Risk Factors Comparison 2024-09-19 to 2023-09-14 Form: 10-K

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

~~Human Resources, Hiring and Professional DevelopmentThe development, attraction and retention of employees is critical to our success. We work diligently to attract the best talent from a diverse range of sources in order to meet the current and future demands of our business. We leverage both formal and informal programs to identify, foster and retain top talent. Business EthicsOur Code of Business Conduct and Ethics is designed to ensure that the conduct of our business is consistent with the highest standards of business ethics. Our Code of Business Conduct and Ethics serves as a critical tool to help employees recognize and report unethical conduct, while preserving our culture of excellence. Our Board of Directors, management and staff are provided with training regarding our Code of Business Conduct and Ethics. On May 30, 2023, we adopted an amended and restated Code of Business Conduct and Ethics. The purpose of amending and restating the prior code was to improve its readability and clarify certain areas of importance, including with respect to compliance with laws, accounting and auditing matters, conflicts of interest, insider trading, confidentiality obligations and the reporting of violations of our Code of Business Conduct and Ethics. Corporate InformationWe were incorporated in Delaware in 2010 and we re- incorporated in Nevada in June 2021. We maintain an executive office located at 275 Shoreline Drive, Suite 500, Redwood City, CA 94065 and our phone number is (650) 206- 4507. Our website is located at www. rezolutebio. com. We file annual, quarterly, current reports, proxy statements and other information with the Securities and Exchange Commission (" SEC "). The SEC maintains a website that contains our public~~ filings and other information regarding the Company, at www. sec. gov. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated into this document. Item 1A. Risk Factors. Investors should consider carefully the following risks before deciding to purchase any of our securities. If any of the events or developments described below actually occur, our business, results of operations and financial condition would likely suffer and investors may lose all or part of their investment. In addition, it is also possible that other risks and uncertainties that affect our business may arise or become material in the future. Risks Related to Our Product Development and CommercializationAny delays in the commencement or completion, or termination or suspension, of our future clinical trials, if any, could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects. Before obtaining approval from the government authorities or professional bodies with authority to grant regulatory approval for our drug candidates in a particular country, such as the European Medicines Agency (" EMA "), the Food and Drug Administration of the U. S. Department of Health and Human Services (" FDA ") and analogous authorities in other jurisdictions outside of the United States (" Regulatory Authorities "), we must conduct extensive clinical studies to demonstrate safety and efficacy. Clinical testing is expensive, time consuming and uncertain as to **the** outcome. Any delays in the commencement or completion of our ongoing, planned or future clinical trials could significantly increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues. We do not know whether our planned trials will begin on time or at all, or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to: ● Regulatory Authorities disagreeing as to the design or implementation of our clinical trials or with our recommended dose for any of our pipeline programs; ● obtaining Regulatory Authority authorization to commence a trial or reaching a consensus with such Regulatory Authorities on trial design; ~~5~~ ● identifying and activating investigators and clinical trial sites to conduct trials; ● obtaining approval from one or more independent institutional review ~~board~~ **boards** (" IRB ") or Ethics Committee (" EC ") at each clinical trial site before each trial may be initiated; ● IRBs / ECs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial; ● changes to **a** clinical trial protocol; ● clinical sites deviating from trial protocol or dropping out of a trial; ● failing to manufacture or obtain sufficient quantities of drug candidate, or, if applicable, combination therapies for use in clinical trials; ● patients failing to enroll or remain in our trial at the rate we expect, or failing to return for post- treatment follow- up; ● patients choosing an alternative treatment, or participating in competing clinical trials; ● lack of adequate funding to continue the clinical trial; ● patients experiencing severe or unexpected drug- related adverse effects; ● occurrence of serious adverse events in trials of the same class of agents conducted by other companies; ● selecting or being required to use clinical end points that require prolonged periods of clinical observation or analysis of the resulting data; ● a facility manufacturing our drug candidates, or any of their components, including without limitation, our own facilities being ordered by Regulatory Authorities to temporarily or permanently shut down due to violations of current good manufacture practices, regulations or other applicable requirements, or infections or cross- contaminations in the manufacturing process; ● lack of stability of our clinical trial material or any quality issues that arise with the clinical trial material; **7** ● any changes to our manufacturing process that may be necessary or desired; ● our, or our third- party contractors, not performing data collection or analysis in a timely or accurate manner or improperly disclosing data prematurely or otherwise in violation of a clinical trial protocol; ● any third- party contractors becoming debarred or suspended or otherwise penalized by Regulatory Authorities or other government or regulatory bodies for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications; ● a clinical trial being suspended or terminated by us, by the IRBs / ECs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by Regulatory Authorities, due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by Regulatory Authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using the

product under investigation, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial; or ● changes in regulatory requirements and policies and our need to amend clinical trial protocols to comply with these changes and potentially resubmit our clinical trial protocols to IRBs / ECs for reexamination. Delays in initiating a new phase of clinical trials resulting from action by FDA or any other Regulatory Authority would delay the approval obtainment and commercialization of our product candidates and our ability to generate revenue, which would have an adverse effect on our business. ~~For example, as discussed in the Management' s Discussion and Analysis of Financial Condition and Results of Operations section of this Annual Report on Form 10- K, the FDA has re- imposed a human drug exposure limit equating to repeat doses of approximately 3 mg / kg per week, a limit which was previously removed during the RIZE study (the " New Restrictions "). As is customary in pediatric drug development, there is a progression of the inclusion of younger participants as a program advances through different stages and continues to demonstrate a good safety profile and a prospect of benefit for children based on previous stages; and the Company' s progression to include younger participants is dampened by the imposition of the New Restrictions by the FDA. The Company and FDA have discussed potential solutions that could enable removal of the New Restrictions and as a result, the Company is pursuing some additional nonclinical studies to potentially address FDA' s concerns, in parallel with the initiation and advancement of the Phase 3 (" sunRIZE ") study outside of the U. S. It is possible that the Company may not satisfy FDA' s nonclinical concerns, which will cause further delays and negatively impact the Company' s development plans for congenital hyperinsulinism (" HI ") in the U. S. 6 The clinical hold in the U. S. on RZ358 may impact our development plans and may impact our ability to access the capital markets. Our most advanced product candidate, RZ358, is currently under clinical hold in the U. S. It may take considerable time and expense to respond to the New Restrictions that have been placed on RZ358 by the FDA, and no assurance can be given that the FDA will remove the New Restrictions or that we will receive FDA approval for RZ358, in which case our business and prospects will likely suffer material adverse consequences. In May 2023, based on historical rat toxicology found during an early RZ358 development program, the FDA affirmed its decision to impose the New Restrictions after the Company completed its multinational Phase 2b RIZE study conducted in participants 2 years of age and older, which consisted of the age restriction of 12 years and above for U. S. patients, and to re- impose impose a human drug exposure limit equating to repeat doses of approximately 3 mg / kg per week, a limit which was previously removed during the RIZE study. The New Restrictions delay the Company' s progression to include younger participants and consequentially delay the sunRIZE study in the U. S. A clinical hold for RZ358 and sunRIZE continues to be in place in the U. S., and we do not know whether or when the clinical hold for the development of RZ358 will be lifted. However, we currently expect to commence the sunRIZE study outside of the U. S. as we have concluded our pre- sunRIZE regulatory and scientific advice meetings with Regulatory Authorities outside of the U. S. and have reached agreements on the design of the sunRIZE study that will include participants 3 months of age and older. Positive or promising results from clinical trials of RZ358 conducted in jurisdictions outside of the U. S. may not be predictive of similar results, or may not be replicated, in clinical trials within the U. S. Accordingly, even if we continue to observe the lack of adverse liver findings in the sunRIZE study outside of the U. S., it is not guaranteed that the FDA will accept such findings and lift the New Restrictions which could impact our development plans or ability to file for approval or market RZ358 in the U. S. It may take a considerable period of time, the length of which is not certain at this time, and expense for us to fully address FDA' s concerns, if at all. Even if we are able to fully respond to the FDA' s questions, the FDA may subsequently make additional requests that we would need to fulfill prior to the lifting of the New Restrictions. It is possible that we will be unable to fully address the FDA' s concerns and as a result the New Restrictions may never be lifted, and we may never be able to begin the sunRIZE study or complete our clinical trials of RZ358 in the U. S. Many of the factors that cause, or lead to, a delay in the commencement or completion of the sunRIZE study may also ultimately lead to the denial of regulatory approval from the FDA for RZ358. If we don' t receive regulatory approval from the FDA for RZ358 our ability to raise capital and the terms of such raise could be impacted. If we are unable to commercialize RZ358, need to limit the scope of our RZ358 program, or experience significant delays in development, our business, results of operations, financial condition, and our prospects will be adversely affected. Results of preclinical testing or earlier clinical studies or approval from a Regulatory Authority for the next phase of clinical trials are not necessarily predictive of future results, therefore none of the product candidates we advance into clinical studies may have favorable results in later clinical studies or receive regulatory approval. Success in preclinical testing does not ensure that clinical studies will generate adequate data to demonstrate the efficacy and safety of an investigational drug or biologic. Even if our clinical studies produce promising results or a Regulatory Authority provided approval for the next phase of clinical trials, there is no assurance that such results will be replicated or exceeded in later clinical studies. A number of companies in the biotechnology industry, including those with greater resources and experience, have suffered significant setbacks in clinical studies, even after seeing promising results in earlier preclinical and clinical studies. We do not know whether our clinical studies will demonstrate adequate efficacy and safety to justify the continuing advancement of a program. If later stage clinical studies, such as the sunRIZE study to be conducted outside of the U. S., do not produce favorable results, our ability to achieve regulatory approval for our product candidates may be adversely impacted. Even if we believe that our product candidates have performed satisfactorily in preclinical testing and clinical studies, we may still fail to obtain FDA or other Regulatory Authority approval for our product candidates. 7~~ Adverse events in our clinical trials may force us to stop development of our product candidates or prevent regulatory approval of our product candidates. Our product candidates may produce serious adverse events in patients during clinical trials. These adverse events could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA, or other Regulatory Authorities requesting additional preclinical data or denying approval of our product candidates for any or all targeted indications. An IRB / EC, independent Data Safety Monitoring Board, the FDA, other Regulatory Authorities or the Company itself may suspend or terminate clinical trials at any time. We cannot assure you that any of our product candidates will prove safe for human use. We are exposed to additional risks as we conduct the sunRIZE study outside of the U. S. and may not be successful in meeting the study' s primary endpoint. ~~We~~

Prior to the FDA' s lift of the partial clinical hold in September 2024, we initiated and are ~~initiating and~~ advancing the sunRIZE study outside of the U. S. The sunRIZE study may not produce positive results and meet its primary endpoint outside of the U. S. We may need to commence and complete additional clinical trials that satisfy the specified primary endpoint criteria in order to obtain necessary regulatory approvals from the EMA for **ersodetug** ~~RZ358. It is possible that we may not observe the lack of adverse liver findings in the sunRIZE study outside of the U. S., which could potentially impact the FDA' s decision regarding the New Restrictions~~ . Conducting clinical trials outside the U. S. also exposes us to additional risks, including risks associated with: ● additional foreign regulatory requirements; ● foreign exchange fluctuations; ● compliance with foreign manufacturing, customs, shipment and storage requirements; ● potential political or economic instability in the jurisdictions where we initiate clinical trials; ● cultural differences in medical practice and clinical research; and ● diminished protection of intellectual property in some countries. After the completion of our clinical studies, we cannot predict whether or when we will obtain regulatory approval to commercialize our product candidates and we cannot, therefore, predict the timing of any future revenue from these product candidates. Even if we achieve positive clinical results and file for regulatory approval, we cannot commercialize any of our product candidates until the appropriate Regulatory Authorities have reviewed and approved the applications for such product **8** candidates. We cannot **provide** ~~assure~~ **assurance** that the Regulatory Authorities will complete their review processes in a timely manner or that we will obtain regulatory approval for any product candidate we develop. Satisfaction of regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action or changes in Regulatory Authority policy during the period of product development, clinical studies and regulatory review ~~. Even if U. S. regulatory approval is obtained for a particular drug candidate, the FDA may still impose significant restrictions on marketing, indicated uses and / or require potentially costly post- approval studies or post- approval surveillance. For example, the label ultimately approved, if any, may include restrictions on use. Further, the FDA may require that long- term safety data may need to be obtained as a post- approval requirement. Even if the FDA or a foreign Regulatory Authority approves a product candidate, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and / or production of such product and may impose requirements for post- approval studies, including additional research and development and clinical trials. The FDA and other Regulatory Authorities also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including substantial monetary penalties and withdrawal of product approval~~ . If we or a Regulatory Authority discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a Regulatory Authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or ~~8~~ withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a Regulatory Authority may: issue warning letters or untitled letters; seek an injunction or impose civil or criminal penalties or monetary fines; suspend or withdraw regulatory approval; suspend any ongoing clinical studies; refuse to approve pending applications or supplements to applications filed by us; suspend or impose restrictions on operations, including costly new manufacturing requirements; or seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall. The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue. If our product candidates do not meet safety or efficacy requirements, they will not receive regulatory approval and we will be unable to market them. The process of drug development, regulatory review and approval typically is expensive, takes many years and the timing of any approval cannot be accurately predicted. If we fail to obtain regulatory approval for our current or future product candidates, we will be unable to market and sell such products and therefore may never be profitable. As part of the regulatory approval process, we must conduct preclinical studies and clinical trials for each product candidate to demonstrate safety and efficacy. The number of preclinical studies and clinical trials that will be required varies depending on the product candidate, the indication being evaluated, the trial results and regulations applicable to any particular product candidate. The results of preclinical studies and initial clinical trials of our product candidates do not necessarily predict the results of later- stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through initial clinical trials. We cannot assure you that the data collected from the preclinical studies and clinical trials of our product candidates will be sufficient to support approval by the FDA or a foreign Regulatory Authority. In addition, the continuation of a particular study after review by an independent ~~data~~ **Data** ~~safety~~ **Safety** ~~monitoring~~ **Monitoring** ~~board~~ **Board** does not necessarily indicate that our product candidate will achieve the clinical endpoint. The FDA and other Regulatory Authorities can delay, limit or deny approval for many reasons, including: a product candidate may not be safe or effective; our manufacturing processes or facility may not meet the applicable requirements; and changes in Regulatory Authority approval policies or adoption of new regulations may require additional clinical trials or work on our end. Any delay in, or failure to receive or maintain, approval for any of our products could prevent us from ever generating meaningful revenues or achieving profitability. Our product candidates are prone to the risks of failure inherent in drug development. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate safety in preclinical studies and effectiveness with substantial evidence gathered in well- controlled clinical studies. With respect to approval in the U. S., to the satisfaction of the FDA and, with respect to approval in other countries, to the satisfaction of Regulatory Authorities in those countries, we must demonstrate that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. **9** Despite our efforts, our product candidates may not: offer therapeutic benefit or other improvements over existing, comparable therapeutics; be proven safe and effective in clinical studies; meet applicable regulatory standards; be capable of being produced in sufficient quantities at acceptable costs; be successfully commercialized; or obtain favorable reimbursement. We are not permitted to market any of our other product

candidates in the U. S. until we receive approval of a new drug application, or approval of a biologics license application, from the FDA, or in any foreign countries until we receive the requisite approval from such countries. We have not submitted a new drug application or biologics license application or received marketing approval for any of our product candidates. ~~9~~ Preclinical testing and clinical studies are long, expensive and uncertain processes. We may spend several years completing our testing for any particular product candidate, and failure can occur at any stage. Negative or inconclusive results or adverse medical events during a clinical study could also cause us, one or more IRBs / ECs at clinical trial sites, a Data Safety Monitoring Board or the FDA or other Regulatory Authority to terminate a clinical study or require that we repeat it or conduct additional studies. Additionally, data obtained from a clinical study is susceptible to varying interpretations and the FDA or other Regulatory Authorities may interpret the results of our clinical studies less favorably than we do. The FDA and equivalent foreign Regulatory Authorities have substantial discretion in the approval process and may decide that our data is insufficient to support a marketing application and require additional preclinical, clinical or other studies. Due to our reliance on contract research organizations or other third parties to conduct clinical trials, we may not have complete control over the timing, conduct and expense of our clinical trials. We rely primarily on third parties to conduct our clinical trials. As a result, we will have less control over the conduct of the clinical trials, the timing and completion of the trials, the required reporting of adverse events and the management of data developed through the trial than would be the case if our own staff conducted all aspects of our clinical trials. Communicating with outside parties can also be challenging, potentially leading to mistakes and difficulties in coordinating activities. Outside parties may have staffing difficulties, may undergo changes in priorities or may become financially distressed, adversely affecting their willingness or ability to conduct our trials. We may experience unexpected increased costs that are beyond our control. Problems with the timeliness or quality of the work of a contract research organization may lead us to seek to terminate the relationship and use an alternative service provider. However, making this change may be costly and may delay our trials, and contractual restrictions may make such a change difficult or impossible. Additionally, it may be impossible to find a replacement organization that can conduct our trials in an acceptable manner and at an acceptable cost. Any failure or delay by our third- party suppliers on which we rely or intend to rely to provide materials necessary to develop and manufacture our drug products may delay or impair our ability to commercialize our product candidates. We rely upon a small number of third- party suppliers for the manufacture of certain raw materials that are necessary to formulate our drug products for preclinical and clinical testing purposes. We intend to continue to rely on them in the future. We also expect to rely upon third parties to produce materials required for the commercial production of our product candidates if we succeed in obtaining necessary regulatory approvals. If we are unable to arrange for third- party sources, or do so on commercially unreasonable terms, we may not be able to complete development of or market our product candidates. In addition, third- party suppliers that we engage may be adversely impacted by COVID- 19. It is possible that our raw material suppliers may not be able to sell these raw materials at the times we need them or on commercially reasonable terms due to forces outside of our control including, but not limited to, inflation and global conflicts. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Our third- party manufacturers and suppliers may encounter delays in providing their services as a result of supply chain constraints. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Although we generally do not begin a clinical study unless we believe we have a sufficient supply of a product candidate to complete the clinical study, any significant delay in the supply of raw material components needed to produce a product candidate for a clinical study due to the need to replace a third- party manufacturer could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If we or our manufacturers are unable to purchase these raw materials after regulatory approval has been obtained for our product **10** candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply of such product candidates, which would impair our ability to generate revenues from the sale of our product candidates. If we successfully commercialize any of our product candidates, we may be required to establish commercial manufacturing capabilities of larger scale. In addition, as our drug development pipeline increases and matures, we will have a greater need for clinical study and commercial manufacturing capacity. We have no experience manufacturing pharmaceutical products on a commercial scale and we may need to rely on third- party manufacturers with capacity for increased production scale to meet our projected needs for commercial manufacturing, the satisfaction of which on a timely basis may not be met. ~~10~~ If we use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages. Our research and development activities involve the controlled use of potentially hazardous substances, including toxic chemical and biological materials. We could be held liable for any contamination, injury or other damages resulting from these hazardous substances. In addition, our operations produce hazardous waste products. While third parties are responsible for disposal of our hazardous waste, we could be liable under environmental laws for any required cleanup of sites at which our waste is disposed. Federal, state, foreign and local laws and regulations govern the use, manufacture, storage, handling and disposal of these hazardous materials. If we fail to comply with these laws and regulations at any time, or if they change, we may be subject to criminal sanctions and substantial civil liabilities, which may harm our business. Even if we continue to comply with all applicable laws and regulations regarding hazardous materials, we cannot eliminate the risk of accidental contamination or discharge and our resultant liability for any injuries or other damages caused by these accidents. Guidelines and recommendations published by various organizations may adversely affect the use of any products for which we may receive regulatory approval. Government agencies issue regulations and guidelines directly applicable to us and to our product candidates. In addition, professional societies, practice management groups, private health or science foundations and organizations involved in various diseases from time to time publish guidelines or recommendations to the medical and patient communities. These various sorts of recommendations may relate to such matters as product usage and use of related or competing therapies. For example, organizations like the American Diabetes Association have made recommendations about therapies in the diabetes therapeutics market. Changes to these recommendations or other guidelines advocating alternative

therapies could result in decreased use of any products for which we may receive regulatory approval, which may adversely affect our results of operations. Risks Related to Our **BusinessChanges** ~~BusinessWe could be negatively impacted and unable to raise capital on favorable terms or generate revenue if we are not successful with the sunRIZE study outside of the U. S. and if the FDA does not lift the New Restrictions on RZ358. RZ358 is our lead clinical asset. We have expended considerable resources and efforts on the development of RZ358. As we continue to pursue the development of RZ358, there is no guarantee that we will be able to successfully complete clinical trials for RZ358 outside of the U. S. or that the FDA will lift the New Restrictions imposed on RZ358 within the U. S. If we do not receive positive results from the sunRIZE study outside of the U. S. or if the FDA continues to impose the New Restrictions by such time, our ability to raise additional capital, if at all, on favorable terms may be impeded by our inability to advance the development of our product candidates. Changes~~ in financial accounting standards or policies have affected, and in the future may affect, our reported financial condition or results of operations; there are inherent limitations to our system of internal controls; changes in corporate governance policies and practices may impact our business. We prepare our consolidated financial statements in conformity with **accounting principles generally accepted in the United States of America (“** GAAP **”)** . The preparation of our financial statements in accordance with GAAP requires that we make estimates and assumptions that affect the recorded amounts of assets, liabilities and net income during the reporting period. A change in the facts and circumstances surrounding those estimates could result in a change to our estimates and could impact our future operating results. GAAP is subject to interpretation by the Financial Accounting Standards Board (“ FASB ”), the SEC and various bodies formed to interpret and create accounting policies. A change in those policies can have a significant effect on our reported results and may affect our reporting of transactions which are completed before a change is announced. In general, changes to accounting rules or challenges to our interpretation or application of the rules by regulators may have a material adverse effect on our reported financial results or on the way we conduct business. 11 Our system of internal and disclosure controls and procedures was designed to provide reasonable assurance of achieving its objectives. However, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been or will be detected. As a result, there can be no assurance that our system of internal and disclosure controls and procedures will be successful in preventing all errors, theft and fraud, or in informing management of all material information in a timely manner. Finally, corporate governance, public disclosure and compliance practices continue to evolve based upon continuing legislative action, SEC rulemaking and policy positions taken by large institutional stockholders and proxy advisors. As a result, the number of rules, regulations and standards applicable to us may become more burdensome to comply with, could increase scrutiny of our practices and policies by these or other groups and increase our legal and financial compliance costs and the amount of time management must devote to governance and compliance activities. For example, the SEC has recently proposed rules requiring that issuers provide significantly increased disclosures concerning cybersecurity matters and the impact of climate changes on their business and has adopted rules requiring public companies to adopt more stringent executive compensation clawback policies. Increasing regulatory burdens and corporate governance requirements could also make it more difficult for us to attract and retain qualified members of our Board of Directors and qualified executive officers. We have a history of losses and may not achieve profitability in the future. We will need substantial additional capital to fund our operations. If we fail to obtain additional capital, we will be unable to sustain operations. We incurred net losses of $ **68. 5 million and $** 51. **8** ~~2 million and $ 41. 1~~ million for the fiscal years ended June 30, **2024 and** 2023 ~~and 2022~~ , respectively. As of June 30, ~~2023~~ **2024** , we had an accumulated deficit of $ ~~261~~ **329** . ~~0~~ **4** million. Cash used in our operating activities amounted to $ **57. 4 million and $** 44. 5 ~~million and $ 39. 6~~ million for the fiscal years ended June 30, **2024 and** 2023 ~~and 2022~~ , respectively. We expect that the amount of cash used in our operating activities will continue to increase for the next several years. As of June 30, ~~2023~~ **2024** , we had cash and cash equivalents of $ ~~16~~ **70** . ~~0~~ **4** million and investments in marketable debt securities of $ ~~102~~ **56** . ~~3~~ **7** million that is expected to provide us with adequate capital resources to fund planned activities at least through the ~~third~~ **second** quarter of calendar year ~~2025~~ **2026** . Since our inception, we have not generated meaningful revenue. We expect to continue to incur operating losses for the foreseeable future as we develop and commercialize our product candidate pipeline, and we expect to need additional capital from external sources before we will be able to begin generating revenue, if ever. If we are unable to raise additional capital, we may have to significantly delay, scale back or discontinue one or more of our research and development programs. We may be required to cease operations or seek partners for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available. In the absence of additional capital we may also be required to relinquish, license or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize on terms that are less favorable than might otherwise be available. If we are unable to secure additional capital, we may be required to take additional measures to reduce costs in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. These measures could cause significant delays in the development of our product candidates. We face potential product liability exposure, and, if successful claims are brought against us, we may incur substantial liability. The use of our product candidates in clinical studies and the sale of any products for which we obtain marketing approval expose 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. If we cannot successfully defend ourselves against product liability claims, we could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in: impairment of our business reputation; withdrawal of clinical study participants; costs of related litigation; distraction of management’ s attention from our primary business; substantial monetary awards to patients or other claimants; the inability to commercialize our product candidates; and decreased demand for our product candidates, if approved for commercial sale. We currently have clinical trial insurance for our active clinical programs. This product liability insurance coverage for our clinical studies may not be sufficient to reimburse us for all expenses or losses we may suffer. Moreover, insurance 12 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 and when we obtain marketing approval for any of our product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain this product liability insurance on commercially reasonable terms. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim, or series of claims, brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business. We may not be able to use a significant portion of our net operating loss carryforwards, which could adversely affect our profitability. Federal and state laws impose substantial restrictions on the utilization of net operating loss (" NOL ") carryforwards in the event that certain ownership changes occur as defined in Section 382 of the Internal Revenue Code (" IRC "). Due to our financing activities, we experienced ownership changes that have resulted in significant limitations on the future use of our NOL carryforwards. As of June 30, ~~2023~~ **2024** , we have US federal NOL carryforwards of approximately $ ~~153~~ **171** . ~~2~~ **7** million, of which $ 33. 4 million will expire without any opportunity for utilization due to the limitations set forth in IRC Section 382. Assuming that further IRC Section 382 ownership changes do not occur, the remaining $ ~~119~~ **138** . ~~8~~ **3** million of NOL carryforwards consist of approximately (i) $ ~~17~~ **38** . ~~1~~ **0** million that never expire and are currently available to offset taxable income, (ii) $ ~~7.~~ 9 **. 6** million that are currently available to offset taxable income but if not utilized will expire in 2031 through 2035, (iii) $ ~~13~~ **11** . ~~4~~ **7** million that becomes available through 2038 and that expire by June 30, 2038 if not utilized, and (iv) $ ~~81~~ **79** . ~~4~~ **0** million that never expire. With respect to $ ~~81~~ **79** . ~~4~~ **0** million of NOL carryforwards that never expire, this amount will become available in varying annual amounts for an aggregate of approximately $ ~~15~~ **13** . ~~6~~ **2** million through fiscal year 2038, and $ 1. 2 million annually thereafter. It is possible that any future ownership changes could result in further limitations on the use of our NOL carryforwards or other tax attributes, which could adversely affect our future financial position, profitability and cash flows. If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline. We are subject to Section 404 of The Sarbanes- Oxley Act of 2002 (" Section 404 "), and the related rules of the SEC which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. Effective April 27, 2020, the SEC adopted amendments to the " accelerated filer " and " large accelerated filer " definitions in Rule 12b- 2 under the Securities and Exchange Act of 1934. The amendments exclude from the " accelerated filer " and " large accelerated filer " definitions an issuer that is eligible to be a smaller reporting company and that had annual revenues of less than $ 100 million in the most recent fiscal year for which audited financial statements are available. We determined that our Company does not meet the accelerated or large accelerated filer definitions as of June 30, ~~2023~~ **2024** . For so long as we remain a smaller reporting company and a non- accelerated filer, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies, including, but not limited to, not being required as a non- accelerated filer to comply with the auditor attestation requirements of Section 404 (b). An independent assessment by our independent registered public accounting firm of the effectiveness of internal control over financial reporting could detect problems that our management' s assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation. 13 ~~Although~~ **After remediation of a material weakness identified during the fiscal quarter ended March 31, 2024,** we have determined that our internal control over financial reporting was effective as of June 30, ~~2023~~ **2024 . However** , we cannot **provide** ~~assure~~ **assurance** ~~you~~ that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to ~~remedy~~ **remediate** any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. Operations outside the United States may be affected by different local politics, business and cultural factors, different regulatory requirements and prohibitions between jurisdictions. We intend to seek regulatory approval in foreign countries for all of our potential products prior to commercialization. Pharmaceutical therapies are subject to rigorous preclinical testing and clinical trials and other pre- market approval requirements by Regulatory Authorities in foreign countries. Operations outside the United States may be affected by different local business and cultural factors, different regulatory requirements and prohibitions between jurisdictions, including the Foreign Corrupt Practices Act and local laws prohibiting corrupt payments, and changes in regulatory requirements for financing activities. **Our collection, use, processing, and cross- border transfer of personal information, including individually identifiable health information, is governed by restrictive regulations. Our business is broadly regulated by U. S. and foreign regulatory authorities, and we must comply with all applicable rules and regulations concerning our use, processing, handling, maintenance, and protection of personal information. In the U. S., the Health Insurance Portability and Accountability Act (" HIPAA ") imposes requirements at the federal level relating to the privacy, security and transmission of individually identifiable health information, while individual states, such as California, have adopted privacy regulations restricting the use of personal information and providing individuals certain rights with respect to the collection and use of their data. Further, the collection and use of personal information in Europe is governed by the EU' s General Data Protection Regulation and the United Kingdom' s implementation of the same, or the GDPR. Failure to comply with the requirements of the GDPR and other applicable data protection laws of the EU member states and the United Kingdom, or other applicable privacy rules and regulations in other countries,**

may result in significant fines and other administrative penalties. We may be required to put in place additional mechanisms to comply with current and future privacy and data protection regulations applicable to our business. This may interrupt or delay our development activities and / or require us to change our business practices, which could adversely affect our business, financial condition, results of operations and prospects. We could recognize losses on securities held in our **marketable debt** securities portfolio, particularly if interest rates increase or economic and market conditions deteriorate. As of June 30, ~~2023~~ **2024**, the fair value of the investments in our marketable debt securities portfolio was approximately $ ~~102~~ **56**. ~~3~~ **7** million. Factors beyond our control can significantly influence the fair value of securities in our portfolio and can cause potential adverse changes to the fair value of these securities. For example, fixed- rate securities acquired by us are generally subject to decreases in market value when interest rates rise. Additional factors include, but are not limited to, rating agency downgrades of the securities or our own analysis of the value of the security, defaults by the issuer with respect to the underlying securities, and continued instability in the credit markets. Any of the foregoing factors could ~~cause other~~ **result in credit** - **related loss** ~~than- temporary impairment in future periods~~ and result in realized losses. The process for determining whether ~~impairment is other~~ **allowances are needed for credit** - **related losses** ~~than- temporary~~ usually requires difficult, subjective judgments about the future financial performance of the issuer and any collateral underlying the security in order to assess the probability of receiving all contractual principal and interest payments on the security. As of June 30, ~~2023~~ **2024**, we had $ ~~351~~ **79**, 000 in net unrealized losses in our marketable debt securities. Unrealized losses in our marketable debt securities portfolio may increase in the future due to the aforementioned economic factors. While our goal **14** is to hold each security until maturity, that may not be possible in light of our policy to preserve capital and liquidity and because investment in securities with unrealized losses has a diminished utility as a source of liquidity prior to maturity. Selling securities with an unrealized loss would result in the realization of such losses, which could have an adverse effect on our financial condition and results of operations. ~~The collapse of certain banks and potentially other financial institutions may adversely impact us. On March 10, 2023, Silicon Valley Bank (" SVB ") was shut down, followed on March 11, 2023 by Signature Bank and on May 1, 2023 by First Republic Bank whereby, the Federal Deposit Insurance Corporation was appointed as receiver for each of those banks. As a result, there have been reports of instability at other banks across the globe. Despite the steps taken to date by U. S. agencies to protect depositors, the follow- on effects of the events surrounding the failures of SVB, Signature Bank, and First Republic Bank and the pressure on other banks are unknown. Such effects could include failures of other financial institutions to which we face direct or more significant exposure, and the extent of the impacts relating to financial institution instability or failure is uncertain. Our investment portfolio did not and currently does not contain any securities of SVB, and we did not have any deposit accounts with SVB. We are monitoring the situation and intend to minimize any disruptions to our operations should they arise. However, there may be risks that we have not yet identified, and we cannot guarantee that we will be able to avoid negative consequences directly or indirectly from the foregoing events or other impacts on financial institutions. 14~~ Unfavorable global and regional economic, political and health conditions could adversely affect our business, financial condition or results of operations. Our business could be adversely affected by global or regional economic, political and health conditions. Various macroeconomic factors could adversely affect our business, financial condition and results of operations, including changes in inflation, interest rates and overall economic conditions and uncertainties, including those resulting from political instability, trade disputes between nations and the current and future conditions in the global financial markets. For example, beginning in fiscal year ended June 30, 2023, much of the world, including the U. S. and the E. U., began to experience inflation levels not seen in more than 30 years. As a result, prices for many of our inputs have risen, in some cases dramatically. If inflation stays at elevated levels or increases, we may not be able to mitigate the impact of the increased costs we will bear, which could have an impact on our results of operations and financial condition. A global financial crisis or global or regional political and economic instability, wars, terrorism, civil unrest, outbreaks of disease (for example, COVID- 19), and other unexpected events, such as supply chain constraints or disruptions, could cause extreme volatility in the capital and credit markets and disrupt our business. Business disruptions could include, among others, disruptions to our commercial activities, including due to supply chain or distribution constraints or challenges, clinical enrollment, clinical site availability, patient accessibility, and conduct of our clinical trials, as well as temporary closures of the facilities of suppliers or contract manufacturers in the biotechnology supply chain. In addition, during certain crises and events, patients may prioritize other items over certain or all of their treatments and / or medications, which could have a negative impact on our commercial sales. A severe or prolonged economic downturn, political disruption or adverse health conditions could result in a variety of risks to our business, including our ability to raise capital when needed on acceptable terms, if at all. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business. Certain Provisions of Nevada law may have anti- takeover effects. Certain provisions of Nevada law applicable to us could also delay or make more difficult a merger, tender offer or proxy contest involving us, including Sections 78. 411 through 78. 444 of the Nevada Revised Statutes, which prohibit a Nevada corporation from engaging in any business combination with any" interested shareholder" (as defined in the statute) for a period of two years unless certain conditions are met. In addition, our senior management is entitled to certain payments upon a change in control. Risks Related to Our Intellectual PropertyOur current patent positions and license portfolio may not include all patent rights needed for the full development and commercialization of our product candidates. We cannot be sure that patent rights we may need in the future will be available to license on commercially reasonable terms, or at all. We typically develop our product candidates using compounds that we have acquired or in- licensed, including the original composition of matter patents and patents that claim the activities and methods for such compounds' production and use. For example, in 2017 we in- licensed (i) a fully human monoclonal antibody from XOMA Corporation (" XOMA ") as well as (ii) a plasma kallikrein inhibitor portfolio from ActiveSite Pharmaceuticals (" ActiveSite ") and in consideration for such licenses, we will owe milestone payments and royalties as we progress product candidates through development. As we learn more about the mechanisms of action and new

methods of manufacture and use of these product candidates, we may file additional patent applications for these new inventions, or we may need to ask our licensors to file them. We may also need to license additional patent rights or other rights on compounds, treatment methods or manufacturing processes because we learn that we need such rights during the continuing development of our product candidates. **15** Although our patents may prevent others from making, using or selling similar products, they do not ensure that we will not infringe the patent rights of third parties. We may not be aware of all patents or patent applications that may impact our ability to make, use or sell any of our product candidates or proposed product candidates. For example, because we sometimes identify the mechanism of action or molecular target of a given product candidate after identifying its composition of matter and therapeutic use, we may not be aware until the mechanism or target is further elucidated that a third **-** party has an issued or pending patent claiming biological activities or targets that may cover our product candidate. ~~15~~ U. S. patent applications filed after November 29, 2000 are confidential in the U. S. Patent and Trademark Office for the first 18 months after such applications' earliest priority date, and patent offices in other countries often publish patent applications for the first time six months or more after filing. Furthermore, we may not be aware of published or granted conflicting patent rights. Any conflicts resulting from patent applications and patents of others could significantly reduce the coverage of our patents and limit our ability to obtain meaningful patent protection. If others obtain patents with conflicting claims, we may need to obtain licenses to these patents or to develop or obtain alternative technology. We may not be able to obtain any licenses or other rights to patents, technology or know- how from third parties necessary to conduct our business as described in this Annual Report and such licenses, if available at all, may not be available on commercially reasonable terms. Any failure to obtain such licenses could delay or prevent us from developing or commercializing our drug candidates or proposed product candidates, which would harm our business. Litigation, patent office administrative proceedings or patent interference proceedings may be necessarily brought against us or third parties, as discussed below, to enforce any of our patents or other proprietary rights or to determine the scope and validity or enforceability of the proprietary rights of such third parties. In addition, we may face claims by third parties that our agreements with employees, contractors, or consultants obligating them to assign intellectual property to us are ineffective, or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes. In some instances, there may not be adequate written provisions to address clearly the resolution of intellectual property rights that may arise under our agreements, and we may be limited in our ability to use, make or sell these inventions. Litigation may be necessary to resolve these disputes, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property. Either outcome could have an adverse impact on our business. If our or our licensors' patent positions do not adequately protect our product candidates or any future products, others could compete with us more directly, which would harm our business. Our commercial success will depend in part on our and our licensors' ability to obtain additional patents and protect our existing patent positions, particularly those patents for which we have secured exclusive rights, as well as our ability to maintain adequate protection of other intellectual property for our technologies, product candidates and any future products in the U. S. and other countries. If we or our licensors do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize our product candidates and delay or render impossible our achievement of profitability. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the U. S., and we may encounter significant problems in protecting our proprietary rights in these countries. The patent positions of biotechnology and pharmaceutical companies, including our own patent position, involve complex legal and factual questions, and, therefore, validity and enforceability cannot be predicted with certainty. Patents may be challenged, deemed unenforceable, invalidated or circumvented. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and patent scope can be reinterpreted by the courts after issuance. Moreover, many jurisdictions permit third parties to challenge issued patents in administrative proceedings, which may result in further narrowing or even cancellation of patent claims. We cannot predict whether the patent applications we are currently pursuing will **be** ~~issue~~ **issued** as patents in any particular jurisdiction or whether the claims of any patents, if issued, will provide sufficient protection from competitors. We and our licensors will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies, product candidates and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets. **16** The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that: ● we or our licensors were the first to make the inventions covered by each of our pending patent applications; ● we or our licensors were the first to file patent applications for these inventions; ● others will not independently develop similar or alternative technologies or duplicate any of our technologies; ● any of our or our licensors' pending patent applications will result in issued patents; ● any of our or our licensors' patents will be valid or enforceable; ~~16~~ ● any patents issued to us **,** or our licensors and collaborators will provide a basis for commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties; ● we will develop additional proprietary technologies or product candidates that are patentable; or ● the patents of others will not have an adverse effect on our business. We may be unable to adequately prevent disclosure of trade secrets and other proprietary information. We rely on trade secrets to protect our proprietary know- how and technological advances, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time- consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection could enable competitors to use our proprietary information to develop products that compete with our products

or cause additional, material adverse effects upon our competitive business position. Litigation regarding patents, patent applications and other proprietary rights may be expensive and time consuming. If we are involved in such litigation, it could cause delays in bringing product candidates to market and harm our ability to operate. Our commercial success will depend in part on our ability to manufacture, use, sell and offer to sell our product candidates and proposed product candidates without infringing patents or other proprietary rights of third parties. Although we are not currently aware of any litigation or other proceedings or third- party claims of intellectual property infringement related to our product candidates, the pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents in the future and allege that the use of our technologies infringes these patent claims or that we are employing their proprietary technology without authorization. Likewise, third parties may challenge or infringe upon our or our licensors' existing or future patents. Proceedings involving our patents or patent applications or those of others could result in adverse decisions regarding the patentability of our inventions relating to our product candidates or the enforceability, validity or scope of protection offered by our patents relating to our product candidates. Even if we are successful in these proceedings, we may incur substantial costs and divert management' s time and attention in pursuing these proceedings. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time- consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non- infringing technology, fail to defend an infringement action successfully or have our patents declared invalid, we may incur substantial monetary damages; encounter significant delays in bringing our product candidates to market; or be precluded from participating in the manufacture, use or sale of our product candidates or methods of treatment requiring licenses. **17** If our patent and other intellectual property protection is inadequate, future sales and profits may never materialize or competitors could force our products completely out of the market. Patents which prevent the manufacture or sale of our products may be issued to others. We may have to license those patents and pay significant fees or royalties to the owners of the patents in order to keep marketing our products. This would cause profits ~~on~~ **from any** sales to suffer. We have been granted patents or licensed patents in the United States, but patent applications that have been, or may in the future be, filed by us may not result in the issuance of additional patents. The scope of any patent issued may not be sufficient to protect our technology. The laws of foreign jurisdictions in which we intend to sell our products may not protect our rights to the same extent as the laws of the United States. ~~17~~ In addition to patent protection, we also rely on trade secrets, proprietary know- how and ~~technology~~ **technological** advances. We enter into confidentiality agreements with our employees and others, but these agreements may not be effective in protecting our proprietary information. Others may independently develop substantially equivalent proprietary information or obtain access to our know- how. Litigation, which is expensive, may be necessary to enforce or defend our patents or proprietary rights and may not end favorably for us. We may also choose to initiate litigation against other parties who we come to believe are infringing these patents. If such litigation is unsuccessful or if the patents are invalidated or canceled, we may have to write off the related intangible assets and such an event could significantly reduce our earnings. Any of our licenses, patents or other intellectual property may be challenged, invalidated, canceled, infringed or circumvented and may not provide any competitive advantage to us. Risks Related to Our Common StockExercise or conversion of warrants, stock options and other convertible securities will dilute shareholder' s percentage of ownership. In addition to pre- funded warrants (" PFWs "), we have issued stock options and other warrants to purchase shares of our common stock. In the future, we may grant additional stock options, warrants and convertible securities. The exercise, conversion or exchange of stock options, warrants and convertible securities will dilute the percentage ownership of our shareholders. The dilutive effect of the exercise or conversion of these securities may adversely affect our ability to obtain additional capital. The holders of these securities may be expected to exercise or convert such stock options, warrants and convertible securities at a time when we would be able to obtain additional equity capital on terms more favorable than such securities or when our common stock is trading at a price higher than the exercise or conversion price of the securities. Our ~~common stock may be delisted from the Nasdaq Capital Market if we fail to comply with continued listing standards. Our common stock is currently traded on Nasdaq under the symbol " RZLT ". If we fail to meet any of the continued listing standards of Nasdaq, our common stock could be delisted from Nasdaq. The continued listing standards include specifically enumerated criteria, such as: $ 1. 00 minimum closing bid price (the " Share Price Condition "); shareholders' equity of at least $ 2. 5 million; 500, 000 shares of publicly- held common stock with a market value of at least $ 1 million; 300 round- lot shareholders; and compliance with Nasdaq' s corporate governance requirements, as well as additional or more stringent criteria that may be applied in the exercise of Nasdaq' s discretionary authority. In order to obtain the initial listing of our shares for trading on the Nasdaq Capital Market in November 2020, we effected a reverse stock split in the ratio of 50 shares for 1 share in order to comply with the Share Price Criteria. If the trading price for our shares decreases below $ 1. 00 per share in the future, Nasdaq could delist our shares if the trading price does not subsequently increase above $ 1. 00 per share during prescribed periods and under prescribed conditions set forth in Nasdaq' s listing rules. Our~~ stock price may be volatile. The market price of our common stock is likely to be highly volatile and could fluctuate widely in price in response to various factors, many of which are beyond our control, including (i) limited trading activity on our common stock, (ii) positive or negative results achieved in our clinical activities, including regulatory determinations, (iii) our ability to obtain financing, (iv) additions or departures of key personnel, (v) the specific terms associated with new debt or equity financings, (vi) our ability to execute our business plan, (vii) loss of any strategic relationship, and (viii) economic and other external factors. In addition, the securities markets have from time- to- time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our common stock. ~~18~~ Offers or availability for sale of a substantial number of shares of our common stock may cause the price of our common stock to decline. If our shareholders sell substantial amounts of our common stock in the public market upon the expiration of any statutory holding period or lockup agreements, under Rule 144, or issued upon the exercise of

outstanding PFWs, stock options, warrants or other convertible securities, it could create a circumstance commonly referred to as an " overhang " and in **18** anticipation of which the market price of our common stock could fall. The existence of an overhang, whether or not sales have occurred or are occurring, also could make more difficult our ability to raise additional financing through the sale of equity or equity- related securities in the future at a time and price that we deem reasonable or appropriate. The shares of our restricted common stock will be freely tradable upon the earlier of: (i) effectiveness of a registration statement covering such shares and (ii) the date on which such shares may be sold without registration pursuant to Rule 144 (or other applicable exemption) under the Securities Act of 1933, as amended (" Securities Act "). Investor relations activities and supply and demand factors may affect the price of our common stock. We expect to utilize various techniques such as non- deal road shows and investor relations campaigns in order to generate investor awareness. These campaigns may include personal, video and telephone conferences with investors and prospective investors in which our business practices are described. We may provide compensation to investor relations firms and pay for newsletters, websites, mailings and email campaigns that are produced by third parties based upon publicly- available information concerning us. We do not intend to review or approve the content of such analysts' reports or other materials based upon analysts' own research or methods. Investor relations firms should generally disclose when they are compensated for their efforts, but whether such disclosure is made or complete is not under our control. In addition, investors may, from time to time, also take steps to encourage investor awareness through similar activities that may be undertaken at the expense of the investors. Investor awareness activities may also be suspended or discontinued **,** which may impact the trading market of our common stock. We have no current plan to pay dividends on our common stock and investors may lose the entire amount of their investment. We have never paid cash dividends on our common stock and do not anticipate paying any cash dividends on our common stock for the foreseeable future. Accordingly, any income derived from our common stock would only come from a rise in the market price of our common stock, which is uncertain and unpredictable. We cannot assure investors of a positive return on their investment. Changes in U. S. tax law could adversely affect our business. Changes to tax laws (which changes may have retroactive application) could adversely affect us or **the** holders of our common stock. For example, for the fiscal year ended June 30, 2023, we became subject to Internal Revenue Code Section 174 that requires capitalization of the vast majority of research and development costs whereas under prior tax law substantially all of these costs were deductible in the year incurred. Section 174 provides that such newly- capitalized costs may be amortized and become deductible over a period of 5 years for U. S. based costs and 15 years for foreign- based costs. It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws or regulations may be enacted under existing or new tax laws. This could result in an increase in our tax liability or require changes in our business in order to mitigate any adverse effects of changes in tax laws. Item 1B. Unresolved Staff Comments. Not required for smaller reporting companies. **Item 1C. Cybersecurity. We have established processes for assessing, identifying and managing cybersecurity risks, which are built into our information technology function and are designed to safeguard our information assets and operations from internal and external cyber threats, including protecting employee and patient information from unauthorized access to or attacks on our networks and systems. These processes include physical, procedural and technical safeguards, response plans, regular tests on our systems, incident simulations and routine reviews of our policies and procedures to identify risks and enhance our practices. We also employ processes to identify material risks from cybersecurity threats associated with our use of third- party service providers.** 19