is no guarantee that we will be able to detect activities that do not comply with the applicable regulatory requirements or our study plans and protocols. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. Because we have relied on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third- party providers. To the extent we are unable to identify and successfully manage the performance of third- party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our CROs and clinical trial sites, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. If we lose our relationships with CROs, our drug development efforts could be delayed. We rely on third- party vendors and CROs for preclinical studies and clinical trials related to our drug development efforts. Switching or adding additional CROs would involve additional cost and requires management time and focus. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. We may also terminate a CRO for a number of reasons. Identifying, qualifying and managing performance of third- party service providers can be difficult, time consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. If any of our relationships with our third- party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. We have limited experience manufacturing our product candidates on a large clinical or commercial scale and have no manufacturing facility. We are dependent on third- party manufacturers for the manufacture of our product candidates for clinical trials as well as on third parties for our supply chain, and if we experience problems with any third parties, the manufacturing of our product candidates or products could be delayed. We do not own or operate facilities for the manufacture of our product candidates. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. We currently rely on a single source CMO, for the chemical manufacture of active pharmaceutical ingredient for each of our product candidates. To meet our projected needs for clinical supplies to support our activities through regulatory approval and commercial manufacturing, the CMOs with whom we currently work will need to increase the scale of production. We may need to identify additional CMOs for continued production of supply for our product candidates. In addition, regulatory authorities enforce cGMP through periodic inspections and remote regulatory assessments of active pharmaceutical ingredient (**“** API **”**) and drug product

manufacturing sites, quality control contract laboratories and distribution centers. If we or our CMO fail to comply with applicable cGMPs, the manufacturing data generated and subsequent API lots and drug product batches in ~~43our~~ -- **our** supply chain may be deemed unreliable. Clinical trials using the product candidate may also be deemed to be unreliable. As such, the FDA or comparable foreign regulatory authorities may require us to perform additional API and drug product manufacturing and manufacturing development before continuing clinical trials or approving our marketing applications, may require us to conduct additional studies, and any such deficient product we supply to any collaboration partner may subject us to certain obligations under relevant agreements. We or our contractors may also face enforcement actions. We have not yet qualified alternate suppliers in the event the current ~~CMOs~~ -- **CMO** we utilize ~~are~~ **is** unable to ~~scale~~ **50scale** production, or if we otherwise experience any problems with them. By example, our third- party manufacturers may not be able to obtain sufficient quantities of any necessary supplies such as due to changing trade policies or supply shortages. Although alternative third- party suppliers with the necessary manufacturing and regulatory expertise and facilities exist, as we have experienced with respect to our existing CMOs, it could be expensive and take a significant amount of time to arrange for alternative suppliers. If we are unable to arrange for alternative third- party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of our product candidates, or market or distribute them. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, including a failure to synthesize and manufacture our product candidates or any products we may eventually commercialize in accordance with our specifications, and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMPs and similar foreign standards. Any failure by our third- party manufacturers to comply with cGMPs or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for the FDA to issue a warning letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure of outside supplies of the product candidate, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention of product, refusal to permit the import or export of products, injunction, or imposing civil and criminal penalties. Noncompliance with the applicable manufacturing requirements may also require costly corrective and preventative actions. The manufacturing facilities that we use must also be approved by the FDA under a pre- approval inspection. If the facilities cannot pass these inspections, the FDA will not approve our marketing application. These manufacturing facilities will further be subject to continuing regulatory oversight and inspection, and, thus, they must continue to expend time and resources to maintain regulatory compliance. **We have entered into certain related party transactions and may continue to rely on related parties for certain development and support activities. We have entered into, and may continue to enter into, transactions with related parties for certain development and support activities. For example, we have entered into master research and development agreements with ChemDiv, Inc. and Viriom, Inc., both of which are related parties, to provide certain research and development related services for virology product candidates. For additional information related to these and other related party transactions, please see Note 12, Research and Development Arrangements and Related Party Transactions, to our consolidated financial statements included in Part IV in this Annual Report. Such related party transactions may not have been entered into on an arm' s- length basis, and we may have achieved more favorable terms because such transactions were entered into with our related parties. We rely on, and will continue to rely on, our related parties to maintain these services. If the pricing for these services changes, or if our related parties cease to provide these services, including by terminating agreements with us, we may be unable to obtain replacements for these services on the same terms without disruption to our business. This could have a material effect on our business, results of operations and financial condition.** Risks Related to Our Intellectual PropertyWe could be required to incur significant expenses to perfect our intellectual property rights, and our intellectual property rights may be inadequate to protect our competitive position. If we are unable to protect our intellectual property rights, our competitive position could be harmed. We depend on our ability to protect our proprietary technology. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our commercial success will depend in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. Where we ~~have~~ **51have** the right to do so under our license agreements, we seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and products that are important to our business. The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patents, including those patent rights licensed to us by third parties, are highly uncertain. The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the United States. The ~~44rights~~ -- **rights** already granted under any of our currently issued patents and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be adversely affected. With respect to patent rights, we do not know whether any of the pending patent applications for any of our licensed compounds will

result in the issuance of patents that protect our technology or products, or if any of our issued patents will effectively prevent others from commercializing competitive technologies and products. Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Further, the examination process may require us or our licensor to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or have licensed from third parties may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our patented technology, trademarks and other intellectual property rights is expensive, difficult and may in some cases not be possible. In some cases, it may be difficult or impossible to detect third- party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult. Even if patents are granted that cover commercially valuable **molecules or** compounds, we may decide to allow such patents to lapse, or if in- licensed, return the patents to the licensor. The effects of doing so are uncertain. In the case of returning granted patents to a licensor, we may encounter a scenario in which we need the patents in the future and are unable to obtain a new license to such patents on commercially reasonable terms or at all. The licensor may license the returned patents to a competitor, who may then enforce the patents against us. ~~In the first quarter of 2023, we returned a portion of the patents that we in- licensed from Temple University back to Temple. The long- term economic effects of doing so are uncertain.~~ We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful. Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. This can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or a court may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. ~~Third~~ **52Third** parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could harm our business. Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates, and to use our proprietary technologies without infringing the proprietary rights of third parties. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference or derivation proceedings ~~45before --~~ **before** the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party' s intellectual property rights, we could be required to obtain a license from such third party to continue developing and commercializing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we are able to obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business. We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. Many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, including each member of our senior management, executed proprietary rights, non- disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee' s former employer. Risks Related to Ownership of Our **SecuritiesWe may be required to raise additional financing by issuing new securities with terms or rights superior to those of our existing securityholders, which could adversely affect the market price of shares of** ~~Common~~ **common** ~~Stock~~ **stock** and ~~Common Stock WarrantsWe~~ **our business. We will require additional financing to fund future operations, including for research and development, clinical trials, expansion in current and new markets, development and acquisition, capital costs and the costs of any necessary implementation of technological innovations or alternative technologies. We** may not **be able to obtain financing on favorable terms, if at all. If we raise additional funds by issuing equity securities, the percentage ownership of our current stockholders will be reduced, and the holders of the new equity securities may have rights superior to those of our existing securityholders, which could adversely affect the market price of our common stock and the voting power of shares of our common stock. If we raise additional funds by issuing debt securities, the holders of these debt securities would similarly have**

some rights senior to those of our existing securityholders, and the terms of these debt securities could impose restrictions on operations and create a significant interest expense for us which could have a materially adverse effect on our business. If we are unable to comply with the ~~Nasdaq~~ continued listing requirements ~~. If we are unable to comply with the continued listing requirements~~ of the Nasdaq Capital Market, our ~~Common~~ **common** ~~Stock~~ **stock** could be delisted, which could affect our common stock' s market price and liquidity and reduce our ability to raise capital. **Our common stock is listed** ~~We are required to meet certain qualitative and financial tests to maintain the listing of our securities~~ on the Nasdaq Capital Market (**“** Nasdaq **”**) ~~. As of March 25~~, ~~2024~~ **a national securities exchange** , **which imposes** ~~we were not in compliance with the Nasdaq~~ continued listing requirements ~~related~~ **with respect** to **issuers whose securities are listed on Nasdaq. If we fail to satisfy the continued listing standards, such as, for example, Nasdaq’ s** minimum bid price **requirement or stockholders equity requirements, Nasdaq may issue a non- compliance letter or initiate delisting proceedings. 53As previously disclosed, on November 20, 2024, we received a letter from the staff (the “ Staff ”) of the Listing Qualifications Department of Nasdaq notifying us that the Company was no longer in compliance with the minimum $ 2. 5 million stockholders’ equity requirement for continued listing on Nasdaq as set forth in Listing Rule 5550 (b) (1) (the “ Rule ”). After a hearing, the Nasdaq Hearings Panel granted the Company an exception until February 18, 2025 to demonstrate compliance with the Nasdaq listing rules** . On ~~September~~ **February** 25, ~~2023~~ **2025** , we received a letter from Nasdaq ~~indicating~~ **confirming** that ~~we failed to comply~~ **the Company had regained compliance** with the **Rule. Pursuant to** ~~minimum bid price requirement of Nasdaq~~ Listing Rule ~~5550~~ **5815** (**d) (4) (B), the Company will be subject to** a **mandatory panel monitor for a period of one year from the date of such letter. If, within that one- year monitoring period, the Staff finds that the Company is no longer in compliance with the Rule, then, notwithstanding Rule 5810 (c**) (2), ~~which requires that companies listed on Nasdaq maintain~~ **we will not be permitted to provide the Staff with** a **plan** ~~minimum closing bid price~~ of ~~at least $ 1. 00 per share. Under Nasdaq Listing~~ **compliance with respect to such deficiency and the Staff will not be permitted to grant additional time for us to regain compliance with respect to such deficiency, nor will we be afforded an applicable cure or compliance period pursuant to** Rule 5810 (c) (3) **. Instead** ~~(A)~~ , ~~we had~~ **the Staff will issue** a **Delist Determination Letter and we** ~~180 calendar day grace period, or until March 25, 2024, to regain compliance by meeting the continued listing standard. The continued listing standard~~ will **have an opportunity to request** ~~be met if the Company’ s common stock has~~ a **new hearing** ~~minimum closing bid price of at least $ 1. 00 per share for a minimum of ten consecutive business days during the 180- calendar day grace period. We did not regain compliance~~ with the ~~minimum bid price requirement by March 25, 2024. On March 27, 2024, we received a letter from Nasdaq granting the Company a second 180 calendar day period to regain compliance under Nasdaq Listing Rule 5810 (c) (3) (A), or until September 23, 2024. Their determination to grant the second compliance period was based on our meeting the continued listing requirement for market value of publicly held shares and all other~~ initial ~~listing standards for The Nasdaq Capital Market, except for the minimum bid price requirement, and our notification to Nasdaq of its intention to cure the minimum bid price deficiency during the second compliance period, by effecting a reverse stock split, if necessary. If we do not regain compliance by September 25, 2024, Nasdaq will provide notice that the Company’ s common stock will be delisted. At that time, we may appeal the Nasdaq staff’ s determination to a Nasdaq~~ Hearings Panel ~~. We intend to monitor the closing bid price of the Company’ s common stock and continue to consider our~~ **or a newly convened Hearings Panel if the initial Hearings Panel is** ~~available~~ **unavailable** ~~options to resolve the noncompliance with the minimum bid price requirement. 46There can be no assurance that we will be able to regain compliance with the minimum bid price requirement or will otherwise be in compliance with other Nasdaq listing criteria~~ . If we are unable to maintain compliance with the continued listing requirements of Nasdaq, our common stock could be delisted, making it could be more difficult to buy or sell our securities and to obtain accurate quotations, and the price of our securities could suffer a material decline. Delisting could also impair our ability to raise capital **. If we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock may decline. As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. In addition, we are required to furnish a report by management on the effectiveness of our internal control over financial reporting, pursuant to Section 404 of the Sarbanes- Oxley Act. As discussed elsewhere in this Annual Report, as of December 31, 2024, based on an analysis completed by management, our internal controls were not effective due to the existence of material weaknesses. The process of designing, implementing and testing the internal control over financial reporting required to comply with this obligation is time- consuming, costly and complicated. If we identify material weaknesses in our internal control over financial reporting (as we have for the period covered by this Annual Report), if we are unable to comply with the requirements of Section 404 of the Sarbanes- Oxley Act in a timely manner, or if we are unable to assert that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could decline, and we could also become subject to investigations by the stock exchange on which our common stock is listed, the Commission or other regulatory authorities, which could require additional financial and management resources. Future issuances of stock or other securities could dilute the holdings of stockholders and could materially affect the price of the shares of our common stock. As discussed elsewhere in this Annual Report, we will need to obtain additional financing in the future to carry out our business objectives. We may do so through the sale and issuance of shares of our common stock or securities convertible or exercisable for shares of our common stock. Additionally, there are currently warrants to purchase an aggregate of 5, 848, 082 shares of our common stock outstanding and shares of Series C Preferred Stock convertible into an aggregate of 2, 959, 158 shares of our common stock outstanding. Any issuance of shares of our common stock, including upon the exercise or conversion of outstanding warrants and shares of Series C Preferred, respectively, or issuance of securities exercisable for or convertible into shares of our common stock, will result in the**

dilution of the ownership interests of our existing stockholders. Additionally, the issuance of a significant number of shares of our common stock could result in a decrease in the price of our common stock. 54We have used and intend to continue to use equity incentives for employees, advisors, directors, key consultants and select affiliates. Any issuance of stock upon the conversion of options, restricted stock units and / or other incentive rights will result in the dilution of the ownership interests of our existing stockholders . Our share price and the liquidity of our stock may be volatile and result in substantial losses to our stockholders. The trading price of our common stock is highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition, the stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of these risks or any of a broad range of other risks could have a dramatic and material adverse impact on the market price of our common stock. We may be subject to securities litigation, which is expensive and could divert management attention. In the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management' s attention from other business concerns, which could seriously harm our business **. We do not anticipate paying any cash dividends on our capital stock in the foreseeable future. Accordingly, stockholders must rely on capital appreciation, if any, for any return on their investment. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future** . Some provisions of our charter documents and Delaware law may have anti- takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our Tenth Amended and Restated Certificate of Incorporation, as amended ~~, or~~ **("** Certificate of Incorporation ~~,~~ **")** and Amended and Restated Bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These include provisions that will: ● permit our board of directors to issue up to 5, 000, 000 shares of preferred stock, with any rights, preferences and privileges as they may designate (as of ~~February 29~~ **March 26** , ~~2024~~ **2025** , we had ~~no~~ **7, 397. 893** shares of **Series C** ~~preferred~~ **Preferred** stock issued and outstanding); ● provide that all vacancies on our board of directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum; ● require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent; ● provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder' s notice; ● not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common **55** ~~stock entitled to vote in any election of directors to elect all of the directors standing for election; and ● provide that special meetings of our stockholders may be called only by the board of directors or by such person 47~~