Risk Factors Comparison 2024-04-15 to 2023-03-30 Form: 10-K

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An investment in our common stock is speculative and illiquid and involves a high degree of risk including the risk of a loss of your entire investment. You should carefully consider the risks and uncertainties described below and the other information contained in this report and our other reports filed with the Securities and Exchange Commission. The risks set forth below are not the only ones facing us. Additional risks and uncertainties may exist that could also adversely affect our business, operations and financial condition. If any of the following risks actually materialize, our business, financial condition and / or operations could suffer. In such event, the value of our common stock could decline, and you could lose all or a substantial portion of the money that you pay for our common stock. Summary Risk Factors Our business is subject to numerous risks and uncertainties. The following summarizes key risks and uncertainties that could materially adversely affect us. You should read this summary together with the more detailed risk factors contained below. ● we have never generated any product revenues; ● we expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability; ● our recurring losses from operations have raised substantiated doubt regarding our ability to continue as a going concern; ● we are heavily dependent on the success of brilaroxazine, our only advanced product candidate, which is still under clinical development, and if brilaroxazine does not receive regulatory approval or is not successfully commercialized, our business will be harmed; ● ~~the~~ **we face risks related to health epidemics and outbreaks, including** COVID- 19 ~~outbreak and global pandemic~~ or ~~other~~ future health crises, pandemics or other events **, which** could adversely impact our business, including our clinical trials; ● ~~we will~~ **raising additional funds by issuing securities may cause dilution to existing stockholders, and raising funds through lending and licensing arrangements may restrict our operations or** require **us to relinquish proprietary rights; ● the restatement of our previously issued financial statements and associated analysis and ongoing remedial measures have been time consuming and expensive and could expose us to** additional ~~capital to fund~~ **risks that could materially adversely affect** our **financial position, results of** operations ~~,~~ and ~~if~~ **cash flows; ● in connection with the preparation of our financial statements for the fiscal year ended December 31, 2023, we identified material weaknesses in our internal control over financial reporting and clinical trial expenses. If** we fail to ~~obtain necessary~~ **maintain an effective system of internal control over** ~~financing~~ **financial reporting and clinical trial expenses** , we may not be able to **accurately report** ~~complete the development and commercialization of brilaroxazine or~~ **our** ~~RP1208~~ **financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our Common Stock and listed Warrants** ; ● if the interpretations, estimates or judgments we use to prepare our financial statements prove to be incorrect, we may be required to restate our financial results, which could have a number of material adverse effects on us; ● clinical trials are very expensive, time- consuming, difficult to design and implement and involve an uncertain outcome; ● we face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively; ● we do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of brilaroxazine, RP1208 and any future product candidate; ● we rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business; ● 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 sufficiently broad, we may not be able to compete effectively in our markets; ● **our officers, directors, and principal stockholders exercise significant control over our Company, and will control our Company for the foreseeable future, including the outcome of matters requiring stockholder approval. ●** if we fail to maintain compliance with the requirements of The Nasdaq Capital Market for continued listing, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted; ● certain of our warrants are accounted for as liabilities and the changes in value of such warrants could have a material effect on our financial results; ~~● we are an~~ **and** ~~emerging growth company within the meaning of the Securities Act of 1933, as amended (the " Securities Act ") and have taken advantage of certain exemptions from disclosure requirements available to emerging growth companies; this could make our securities less attractive to investors and may make it more difficult to compare our performance with other public companies;~~ ● we do not currently intend to pay dividends on our common stock in the foreseeable future, and consequently, any gains from an investment in our common stock will likely depend on appreciation in the price of our common stock ~~; and ● our officers, directors, and principal stockholders exercise significant control over our Company, and will control our Company for the foreseeable future, including the outcome of matters requiring stockholder approval~~ . Risks Related to Our Business, Financial Position and Capital Requirements We have never generated any product revenues. We are a ~~clinical~~ **late** - stage ~~biopharmaceutical~~ -- **pharmaceutical** company. Although we were formed in May 2006, to date, we have not generated any product revenues from our product candidates currently in development. We have not yet demonstrated an ability to successfully complete a ~~large~~ **full pre** - **marketing development program** ~~scale, pivotal clinical trial~~ , obtain marketing approval, manufacture a commercial scale product, or arrange for a third- party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, we have no meaningful operations upon which to evaluate our business and predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products. Our ability to generate revenue and become profitable depends upon our ability to successfully complete the development of our product candidates, brilaroxazine for the treatment of schizophrenia, respiratory / pulmonary diseases such as Pulmonary Arterial Hypertension, or PAH, and Idiopathic Pulmonary Fibrosis, or IPF, and for other neuropsychiatric diseases, such as

bipolar disorder, or BD, major depressive disorder, or MDD, Alzheimer' s psychosis / agitation, or AD, Parkinson' s psychosis, or PD, and attention deficit hyperactivity disorder, or ADHD / ADD, and RP1208 for the treatment of depression and obesity, and obtain the necessary regulatory approvals for their commercialization. We have never been profitable, have no products approved for commercial sale and to date have not generated any revenue from product sales. Even if we receive regulatory approval for the commercialization of brilaroxazine, we do not know when this product candidate will generate revenue, if at all. RP1208 is in pre- clinical development. Our ability to generate product revenue depends on a number of factors, including our ability to: ● successfully develop, complete pre- clinical and clinical trials and obtain regulatory approval for the marketing of our product candidates; ● set an acceptable price for our product candidates and obtain coverage and adequate reimbursement from third- party payors; ● establish sales, marketing and distribution systems for our product candidates; ● add operational, financial and management information systems and personnel, including personnel to support our clinical, manufacturing and planned future commercialization efforts and operations; ● initiate and continue relationships with third- party manufacturers and have commercial quantities of our product candidates manufactured at acceptable cost levels; ● attract and retain an experienced management and advisory team; ● achieve broad market acceptance of our products in the medical community and with third party payors and consumers; ● launch commercial sales of our products, whether alone or in collaboration with others; and ● maintain, expand and protect our intellectual property portfolio. Because of the numerous risks and uncertainties associated with product development, 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. Our expenses could increase beyond expectations if we are required by the FDA, and comparable non- U. S. regulatory authorities, to perform studies or clinical trials in addition to those that we currently anticipate. Even if our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of these products. If we cannot successfully execute any one of the foregoing, our business, prospects and results of operations may be adversely affected. We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability. Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. We have never generated any revenues and cannot estimate with precision the extent of our future losses. We do not currently have any products that are available for commercial sale and we may never generate revenue from selling products or achieve profitability. We expect to continue to incur substantial and increasing losses through the projected commercialization of brilaroxazine and RP1208. For the year ended December 31, ~~2022~~ **2023**, we reported a loss of $ ~~24~~ **39**. 3 million and a negative cash flow from operations of $ ~~19~~ **28**. ~~0~~ **3** million. We had an accumulated deficit of $ ~~91~~ **134**. ~~2~~ **4** million and had cash and cash equivalents of $ ~~18~~ **23**. ~~5~~ **4** million as of December 31, ~~2022~~ **2023**. Brilaroxazine has not been approved for marketing in the United States and may never receive such approval. Although RP1208 may be in IND enabling studies for depression and may be in animal efficacy studies for obesity within a short time frame following the receipt of adequate additional financing, it is not currently in an IND- enabling study or animal efficacy study, respectively, and may never meet the requirements for filing an IND. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. Our ability to produce revenue and achieve profitability is dependent on our ability to complete the development of our product candidates, obtain necessary regulatory approvals, and have our product candidates manufactured and successfully marketed. We cannot assure you that we will be profitable even if we successfully commercializes our product candidates. If we do not successfully obtain regulatory approval to market our product candidates, our revenues will be dependent, in part, upon, among other things, the size of the markets in the territories for which we gain regulatory approval, the number of competitors in such markets, the accepted price for our product candidates and whether we own the commercial rights for that territory. If the indication approved by regulatory authorities is narrower than we expects, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of our product candidates, even if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Failure to become and remain profitable may adversely affect the timing of our clinical results and our ability to raise capital and continue operations. We expect our research and development expenses to be significant in connection with the following ongoing and planned research: ● **further** ~~Phase 3~~ studies **in connection with our clinical development plan** for brilaroxazine for ~~the treatment of~~ schizophrenia **, including our ongoing 1- year open label extension (OLE) trial evaluating long- term safety and tolerability, our planned registrational RECOVER- 2 Trial**; ● Phase 2 studies for the treatment of PAH, IPF, BD, MDD, AD, PD, ADHD / ADD; ● pre- clinical studies and clinical studies for RP1208 for the treatment of depression and obesity. Further, we will require additional capital to proceed with the planned research described above. See " Risks Related to Our Business, Financial Position and Capital Requirements — We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of brilaroxazine and RP1208. " In addition, if we obtain regulatory approval for brilaroxazine, we expect to incur increased sales and marketing expenses. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have an adverse effect on our financial position and working capital. Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern. We have recognized recurring losses, and as of December 31, ~~2022~~ **2023**, had an accumulated deficit of $ ~~91~~ **134**. ~~2~~ **4** million. We anticipate operating losses to continue for the foreseeable future due to, among other things expenses related to ongoing activities to research, develop and commercialize our product candidates. We expect the cash and cash equivalents of $ ~~18~~ **23**. ~~5~~ **4** million at December 31, ~~2022~~ **2023** to be insufficient to meet our operating and capital requirements at least 12 months from the filing of this Annual Report on Form 10- K. Our forecast of the period of time through which our current financial resources will be adequate to support our operations and the costs to support our general and administrative and research and development activities are forward- looking statements and involve risks and uncertainties. The financial statements do not include any adjustments that might be necessary

should we be unable to continue as a going concern. As further described below, our ability to continue as a going concern is dependent on our ability to raise additional working capital through public or private equity or debt financings or other sources, which may include collaborations with third parties as well as disciplined cash spending. Should we be unable to raise sufficient additional capital, we may be required to undertake cost- cutting measures including delaying or discontinuing certain clinical activities. The sale of equity and convertible debt securities may result in dilution to our stockholders and certain of those securities may have rights senior to those of our common stock. If we raise additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these securities or other debt could contain covenants that would restrict our operations. Any other third- party funding arrangement could require us to relinquish valuable rights. The source, timing and availability of any future financing will depend principally upon market conditions, and, more specifically, on the progress of our clinical development programs. Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us, among other things, to delay, scale back or eliminate some or all of our planned clinical trials. These factors among others create a substantial doubt about our ability to continue as a going concern. We are heavily dependent on the success of brilaroxazine, our only advanced product candidate, which is still under clinical development, and if brilaroxazine does not receive regulatory approval or is not successfully commercialized, our business will be harmed. We currently have no products that are approved for commercial sale and may never be able to develop marketable drug products. We expect that a substantial portion of our efforts and expenditures in the foreseeable future will be devoted to brilaroxazine. Our only other product candidate is RP1208, which is in the pre- clinical phase. We do not expect to allocate a significant portion of our efforts or resources to the clinical trials or development of this product candidate in the foreseeable future. Accordingly, our business currently depends heavily on the successful development, regulatory approval and commercialization of brilaroxazine. We cannot be certain that brilaroxazine will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are and will remain subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market brilaroxazine in the United States until we receive approval of a new drug application, or NDA, from the FDA, or in any foreign countries until we receives the requisite approval from such countries. We have not submitted an NDA to the FDA or comparable applications to other regulatory authorities and do not expect to be in a position to do so for the foreseeable future. Obtaining approval of an NDA is an extensive, lengthy, expensive and inherently uncertain process, and the FDA may delay, limit or deny approval of brilaroxazine and our other product candidates for many reasons, including: ● We may not be able to demonstrate that brilaroxazine is safe and effective as a treatment for our targeted indications to the FDA' s satisfaction; ● the FDA may require additional Phase 3 trials of brilaroxazine in schizophrenia, which would increase our costs and prolong its development; ● the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval; ● the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials; ● the contract research organizations, or CROs, that we retain to conduct clinical trials may take actions outside of our control that materially adversely impact our clinical trials; ● the FDA may not find the data from preclinical studies and clinical trials sufficient to demonstrate that the clinical and other benefits of brilaroxazine outweigh its safety risks; ● the FDA may disagree with our interpretation of data from our preclinical studies and clinical trials or may require that we conduct additional studies; ● the FDA may not accept data generated at our clinical trial sites; ● if our NDA is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions; ● the FDA may require development of a risk evaluation and mitigation strategy, or REMS, as a condition of approval; ● the FDA may identify deficiencies in the manufacturing processes or facilities of our third party manufacturers; or ● the FDA may change its approval policies or adopt new regulations. ~~The~~ **We face risks related to health epidemics and outbreaks, including** COVID- 19 ~~outbreak and global pandemic~~ or ~~other~~ future health crises, pandemics or other events **, which** could adversely impact our business, including our clinical trials. ~~Public health crises such as~~ **Disease outbreaks, epidemics and** pandemics ~~or similar outbreaks could adversely impact our business. In December 2019~~ , **including** ~~a novel strain of coronavirus, or~~ COVID- 19, ~~surfaced~~ in ~~Wuhan~~ **regions where we have concentrations of clinical trial sites and other business operations** , ~~China. Since~~ **could adversely affect our business, including by causing significant disruptions in our operations and / or in** ~~then~~ **the operations of manufacturers and CROs upon whom we rely. Disease outbreaks** , **epidemics and pandemics may have negative impacts on our ability to initiate new clinical trial sites, enroll new patients and maintain existing patients who are participating in clinical trials, which may result in increased clinical trial costs, longer timelines and delays in our ability to obtain regulatory approvals of our product candidates, if at all. For example, patient enrollment and recruitment could be delayed due to local clinical trial site protocols designed to protect staff and patients from certain outbreaks, which could delay the expected timelines for data readouts of our preclinical studies and clinical trials. Additionally, general supply chain issues may be exacerbated during disease outbreaks, epidemics or pandemics and may also impact the ability of our clinical trial sites to obtain basic medical supplies used in our trials in a timely fashion, if at all. Moreover, the extent to which disease outbreaks, epidemics and pandemics may impact our business, results of operations and financial position will depend on future developments, which are highly uncertain and cannot be predicted with confidence. New health epidemics or pandemics may emerge that result in similar or more severe disruptions to our business. A future disease outbreak, epidemic or pandemic adversely affects our business, financial condition, results of operations and growth prospects. As a result of the** COVID- 19 ~~has spread globally. As a result of the COVID- 19 outbreak, or similar pandemics~~ **pandemic** ~~or other events, and government response to pandemics or other such events~~ , we have and may in the future experience disruptions that could severely impact our business and clinical trials **. The**

future ~~, including: ● delays or difficulties in enrolling patients in our clinical trials; ● interruption of key clinical trial activities, such as clinical trial site data monitoring and efficacy, safety and translational data collection, processing~~ - **progression** ~~and analyses, due to limitations on travel imposed or recommended by federal, state or local governments, employers and others or interruption~~ of ~~clinical trial subject visits, which may impact~~ the ~~collection and integrity of subject data and clinical study endpoints; ● delays or difficulties in initiating or expanding clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff; ● increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting~~ COVID- 19 **epidemic and** ~~or being forced to quarantine; ● diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites~~ -- **its effects** ~~and hospital staff supporting the conduct of our clinical trials; ● delays or disruptions in preclinical experiments and investigational new drug application- enabling studies due to restrictions of~~ on ~~- site staff and unforeseen circumstances at contract research organizations and vendors; ● interruption or~~ **our business and** ~~delays in the~~ operations **are uncertain** ~~of the FDA and comparable foreign regulatory agencies; and ● interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems~~ . The **impacts of a potential resurgence of** COVID- 19 **could pose** ~~outbreak continues to rapidly evolve. The extent to which~~ the ~~outbreak may impact~~ **risk that we** ~~our~~ - **or our employees, suppliers, future customers in the event of product approval, and others may be restricted or prevented from conducting** business ~~and clinical trials will depend on future developments~~ **activities for indefinite or intermittent periods of time** , **including** ~~which are highly uncertain and cannot be predicted with confidence, such~~ as **a result** ~~the ultimate geographic spread~~ of ~~the disease~~ **employee health and safety concerns** , ~~the duration of the outbreak~~ **shutdowns, shelter in place orders** , travel restrictions and **other** actions ~~to contain the outbreak~~ **and restrictions that may be prudent or required by governmental authorities. This could disrupt** ~~or~~ **our** ~~treat its~~ **ability to operate our business, including producing drug product and administering our preclinical and clinical studies. In addition, fluctuations in demand and other implications associated with the COVID- 19 pandemic have resulted in, and could continue resulting in, certain supply chain constraints and challenges in the broader markets and economy generally, which could** impact ~~, such as social distancing and quarantines or our lock- downs in the United States and other countries,~~ business ~~closures or business disruptions~~ and **supply sources** ~~the effectiveness of actions taken in the United States and other countries to contain and treat the disease~~ . We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of brilaroxazine or RP1208. We expect to spend substantial amounts to complete the development of, seek regulatory approvals for, and commercialize brilaroxazine and RP1208. We will require additional capital to complete the development and potential commercialization of brilaroxazine for the treatment of schizophrenia and to continue the development of brilaroxazine for PAH, IPF, BD, MDD, AD, PD, ADHD / ADD and other potential indications, and to continue the development of RP1208 for the treatment of depression and obesity. No assurance can be given that such additional capital will be available on terms acceptable to us, if at all. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our planned development programs or any future commercialization efforts. In addition, attempting to secure additional financing may divert the time and attention of our management from day- to- day activities and harm our product candidate development efforts. Because the length of time and activities associated with successful development of brilaroxazine and RP1208 is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near and long- term, will depend on many factors, including, but not limited to: ● the initiation, progress, timing, costs and results of our planned clinical trials for brilaroxazine and pre- clinical research for RP1208; ● the outcome, timing and cost of meeting regulatory requirements established by the FDA, the European Medicines Agency, or EMA, and other comparable foreign regulatory authorities; ● the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights; ● the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us with respect to brilaroxazine, RP1208 or any future product candidates; ● the effect of competing technological and market developments; ● the cost and timing of completion of commercial- scale manufacturing activities; ● the cost of establishing sales, marketing and distribution capabilities for brilaroxazine, RP1208 or any future product candidates, in regions where we choose to commercialize our products on our own; and ● the initiation, progress, timing and results of our commercialization of brilaroxazine, RP1208 or any future product candidates, if approved for commercial sale. We cannot be certain that such funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of brilaroxazine or RP1208 or potentially discontinue operations. Raising additional funds by issuing securities may cause dilution to existing stockholders, and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights. We expect that significant additional capital will be needed in the future to continue our planned operations. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, strategic alliances and license and development agreements in connection with any collaborations. We do not have any committed external source of funds. To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect then- existing stockholders' interests. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. Any debt

financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem our shares or make investments. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise develop and market ourselves. We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations. As of December 31, ~~2022~~ **2023**, we had ~~ten~~ **fifteen** employees, and we are highly dependent on our management personnel, especially Laxminarayan Bhat, our Chief Executive Officer and Narayan Prabhu, our Chief Financial Officer. We expect to hire a significant number of additional employees for our managerial, clinical, scientific, operational, sales and marketing teams. We may have operational difficulties in connection with identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management has no prior experience in managing these growth activities and may need to divert a disproportionate amount of our attention away from our day- to- day activities and devote a substantial amount of time to such activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and / or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize brilaroxazine and RP1208 and compete effectively will depend, in part, on our ability to effectively manage any future growth. Many of the other pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high- quality candidates and consultants than what we have to offer. If we are unable to continue to attract and retain high- quality personnel and consultants, the rate and success at which we can discover and develop product candidates and our business will be limited. We are subject to state laws in California that require gender and diversity quotas for boards of directors of public companies headquartered in California. In September 2018, California enacted SB 826, requiring public companies headquartered in California to maintain minimum female representation on their boards of directors as follows: by December 31, 2019, public company boards must have a minimum of one female director; by December 31, 2021, public company boards with five members will be required to have at least two female directors, and public company boards with six or more members will be required to have at least three female directors. On May 13, 2022, the Los Angeles Superior Court declared SB 826 unconstitutional and, although the California Secretary of State has directed counsel to file an appeal of the decision, the State of California is currently precluded from enforcing SB 826 **. The California Secretary of State has appealed the order and such appeal is currently pending. On September 16, 2022, the appellate court ruled to temporarily stay enforcement of the trial court' s order, which prevented the California Secretary of State from collecting diversity data on corporate disclosure forms pursuant to SB 826, pending a further order of the appellate court. On December 1, 2022, the appellate court vacated the temporary stay order and on February 3, 2023, a record on appeal was filed and such appeal is currently pending. To the extent that this ruling of the appellate court permits the Secretary of State of California to collect and report diversity data, we may be required to comply with additional disclosure requirements. However, ultimate enforceability of SB 826 remains uncertain** . Additionally, on September 30, 2020, California enacted AB 979, requiring public companies with principal executive offices in California to each have at least one director from an underrepresented community based on ethnicity and sexual orientation by December 31, 2021. By December 31, ~~2022~~ **2023**, each of these companies will be required to have at least two directors from such underrepresented communities if such company has more than four but fewer than nine directors, or at least three directors from underrepresented communities if the company has nine or more directors. On April 1, 2022, the Los Angeles Superior Court declared AB 979 unconstitutional and, although the California Secretary of State has filed a notice of appeal in the case, the State of California is currently precluded from enforcing AB 979. **On June 6, 2022, a notice of appeal was filed. On September 16, 2022, the appellate court ruled to temporarily stay enforcement of the trial court' s order, which prevented the California Secretary of State from collecting diversity data on corporate disclosure forms pursuant to AB 979, pending a further order of the appellate court. On December 1, 2022, the appellate court vacated the temporary stay order and on February 3, 2023, a record on appeal was filed and such appeal is currently pending. To the extent that this ruling of the appellate court permits the Secretary of State of California to collect and report diversity data, we may be required to comply with additional disclosure requirements.** The current composition of our board of directors does not include a female director and if the State of California successfully appeals the court decisions regarding SB 826 or AB 979, failure to achieve designated minimum levels in a timely manner will expose us to financial penalties and reputational harm. If the State of California successfully appeals the court decisions regarding SB 826 or AB 979, we cannot assure that we can recruit, attract and / or retain qualified members of ~~the~~ **our** board **of directors** and meet gender and diversity quotas as required by California law (provided that such laws are not repealed before the compliance deadlines), which may cause certain investors to divert their holdings in our securities and expose us to financial penalties and / or reputational harm. Our employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations. We are exposed to the risk that our employees and contractors, including principal investigators, consultants, commercial collaborators, service

providers and other vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing standards; federal and state healthcare fraud and abuse and health regulatory laws and other similar foreign fraudulent misconduct laws; or laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter third- party 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 financial results, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If we seek to enter into strategic alliances for the development of brilaroxazine or RP1208 but fail to enter into and maintain successful strategic alliances, our development costs may increase and our ability to develop brilaroxazine or RP1208 may be significantly delayed. We may seek to enter into strategic alliances or collaborative arrangements with pharmaceutical companies or other industry participants in order to advance our development of brilaroxazine or, in the future, RP1208 or other product candidates, and to reduce our costs of development. If we seek such alliances or collaborative arrangements, we may not be able to negotiate such alliances or collaborative arrangements on acceptable terms, if at all. We face significant competition from other biopharmaceutical companies for appropriate partners in such alliances or arrangements. Furthermore, if we are successful in entering strategic alliances or collaborative arrangements, we may not be able to maintain such alliances or arrangements for a sufficient amount of time to commercialize brilaroxazine, RP1208 or other product candidates, or such alliances or arrangements may not result in successful development of our products. If we seek suitable alliances or arrangements but then fail to create or to maintain these, we may have to limit the size or scope of, or delay, our development of brilaroxazine, RP1208 or other future product candidates. If we elect to fund our development or research programs on our own, we will have to increase our expenditures and will need to obtain additional funding, which may be unavailable or available only on unfavorable terms. See " Risks Related to Our Business, Financial Position and Capital Requirements — We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of brilaroxazine and RP1208. " To the extent we are able to enter into collaborative arrangements or strategic alliances, we will be exposed to risks related to those collaborations and alliances. Biotechnology companies at our stage of development may become dependent upon collaborative arrangements or strategic alliances to complete the development and commercialization of drug candidates, particularly after the Phase 2 stage of clinical testing. If we elect to enter into collaborative arrangements or strategic alliances, these arrangements may place the development of brilaroxazine, RP1208 or other future product candidates outside our control, may require that we relinquish important rights or may otherwise be entered on terms unfavorable to us. Dependence on collaborative arrangements or strategic alliances will subject us to a number of risks, including the risk that: ● We may not be able to control the amount and timing of resources that our collaborators may devote to brilaroxazine and RP1208; ● our collaborators may experience financial difficulties; ● we may be required to relinquish important rights, such as marketing and distribution rights; ● business combinations or significant changes in a collaborator' s business strategy may also adversely affect a collaborator' s willingness or ability to complete our obligations under any arrangement; ● a collaborator could independently move forward with a competing drug candidate developed either independently or in collaboration with others, including our competitors; and ● collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our drug candidates. Our business and operations would suffer in the event our computer systems and networks fail. Our business depends on the proper functioning and availability of our computer systems and networks. Our computer systems, as well as those of our CROs and other contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of preclinical or clinical trial data from completed, ongoing or planned 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 were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of brilaroxazine, RP1208 or any future product candidate could be delayed. Any successful cyber security attack or other unauthorized attempt to access our systems also could result in negative publicity which could damage our reputation or brand with our patients, referral sources, payors or other third parties and could subject us to substantial penalties under HIPAA and other federal and state privacy laws, in addition to private litigation with those affected. **Computer system interruptions, cyber- attacks or security breaches could significantly disrupt our product development programs and our ability to operate our business. Our computer systems, as well as those of various third parties on which we rely, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. We rely on our third- party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. The risk of a security breach or disruption, particularly through cyber- attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of**

attempted attacks and intrusions from around the world have increased. While we have not experienced any significant system failure, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of nonclinical or clinical trial data from completed, ongoing or planned 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 were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of any product candidate could be delayed. Furthermore, federal, state and international laws and regulations, such as the European Union' s General Data Protection Regulation, or the GDPR, which took effect in May 2018, and the California Consumer Protection Act, which took effect on January 1, 2020, can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties and significant legal liability, if our information technology security efforts fail or if our privacy practices do not meet the requirements of such laws. Other states are considering similar laws that could impact our use of research data with respect to individuals in those states. There are extensive documentation obligations and transparency requirements, which may impose significant costs on us. In addition, our software systems include cloud- based applications that are hosted by third- party service providers with security and information technology systems subject to similar risks. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed, any of which could materially adversely affect our business, financial condition, results of operations and growth prospects. Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop. The use of brilaroxazine and RP1208 in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in: ● impairment of our business reputation and significant negative media attention; ● withdrawal of participants from our clinical trials; ● significant costs to defend the related litigation; ● distraction of management' s attention from our primary business; ● substantial monetary awards to patients or other claimants; ● inability to commercialize brilaroxazine, RP1208 or any future product candidate; ● product recalls, withdrawals or labeling, marketing or promotional restrictions; ● decreased demand for brilaroxazine, RP1208 or any future product candidate, if approved for commercial sale; and ● loss of revenue. Any product liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for brilaroxazine or RP1208, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the commercialization of any product candidates we develop. ~~If we fail to maintain~~ **The restatement of our previously issued financial statements** ~~an~~ **and** ~~effective system~~ **associated analysis and ongoing remedial measures have been time consuming and expensive and could expose us to additional risks that could materially adversely affect our financial position, results** of **operations and cash flows. As discussed in the Explanatory Note to this Annual Report on Form 10- K and in Note 2, " Restatement of Previously Issued Annual Consolidated Financial Statements For the Fiscal Year Ended December 31, 2022, " and Note 10, " Quarterly Financial Data – (Unaudited and Restated), " to the consolidated financial statements included in this Annual Report on Form 10- K, we are restating our previously issued financial statements for (i) our audited consolidated financial statements for the fiscal year ended December 31, 2022, (ii) our unaudited consolidated financial statements covering the quarterly reporting period of September 30, 2022 during fiscal year 2022; and (iii) our unaudited consolidated financial statements covering the quarterly reporting periods during fiscal year 2023, consisting of September 30, 2023, June 30, 2023, and March 31, 2023. These restatements have been, and the remediation efforts we have begun to undertake are and will be, time- consuming and expensive and could expose us to a number of additional risks that could materially adversely affect our financial position, results of operations and cash flows. In particular, we have incurred significant expenses, including audit, legal, consulting and other professional fees, in connection with the restatement of our previously issued financial statements and the ongoing remediation of material weaknesses in our** internal control over financial reporting ~~our ability to produce accurate~~ and **clinical trial expenses. We are implementing and will continue to implement additional processes utilizing existing resources and adding new resources as needed. To the extent these steps are not successful, we could be forced to incur additional** ~~timely~~ -- **time and expense. Our management' s attention has also been diverted from the operation of our business in connection with the restatements and ongoing remediation of material weaknesses in our internal controls. In connection with the preparation of our** financial statements **for** ~~could be impaired, investors may lose confidence in our financial reporting and~~ the **fiscal year ended December 31** ~~trading price of our common stock and warrants could be adversely affected. In addition~~ , **2023** ~~because of our status as an emerging growth company and a non- accelerated filer~~ , **we identified material weaknesses in** ~~our independent registered public accountants are not required to provide an attestation report as to~~ our internal control over financial reporting ~~for the foreseeable future~~ **and clinical trial expenses** . **If** ~~As a public company,~~ we **fail** ~~are~~

~~required~~ to maintain **an effective system of** internal control over financial reporting and **clinical** ~~to report any material~~ --- **trial expenses** ~~weaknesses in such internal controls. A material weakness is a deficiency~~ , **we may** ~~or a combination of deficiencies, in internal control, such that there is a reasonable possibility that a material misstatement of the entity' s financial statements will~~ not be **able to accurately report our financial results or** ~~prevented~~ -- **prevent fraud. As a result** , **stockholders could lose confidence in** ~~or~~ **our financial** ~~detected in a timely manner. We are also required to disclose changes made in our internal control~~ and ~~procedures on a quarterly basis. Section 404 of the~~ **other public reporting** ~~Sarbanes- Oxley Act (" Section 404")~~ , ~~requires that we evaluate~~ **which would harm our business** and ~~determine~~ the ~~effectiveness~~ **trading price** of **our Common Stock and listed Warrants. Effective** internal controls over financial reporting ~~and~~ **are necessary for us to** provide ~~a management~~ **reliable financial** ~~report~~ **reports** ~~on~~ **and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes- Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our** internal ~~control~~ **controls** over financial reporting **that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our securities** . We have limited operating history and limited personnel in our finance and accounting functions, which may result in a lack of segregation of duties and we are at the relatively very early stages of establishing our systems of internal controls, and we may be unable to effectively maintain such systems ~~, especially in light of the fact that we now have to operate as a publicly reporting company~~ . This would leave us without the ability to reliably assimilate and compile financial information and significantly impair our ability to prevent error and detect fraud, all of which would have a negative impact on our internal controls over financial reporting. We **are** ~~may not be able to complete our evaluation, testing and any~~ required ~~remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable~~ to ~~assert that~~ **disclose changes made in** our internal controls ~~are effective. If we identify material weaknesses in our internal control over financial reporting in the future or if we are unable to successfully remediate the identified material weaknesses, or if we are otherwise unable to maintain an~~ **and procedures on a quarterly basis** ~~effective system of internal control over financial reporting, the reliability of our financial reporting, investor confidence in our Company~~ and ~~the value of~~ our **management** ~~common stock and warrants could be materially and adversely affected. Effective internal control over financial reporting~~ is ~~necessary~~ **required to assess the effectiveness of these controls annually. However,** for ~~us to provide reliable and timely financial reports and, together with adequate disclosure controls and procedures, are designed to reasonably detect and prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. For~~ as long as we are ~~an " emerging growth company " and / or~~ a non- accelerated filer under the U. S. securities laws, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 ~~. We expect that our eligibility to qualify as an emerging growth company will end on December 31, 2023, the last day~~ of the **Sarbanes- Oxley Act** ~~fiscal year following the fifth anniversary of Tenzing' s initial public offering~~ . An independent assessment of the effectiveness of **our** internal ~~control~~ **controls** over financial reporting could detect problems that **our** management' s assessment might not. Undetected material weaknesses in our internal ~~control~~ **controls** over financial reporting **and clinical trial expenses** could lead to **restatements of our** financial ~~statement~~ **statements** ~~restatements~~ and require us to incur the expense of remediation. ~~Moreover~~ **As discussed in the Explanatory Note to this Annual Report on Form 10- K and in Note 2** , ~~we do not expect~~ **" Restatement of Previously Issued Annual Consolidated Financial Statements For the Fiscal Year Ended December 31, 2022, " and Note 10, " Quarterly Financial Data – (Unaudited and Restated), " to the consolidated financial statements included in this Annual Report on Form 10- K, our audit committee and management concluded** that ~~disclosure controls or~~ **our previously issued consolidated financial statements for the Restatement Periods should be restated to correct historical errors related principally to the timing of recognition of our estimated accrual of certain research and development expenses. The analysis concluded that we previously excluded certain clinical trial expenses and associated costs from the appropriate periods as required under applicable accounting guidelines, and therefore we misstated research and development expenses, and accrued clinical expenses during the Restatement Periods. We principally attribute the errors necessitating the restatement to material weaknesses in our** internal control over financial reporting **and clinical trial expenses identified during the preparation of our financial statements for the fiscal year ended December 31, 2023. We identified (i) a material weakness in internal control activities due to a failure in the design and implementation of our controls to review clinical trial expenses, including the evaluation of the terms of clinical trial contracts, specifically, we failed to properly review and evaluate progress of expenses incurred in clinical trial contracts resulting in us not properly accruing for clinical trial expenses that were incurred but for which invoices were not yet received, and (ii) a material weakness in internal controls due to insufficient resources including in relation to our financial close and reporting process with appropriate knowledge and expertise to design, implement, document and operate effective internal controls over financial reporting. This material weakness has a pervasive impact and consequently, impacts control activities over all financial statement account balances, classes of transactions, and disclosure. We are committed to continuing to improve our internal control over financial reporting. As of the date hereof, we have commenced procedures to remediate the material weaknesses. We** will ~~prevent all error~~ **continue to monitor the design** and ~~all fraud. A~~ **effectiveness of these procedures and** ~~control~~ **controls** ~~system~~ **and make any further changes we determine appropriate. However** , ~~no matter how~~ **these material weaknesses** ~~well~~ **will** ~~designed and operated, can provide only reasonable,~~ not ~~absolute, assurance that the control system' s objectives will be met. Further, the design of a~~

~~control system must reflect the fact that there are resource constraints and the benefits of controls must~~ be considered ~~relative to~~ **remediated until** ~~their~~ -- **the applicable remedial actions** ~~costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any,~~ have been ~~detected. Failure of our~~ **fully implemented and we have concluded that these** ~~control~~ **controls are operating effectively** ~~systems to prevent error or~~ **for a sufficient period of time** ~~fraud could materially adversely impact our Company~~ . If the interpretations, estimates or judgments we use to prepare our financial statements prove to be incorrect, we may be required to restate our financial results, which could have a number of material adverse effects on us. We are subject to complex securities laws and regulations and accounting principles and interpretations. The preparation of our financial statements requires us to interpret accounting principles and guidance and to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. We base our interpretations, estimates and judgments on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for the preparation of our financial statements. Generally accepted accounting principles presentation is subject to interpretation by the SEC, the Financial Accounting Standards Board and various other bodies formed to interpret and create appropriate accounting principles and guidance. If one of these bodies disagrees with our accounting recognition, measurement or disclosure or any of our accounting interpretations, estimates or assumptions, it may have a significant effect on our reported results and may retroactively affect previously reported results. Specifically, prior to and in connection with the closing of our Business Combination, our predecessor company, Tenzing, issued public warrants to purchase 6, 325, 000 shares (the " Public Warrants ") and private placement warrants to purchase 556, 313 shares (the " Private Warrants "). For a full description of the Public Warrants and the Private Warrants, refer to (i) the registration statement on Form S- 4 (File No. 333- 245057), filed in connection with the Business Combination, declared effective by the SEC on November 10, 2020 and (ii) our " Description of Securities " included as Exhibit 4. 1 to this Annual Report on Form 10- K. Each of the Public Warrants and Private Warrants entitles the holder to purchase one share of our common stock at a price of $ 11. 50 per share, subject to adjustment. We originally classified the Public Warrants and the Private Warrants as equity in our previously issued audited consolidated balance sheet as of December 31, 2020, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for the year then ended, and the related notes (collectively, referred to as the" Financial Statements") included in our Annual Report on Form 10- K filed on March 22, 2021. On April 12, 2021, the Staff of the Securities and Exchange Commission (" SEC Staff ") released the Staff Statement on Accounting and Reporting Considerations for Warrants Issued by Special Purpose Acquisition Companies (the " Statement "). In the Statement, SEC Staff made the observation that certain contractual provisions included in many Special Purpose Acquisition Company warrant agreements may result in such warrants needing to be classified as a liability rather than as equity. We have reviewed the Statement and the terms of our Public Warrants and Private Warrants with our third- party technical accounting advisor and our independent auditors and management has concluded that the Private Warrants should be reclassified as liabilities measured at fair value, which will result in non- cash gains or losses from changes in fair value reported each period in earnings. However, no assurance can be given that additional guidance or new regulations or accounting principles and interpretations will not be released that would require us to reclassify the Public Warrants as liabilities measured at fair value, with changes in fair value reported each period in earnings and / or require a restatement of our Financial Statements with respect to treatment of the Public Warrants. Any restatement of our financial results could, among other potential adverse effects: ● result in us incurring substantial costs; ● affect our ability to timely file our periodic reports until the restatement is completed; ● divert the attention of our management and employees from managing our business; ● result in material changes to our historical and future financial results; ● result in investors losing confidence in our operating results; ● subject us to securities class action litigation; and ● cause our stock price to decline. Unfavorable global economic conditions and adverse developments with respect to financial institutions and associated liquidity risk could adversely affect our business, financial condition and stock price. The global credit and financial markets are currently, and have from time to time experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, rising interest and inflation rates, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the ongoing conflict between Russia and Ukraine, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. More recently **in 2023** , the closures of Silicon Valley Bank (" SVB ") and Signature Bank and their placement into receivership with the Federal Deposit Insurance Corporation (the " FDIC ") created bank- specific and broader financial institution liquidity risk and concerns. **Although the Department of the Treasury, the Federal Reserve, and the FDIC jointly released a statement that depositors at SVB and Signature Bank would have access to their funds, even those in excess of the standard FDIC insurance limits, under a systemic risk exception, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market- wide liquidity shortages, impair the ability of market participants to access near- term working capital needs, and create additional market and economic uncertainty. Since the March 2023 failure and FDIC takeover of SVB and the inability of its customers to readily access their cash deposits, there has been a heightened risk and greater focus on the potential failures of other banks in the future.** As of December 31, ~~2022~~ **2023** , we maintained all of our cash with ~~two~~ **three** financial institutions, including SVB, and certain of our cash balance with these financial institutions were in excess of the FDIC insurance limit ~~. On March 12, 2023, federal regulators announced that the FDIC would complete its resolution of SVB in a manner that fully protects all depositors. As of March 30, 2023, the filing date of this annual report, we have transferred the majority of our cash to a different financial institution. Since~~

~~the March 2023 failure and FDIC takeover of SVB and the inability of its customers to readily access their cash deposits, there has been a heightened risk and greater focus on the potential failures of other banks in the future~~ . If these banks fail in the future, we may not be able to immediately (or ever) recover our cash in excess of the FDIC insured limits which would adversely impact our operating liquidity and could negatively impact our operations, results of operations and financial performance. Although as described above federal regulators announced that the FDIC would complete its resolution of SVB in a manner that protects all depositors under a systemic risk exception, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market- wide liquidity shortages, impair the ability of companies to access near- term working capital needs, and create additional market and economic uncertainty. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment or continued unpredictable and unstable market conditions. If the equity and credit markets deteriorate, or if adverse developments are experienced by financial institutions, it may cause short- term liquidity risk and also make any necessary debt or equity financing more difficult, more costly, more onerous with respect to financial and operating covenants and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, financial institutions, manufacturers and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to attain our operating goals on schedule and on budget. Risks Related to Development, Regulatory Approval and Commercialization Drug development is a very expensive, lengthy and uncertain process. The process of taking a drug from discovery to approval generally takes many years, costs tens of millions of dollars or more and has a low probability of success. It also requires the efforts and coordination of people of diverse expertise and experience. Failure may occur at any stage and for multiple reasons, including unsuccessful preclinical and clinical development, inability to create a successful product formulation, and lack of a reproducible and controlled manufacturing process. Clinical trials are very expensive, time-consuming, difficult to design and implement and involve an uncertain outcome. Our only advanced product candidate, brilaroxazine, is still in development and will require extensive clinical testing before we are prepared to submit an NDA for regulatory approval. We cannot predict with any certainty if or when we might submit an NDA for regulatory approval for brilaroxazine or whether any such NDA will be approved by the FDA. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time- consuming. We estimate that the Phase 3 clinical trials of brilaroxazine for schizophrenia indication will take at least ~~three years~~ **eighteen months** to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials, and the results of early clinical trials of brilaroxazine therefore may not be predictive of the results of our planned clinical studies. The commencement and completion of clinical trials may be delayed by one or more factors, including: ● failure to obtain regulatory approval to commence a trial, including in other countries in the global portion of our planned clinical studies; ● unforeseen safety issues; ● determination of dosing issues; ● lack of effectiveness during clinical trials; ● inability to reach agreement on acceptable terms with prospective CROs and clinical trial sites; ● slower than expected rates of patient recruitment or failure to recruit suitable patients to participate in a trial; ● failure to manufacture sufficient quantities of a drug candidate for use in clinical trials; ● inability to monitor patients adequately during or after treatment; and ● inability or unwillingness of medical investigators to follow our clinical protocols. In addition, our management has limited prior experience in managing and completing late- stage clinical trials, and may not be able to successfully design and implement these trials or respond to adverse factors that may arise in the course of conducting these trials. Further, we, the FDA or an institutional review board, or IRB, at a clinical trial site may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including the FDA' s current Good Clinical Practice, or GCP, regulations, that we are exposing participants to unacceptable health risks, or if the FDA finds deficiencies in our investigational new drug, or IND, submissions or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of brilaroxazine could be harmed, and our ability to generate revenues from brilaroxazine may be delayed. In addition, any delays in our clinical trials could increase our costs, slow down the approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and results of operations. Moreover, while we are not currently intending to engage any principal investigators as advisors or consultants, it is conceivable that principal investigators for our clinical trials may serve as scientific advisors or consultants from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of one or more of our product candidates. The results of our clinical trials may not support our brilaroxazine, RP1208 and any future product candidate claims. Even if our clinical trials are completed as planned, we cannot be certain that our results will support the safety and effectiveness of brilaroxazine for the treatment of schizophrenia or any other potential indication, including but not limited to PAH, IPF, BD, MDD, AD, PD, ADHD / ADD, or any of other product candidates, including RP1208. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the

results of prior clinical trials and preclinical testing. A failure of a clinical trial to meet its predetermined endpoints would likely cause us to abandon a product candidate and may delay development of any other product candidates. Any delay in, or termination of, our clinical trials will delay the submission of our NDAs with the FDA and, ultimately, our ability to commercialize brilaroxazine, RP1208 or any future product candidate, and generate product revenues. Enrollment and retention of patients in clinical trials is an expensive and time- consuming process and could be made more difficult or rendered impossible by multiple factors outside of our control. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical sites and the eligibility criteria for the study. Furthermore, any negative results we may report in clinical trials of our product candidate may make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop brilaroxazine, RP1208 or any future product candidate, or could render further development impossible. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance. ~~The~~ **Any** continued **or worsening** spread **or future outbreaks** of COVID- 19 globally could adversely impact our clinical trial operations, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID- 19 if an outbreak occurs in their geography. Disruptions or restrictions on the ability of patients enrolled in our clinical studies to travel, or the ability of staff at study sites to travel, as well as temporary closures of our facilities or the facilities of our clinical trials partners and their contract manufacturers, would negatively impact our clinical trial activities. We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively. Drug development is highly competitive and subject to rapid and significant technological advancements. As a significant unmet medical need exists for the treatment of schizophrenia, there are several large and small pharmaceutical companies focused on delivering therapeutics for the treatment of schizophrenia. Further, it is likely that additional drugs will become available in the future for the treatment of schizophrenia. We are aware of other companies that are working to develop drugs that would compete against brilaroxazine for schizophrenia treatment. Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the United States and in foreign countries. Our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small number of our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, drugs that are more effective or less costly than any product candidate that we may develop. We will face competition from other drugs currently approved or that will be approved in the future for the treatment of schizophrenia. Therefore, our ability to compete successfully will depend largely on our ability to: ● develop and commercialize medicines that are superior to other products in the market; ● demonstrate through our clinical trials that brilaroxazine is differentiated from existing and future therapies; ● attract qualified scientific, product development and commercial personnel; ● obtain patent or other proprietary protection for our medicines; ● obtain required regulatory approvals; ● obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third- party payors; and ● successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new medicines. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any product candidate it develops. The inability to compete with existing or subsequently introduced drugs would have an adverse impact on our business, financial condition and prospects. Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in- license novel compounds that could make brilaroxazine less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval for or commercializing medicines before we do, which would have an adverse impact on our business and results of operations. If we are not able to obtain required regulatory approvals, we will not be able to commercialize brilaroxazine, RP1208 or any other product candidates, and our ability to generate revenue will be materially impaired. Brilaroxazine and the activities associated with its development and commercialization, including its design, research, testing, manufacture, safety, efficacy, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA and similar regulatory authorities outside the United States. Failure to obtain marketing approval for brilaroxazine will prevent us from commercializing it. We have not received approval from regulatory authorities to market any product candidate in any jurisdiction, and it is possible that none of brilaroxazine, RP1208 nor any other product candidates we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us to commence product sales. Prior to submitting an NDA to the FDA, a marketing authorization application, or MAA, to the EMA, or an equivalent application to other foreign regulatory authorities for approval of brilaroxazine, we will need to complete our ~~Phase 3~~ **clinical studies including the** RECOVER **- 2** ~~trial~~ **Trial** . We expect to rely on third- party CROs and consultants to assist us in filing and supporting the applications necessary to gain marketing approvals. Securing marketing approval requires the

submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish brilaroxazine' s safety and efficacy for that indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates. We have been granted orphan drug designation in the United States for brilaroxazine for the treatment of IPF and PAH. Upon receipt of regulatory approval, orphan drug status will provide us with seven years of market exclusivity in the United States under the Orphan Drug Act. However, there is no guarantee that the FDA will grant orphan drug designation for any of our drug candidates for any future indication, which would make us ineligible for the additional exclusivity and other benefits of orphan drug designation. Moreover, there can be no assurance that another company also holding orphan drug designation for the same indication or which may receive orphan drug designation in the future will not receive approval prior to when we do, in which case our competitor would have the benefit of the seven years of market exclusivity, and we would be unable to commercialize our product candidate for the same indication until the expiration of such seven- year period. Even if we are the first to obtain approval for the orphan drug indication, there are circumstances under which a competing product may be approved for the same indication during our seven- year period of exclusivity. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200, 000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug available in the Unites States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of regulatory review and approval process. In addition to the potential period of exclusivity, orphan designation makes a company eligible for grant funding to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee. If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as (i) the drug' s orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant' s product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. If a drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity. There can be no assurance that we will receive orphan drug designation for brilaroxazine for any additional indications or for RP1208, if we elect to seek such designation. Brilaroxazine, RP1208 and any future product candidate may cause adverse effects or have other properties that could delay or prevent its regulatory approval or limit the scope of any approved label or market acceptance. Adverse events caused by brilaroxazine, RP1208 and any future product candidate could cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. If an unacceptable frequency or severity of adverse events are reported in our clinical trials for brilaroxazine, RP1208 or any future product candidates, our ability to obtain regulatory approval for such product candidates may be negatively impacted. Furthermore, if any of our product candidates are approved and then cause serious or unexpected side effects, a number of potentially significant negative consequences could result, including: ● regulatory authorities may withdraw their approval of the product or require a REMS to impose restrictions on its distribution or other risk management measures; ● regulatory authorities may require the addition of labeling statements, such as warnings or contraindications; ● we may be required to change the way the product is administered or to conduct additional clinical trials; ● we could be sued and held liable for harm caused to patients; ● we could elect to discontinue the sale of our products; and ● our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing brilaroxazine, RP1208 and any future product candidate. The results of pre- clinical testing are not necessarily predictive of future results, and RP1208 and other product candidates may not have favorable results in our planned clinical trials. Any positive results from our pre- clinical testing of RP1208 and any future product candidates may not necessarily be predictive of the results from our planned clinical trials. Many companies in the pharmaceutical industry have suffered significant setbacks in clinical trials after achieving positive results in pre- clinical development, and we cannot be certain that we will not face similar setbacks. The pre-clinical data we have obtained for RP1208 may not predict results from studies in larger numbers of subjects drawn from more diverse populations or in a commercial setting, and also may not predict the ability of RP1208 to achieve its intended goals, or to do so safely. Moreover, pre- clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in pre- clinical studies and clinical trials nonetheless failed to obtain FDA or EMA approval. If we fail to produce positive results in our clinical trials, the development timeline and regulatory approval and commercialization prospects for our products and, correspondingly, our business and financial prospects, would be materially adversely affected. Changes in product candidate manufacturing or formulation may result in additional costs, delay or non- approval. ~~As~~ **In order to win approval, we must show that we are able to manufacture our products in a controlled, consistent and quality manner. Should we not be able to do so, our products will not be approved. In addition, as** product candidates are developed through preclinical studies to late- 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 or approval by the FDA, EMA or other regulatory authorities. 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 or prevent approval of our product candidates and jeopardize our ability to commence product sales and generate revenue. We have orphan drug designation for some of our product candidates in the United States and may seek such designation for other candidates. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals in the United States. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same indication for that drug during that time period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. We cannot assure you that any future application for orphan drug designation with respect to any product candidate will be granted. If we are unable to obtain orphan drug designation in the United States, we will not be eligible to obtain the period of market exclusivity that could result from orphan drug designation or be afforded the financial incentives associated with orphan drug designation. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Any fast track designation or grant of priority review status by the FDA may not actually lead to a faster development or regulatory review or approval process, nor will it assure FDA approval of our product candidates. Additionally, our product candidates may treat indications that do not qualify for priority review vouchers. We may seek fast track designation or priority review of applications for approval of our product candidates. If a drug is intended for the treatment of a serious or life- threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. If a product candidate offers major advances in treatment, the FDA may designate it eligible for priority review. The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular product candidate is eligible for these designations, we cannot assure you that the FDA would decide to grant them. Even if we do receive fast track designation or priority review, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Any breakthrough therapy designation granted by the FDA for our product candidate may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidate will receive marketing approval. We may apply for a breakthrough therapy designation for one or more of our product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life- threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for accelerated approval if the relevant criteria are met. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe our product candidate meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Even if we obtain FDA approval for brilaroxazine, RP1208 or any future product candidate in the United States, we may never obtain approval for or commercialize it in any other jurisdiction, which would limit our ability to realize our full market potential. In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country- by- country basis regarding safety and efficacy. Approval by FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our

ability to realize the full market potential of any product we develop will be unrealized. Even if we obtain regulatory approval for brilaroxazine, RP1208 or any future product candidate, we will still face extensive regulatory requirements and our products may face future development and regulatory difficulties. Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post- approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, establishment registration and drug listing requirements, continued compliance with current Good Manufacturing Practice, or cGMP, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and current GCP requirements for any clinical trials that we conduct post- approval. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including any requirement to implement a REMS. If brilaroxazine, RP1208 or any future product candidate receives marketing approval, the accompanying label may limit the approved use of our drug candidate, which could limit sales of the product. The FDA may also impose requirements for costly post- marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post- approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off- label use and if we do not market our products for their approved indications, we may be subject to enforcement action for off- label marketing. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to FDA enforcement actions and investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws. In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including: ● restrictions on manufacturing such products; ● restrictions on the labeling or marketing of a product; ● restrictions on product distribution or use; ● requirements to conduct post- marketing studies or clinical trials; ● warning letters; ● withdrawal of the products from the market; ● refusal to approve pending applications or supplements to approved applications that we submit; ● recall of products; ● fines, restitution or disgorgement of profits or revenues; ● suspension or withdrawal of marketing approvals; ● refusal to permit the import or export of our products; ● product seizure; or ● injunctions or the imposition of civil or criminal penalties. The FDA' s policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of brilaroxazine, RP1208 or any future product candidate. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained. Even if brilaroxazine, RP1208 or any future product candidate receives marketing approval, it may fail to achieve market acceptance by physicians, patients, third- party payors or others in the medical community necessary for commercial success. If brilaroxazine, RP1208 or any future product candidate receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors and others in the medical community. If it does not achieve an adequate level of acceptance, we may not generate significant product revenues and become profitable. The degree of market acceptance of brilaroxazine, RP1208 or any future product candidate, if approved for commercial sale, will depend on a number of factors, including, but not limited to: ● the efficacy and potential advantages compared to alternative treatments; ● effectiveness of sales and marketing efforts; ● the cost of treatment in relation to alternative treatments, including any similar generic treatments; ● our ability to offer our products for sale at competitive prices; ● the convenience and ease of administration compared to alternative treatments; ● the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; ● the strength of marketing and distribution support; ● the availability of third- party coverage and adequate reimbursement; ● the prevalence and severity of any side effects; and ● any restrictions on the use of our product together with other medications. Because we expect sales of brilaroxazine, RP1208 or any future product candidate, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of this product to find market acceptance would harm our business and require us to seek additional financing. If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third- parties, we may not be successful in commercializing brilaroxazine, RP1208 or any future product candidate, if approved. We do not have any infrastructure for the sales, marketing or distribution of our products, and the cost of establishing and maintaining such an organization may exceed the cost- effectiveness of doing so. In order to market any product that may be approved, we must build our sales, distribution, marketing, managerial and other non- technical capabilities or make arrangements with third parties to perform these services. To achieve commercial success for any product for which we have obtained marketing approval, we will need a sales and marketing organization. We expect to build a focused sales, distribution and marketing infrastructure to market brilaroxazine, RP1208 or any future product candidate in the United States, if approved. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any product launch, which would adversely impact the commercialization of brilaroxazine, RP1208 or any future product candidate. For example, if the commercial launch of brilaroxazine, RP1208 or any future product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to commercialize our products on our

own include: ● our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel; ● the inability of sales personnel to obtain access to physicians or attain adequate numbers of physicians to prescribe any drugs; and ● unforeseen costs and expenses associated with creating an independent sales and marketing organization. We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of brilaroxazine in markets outside of the United States. Therefore, our future success will depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator' s strategic interest in the product and such collaborator' s ability to successfully market and sell the product. We intend to pursue collaborative arrangements regarding the sale and marketing of brilaroxazine, RP1208 or any future product candidate, if approved, for markets outside of the United States; however, we cannot assure you that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. If we are unable to build our own sales force or negotiate a collaborative relationship for the commercialization of brilaroxazine, RP1208 or any future product candidate we may be forced to delay the potential commercialization of brilaroxazine, RP1208 or any future product candidate or reduce the scope of our sales or marketing activities for brilaroxazine, RP1208 or any future product candidate. If we elect to increase our expenditures to fund commercialization activities itself, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring brilaroxazine, RP1208 or any future product candidate to market or generate product revenue. We could enter into arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be ideal and we may be required to relinquish rights to brilaroxazine, RP1208 or any future product candidate or otherwise agree to terms unfavorable to it, any of which may have an adverse effect on our business, operating results and prospects. If we are unable to establish adequate sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing brilaroxazine, RP1208 or any future product candidate and may not become profitable. We will be competing with many companies that currently have extensive and well- funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies. If we obtain approval to commercialize any products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business. If brilaroxazine, RP1208 or any future product candidate is approved for commercialization, we intend to enter into agreements with third parties to market it in certain jurisdictions outside the United States. We expect that it will be subject to additional risks related to international operations or entering into international business relationships, including: ● different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries; ● reduced protection for intellectual property rights; ● unexpected changes in tariffs, trade barriers and regulatory requirements; ● economic weakness, including inflation, or political instability in particular foreign economies and markets; ● compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; ● foreign reimbursement, pricing and insurance regimes; ● foreign taxes; ● foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country; ● workforce uncertainty in countries where labor unrest is more common than in the United States; ● potential noncompliance with the U. S. Foreign Corrupt Practices Act, the U. K. Bribery Act 2010 and similar anti- bribery and anticorruption laws in other jurisdictions; ● production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and ● business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires. We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the European Union and many of the individual countries in Europe with which we will need to comply. Our subsidiary may not be in compliance with the laws of foreign countries, and it may face penalties and fines imposed by the Indian government. We have not retained local counsel to assess whether our subsidiary, Reviva Pharmaceuticals India Private Limited, is in compliance with applicable local law. There can be no assurance that we will be able to initially meet such requirements or maintain compliance with the laws and regulations of each foreign country in which our subsidiary operates. As a result, we, Reviva Pharmaceuticals India Private Limited and our other subsidiary may be subject to adverse legal consequences, including but not limited to penalties and fines, which could adversely affect our business, financial condition or results of operations. We are subject to U. S. foreign investment regulations, which may impose additional burdens on or may limit certain investors' ability to purchase shares of our common stock in amounts deemed by the U. S. government to confer control, potentially making our common stock less attractive to investors, and may also impact our ability to generate revenues outside of the U. S. In 2018, Congress passed the Foreign Investment Risk Review Modernization Act of 2018 (" FIRRMA "), which expanded the jurisdiction of the Committee on Foreign Investment in the United States (" CFIUS ") to review direct or indirect foreign investments in U. S. companies. Among other things, FIRRMA empowers CFIUS to require certain foreign investors to make mandatory filings, permits CFIUS, to charge filing fees related to such filings, and empowers CFIUS to self- initiate national security reviews of foreign direct and indirect investments in U. S. companies. In the case that CFIUS determines an investment to be a threat to national security, CFIUS has the power to unwind or place restrictions on the investment. Any such restrictions on the ability to purchase shares of our common stock may have the effect of delaying or deterring any particular investment and could also affect the price that some investors are willing to pay for our common stock. In addition, such restrictions could also limit the opportunity for our stockholders to receive a premium for their shares of our common stock in relation to any potential change in control. Our current and future relationships with foreign actors such as, health care and administrative professionals at foreign state owned hospitals or foreign government healthcare regulators will be subject to applicable anti- corruption laws regulatory laws, which could expose us to penalties. Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third- party payors and customers, may expose us to broadly applicable anti- corruption

and anti- bribery laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we market, sell and distribute our products. Such laws include the Foreign Corrupt Practices Act of 1977, as amended (the " FCPA ") prohibits any offer, payment, promise to pay or authorization to pay any money, gift or thing of value to any Foreign Official, political party, or candidate for office for the purpose of influencing any act or failure to act by the recipient, in his or her official capacity, in order to obtain or retain business, or inducing the recipient to use influence to affect a decision of a foreign government or agency in order to obtain or retain business for anyone. The FCPA also imposes recordkeeping requirements and internal controls provisions, which, among other things, require the issuer to keep accurate books, records, and accounts. Our current and future relationships with investigators, health care professionals, consultants, third- party payors, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties. Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third- party payors and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our products for which we obtain marketing approval. Such laws include: ● the federal Anti- Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti- Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act; ● the federal false claims laws, including the civil False Claims Act, impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; ● HIPAA imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation; ● HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; ● the federal Physician Payment Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other " transfers of value " made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other " transfers of value " to such physician owners (covered manufacturers are required to submit reports to the government by the 90th day of each calendar year); and ● analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to it, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize brilaroxazine, RP1208 or any future product candidate and affect the prices we may obtain. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system and efforts to control health care costs, including drug prices, that could have a significant negative impact on our business, including preventing, limiting or delaying regulatory approval of our drug candidates and reducing the sales and profits derived from our products once they are approved. For example, in the United States, the Patient Protection and Affordable Care Act of 2010 (" ACA ") substantially changed the way health care is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Many provisions of ACA impact the biopharmaceutical industry, including that in order for a biopharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U. S.

government agencies, the manufacturer must extend discounts to entities eligible to participate in the drug pricing program under the Public Health Services Act, or PHS. We cannot be sure whether additional legislative changes will be enacted, or whether government regulations, guidance or interpretations will be changed, or what the impact of such changes would be on the marketing approvals, sales, pricing, or reimbursement of our drug candidates or products, if any, may be. Coverage and adequate reimbursement may not be available for brilaroxazine, RP1208 or any future product candidate, which could make it difficult for us to sell our products profitably. Market acceptance and sales of any product candidates that we develop, will depend in part on the extent to which reimbursement for these products and related treatments will be available from third- party payors, including government health administration authorities and private health insurers. Third- party payors decide which drugs they will pay for and establish reimbursement levels. Third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a plan- by- plan basis. One payer' s determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Additionally, a third- party payor' s decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Each plan determines whether or not it will provide coverage for a drug, what amount it will pay the manufacturer for the drug, and on what tier of its formulary the drug will be placed. The position of a drug on a formulary generally determines the co- payment that a patient will need to make to obtain the drug and can strongly influence the adoption of a drug by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third- party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. A primary trend in the U. S. healthcare industry and elsewhere is cost containment. Third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize any product candidates that we develop. Additionally, there have been a number of legislative and regulatory proposals to change the healthcare system in the United States and in some foreign jurisdictions that could affect our ability to sell any future drugs profitably. These legislative and regulatory changes may negatively impact the reimbursement for any future drugs, following approval. Risks Related to Our Dependence on Third Parties We do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of brilaroxazine, RP1208 and any future product candidate. We do not have experience in drug formulation or manufacturing and do not own or operate, and do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. We also will rely on third-party manufacturers to supply us with sufficient quantities of brilaroxazine to be used, if approved, for the commercialization of brilaroxazine. If we are unable to initiate or continue our relationship with one or more of these third- party contractors, we could experience delays in our development efforts as we locate and qualify new manufacturers. Further, our reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured our product candidates, including: ● inability to meet our product specifications and quality requirements consistently; ● delay or inability to procure or expand sufficient manufacturing capacity; ● manufacturing and product quality issues related to scale- up of manufacturing; ● costs and validation of new equipment and facilities required for scale- up; ● failure to comply with cGMP and similar foreign standards; ● inability to negotiate manufacturing agreements with third parties under commercially reasonable terms; ● termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us; ● reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell brilaroxazine, RP1208 or any future product candidate in a timely fashion, in sufficient quantities or under acceptable terms; ● lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier; ● operations of our third- party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier; ● carrier disruptions or increased costs that are beyond our control; and ● failure to deliver our products under specified storage conditions and in a timely manner. Any of these events could lead to clinical trial delays, failure to obtain regulatory approval or impact our ability to successfully commercialize our products. Some of these events could be the basis for FDA action, including injunction, recall, seizure, or total or partial suspension of production. We rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business. We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we expect to have limited influence over their actual performance. We rely upon CROs to monitor and manage data for our clinical programs, as well as the execution of future nonclinical studies. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs will be required to comply with the Good Laboratory Practices and GCPs, which are regulations and guidelines enforced by the FDA and are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Conference on Harmonization guidelines for any of our product candidates that are in preclinical and clinical development. The Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with 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. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process. Our CROs will be independent contractors and not our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to 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 or regulatory requirements or for any 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 any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed. If our relationship with any one or more of these CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, 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 an adverse impact on our business, financial condition and prospects. Risks Related to Our Intellectual Property 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 sufficiently broad, we may not be able to compete effectively in our markets. We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our drug development programs and product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to brilaroxazine, RP1208 and any future product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our development programs and product candidates. The patent prosecution process is expensive and time- consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own may fail to result in issued patents with claims that cover brilaroxazine, RP1208 or any future product candidate in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover brilaroxazine, RP1208 or any future product candidate, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful opposition to these patents or any other patents that we own could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. If the patent applications we hold with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for brilaroxazine, RP1208 or any future product candidate, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize future drugs. Any such outcome could have a material adverse effect on our business. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. ~~For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does.~~ Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make **or the first to file** the inventions claimed in our owned patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. Moreover, we may be subject to a third party pre- issuance submission of prior art to the U. S. Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after

such candidates are commercialized. As a result, our owned patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse may in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering brilaroxazine, RP1208 or any future product candidate. Our competitors might be able to enter the market, which would have an adverse effect on our business. Third party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights, may delay or prevent the development and commercialization of brilaroxazine, RP1208 and any future product candidate. Our commercial success depends in part on avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter party review, and post- grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization. Based on our general knowledge in this field of technology and based on the patent prosecution of brilaroxazine conducted in the United States and in foreign countries, we do not believe that there are valid patents which contain granted claims that could be asserted with respect to brilaroxazine, however, we may be incorrect. There may be third- party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third- party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third- party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know- how and inventions. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third- party patents do not exist which might be enforced against our future drugs or product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and / or other forms of compensation to third parties. We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful. Competitors may infringe or otherwise violate our patents or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents

at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us, such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a patent invalidity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non- enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post- grant proceedings such as ex parte reexaminations, inter partes review, or post- grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business. We may not be able to prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees. 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. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of securities that may be issued by us. We may not be able to protect our intellectual property rights throughout the world, which could impair our business. Filing, prosecuting and defending patents covering brilaroxazine, RP1208 and any future product candidate throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. Because we expect to rely on third parties to manufacture brilaroxazine, RP1208 and any future product candidates, and we expect to collaborate with third parties on the development of brilaroxazine, RP1208 and any future product candidates, we must, at times, share trade secrets with them. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know- how and trade secrets, a competitor' s discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. In addition, these agreements typically restrict the ability of our advisors, employees, third- party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third- party collaborators. A competitor' s discovery of our trade secrets would impair our competitive position and have an adverse impact on our business. Risks Related to Our Securities Our officers, directors, and principal stockholders exercise significant control over our Company, and will control our Company for the foreseeable future, including the outcome of matters requiring stockholder approval. Our officers, directors and principal stockholders who beneficially own more than 5 % of our common stock, in the aggregate, beneficially own shares representing approximately ~~41~~ **47** . ~~87~~ **5** % of our outstanding capital stock as of March ~~14~~ **29** , ~~2023~~ **2024** . As a result, such entities and individuals have the ability, acting together, to control the election of our directors and the outcome of corporate actions requiring stockholder approval, such as: (i) a merger or a sale of our Company, (ii) a sale of all or substantially all of our assets, and (iii) amendments to our certificate of incorporation and bylaws. This concentration of voting power and control could have a significant effect in delaying, deferring or preventing an action that might otherwise be beneficial to our other stockholders and be disadvantageous to our stockholders with interests different from those entities and individuals. These individuals also have significant control over our business, policies and affairs as officers and directors of our Company. An active trading market for our common stock or warrants may not be sustained. An active trading market for our common stock or warrants may not develop or continue or, if developed, may not be sustained. The lack of an active market for our common stock or warrants may impair investors' ability to sell their common stock or warrants at the time they wish to sell them or at a price that they consider reasonable, may reduce the fair market value of their shares of common stock or warrants and may impair our ability to raise capital to continue to fund operations by selling securities and may impair our ability to acquire additional intellectual property assets by using our securities as consideration **.** A sale of a substantial number of shares of our

common stock or warrants in the public market could cause the market price of our common stock or warrants to drop significantly, even if our business is doing well. The price of our common stock or warrants could decline as a result of sales of a large number of shares of our common stock or warrants or the perception that these sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. In addition, in the future, we may issue additional shares of common stock, warrants or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock or warrants to decline. If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our common stock or warrants, the price of our common stock or warrants could decline. The trading market for our common stock and warrants relies in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts. The price of our common stock could decline if one or more equity analysts downgrade our common stock or warrants or if analysts issue other unfavorable commentary or cease publishing reports about us or our business. The price of our common stock or warrants may be volatile, which could subject us to securities class action litigation and our stockholders could incur substantial losses. The market price for our common stock or warrants may be volatile and subject to wide fluctuations in response to factors including the following: ● actual or anticipated fluctuations in our quarterly or annual operating results; ● actual or anticipated changes in our growth rate relative to our competitors; ● failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public; ● issuance of new or updated research or reports by securities analysts; ● share price and volume fluctuations attributable to inconsistent trading volume levels of our securities; ● additions or departures of key management or other personnel; ● disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our products; ● announcement or expectation of additional debt or equity financing efforts; ● sales of our securities by us, our insiders or our other stockholders; and ● general economic, market or political conditions in the United States or elsewhere. In particular, the market prices of pharmaceutical companies like ours have been highly volatile due to factors, including, but not limited to: ● any delay or failure to conduct a clinical trial for a company' s product or to receive approval from the FDA and other regulatory agencies; ● developments or disputes concerning a company' s intellectual property rights; ● technological innovations of such companies or their competitors; ● changes in market valuations of similar companies; ● announcements by such companies or their competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies, or patents; ● failure to complete significant transactions or collaborate with vendors in manufacturing a product; and ● proposals for legislation that would place restrictions on the price of pharmaceutical products. These and other market and industry factors may cause the market price and demand for our common stock and warrants to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock or warrants and may otherwise negatively affect the liquidity of our common stock or warrants. In addition, the stock market in general ~~,~~ and Nasdaq ~~and emerging growth companies in particular,~~ have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management. If we fail to maintain compliance with the requirements of The Nasdaq Capital Market for continued listing, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted. Our common stock is listed for trading on The Nasdaq Capital Market. There can be no assurance that we will be able to continue to maintain compliance with the Nasdaq continued listing requirements, and if we are unable to maintain compliance with the continued listing requirements, including the $ 1. 00 Minimum Bid Price Requirement set forth in Nasdaq Listing Rule 5550 (a) (2), our securities may be delisted from Nasdaq, which could reduce the liquidity of our common stock materially and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and business development opportunities. Such a delisting likely would impair your ability to sell or purchase our common stock when you wish to do so. Further, if we were to be delisted from Nasdaq, our common stock may no longer be recognized as a " covered security " and we would be subject to regulation in each state in which we offer our securities. Thus, delisting from Nasdaq could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly impact the ability of investors to trade our securities and would negatively impact the value and liquidity of our common stock. Certain of our warrants are accounted for as liabilities and the changes in value of such warrants could have a material effect on our financial results. On April 12, 2021, the SEC Staff released the Staff Statement on Accounting and Reporting Considerations for Warrants Issued by Special Purpose Acquisition Companies (the " Statement "). In the Statement, SEC Staff made the observation that certain contractual provisions included in many Special Purpose Acquisition Company warrant agreements may result in such warrants needing to be classified as a liability rather than as equity. As a result of the SEC Statement, we reevaluated the accounting treatment of our Private Warrants and Public Warrants, and determined to classify the Private Warrants as derivative liabilities measured at fair value, with changes in fair value each period reported in earnings. As a result, included on our ~~restated~~ consolidated balance sheet as of December 31, ~~2021~~ **2023** contained elsewhere in this Annual Report on Form 10- K, are derivative liabilities related to embedded features contained within our Private Warrants. Accounting Standards Codification 815, Derivatives and Hedging (" ASC 815 "), provides for the remeasurement of the fair value of such derivatives at each balance sheet date, with a resulting non- cash gain or loss related to the change in the fair value being recognized in earnings in the statement of operations. As a result of the recurring fair value measurement, our consolidated financial statements and

results of operations may fluctuate quarterly, based on factors, which are outside of our control. Due to the recurring fair value measurement, we expect that we will recognize non- cash gains or losses on our Private Warrants each reporting period and that the amount of such gains or losses could be material. We ~~are an emerging growth company within the meaning of the Securities Act and have taken advantage of certain exemptions from disclosure requirements available to emerging growth companies; this could make our securities less attractive to investors and may make it more difficult to compare our performance with other public companies. We are an " emerging growth company " within the meaning of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012 (the " JOBS Act "), and have taken advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on certain executive compensation matters. As a result, our stockholders may not have access to certain information they may deem important. We expect that our eligibility to qualify as an emerging growth company will end on December 31, 2023, the last day of the fiscal year following the fifth anniversary of Tenzing' s initial public offering. We cannot predict whether investors will find our securities less attractive because we rely on these exemptions. If some investors find the securities less attractive as a result of reliance on these exemptions, the trading prices of our securities may be lower than they otherwise would be, there may be a less active trading market for our securities and the trading prices of the securities may be more volatile. Further, Section 102 (b) (1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Securities Exchange Act of 1934, as amended, (the " Exchange Act ")) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that an emerging growth company can elect to opt out of the extended transition period and comply with the requirements that apply to non- emerging growth companies but any such an election to opt out is irrevocable. We have elected not to opt out of such extended transition period. Accordingly, when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, will adopt the new or revised standard at the time private companies adopt the new or revised standard, unless early adoption is permitted by the standard, and we elect early adoption. This may make comparison of our financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used. We~~ will incur significantly increased costs and devote substantial management time as a result of operating as a public company particularly ~~after~~ **since** we are no longer an " emerging growth company. " As a relatively new public company, we now incur significant legal, accounting and other expenses that we did not incur when we were a private company. For example, we are required to comply with certain of the requirements of the Sarbanes- Oxley Act and the Dodd- Frank Wall Street Reform and Consumer Protection Act, as amended, as well as rules and regulations subsequently implemented by the SEC, including the ongoing maintenance of effective disclosure and financial controls and compliant corporate governance practices. We expect that compliance with these requirements will increase our legal and financial compliance costs and will make some activities more time consuming and costly. In addition, we expect that our management and other personnel will need to divert attention from operational and other business matters to devote substantial time to these public company requirements. In particular, we expect to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes- Oxley Act. In addition, ~~after~~ **since** we no longer qualify as an emerging growth company (our eligibility to qualify as an emerging growth company ~~will end~~ **ended** on December 31, 2023, the last day of the fiscal year following the fifth anniversary of Tenzing' s initial public offering), we expect **management to devote more time and the Company** to incur additional ~~management time and~~ cost to comply with the more stringent reporting requirements applicable to companies that are not emerging growth companies. **Also** ~~In addition~~, if we become subject to the requirements applicable to accelerated filers or large accelerated filers, including complying with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act, our compliance burdens and expenses will further increase. We have not yet completed the process of compiling the system and processing documentation needed to comply with such requirements. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. In that regard, we currently do not have an internal audit function, and although we have contracted for certain accounting staff, we may need to hire or contract for additional accounting and financial staff with appropriate public company experience and technical accounting knowledge, particularly as the Company grows. We cannot predict or estimate the amount of additional costs we may incur as a result of ~~becoming~~ -- **being** a public company **, including as a result of our exit from emerging growth company status,** or the timing of such costs. We do not currently intend to pay dividends on our common stock in the foreseeable future, and consequently, any gains from an investment in our common stock will likely depend on appreciation in the price of our common stock. We have never declared or paid cash dividends on our common stock and do not anticipate paying any cash dividends to holders of our common stock in the foreseeable future. Consequently, investors must rely on sales of their common stock and warrants after price appreciation, which may never occur, as the only way to realize any future gains on their investments. There is no guarantee that shares of our common stock or warrants will appreciate in value or even maintain the price at which the stockholders have purchased their shares or warrants. Upon our dissolution, the stockholders may not recoup all or any portion of their investment. In the event of our liquidation, dissolution or winding- up, whether voluntary or involuntary, the proceeds and / or assets of remaining after giving effect to such transaction, and the payment of all debts and liabilities and distributions required to be made to holders of any outstanding preferred stock will then be distributed to the stockholders of common stock on a pro rata basis. There can be no assurance that we will have available assets to pay to the holders of our common stock, or any amounts, upon such a liquidation, dissolution or winding- up. Our certificate of incorporation, as amended and restated,

allows for our board of directors to create new series of preferred stock without further approval by the stockholders, which could adversely affect the rights of the holders of our common stock. Our board of directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our board of directors has the authority to issue up to 10 million shares of preferred stock without further stockholder approval. As a result, our board of directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation and the right to receive dividend payments before dividends are distributed to the holders of our common stock. In addition, our board of directors could authorize the issuance of a series of preferred stock that has greater voting power than the common stock or that is convertible into our common stock, which could decrease the relative voting power of our common stock or result in dilution to existing stockholders. Delaware law and our certificate of incorporation, as amended and restated, and our bylaws contain certain provisions, including anti- takeover provisions that limit the ability of stockholders to take certain actions and could delay or discourage takeover attempts that stockholders may consider favorable. Our certificate of incorporation, as amended and restated, and our bylaws, and the Delaware General Corporation Law, as amended (the " DGCL "), contain provisions that could have the effect of rendering more difficult, delaying, or preventing an acquisition deemed undesirable by our board of directors and therefore depress the trading price of our common stock. These provisions could also make it difficult for stockholders to take certain actions, including electing directors who are not nominated by the current members of our board of directors or taking other corporate actions, including effecting changes in management. Among other things, our certificate of incorporation, as amended and restated, and our bylaws include provisions regarding: ● the ability of our board of directors to issue shares of preferred stock, including " blank check " preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer; ● the limitation of the liability of, and the indemnification of, our directors and officers; ● the right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors; ● a prohibition on stockholder action by written consent (except as required for holders of future series of preferred stock), which forces stockholder action to be taken at an annual or special meeting of stockholders and could delay the ability of stockholders to force consideration of a stockholder proposal or to take action, including the removal of directors; ● the requirement that a special meeting of stockholders may be called only by our board of directors, which could delay the ability of stockholders to force consideration of a proposal or to take action, including the removal of directors; ● controlling the procedures for the conduct and scheduling of our board of directors and stockholder meetings; ● the requirement for the affirmative vote of holders of at least a majority of the voting power of all of the voting power of the then outstanding shares of the voting stock, voting as a single class, to amend, alter, change or repeal any provision of our bylaws and certain provisions in our certificate of incorporation, as amended and restated, respectively, which could preclude stockholders from bringing matters before annual or special meetings of stockholders and delay changes in our board of directors and also may inhibit the ability of an acquirer to effect such amendments to facilitate an unsolicited takeover attempt; ● the ability of our board of directors to amend our bylaws by an affirmative vote of a majority of our board of directors, which may allow our board of directors to take additional actions to prevent an unsolicited takeover and inhibit the ability of an acquirer to amend our bylaws to facilitate an unsolicited takeover attempt; and ● advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which could preclude stockholders from bringing matters before annual or special meetings of stockholders and delay changes in our board of directors and also may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer' s own slate of directors or otherwise attempting to obtain control of us. These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our board of directors or management. In addition, as a Delaware corporation, we will generally be subject to provisions of Delaware law, including Section 203 of the DGCL. Any provision of our certificate of incorporation, as amended and restated, our bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock. Our certificate of incorporation, as amended and restated, designates a state or federal court located within the State of Delaware as the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to choose the judicial forum for disputes with us or our directors, officers, or employees. Our certificate of incorporation, as amended and restated, provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware, or if such court does not have subject matter jurisdiction, any other court located in the State of Delaware with subject matter jurisdiction, will be the sole and exclusive forum for (i) any derivative action or proceeding brought on the Company' s behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer, other employee or stockholder of the Company to the Company or the Company' s stockholders, (iii) any action asserting a claim against the Company or our officers or directors arising pursuant to any provision of the **DGCL** ~~Delaware General Corporation Law~~ or our certificate of incorporation, as amended and restated, or our bylaws or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware, or (iv) any action asserting a claim against the Company or any director or officer of the Company governed by the internal affairs doctrine of the law of the State of Delaware; provided, that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state court sitting in the State of Delaware. Additionally, our certificate of incorporation, as amended and restated, provides that, unless the Company consents to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act; provided, however, that such provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Any person or

entity purchasing or otherwise acquiring any interest in any of our securities will be deemed to have notice of and consented to these provisions. These exclusive- forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum of its choosing for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If a court were to find these exclusive- forum provisions to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could harm our results of operations. Item 1B. UNRESOLVED STAFF COMMENTS