**Risk Factors Comparison 2025-03-04 to 2024-02-29 Form: 10-K**

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

Our business is subject to numerous risks. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this Annual Report on Form 10- K, including our **audited** consolidated financial statements and the related notes ~~, and in our other filings with the SEC~~ . Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In such event, the trading price of our common stock could decline and you might lose all or part of your investment. Risks Related to Our Financial Condition and Need for Additional Capital We have ~~a limited operating history and have~~ incurred significant losses since inception. Our only product approved for sale is DANYELZA ~~, and we have never generated any substantial revenue from product sales~~ . We expect to incur significant losses for the foreseeable future. We may never achieve or maintain profitability, which may cause the market value of our common stock to decline significantly ~~. We are a commercial- stage biopharmaceutical company with a limited operating history~~ . Since our inception in 2015, we have incurred significant losses each year. As of December 31, ~~2023~~ **2024** our accumulated deficit was approximately $ ~~457~~ **487** . ~~5~~ **1** million. We have financed our operations principally through private placements, the initial public offering of our common stock in 2018 as well as subsequent public offerings of our common stock in November 2019 and February 2021, the proceeds from the sales of DANYELZA and the sale of the **priority review voucher, or** PRV **,** granted to us upon FDA approval of DANYELZA ~~. To date, we have devoted substantially all our efforts to research and development, and more recently, commercialization of DANYELZA, which is our only approved product to date and development of omburtamab and SADA PRIT technology~~ . On November 25, 2020, DANYELZA was approved by the FDA for the treatment, in combination with GM- CSF, of pediatric patients one year of age and older and adult patients with relapsed / refractory, or R / R, high- risk neuroblastoma, or NB, in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy. Although in May 2022 our biologic license application, or BLA, for omburtamab was accepted for priority review by the FDA, in November 2022 the FDA issued a complete response letter, or CRL, for the BLA for omburtamab. ~~The letter indicated that the FDA completed the review of the application and determined that it is unable to approve the BLA in its current form. This was consistent with the outcome of the ODAC Meeting held in October 2022. In the CRL, and in our Type A meeting held subsequent to receipt of the CRL, the FDA made recommendations for us to consider in terms of trial design to demonstrate substantial evidence of effectiveness and a favorable benefit- risk profile.~~ As part of our strategic restructuring plan announced in January 2023, we deprioritized the omburtamab program for all indications **, which was ultimately stopped in November 2024 in connection with** ~~and~~ **an** ~~product candidates~~ **amendment to our license agreement with MSK** . ~~We~~ **Our research and development efforts** are **now focused** ~~currently considering the future for our omburtamab development program, and we received an 18- month extension for BLA of omburtamab, which expires~~ on ~~May 30, 2025. We can provide no assurance that the development of omburtamab will continue or that omburtamab will ultimately receive FDA approval. We are~~ using ~~our proprietary Self- Assemly DisAssembly Pretargeted, or~~ SADA PRIT ~~,~~ technology ~~platform, a concept we also refer to as Liquid RadiationTM,~~ to advance a series of antibody constructs, using a two- step pre- targeting approach. The ~~bispecific~~ antibody fragments bind to the tumor before a radioactive payload is subsequently injected. **The aim is specifically to deliver the radioactive payload to the tumor while minimizing exposure to healthy tissue.** GD2- SADA for ~~potential~~ use in GD2- positive solid tumors is our first **investigational** SADA PRIT construct ~~, and we had our first clinical patients dosed in April 2023 in our Phase 1, dose- escalation, single- arm, open- label, non- randomized, multicenter trial, for the treatment of certain solid tumor cancers, including small cell lung cancer, sarcoma, and malignant melanoma. The IND for our first hematological target, the CD38- SADA construct for the treatment of patients with Relapsed or Refractory Non- Hodgkin Lymphoma was cleared in October 2023, and we expect to dose the first patient in 2024~~ . We are still in **the** early stages of development of **this product candidate and it may have toxicities or lack of efficacy that prohibit further development or preclude its approval. We are still in the early stages of development of the** SADA PRIT technology platform. We may not be successful in our efforts to use the SADA PRIT ~~technology~~ **Technology** to build **any** ~~a pipeline of~~ product candidates. Our investment in developing **the** SADA PRIT ~~technology~~ **Technology** may contribute to the risk that we may never achieve profitability. Our other product candidates are in the early stages of clinical development or pre- clinical research. As a result, we expect that it will be a number of years, if ever, before we have any of these other product candidates approved and ready for commercialization. We expect to continue to incur significant expenses and operating losses for the foreseeable future. The net losses we incur ~~may~~ fluctuate significantly from quarter to quarter. Our only **product** approved ~~product~~ for sale is DANYELZA, which received FDA accelerated approval on November 25, 2020. We began limited sales and shipments of DANYELZA in February 2021 and the revenue generated from product sales does not fully fund our operating expenses. We do not anticipate generating revenue that will fully fund our operating expenses for a period of time, if ever. No assurance can be given that we will ever receive regulatory approval for any of our product candidates other than DANYELZA. Our ability to generate revenue and achieve profitability depends significantly on our success in many factors, including: ● **expanding market acceptance of DANYELZA and increasing our share of the total addressable patient population for this treatment; ●** the successful commercialization of **any** ~~DANYELZA and our~~ product candidates for which we may obtain regulatory approvals and marketing authorizations, either directly or with a collaborator or distributor; ● completing research regarding, and non- clinical and clinical development of, our product candidates; ● obtaining and maintaining regulatory

approvals, marketing authorizations and coverage and reimbursements from payors for DANYELZA **, our SADA PRIT product candidates** and **any other** product candidates for which we complete clinical studies; ● ~~developing and~~ maintaining a sustainable and scalable manufacturing process for DANYELZA ~~and our other product candidates~~, including ~~establishing and~~ maintaining commercially viable supply relationships with third parties including, Patheon / Thermo Fisher ~~and EMD / Merck~~, among others, or establishing our own manufacturing capabilities and infrastructure **; ● establishing a sustainable and scalable manufacturing process for our SADA PRIT product candidates, including establishing commercially viable and regulatorily compliant supply relationships for radioactive materials used in these product candidates**; ● obtaining market acceptance of DANYELZA and our product candidates as viable treatment options; ● addressing any competing products, product candidates, related technologies and / or market developments; ● identifying, assessing, acquiring and / or developing new product candidates; ● negotiating favorable terms in any collaboration, licensing, distribution or other arrangements into which we may enter; ● maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know- how; **47** ● attracting, hiring, and retaining qualified personnel; and ● adequately financing our operations at acceptable terms. We **incur and** anticipate incurring **,** research, development, clinical trial, manufacturing and marketing costs associated with commercializing even approved products. For example, we continue to run clinical studies on our currently marketed product DANYELZA to fulfill the regulatory requirement from the accelerated approval of the product by FDA. The accelerated approval of DANYELZA is subject to certain post- marketing requirements and commitments, including a confirmatory post- marketing trial of clinical benefit, **our ongoing Study 201,** that must be completed in order to convert the BLA to full approval and prevent withdrawal of the license by **the** FDA ~~. The confirmatory post- marketing clinical trial required by the FDA to verify and to further characterize the clinical benefit is our ongoing Study 201, which is designed to enroll a 53minimum of 80 evaluable patients and report overall rate of response, or ORR, duration of response, or DOR, progression free survival, or PFS, and overall survival, or OS. The ORR is the primary endpoint for the study, DOR is the secondary endpoint and PFS and OS are secondary endpoints in long- term follow- up. We anticipate completing the study no later than by March 31, 2027~~. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory authorities, domestic or foreign, to change our manufacturing processes or assays, or to perform clinical, non- clinical, or other types of studies in addition to those that we currently anticipate. If we are successful in obtaining regulatory approvals to market more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for any such product, the ability to obtain reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably expected populations for treatment are narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate sufficient revenue from the sale of DANYELZA or any other approved products, we may never become profitable. Our ~~limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability. We were incorporated and began our operations on April 30, 2015. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, commercializing DANYELZA, conducting clinical trials of DANYELZA and conducting pre- clinical studies and clinical trials of our other product candidates, and identifying additional potential product candidates. Typically, it takes about six to 10 years to develop a new drug from the time it is in Phase 1 clinical trials to when it is approved for treating patients, but in many cases it may take longer. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing multiple pharmaceutical products. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors as we continue to develop and commercialize DANYELZA and our other product candidates. Our~~ payment obligations to MSK and MIT may be a drain on our cash resources, or may cause us to incur debt obligations or issue additional securities to satisfy such payment obligations, which may adversely affect our financial position and results of operations. ~~Under the MSK License, we have committed to funding scientific research as well as conducting certain clinical trial activities at MSK.~~ As **DANYELZA and any other** licensed product candidates progress through clinical development and commercialization, certain milestone payments will ~~come due, and we will owe MSK customary royalties on commercial sales of our approved products, if any. Milestone payments~~ become due upon achievement of the related clinical, regulatory or sales- based ~~milestone~~ **milestones** set forth in the MSK ~~license~~ **License** ~~agreements~~ **Agreement** and all milestones are accrued for when they are probable and estimable. Certain of the clinical and regulatory milestone payments become due at the earlier of completion of the related milestone activity or the date indicated in the MSK ~~license~~ **License** ~~agreements~~ **Agreements**, whether or not the milestone activity has been achieved. Total clinical and regulatory milestones potentially due under the MSK License are $ 2. 5 million and $ ~~9~~ **8**. ~~0~~ **1** million, respectively. ~~There are also sales~~ **Sales** - based milestones ~~that~~ **also** become due should we achieve certain amounts of sales of licensed products with total sales- based milestones potentially due of $ 20. 0 million. Under the **CD33 License Agreement, dated November 13, 2017, between** MSK ~~CD33~~ **and us, or the CD 33** License, we are obligated to make potential payments of $ 0. 6 million, $ 0. 5 million and $ 7. 5 million for clinical, regulatory and sales- based milestones, respectively. In April 2020, we entered into **a license agreement, or** the SADA License Agreement **with MSK and Massachusetts Institute of Technology, or MIT,** which requires us to pay to MSK and MIT mid to high single digit royalties based on annual net sales of licensed products or the performance of licensed services by us and our affiliates and sublicensees. We are obligated to pay annual minimum royalties of $ 40, 000, increasing to $ 60, 000 once a patent has been issued, over the royalty term, commencing on the tenth anniversary of the SADA License **Agreement**. These amounts are non- refundable but are creditable against royalty payments otherwise due under the SADA License **Agreement**. We are ~~54also~~ **also** obligated to pay to MSK and MIT certain clinical, regulatory and sales **-** based milestone payments under the SADA License Agreement.

Certain of the clinical and regulatory milestone payments become due at the earlier of completion of the related milestone activity or the date indicated in the SADA License Agreement. Total clinical and regulatory milestone payments potentially due under the SADA License Agreement are $ 4. 7 million and $ 18. 1 million, respectively. Additionally, we are also obligated to make sales - based milestones payments totaling $ 23. 8 million, that become due should we achieve certain amounts of sales of licensed products under the SADA License **Agreement** . In addition, for each of the SADA PRIT constructs generated by MSK and sold on our behalf by one of our ~~sublicenses~~ **48sublicenses** , **we may** ~~we owe~~ ~~may pay~~ sales - based milestone payments in the total amount of $ 60. 0 million based on the achievement of various levels of cumulative net sales by the sublicensee ~~. Under the SADA License Agreement, we also committed to fund scientific research at MSK under a Sponsored Research Agreement for $ 1. 5 million. The scientific research took place over a period that commenced in September 2020 and ended in February 2022~~ . In addition, we have committed to acquire certain personnel and laboratory services at MSK under a Master Data Services Agreement, or MDSA, and two separate Core Facility Service Agreements, or CFSAs. We have also entered into an Investigator- Sponsored Master Clinical Trial Agreement, or the MCTA, with MSK under which we are providing drug product and funding for certain clinical trials at MSK under separate executed appendices. ~~Additionally, we~~ **Payments under these agreements** have **been** ~~entered into a Sponsored Research Agreement, or the SRA, with MSK pursuant to which we paid MSK to conduct certain research projects over a period of five years related to the intellectual property licensed under the MSK License. The SRA was amended on September 13, 2019,~~ and ~~will expire five years from the date of the amendment. We also remain responsible for any potential downstream payment obligations to MSK related to the GD2- GD3 Vaccine. This includes our obligation to make development and regulatory milestone payments, if achieved, totaling $ 1. 4 million, annual minimum royalties of $ 10, 000, increasing to $ 25, 000 from approval of the first new drug application, or NDA, or BLA for a licensed product over the royalty term, and mid- single digit royalty payments to MSK on sales. These payments~~ could **in the future** be significant and in order to satisfy our obligations to MSK and MIT, we may be required to use our existing cash, incur debt obligations or issue additional equity securities, any of which may materially and adversely affect our financial position and results of operations. We will need substantial additional funding until at least such time as we can generate ~~substantial~~ **adequate** revenue ~~from product sales~~ **to cover our operating expenses** . If we fail to obtain such additional funding, we may be forced to delay, reduce or eliminate our research and drug development programs or current or future commercialization efforts and our license and other agreements may be terminated. Developing pharmaceutical products, including conducting pre-clinical studies and clinical trials and commercialization of any approved products, is a very time- consuming, expensive and uncertain process that takes years to complete. We expect our expenses to **remain significant** ~~increase in connection with our ongoing activities~~ , particularly as we ~~grow our sales and marketing team to support sale of DANYELZA and~~ conduct clinical trials of, and seek marketing approval for our other product candidates. We expect to incur commercialization expenses, which ~~may~~ **have been and will continue to** be significant, related to product sales, marketing, manufacturing and distribution of DANYELZA **and any other products that may be approved** . Accordingly, until at least such time as we can generate ~~substantial additional~~ revenues from sales of DANYELZA or our product candidates, if approved **, that are adequate to support our operational expenses** , we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise **enough** ~~sufficient amounts of~~ additional capital when needed or on attractive terms, we may be forced to delay, reduce or eliminate our research and drug development programs or our future commercialization efforts. Changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We will require additional capital for further development and commercialization of our product candidates and may need to raise additional funds earlier ~~if we choose to expand more rapidly~~ than ~~we presently anticipate~~ **is currently expected** . In addition, we cannot be certain that additional funding will be available on acceptable terms when needed, or at all. Our ability to raise additional capital may be adversely impacted by worsening global economic conditions, with disruptions to, and volatility in, the credit and financial markets in the U. S. and worldwide resulting from the effects of inflationary pressures, health crises, the military conflict between Ukraine and Russia, the state of ~~war between Israel and Hamas~~ **conflict in the Middle East** and the threat of a ~~greater conflict~~ **wider turmoil** , current and potential future bank failures, and otherwise. If these ~~55conditions~~ -- **conditions** persist and deepen, we could experience an inability to access additional capital or our liquidity could otherwise be impacted, which could in the future negatively affect our capacity for certain corporate development transactions or our ability to make other important, opportunistic investments. We have no firmly committed source of additional capital and 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 our product candidates or other research and development initiatives. Our licenses and other agreements may also be terminated if we are unable to meet the payment obligations under such agreements. We could be required to seek collaborators for DANYELZA or our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline. ~~Raising~~ **49Raising** additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to DANYELZA or our **other** product candidates on terms unfavorable to us. We expect our expenses to increase in connection with our planned operations. Until such time, if ever, as we can generate **adequate** ~~substantial additional~~ revenues from the sale of DANYELZA and our product candidates, if approved **, to support our operational expenses** , we expect to finance our cash needs through a combination of cash on hand, securities offerings, debt financings, collaborations, strategic alliances and / or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible securities, ownership interests will be diluted, and the terms of these securities could include liquidation or other preferences and anti- dilution protections that could adversely affect the rights of

common stockholders. In addition, debt financing, if available, would result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or acquisitions, ~~limiting our ability to conduct licensing transactions,~~ creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day ~~-~~ to ~~-~~ day activities, which may adversely affect our management' s ability to oversee the commercialization of DANYELZA or other products candidates, if approved, or the development of our product candidates. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights related to our intellectual property ~~,~~ **or** future revenue streams or any of our future product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, reduce and / or eliminate our product development or current or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves. We may expand our resources to pursue a particular product or product candidate or indication and fail to capitalize on other products or product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Historically, we have focused our efforts and managerial resources on specific products and product candidates and on specific indications such as DANYELZA for the treatment of R / R **HR** ~~high- risk~~ NB in bone and / or bone marrow and omburtamab for **central nervous system, or** CNS **, or leptomeningeal,** or LM **,** from NB, and more, recently, SADA for solid tumors and Non-Hodgkin Lymphoma. As a result **of these decisions** , we may forgo or delay pursuit of opportunities with other products or product candidates or for other indications that may prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Failure to properly assess potential product candidates for indications could result in focusing on product candidates for indications with lower market potential, which could harm our business and financial condition. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through partnering, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate or ~~56product~~ **product** . For example, in November 2022 the FDA issued a CRL for our BLA for omburtamab. The letter indicated that the FDA completed the review of the application and determined that it is unable to approve the BLA in its current form. This was consistent with the outcome of the ODAC Meeting held in October 2022. In its CRL for omburtamab, and in our Type A meeting held subsequent to receipt of the CRL, the FDA made recommendations for us to consider in terms of trial design to demonstrate substantial evidence of effectiveness and a favorable benefit- risk profile. ~~As~~ **However, as** part of our strategic restructuring plan announced in January 2023, we deprioritized the omburtamab program for all indications and product candidates **, which was** ~~. We are currently considering the future for our omburtamab development program and we can provide no assurance that the development of omburtamab will continue or that omburtamab will~~ ultimately ~~receive FDA approval~~ **stopped in November 2024 in connection with an amendment to our license agreement with MSK** . ~~We~~ **In addition, we deprioritized other pipeline programs, including activities relating to the GD2- CD3 Vaccine and CD 33 antibody constructs by delaying trial initiation and overall timelines as part of the restructuring plan. 50We** depend on a limited number of customers for a high percentage of our revenue. If we cannot maintain our current relationships with customers, fail to sustain recurring sources of revenue with our existing customers, or if we fail to enter into new relationships, our future financial condition and results of operations will be adversely affected. Moreover, the financial difficulties or insolvency of one or more of our major customers or their lack of willingness and ability to distribute our approved product, DANYELZA, could adversely affect our financial position and results of operations. We had product sales to certain customers that accounted for more than 10 % of total **net** product revenue ~~, net~~ for the years ended December 31, **2024 and** 2023 ~~and 2022~~ **, respectively** . McKesson, ~~AmerisourceBergen, WEP and~~ Cardinal Health **and Cencora** accounted for ~~46~~ **41** %, ~~22~~ **20** %, ~~10 %~~ and ~~13~~ **16** %, respectively, of the Company' s **net** product revenue ~~, net~~ for the year ended December 31, ~~2023~~ **2024** . McKesson, ~~AmerisourceBergen~~ **Cencora** , **WEP** and Cardinal Health accounted for **46** ~~70. 8~~ %, **22** ~~17. 4~~ %, ~~and~~ 10 ~~. 1~~ **% and 13** %, respectively, of the Company' s **net** product revenue ~~, net~~ for the year ended December 31, ~~2022~~ **2023** . Our future success depends on our ability to maintain these relationships, to increase our penetration among these existing customers and to establish new relationships. We engage in conversations with other companies and institutions regarding potential commercial opportunities on an ongoing basis, which can be time consuming. There is no assurance that any of these conversations will result in a commercial agreement, or if an agreement is reached, that the resulting relationship will be successful. In addition, if our customers order our approved product, DANYELZA, but fail to pay on time or at all, our liquidity, financial condition, results of operations, cash flows and prospects could be materially and adversely affected. Moreover, our product sales are made through arrangements primarily with three national specialty distributors in the United States ~~of America~~ . As of December 31, ~~2023~~ **2024** , the **net** accounts receivable balances from such distributors totaled ~~66~~ **73** % of the Company' s outstanding accounts receivable. A default by any of these customers on their amounts owed to us could have a material adverse effect on our financial position. Future sales and our ability to collect accounts receivable depend, in part, on the financial strength of our customers and our distributors' willingness and ability to successfully market our approved product, DANYELZA. We estimate an allowance for doubtful accounts based on our assessment of specific identifiable customer accounts considered at risk or uncollectible, as well as an analysis of current receivables aging and expected future write- offs and this allowance adversely impacts our results of operations. In the event customers experience greater than anticipated financial difficulties, insolvency, or difficulty marketing DANYELZA, we expect our financial position and results of operations to be further adversely impacted by our failure to collect accounts receivable in excess of the amount due, net of the estimated allowances. Risks related to

product development and commercializationDrug development is a lengthy and expensive process, with an uncertain outcome. If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs, experience delays in completing, or ultimately be unable to complete, the development of our product candidates or be unable to obtain marketing approval. We may encounter substantial delays in our clinical trials, or may not be able to conduct our trials on the timelines we expect. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete pre- clinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates. No assurance can be given that any clinical studies will be conducted as planned or completed on schedule, if at all. In addition, we cannot be sure that we will be able to submit investigational new drug applications, ~~57or~~ **or** INDs, for any of our product candidates in the future and we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin. Moreover, even if these clinical studies begin, issues may arise that could suspend or terminate such clinical trials. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Failure of one or more clinical trials can occur at any stage of testing. The outcome of pre- clinical studies and early- stage clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial, such as the results of our ongoing clinical trials of our lead product candidates, do not necessarily predict final results. Moreover, pre- clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre- clinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. ~~The~~ **51The** nature of the patient populations that we study in our clinical trials means that the treatment effect of our product candidates has to be demonstrated despite being the second **-** or third- line of treatment, and in some cases, despite concomitant treatment with radiation or chemotherapy. Some of our target indications may also be difficult to assess via current imaging technology and other testing methods, which may lead to in- conclusory or equivocal data regarding treatment effect. Furthermore, because our study populations are small, statistical analyses may not fully adjust for these and other potential bias in the data. As was the case for omburtamab, any or all of these factors may mean that we are unable to demonstrate substantial evidence of the effectiveness of ~~or~~ **our** product candidates to the satisfaction of the FDA or comparable foreign regulatory authorities. Our only approved product, DANYELZA, our product candidates and related technologies are novel approaches to cancer treatment that present significant challenges, and our ability to generate product revenue is dependent on the success of DANYELZA or one or more of our product candidates, which might require additional clinical testing before we can seek regulatory approval and begin commercial sales. DANYELZA and our product candidates and related technologies represent novel approaches to cancer treatment generally. Developing and commercializing these products therefore subjects us to a number of challenges. On November 25, 2020, DANYELZA received regulatory approval by the FDA in the United States for the treatment in combination with GM- CSF of high- risk R / R NB. The FDA has issued a post-marketing ~~commitment~~ **mandate requiring us** to provide data **that** ~~on PFS, supporting~~ **supports** the efficacy of the product. We are currently performing clinical studies, such as Study 201, aimed ~~to~~ **at** ~~fulfill~~ **fulfilling** the requirements. There can be no assurance that these studies will generate data sufficient to support the efficacy of the product. **In** ~~Although the FDA accepted our BLA for omburtamab for priority review, in~~ November 2022 **,** the FDA issued a CRL for our BLA for omburtamab. The letter indicated that the FDA completed the review of the application and determined that it is unable to approve the BLA in its current form. In the CRL, and in our Type A meeting held subsequent to receipt of the CRL, the FDA made recommendations for us to consider in terms of trial design to demonstrate substantial evidence of effectiveness and a favorable benefit- risk profile. As part of our strategic restructuring plan announced in January 2023, we deprioritized the omburtamab program for all indications **, which was ultimately stopped in November 2024 in connection with** ~~and product candidates. We are currently considering the future for our omburtamab development program and we received~~ an **amendment** ~~18- month extension for the BLA, which expires on May 30, 2025. there is no assurance that we will continue~~ to ~~develop omburtamab or~~ **our license agreement with MSK** ~~receive approval of our BLA for omburtamab~~ . The SADA PRIT technology is still in **the** early stages of clinical development or pre- clinical research. We may never be able to develop a marketable product other than DANYELZA. Our ability to generate product revenue is highly dependent on our ability to successfully commercialize DANYELZA and to obtain additional regulatory approvals of and successfully commercialize additional product candidates. This will require additional clinical and non- clinical development, regulatory review and approval in ~~each~~ **multiple** ~~jurisdiction~~ **jurisdictions** ~~in which we intend to market them~~ , substantial investment, access to sufficient commercial manufacturing capacity, and significant marketing efforts. We cannot be certain that any of our ~~other~~ product candidates will be successful in clinical studies **,** and they may not receive regulatory approval even if they are successful in clinical studies. The success of our product candidates in development will depend on several factors, including the following: ● successful and timely completion of our ongoing clinical trials; ~~58~~ ● initiation and successful patient enrollment and completion of additional clinical trials on a timely basis; ● safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority for marketing approval; ● timely receipt of marketing and reimbursement approvals for our lead product candidates from applicable regulatory authorities; ● the performance of our future collaborators, if any; **52** ● the extent of any required post- marketing approval commitments to applicable regulatory authorities; ● establishment of supply arrangements with third- party **suppliers of radioactive and other** raw materials ~~and drug product suppliers and manufacturers~~ ; ● establishment of scaled production arrangements with third- party manufacturers **and drug product suppliers** to obtain finished products that are appropriately packaged for sale; ● obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally; ● protection of our rights in our intellectual property portfolio, including our licensed intellectual property; ● successful launch of commercial sales following any marketing approval including the hiring of a direct salesforce and creation of marketing campaigns; ● a continued acceptable safety profile following any marketing approval; ● commercial acceptance by physicians and patients, the medical community and third- party payors; and ● our ability to compete

with other therapies. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. Further, competitors who are developing product candidates with technology similar to ours may experience problems with their product candidates that could identify problems in ~~the~~ **our** technology that would potentially harm our business. Many of our product candidates are based on similar technologies. Therefore, if one product candidate encounters safety or efficacy problems, developmental delays, regulatory issues, or other problems, our other development plans and business could be significantly harmed. The SADA PRIT Technology is still in early..... sanctions or wider military conflict. The commercial success of DANYELZA and of any future approved products, will depend upon the degree of market acceptance by physicians, patients, third- party payors, and others in the medical community. The commercial success of DANYELZA, and of any future approved products, will depend in part on market acceptance by physicians, patients, third ~~-~~party payors, and others in the medical community. For example, current cancer treatments like surgery, chemotherapy or radiation therapy are well ~~-~~established in the medical community, and doctors may continue to rely on these treatments **. DANYELZA was not listed in the treatment recommendations for neuroblastoma in the guideline published in July 2024 by the National Comprehensive Cancer Network, a non- profit alliance of 33 leading cancer care centers. Any potential regulatory approval of product candidates using the SADA PRIT technology does not guarantee the establishment of a viable market for their use. The use of radioactive isotopes in connection with the SADA PRIT technology carries safety, storage, handling and disposal risks, which require adherence to strict regulations and protocols. The perceived or actual risks of radiation exposure could limit market acceptance of the SADA PRIT product candidates** . If DANYELZA or any future approved products do not achieve an adequate level of **market** acceptance, we may not generate significant revenues from sales ~~of drugs~~ and we may not become profitable. The degree of market acceptance of DANYELZA, and of any future product, if approved for commercial sale, will depend on a number of factors, including: ● the efficacy and safety of the product and the prevalence and severity of any side effects; ● developing processes for the safe administration of our products, including long- term follow- up for all patients who receive the product; **53** ● the potential advantages of the product compared to competitive therapies; ● whether the product is designated under physician treatment guidelines as a first, second or third- line therapy; ● our ability, or the ability of any potential future collaborators, to offer the product for sale at competitive prices; ● the product' s convenience and ease of administration compared to alternative treatments and any requirement for in- patient versus out- patient administration; ● the willingness of the target patient population to try, and of physicians to prescribe, the product; ● limitations or warnings, including distribution or use restrictions contained in the product' s approved labeling; ● the strength of sales, marketing and distribution support; ● changes in the standard of care for the targeted indications for the product; ● the willingness of the target patient populations to try new therapies and enroll in ongoing clinical trials, and of physicians to prescribe these therapies; ● relative convenience and ease of administration; ~~61~~ ● availability and amount of coverage and reimbursement from government payors, managed care plans and other third- party payors; and ● the timing of competitive product introductions and other actions by competitors in the marketplace. **The** SADA PRIT Technology is still in early stages of clinical development or pre- clinical research and may not result in approvable or marketable products,which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval,and we may not be successful in our efforts to use the SADA PRIT Technology to build a pipeline of product candidates.We are seeking to identify and develop a broad pipeline of product candidates using the SADA PRIT Technology.We **are still** ~~have only recently begun dosing patients~~ in our Phase 1 trial of GD2- SADA.The scientific research that forms the basis of our efforts to develop product candidates with the SADA PRIT Technology is still ongoing.We are not aware of any FDA- approved therapeutics utilizing a similar technology.Further,the scientific evidence to support the feasibility of developing therapeutic treatments based on the SADA PRIT Technology is both preliminary and limited.As a result,we are exposed to a number of unforeseen risks,and it is difficult to predict the types of ~~59challenges~~ -- **challenges** and risks that we may encounter during development of our product candidates using the SADA PRIT Technology.For example,before the first dosing in our Phase 1 trial of GD1- SADA,we had not tested any of the product candidates being developed using the SADA **PRIT** platform in humans,and most of our current data is limited to animal models and pre- clinical cell lines,the results of which may not translate into humans.Further,relevant animal models and assays may not accurately predict the safety and efficacy of our product candidates based on the SADA **PRIT** Technology in humans,and we may encounter significant challenges creating appropriate models and assays for demonstrating the safety and purity of our product candidates.In addition,the SADA PRIT Technology has potential safety risks related to,but not limited to,the radiation stemming from the delivery of radioactive payloads.As a result,it is possible that safety events or concerns could negatively affect the development of our product candidates ~~developed using~~ **that are based on** the SADA PRIT Technology,including adversely affecting patient enrollment among the patient populations that we intend to treat. ~~Given~~ **54Given** the novelty of the SADA PRIT Technology,we intend to work closely with the FDA and comparable foreign regulatory authorities to perform the requisite scientific analyses and evaluation of our methods to obtain regulatory approval for our product candidates;however,due to a lack of comparable experiences,the regulatory pathway with the FDA and comparable regulatory authorities may be more complex and time- consuming relative to other more well- known therapeutics.Even if we obtain ~~human~~ **adequate** data to support **approval of** our product candidates developed using the SADA PRIT Technology,the FDA or comparable foreign regulatory agencies may lack experience in evaluating the safety and efficacy of our product candidates developed using the SADA PRIT Technology,which could result in a longer than expected regulatory review process,increase our expected development costs,and delay or prevent commercialization of our product candidates.The validation process takes time and resources,may require independent third- party analyses,and may not be accepted or approved by the FDA and comparable foreign regulatory authorities.We cannot be certain that our **SADA PRIT** approach will lead to the development of approvable or marketable products ~~developed using the SADA PRIT Technology,alone or in combination with other therapies~~

.Additionally,an element of our strategy is to use and expand the SADA PRIT Technology to build a pipeline of product candidates and progress those product candidates through clinical development for the treatment of a variety of different cancers.Although our research and development efforts to date have been focused on identifying a pipeline of product candidates directed at cancers,we may not be able to develop product candidates that are safe and effective.Even if we are successful in building a pipeline of product candidates developed using the SADA PRIT Technology,the potential product candidates that we identify may not be suitable for clinical development,including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to ~~be approvable or marketable products that will~~ receive marketing approval and achieve market acceptance.If we do not continue to successfully develop,get approval for and begin to commercialize any product candidates developed using the SADA PRIT Technology,we will face difficulty in obtaining product revenue therefrom in future periods,which **could result in significant harm to our financial position and adversely affect our share price.** We have limited experience operating as a commercial company and the marketing and sale of DANYELZA or any future approved products may be unsuccessful or less successful than anticipated. We may not be successful in ~~commercializing~~ **increasing the sales of** DANYELZA or any future approved product unless we are able to maintain and expand our sales and marketing capabilities or enter into agreements with third parties to sell and market such approved products. While we have commercially launched DANYELZA in the United States and in several other countries, we have limited experience as a commercial company and there is limited information about our ability to successfully overcome many of the risks and uncertainties encountered by companies commercializing drugs in the biopharmaceutical industry. We began small shipments of DANYELZA in February 2021. Other than our commercialization partnerships for DANYELZA and **our discontinued product candidate,** omburtamab **,** covering certain territories outside the United States, we are not currently a party to any strategic collaboration that provides us with access to a collaborator' s resources in selling or marketing drugs. To achieve commercial success for **DANYELZA and** any future approved products we must successfully maintain and expand our sales and marketing organization or outsource these functions to strategic collaborators and other third parties. We have built our own focused, specialized sales and marketing organization in the United States ~~. We~~ **, and we** continue to **selectively** explore ~~selectively~~ **and** ~~establishing~~ **establish** partnerships in markets outside the United States to support the commercialization of **DANYELZA in other jurisdictions** ~~our product candidates for which we obtain marketing approval and that can be commercialized with such capabilities~~ . Risks are involved both with further establishing our own direct sales and marketing capabilities and with entering into arrangements with third parties to perform these services. For example, recruiting and training even a small sales force can be expensive and time- consuming and could delay any commercial launch of a product candidate, if approved. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed, does not occur for any reason, or authorization is lost, 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~~ **55Factors** that may inhibit our efforts to commercialize our drugs on our own after obtaining any marketing approval include: ● our inability to recruit and retain adequate numbers of effective sales and marketing personnel, and continue to develop and expand our sales and marketing efforts; ● our inability to raise financing necessary to maintain and grow our commercialization infrastructure; ● the inability of sales personnel to obtain access to physicians or our failure to educate physicians on the benefits of prescribing DANYELZA or any future approved products; ● the lack of complementary drugs to be offered by our sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive offerings, and the lack of accurately forecast demand for our products and scale manufacturing to meet that demand; ● unforeseen costs and expenses associated with creating an independent sales and marketing organization; ● our inability to obtain sufficient coverage and reimbursement from third- party payors and governmental agencies; ~~62~~ ● our inability to establish and maintain our relationships with healthcare providers who will be treating the patients who may receive our products and any future products; ● our inability to maintain or to gain regulatory authorization for the development and commercialization of our product candidates; ● our **partners' inability to recruit patients through market access named patient programs; and ● our** inability to develop and maintain successful strategic alliances ~~; and ● our inability to develop and maintain successful strategic alliances~~ . If we are unsuccessful in accomplishing these objectives, we may not be able to successfully ~~develop product candidates,~~ **grow or maintain sales of DANYELZA or** commercialize ~~DANYELZA or~~ any future approved products, raise capital, expand our business, or continue our operations. In addition, our revenues from the sale of drugs or the profitability of these revenues to us are likely to be lower from arrangements that we enter into with third parties to perform sales and marketing services ~~(such as with SciClone Pharmaceuticals International Ltd, Takeda Israel, Swixx Biopharma AG, Adium Pharma S. A. and WEP Clinical Ltd.)~~ than if we were ourselves to market and sell any drugs that we develop. We have limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our drugs effectively. In addition, we may not be successful in entering additional arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. If we do not maintain and expand our sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we might not be successful in commercializing DANYELZA or any of our product candidates for which we receive marketing approval, if any. In the event that we are unable to effectively deploy our sales organization or distribution strategy on a timely and efficient basis, if at all, the commercialization of DANYELZA or our product candidates, if approved, could be delayed which would negatively impact our ability to generate product revenues. We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively. The biotechnology and pharmaceutical industries generally, and the cancer drug sector specifically, are characterized by rapidly advancing technologies, evolving understanding of disease etiology, intense competition and a strong emphasis on intellectual property. While we believe that our product candidates and our knowledge and experience provide us with competitive advantages, we face substantial potential competition from many different sources, including large and specialty pharmaceutical

and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions. Many of our competitors have substantially greater ~~financial~~ **56financial** , technical and other resources, such as larger research and development staff and experienced manufacturing organizations as well as established marketing and sales forces. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized, or less costly than DANYELZA, or our other product candidates, or may develop proprietary technologies or secure patent protection that we may need for the commercialization of DANYELZA and the development of our product candidates and related technologies. In addition to the current standard of care for patients, commercial and academic clinical trials are being pursued by a number of parties in the field of immunotherapy. Early results from these trials have fueled continued interest in immunotherapy, which is being pursued by several biotechnology companies as well as by large pharmaceutical companies. Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, pre - clinical studies, conducting clinical trials, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early - stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. ~~63With~~ -- **With** respect to DANYELZA, which targets GD2- positive tumors, United Therapeutics Corporation, or United Therapeutics, has commercialized Unituxin ® (dinutuximab), an antibody against GD2, in the United States, Canada and Japan. Although United Therapeutics has discontinued its efforts to investigate Unituxin ®' s potential activity against adult cancerous tumors, it has maintained its efforts to develop a humanized version of Unituxin ® and plans to develop Unituxin ® within R / R NB. DANYELZA also faces competition from Qarziba ® (dinutuximab beta) a similar antibody product against GD2 developed by Apeiron Biologics AG, or Apeiron. EUSA Pharma (UK) Ltd., or EUSA, has acquired global commercialization rights to Qarziba ® (dinutuximab beta), and it is currently being commercialized in European Union and was approved by the European Commission to treat high- risk NB and R / R NB. In January 2020, EUSA and BeiGene Ltd., or BeiGene, announced an exclusive collaboration to commercialize Qarziba ® in mainland China and in August 2021 EUSA and BeiGene announced that the China National Medical Products Administration, or NMPA, had granted Qarziba ® (dinutuximab beta) conditional marketing approval for the treatment of high- risk NB and R / R NB. EUSA has previously announced plans to file for registration of dinutuximab beta in the United States for the treatment of R / R NB. EUSA was acquired by Recordati in March 2022. In addition, Renaissance Pharma Ltd in the United Kingdom announced in August 2023 a development program focused on Hu14. 18, a humanized anti- GD2 monoclonal antibody, licensed from St. Jude Children' s Research Hospital for the treatment of newly diagnosed high- risk neuroblastoma. US WorldMeds has also received FDA approval of eflornithine hydrochloride, or DFMO, to reduce the risk of relapse in pediatric patients with high- risk neuroblastoma who have completed multiagent, multimodality therapy. The SADA PRIT technology, where bispecific antibody fragments bind to the tumor before a radioactive payload is injected in a two- step approach faces competition from a range of companies developing comparable approaches, involving one- step, two- step or three- step models to bind antibody construct to the tumor and radiate the tumor. OncoOne Research & Development GmbH, or OncoOne, is developing several constructs under their PreTarg- it ® technology, which is a modular platform utilizing bispecific antibodies for delivery of payloads, where the bispecific antibody is first injected and accumulated on the tumor, while unbound antibodies are decomposed and excreted. Subsequently, a payload is administered through a second infusion and binds to the bispecific antibody in the tumor. Additionally, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our DANYELZA or for any other future products, if approved. We may not be able to implement our business plan if the acceptance of DANYELZA or ~~for~~ any other future products, if approved, is inhibited by price competition or **if** ~~the reluctance of~~ physicians ~~to~~ switch from existing methods of treatment to our products, or if physicians switch to other new drug or biologic products or choose to reserve our products for use in limited circumstances. Additionally, a competitor could obtain orphan product exclusivity from the FDA with respect to such competitor' s product. If such competitor product is determined to be the same product as one of our product candidates, that may prevent us from ~~obtaining~~ **57obtaining** approval from the FDA for such product candidate for the same indication for seven years, except in limited circumstances. The market opportunities for DANYELZA and our other product candidates, if approved, may be limited to those patients who are ineligible for or have failed prior treatments and may be small. Also, the market opportunity for DANYELZA and our product candidates, if approved, may be smaller than we expect. Our current target patient populations are based on our beliefs and estimates regarding the incidence or prevalence of certain types of cancers that may be addressable by DANYELZA, and our other product candidates, which are derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, and market research. The total addressable market opportunity for DANYELZA and any other products we may produce, if approved, will ultimately depend upon, among other things, the diagnosis criteria included in the final label for the relevant product, acceptance by the medical community and patient access, drug pricing, and reimbursement. The number of patients in our targeted commercial markets ~~and elsewhere~~ may turn out to be lower than expected **.** ~~, possibly materially, patients~~ **Patients** may not be ~~otherwise~~ amenable to treatment with our drug **and** ~~, or~~ new patients may become increasingly difficult to identify or gain access to, ~~all~~ **as new clinical trials from other entities may deplete the number** of ~~which~~ **patients available. Any of the foregoing** ~~would~~ **could** adversely affect our results of operations and our business. Our current target patient populations are small as we have so far focused our clinical development efforts on rare pediatric cancers. By way of example, only approximately 700 children are diagnosed with NB in the United States each year. Even if we obtain significant market share for DANYELZA, or our other product candidates, if approved, ~~64because~~ -- **because** the initial target populations

we are seeking to treat are small, we may never achieve profitability without obtaining regulatory approval for additional and broader indications, including use of DANYELZA or our product candidates, if approved, for front- line and third- line therapy. DANYELZA is approved only as second- line treatment for patients with R / R high- risk NB in bone and / or bone marrow. **We may have to conduct additional clinical trials prior to submitting for marketing approval of DANYELZA as a front- line or third- line therapy.** Even if we ~~would~~ **conduct such trials and** seek approval as front- line or third- line therapy for DANYELZA **,** ~~or another product candidate~~ there is no guarantee that ~~any~~ **it** will be approved ~~. In addition, we may have to conduct additional clinical trials prior to gaining approval for front- line or third- line therapy~~ . The indications we seek to treat have low prevalence and it may be difficult to identify and enroll patients with these diseases. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the relevant trial until its conclusion. We have experienced and may continue to experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including: ● the size and nature of the patient populations; ● the patient eligibility criteria defined in the protocol; ● the size of the study population required for analysis of the trial' s primary endpoints; ● the proximity of patients to trial sites; ● the design of the trial; ● our ability to recruit clinical trial investigators with the appropriate competencies and experience; ● competing clinical trials for similar therapies or other new therapeutics not involving our product candidates and or related technologies; **58** ● clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating; ● our ability to obtain and maintain patient consents; and ● the risk that patients enrolled in clinical trials will not complete a clinical trial. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead enroll in a trial being conducted by one of our competitors. We expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and radiation, rather than enroll patients in any of our clinical trials. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates, submit regulatory filings, obtain marketing approvals and delay the commercial launch of our product candidates, if approved. ~~65DANYELZA --~~ **DANYELZA** or any current or future product candidates, including those based on the SADA PRIT Technology, may cause serious adverse events, or SAEs, undesirable side effects or have other properties that could halt their clinical development, prevent, delay, or cause the withdrawal, variation or suspension of their regulatory approval, limit their commercial potential, or result in significant negative consequences, including death of patients or cause regulatory authorities to require labeling statements, such as boxed warnings. Even after approval, if we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability, or that of any potential future collaborators, to market the drug could be compromised. As with most biological drug products, use of DANYELZA or any current or future product candidates, including those based on the SADA PRIT Technology, could be associated with undesirable side effects or adverse events which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. Undesirable side effects or unacceptable toxicities caused by our products or product candidates could cause us or regulatory authorities to withdraw marketing approval or to interrupt, delay, or halt clinical trials. Treatment- related undesirable side effects or adverse events could also affect patient recruitment or the ability of enrolled subjects to complete the trial, or could result in potential product liability claims. In addition, these side effects may not be appropriately or timely recognized or managed by the treating medical staff, particularly outside of the research institutions that collaborate with us. We educate and train medical personnel using our products and product candidates, to understand their side effect profiles both for our approved product DANYELZA and our current clinical trials. We anticipate this also to be the case for our future products, if approved, and clinical trials. Inadequate training in recognizing or managing the potential side effects of our products or product candidates could result in adverse effects to patients, including death. Any of these occurrences may materially and adversely harm our business, financial condition and prospects. Undesirable side effects caused by DANYELZA or any other product or product candidate could limit the commercial profile of such product or product candidate or result in significant negative consequences such as a more restrictive label or other limitations or restrictions. In clinical studies, DANYELZA has been shown to cause serious infusion reactions including anaphylaxis, cardiac arrest, bronchospasm, stridor, and hypotension. The most common adverse events were mainly mild and moderate and included infusion- related reaction, pain, tachycardia, vomiting, cough, nausea, diarrhea, decreased ~~appetite~~ **59appetite** , hypertension, fatigue, erythema multiforme, peripheral neuropathy, urticaria, pyrexia, headache, edema, anxiety, localized edema and irritability. DANYELZA has been approved with a boxed warning for serious infusion reactions and neurotoxicity. Clinical trials of our product candidates must be conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials, or those of any potential future collaborator, may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If a product candidate receives marketing approval and we, or others, discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, including during any long- term follow- up observation period recommended or required for patients who receive treatment using our products, a number of potentially significant negative consequences could result, including: ● regulatory authorities may withdraw, suspend or vary approvals of such product or seize the product; ● we,

or any future collaborators, may be required to recall the product, change the way such product is administered to patients or conduct additional clinical trials; ● additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product; ~~66~~ ● regulatory authorities may narrow the indications for use of, or withdraw the approval for such product based on the outcome of post- marketing testing and safety or efficacy of the product, as the FDA did in its approval of DANYELZA for the treatment of R / R high- risk NB rather than NB that was not R / R; ● we, or any future collaborators, may be required to create a Risk Evaluation and Mitigation Strategy, or REMS, or comparable foreign strategies, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and / or other elements to assure safe use; ● we, or any future collaborators, may be subject to fines, injunctions or the imposition of civil or criminal penalties; ● we, or any future collaborators, could be sued and held liable for harm caused to patients; ● the drug may become less competitive; and ● our reputation may suffer. Any of the foregoing could prevent us from achieving or maintaining market acceptance of DANYELZA or a particular product candidate, if approved ~~in the United States. or achieving additional approvals~~ , and could significantly harm our business, results of operations, and prospects, and could adversely impact our financial condition, results of operations, ability to raise additional financing or the market price of our common stock. The outcome of pre- clinical studies and early clinical trials may not be predictive of the success of later clinical trials, interim results of a clinical trial do not necessarily predict final results, and the results of our clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities, and if an adverse safety issue, clinical hold or other adverse finding occurs in one or more of our clinical trials of our lead product candidates, such event could adversely affect our other clinical trials of our lead product candidates. Success in pre- clinical studies and early- stage clinical trials does not mean that future larger registration clinical trials will be successful because product candidates in later- stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and non- U. S. regulatory authorities despite having progressed through ~~pre~~ **60pre** - clinical studies and early- stage clinical trials. Product candidates that have shown promising results in pre- clinical studies and early- stage clinical trials may still suffer significant setbacks in subsequent clinical trials. Additionally, the outcome of pre- clinical studies and early- stage clinical trials may not be predictive of the success of larger, later- stage clinical trials. From time to time, we may publish or report interim or preliminary data from our clinical trials. Interim or preliminary data from clinical trials that we may conduct may not be indicative of the final results of the trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Interim or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim or preliminary data. As a result, interim or preliminary data should be viewed with caution until the final data are available. In addition, the design of a clinical trial can determine whether its results will support approval of a drug and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and conduct a clinical trial to support marketing approval. Further, if our product candidates are found to be unsafe or lack efficacy, we will not be able to obtain marketing approval for them and our business would be harmed. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in pre- clinical studies and earlier clinical trials. In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and ~~67type~~ -- **type** of the patient populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates. We have multiple clinical trials currently ongoing or planned. In the event that an adverse safety issue, clinical hold or other adverse finding occurs in one or more of our clinical trials of the same product candidate, such event could adversely affect our other clinical trials of our other product candidates. We have received clinical holds on our IND applications for certain of our product candidates in the past and there is no assurance that we will not be subject to additional clinical holds in the future, which may ultimately delay or otherwise adversely affect the clinical development of our product candidates. We submitted a BLA to the FDA for radiolabeled 131I- omburtamab for CNS LM from NB in August 2020, and received a Refusal to File letter from the FDA in October 2020. The reason for the FDA' s decision to issue the Refusal to File letter was that upon preliminary review, the FDA determined that certain parts of the Chemistry, Manufacturing and Control, or CMC, Module and the Clinical Module of the BLA required further detail. We completed the resubmission of the BLA for omburtamab in March 2022. Survival and safety data from our pivotal Phase 2 clinical trial 03- 133 formed the primary basis for our resubmission of the BLA for omburtamab, and we compared this data with data from an external cohort comprising data from the Central German Childhood Cancer Registry, or CGCCR, database. Furthermore, we believe interim efficacy, safety and pharmacokinetic data from our pivotal Phase 2 clinical trial 101 supported the BLA resubmission. In May 2022, the FDA indicated that our BLA had been accepted for priority review. The FDA convened an Advisory Committee, which met on October 28, 2022, and voted 16 to 0 that we had not provided sufficient evidence to conclude that omburtamab improves overall survival among the target patient population. In November 2022, the FDA issued a CRL for our BLA for omburtamab indicating that the FDA determined that it was unable to approve the BLA in its current form since it did not provide substantial evidence of effectiveness of omburtamab for the proposed indication. We **determined to discontinue our omburtamab development program. We** do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates. Before obtaining marketing approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered in pre- clinical studies and well- controlled clinical studies, and, with respect to approval in the United States, to the satisfaction of the FDA, that the product candidate is safe and effective for use for that target indication. There is no assurance that the FDA or non- U. S. regulatory authorities will consider our present or future clinical trials to be sufficient to

serve as the basis for approval of any of our product ~~candidates~~ **61candidates** for any indication. The FDA and non- U. S. regulatory authorities retain broad discretion in evaluating the results of our clinical trials and in determining whether the results demonstrate that a product candidate is safe and effective. **On** ~~In the~~ November **24,** ~~2022~~ **2024** ~~CRL~~ **MSK published an abstract at Connective Tissue Oncology Society using DANYELZA Anti- Gd2 Antibody in an ISS multi- center osteosarcoma trial (Study 15- 096). Per the results of this trial, the data missed the established end point of 12- month event free survival,** ~~for -~~ **or EFS** ~~our BLA for omburtamab~~ , ~~the FDA determined~~ **of 40 %. The underlying EFS response rates were as follows: ● Overall population 14 out of 39 patients – 12- month EFS: 36 % ● 2nd CR: 37 % ● 3rd CR: 33 % Looking into further association between 12- month EFS and GD2 expression ● 5 of 16 GD2 positive patients (31 %) were event free at 12 months ● 4 of 8 GD2 positive patients (50 %) with 4 staining intensity were event free at 12 monthsWe believe** that ~~it was unable~~ **this shows DANYELZA' s potential** to ~~approve the BLA~~ **serve a high unmet need within osteosarcoma where survival rates have shown little or no improvement** in ~~its~~ **decades. With the** current **standard** ~~form since it did not provide substantial evidence~~ of **care** ~~effectiveness of omburtamab for the proposed indication. Further~~ , ~~the FDA stated~~ **12- months EFS is typically approximately 20 % (as reported in various published reports). We also believe** that ~~comparisons of overall survival between our Study 101 and~~ the ~~external control~~ **data supporting the use of DANYELZA for targeting GD2 is very compelling and worth further development. We are considering the advancement of a diagnostic tool for GD2, which** could ~~not~~ **prove to** be **a valuable tool** ~~used to estimate the treatment effect of omburtamab on survival and support claims of effectiveness. Additionally, the FDA held that response rate data from our study 101 were not reliable to verify the anti- tumor activity of omburtamab. This was consistent with the outcome of the ODAC Meeting held in October 2022. In its CRL~~ for **a potential pivotal** ~~omburtamab, and in our Type A meeting held subsequent to receipt of the CRL, the FDA made recommendations for us to consider in terms of~~ trial **in this or** ~~design to demonstrate substantial evidence of effectiveness and a favorable benefit- risk profile. If we are required and we determine to conduct additional clinical trials of a product candidate, including if we determine to resume development of omburtamab, we will need substantial additional funds and there -~~ **other** ~~is~~ **GD2 related indications. There can be** no assurance that the **data from this** ~~results of any such additional clinical trials -~~ **trial** will ~~be sufficient~~ **support further development of DANYELZA** for ~~approval~~ **osteosarcoma** . Further, our product candidates may not be approved even if they achieve their primary endpoints in Phase 3 clinical trials or other pivotal trials. The FDA or non- U. S. regulatory authorities may disagree with our trial design and our interpretation of data from pre- clinical studies and clinical trials or conclude that we do not have adequate manufacturing controls or quality systems. For example, as was the case for our BLA for omburtamab, analysis of the clinical data may rely on external control comparator populations to demonstrate efficacy, rather than blinded, placebo- ~~68controlled~~ -- **controlled** comparator populations. Data from our clinical trials may therefore be subject to heightened scrutiny regarding potential sources of bias such as treatment- center selection bias or differences in treatment patterns between countries and over time. Furthermore, because our clinical trials typically enroll a small number of patients, statistical analyses may only partially adjust to account for such potential bias. For example, FDA identified key review issues with our BLA for omburtamab, stating that the external control population for our omburtamab BLA is not fit- for- purpose as a comparator and limits the ability to reliably attribute survival differences to omburtamab treatment, that the BLA application does not include reliable response rate data to provide supportive evidence of the treatment effect of omburtamab, and that differences in survival cannot be reliably attributed to omburtamab and provide a large degree of uncertainty regarding whether the observed differences in overall survival between patients treated with omburtamab and external control populations are due to omburtamab or whether they are due to differences in other anticancer treatment, supportive care regimens, unknown differences between the two populations, or a combination of these factors. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal clinical trial that has the potential to result in approval by the FDA or another regulatory authority. Any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post- marketing clinical trials. The FDA or other non- U. S. regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates. ~~Research~~ **62Research** and development of biopharmaceutical products is inherently risky. We may not be successful in our efforts to create a pipeline of product candidates and develop commercially successful products. If we fail to develop additional product candidates, our commercial opportunity will be limited. Other than DANYELZA, the product candidates and related technologies we have licensed have not yet led, and may never lead, to approved products. ~~Our only approved product~~ DANYELZA was only approved in late 2020 by the FDA and launched in the United States in early 2021 ~~. Further~~ , **with approvals in** ~~DANYELZA was only approved by the other jurisdictions coming more recently Israeli Ministry of Health in Israel, in August 2022, by the NMPA in China in December 2022, by Anvisa in Brazil in April 2023, and by COFEPRIS in Mexico in September 2023~~ . Hence its commercial potential cannot be judged with accuracy at this point in time. Even if we are successful in continuing to build our pipeline, obtaining regulatory approvals and commercializing our other product candidates will require substantial additional funding and ~~are~~ **remain** prone to the risks of failure inherent in medical product development. Investment in biopharmaceutical product development involves significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and / or become commercially viable. We cannot provide any assurance that we will be able to successfully obtain marketing approval for ~~omburtamab~~ or advance any of our other product candidates through the development process. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following: ● we may not be successful in identifying additional product candidates; ● we may not be able to assemble sufficient resources to acquire or discover additional product candidates; ● our product candidates may not succeed in pre- clinical or clinical testing; ● a product candidate may on further study be shown to have harmful side effects or other characteristics that

indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria; ● competitors may develop alternatives that render our product candidates obsolete or less attractive; ● product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights; ~~69~~ ● the market for a product candidate may change so that the continued development of that product candidate is no longer reasonable; ● a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and ● a product candidate may not be accepted as safe and effective by patients, the medical community or third- party payors, as applicable. If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, discover, develop, or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations. As for DANYELZA, no assurance can be given that it will be successfully commercialized, widely accepted in any marketplace or more effective than other commercially available alternatives. ~~We~~ **63We** are dependent on our ability to maintain and continue to leverage our relationship with MSK. We have entered into several agreements with MSK that are important to our business. We may also form or seek other collaborations or strategic alliances or enter into additional licensing arrangements in the future but may not realize the benefits of such collaborations or strategic alliances. If we are unable to enter into future collaborations, or if such collaborations are not successful, our business could be adversely affected. We currently have in place several agreements with MSK, including the MSK License, the CD33 License, the MabVax / MSK License Agreement and the SADA License Agreement, **many of** which are important to us, and we may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. In addition, ~~we anticipate that~~ MSK, because it is a hospital where patients are treated, ~~may become~~ **continues to be** a major source for the distribution and administration of DANYELZA. Any disruption of our relationship with MSK could have a material adverse effect on our business, results of operations and financial condition ~~. In addition, any of these relationships may require us to incur other charges, increase our near and long- term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business~~ . In addition, we face significant competition in seeking appropriate strategic partners and the negotiation of strategic collaborations is time consuming and complex. We may not be successful in our efforts to establish a strategic partnership, other than the one we have with MSK, or other alternative arrangements for our product candidates because potential strategic partners may deem our product candidates to be at too early a stage of development for collaborative effort, because third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or because the commercial potential of our product candidates is too difficult to predict. Further, arrangements with third parties, such as our arrangement with MSK or other current or potential future collaborations that we may enter, are subject to numerous risks, including the following: ● such third parties may have significant discretion in determining the efforts and resources that they will apply to a collaboration; ● such third parties may not pursue development and commercialization of our products or product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities; ~~70~~ ● such third parties may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing; ● such third parties could independently develop, or develop with others, products that compete directly or indirectly with our products or product candidates; ● product candidates discovered through such arrangements or any potential future collaborations with us may be viewed by such third parties as competitive with their own product candidates or products, which may cause such third parties to cease to devote resources to the commercialization of our products or product candidates; ● such third parties with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution; ● such third parties may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability; **64** ● disputes may arise between us and such third- party or any current or potential future collaborator that cause the delay or termination of the research, development or commercialization of our products or product candidates, or that result in costly litigation or arbitration that diverts management attention and resources; ● such third parties may infringe the intellectual property rights of others, which may expose us to litigation and potential liability; ● such arrangements or any current or potential future collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product or product candidate; and ● such third parties may own or co- own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property. As a result, if we are unable to maintain current arrangements or collaborations or enter into and maintain future arrangements and collaborations, or if such arrangements or collaborations are not successful, our business could be adversely affected. If we enter into certain arrangements or collaboration agreements and strategic partnerships or license our products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our **business. Any of these relationships may require us to incur other charges, increase our near and long- term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and** business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. ~~Any~~ **Nevertheless, any** delays in entering into new collaborations or strategic partnership agreements related to our products or product candidates could delay the development and commercialization of our products or product candidates in certain territories for certain indications, which would harm our business prospects, financial condition, and results of operations. If we or third parties, such as contract research organizations,

or CROs, or contract manufacturing organizations, or CMOs, 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 ~~may~~ involve the controlled use of potentially hazardous substances, including chemical and biological materials, by us or third parties, such as CROs and CMOs. We have used **radioactive materials, including** Lutetium- 177, Iodine- 131 and Iodine- 124 label **in our omburtamab** and ~~conjugated antibody treatments~~ **SADA PRIT product candidates** . Our uses involve the inherent risk of exposure ~~71from~~ -- **from** beta ray emissions, which can alter or harm healthy cells in the body. We, our CROs, our CMOs and other third parties are subject to federal, state, and local laws and regulations in the United States and foreign countries governing the use, manufacture, storage, handling, and disposal of medical and hazardous materials. Although we believe that our and such third- parties' procedures for using, handling, storing, and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state, or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition, or results of operations. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals and biological materials. We do not have insurance coverage for pollution cleanup and removal. Currently the costs of complying with applicable federal, state, local and foreign environmental regulations are not significant, and consist primarily of waste disposal expenses. However, compliance could become expensive, and current or future ~~environmental~~ **65environmental** laws or regulations may impair our research, development, production and commercialization efforts. Furthermore, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions. Risks related to our dependence on third partiesWe rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize our product candidates. We rely on third parties to conduct our clinical trials under agreements with MSK, universities, medical institutions, CROs, strategic partners, and others. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory, and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with current good clinical practices, or GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, 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 non- clinical or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under cGMP regulations and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal, foreign or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, 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 other reasons, our clinical trials may be extended, delayed, varied or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. We may also rely on investigator- reported interim data in making business decisions. Independent review of the data could fail to confirm the investigator- reported interim data, which may lead to revisions in disclosed clinical trial results in the future. Any such revisions that reveal more negative data than previously disclosed investigator- reported interim data could have an adverse impact on our business prospects ~~72and~~ -- **and** the trading price of our common stock. Such revisions could also reduce investor confidence in investigator- reported interim data that we disclose in the future. If any of our relationships with these third- party CROs terminate, 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 additional cost and delays and requires management time and focus. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges in the future or that these challenges will not have a material adverse impact on our business, financial condition and prospects. We rely on third parties to manufacture DANYELZA for commercial **and clinical** supply and our product candidates, including our antibody constructs based on the SADA PRIT Technology, for our ongoing and planned pre-clinical studies and clinical studies. Our business could be harmed if third parties fail to provide us **enough** ~~with sufficient quantities of~~ DANYELZA or our other product candidates, including our antibody constructs based on the SADA PRIT Technology, or fail to do so at acceptable quantities, quality levels or prices or fail to maintain adequate compliance with CMC guidelines of the FDA and comparable foreign regulatory authorities. Our third- party manufacturers have in the past and may in the future experience manufacturing difficulties, and any such difficulties could harm our business. We do not currently own any facility that may be used for commercial or clinical- scale manufacturing and processing, and we rely on outside vendors to manufacture DANYELZA for commercial supply and for supplies and ~~processing~~ **66processing** of our product candidates,

including our antibody constructs based on the SADA PRIT Technology, for pre- clinical studies and clinical trials. ~~Our other product candidates have only been manufactured or processed on a limited basis and we and our CMO may not be able to continue manufacturing any of our other product candidates.~~ The manufacturing ~~process~~ **processes** that we have developed may be more difficult or expensive than other approaches currently in use. We may make changes as we work to optimize the manufacturing process, and we cannot be sure that even minor changes in the process will not result in significantly different substances that may not be as safe and effective as any substances deployed by our third- party research institution collaborators. To date, we have obtained the active pharmaceutical ingredient, or API, of DANYELZA from a limited number of third- party manufacturers. We have engaged a separate third- party manufacturer to conduct fill- and- finish and labeling services, as well as for the storage and distribution of DANYELZA to clinical sites and for commercial use. We do not have a long- term supply agreement with any of these third- party API manufacturers, and we purchase our required drug supplies on a purchase order basis. We rely also on CMOs and third- party collaborators for the manufacture of DANYELZA for commercial **and clinical** supply, and we expect that this will be the manufacturing arrangement for any of our other potential products, if approved. ~~If we~~ **The DANYELZA drug substance is manufactured by a single third party, Patheon Biologics B. V. in Groningen, Netherlands, and the DANYELZA drug product is manufactured by a single third party, Patheon Manufacturing Services, LLC at their facility in Greenville, North Carolina. Both facilities** are ~~unable~~ **part of Thermo Fisher Scientific Inc, collectively, Patheon / Thermo Fisher. It is expected that Patheon / Thermo Fisher will transition manufacturing of the DANYELZA drug product** to ~~establish agreements with CMOs~~ **a different facility, and it is anticipated that no DANEYLZA drug product will be manufactured until FDA approval of the new site. We will bear the costs of such approval process, which are currently estimated to be up to $ 6. 0 million. However, there is no guarantee that such FDA approval will be granted** on ~~acceptable terms~~ **our expected timeline and budget** , or at all, **which could** ~~our business and results~~ **result in a delay in our clinical trials and loss** of ~~operations may be materially adversely affected. If we determine to resume development of omburtamab~~ , ~~we expect to continue to be highly dependent on our~~ **or delayed** ~~current CMO~~ , **commercial** ~~EMD / Merck, for the production of omburtamab since this manufacturing process uses a hybridoma cell line in a relatively small scale~~ **sales , which would result** ~~(200 liters) cGMP manufacturing process. Many manufacturers refuse to allow hybridoma cell lines to be used~~ in **loss** ~~their facilities due to the risk~~ of ~~contamination~~ **revenue** . In addition, ~~the relatively small scale~~ **we anticipate increased inventory costs in 2025 associated with stocking surplus** of **DANYELZA to meet our anticipated commercial and clinical needs during** the ~~cGMP system required for~~ **anticipated time period from the closing of Patheon / Thermo Fisher' s current manufacturing facility until its new site becomes FDA approved to produce and begins production of the DANYELZA drug product. During this time period, we will have no** manufacture of ~~omburtamab may increase the~~ **DANYELZA. There is a** risk that we ~~are unable to establish~~ **may underestimate our supply needs during this time period** ~~an~~ **and** ~~alternative manufacturing arrangement on~~ **/ or that this time period will be longer than anticipated, which could result in a delay in our clinical trials and loss of, or delayed,** ~~commercially~~ **commercial** ~~reasonable terms because the small scale~~ **sales ,** ~~may lead to less commercially attractive terms for~~ **or** ~~us.~~ **that we may overestimate our supply needs, which could result in additional write- offs to inventories for expired or unusable product** We are subject to the following additional risks with respect to the third- party manufacture of our antibody- based cancer treatments **, both with respect to the planned transition to the Patheon / Thermo Fisher Monza, Italy site and for any other third- party manufacturer with which we contract** : ● If we need to qualify any new manufacturer of DANYELZA or other product candidates, the respective BLA ~~submissions~~ **submission** will need to be amended, and ultimately the FDA must approve any new manufacturer. Any such approval would require new testing, which may include comparability analyses between the biologic substance manufactured for use in prior clinical trials and the biologic substance manufactured by ~~73such~~ **such** potential new manufacturer. Any such potential new manufacturer would further need to pass cGMP compliance inspections by the FDA or comparable foreign regulatory authorities. ● If we need to qualify any new manufacturer, such third party would have to be educated in, or develop substantially equivalent processes for, production of our product and / or product candidates. ● Any of our third- party manufacturers might be unable to timely manufacture our product and / or product candidates or to produce the quantity and quality required to meet our clinical and commercial needs. ● Any of our third- party manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately. ● Any of our third- party manufacturers may not perform as agreed, according to our schedule or specifications, or at all. Any such third- party manufacturer may not devote sufficient resources to our product candidates, may give greater priority to the supply of other products over our product candidates, or ~~may~~ **67may** not remain in the contract manufacturing business for the time required to supply our clinical trials or commercial needs **. ● We do not have a long- term supply agreement with the manufacturer of the DANYELZA drug substance, or our other active drug ingredients, and we purchase our required drug supplies on a purchase order basis. Any of our third- party manufacturers, including Patheon / Thermo Fisher, could choose to discontinue supplying us with drug substance or drug product and we may not have contractual remedies in such situations** . ● We are exposed to the risk of cross- contamination from other drug substances if more than one product is manufactured at a third- party manufacturer' s production facilities. ● Our third- party manufacturers are subject to ongoing periodic unannounced inspection by the FDA, corresponding state agencies and comparable foreign regulatory authorities to ensure strict compliance with cGMPs and other government regulations and corresponding foreign standards. We have limited control over third- party manufacturers' compliance with these and or any other applicable regulations and standards, and any of our third- party manufacturers could fail to comply with applicable government regulations. ● We may not own, or may have to share, the intellectual property rights to any improvements made by our third- party manufacturers in the manufacturing process for our products. ● Any of our third- party manufacturers could breach, terminate or choose not to renew their agreement with us at a time that is costly or inconvenient for us. ● The raw materials and components used to manufacture and process DANYELZA and our product candidates, particularly those for which we have no other source or supplier, may not

be available or may not be suitable or acceptable for use due to material or component defects. ● Any of our third- party manufacturers could potentially mislabel commercial or clinical supplies, which may result in the wrong dose amounts being supplied or active drug or placebo not being properly identified; ● Any of our third- party manufacturers could misappropriate our proprietary information, including our trade secrets and know- how, which could lead to weaker intellectual property protection for our portfolio or potentially increased competition if a competitor were to obtain such proprietary information. ● Our clinical trials may be interrupted if third- party suppliers fail to deliver clinical supplies on time, or we may experience lost sales if drug supplies are not distributed to commercial vendors in a timely manner, in each case because of inclement weather, natural or man- made disasters, or other circumstances beyond our control. ● Any of our third- party manufacturers may have unacceptable or inconsistent product quality success rates and yields and may have inadequate quality control systems. ~~74Each~~ **● We may experience higher production costs and tariffs with respect to the planned transition to the Patheon / Thermo Fisher Monza, Italy siteEach** of these risks could delay or prevent the completion of our clinical trials, could delay any additional BLA submissions or the approval of any of our product candidates by the FDA, or comparable foreign submission and approvals by the competent regulatory authorities, result in higher costs or adversely impact commercialization of **DANYELZA or** our product candidates **, if approved** . Any shortage in the supply of such raw materials used in the manufacture of our product **and product** candidates could delay or prevent the completion of our clinical trials or the approval of any of our product candidates by the FDA, or comparable foreign regulatory authorities, result in higher costs or adversely impact commercialization of our product **and product** candidates ~~. For example~~ , **as such shortages have** in the past ~~, we experienced a shortage in the supply of Iodine- 131, one of the components of 131I- omburtamab product candidate, from our single- source supplier~~ . ~~In~~ **68In** addition, we have and will continue to rely on third parties to perform certain specification tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and the FDA, or comparable foreign regulatory authorities could place significant restrictions on us until deficiencies are remedied. ~~The~~ **Any** facilities used by our CMOs to manufacture DANYELZA and our product candidates, including our antibody constructs based on the SADA PRIT Technology, must be approved by the FDA pursuant to inspections conducted after submittal of a BLA to the FDA. Comparable requirements are applicable outside the United States. We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. DANYELZA and any product candidates that we may develop may compete with product candidates of other companies for access to manufacturing facilities. There is a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us **, and we currently use only a single CMO for the manufacture of the DANEYLZA drug substance and a single CMO for the manufacture of the DANYELZA drug product** . Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our commercial product and clinical product candidates and harm our business and results of operations. Any performance failure on the part of our existing or future manufacturers could adversely affect our commercialization of approved products, such as DANYELZA, and delay clinical development or marketing approval of other product candidates. For example, we have had to scrap batches of DANYELZA due to our third- party manufacturer' s ~~discontinuation~~ **failure** of the batch manufacture. As a result, during the ~~years~~ - **year** ended December 31, ~~2023 and~~ 2022, **we** ~~the Company~~ recorded charges to write- off ~~inventory~~ **inventories** of ~~$ 0. 8 million and~~ $ 1. 2 million ~~, respectively~~ . ~~We~~ **While we are working to ensure an adequate supply of DANEYLZA during the upcoming anticipated pause in manufacturing in connection with the planned transition to a different facility, we** do not currently have arrangements in place for redundant supply of DANYELZA or other product candidates, ~~and we currently use only a single third- party manufacturer for fill- and- finish services for DANYELZA and other product candidates.~~ If any of our current CMOs cannot perform as agreed, we ~~may~~ **would** be required to replace such manufacturer and we may incur added costs and delays in identifying and qualifying any such replacement **and may experience reduced sales during such process that could have a material adverse effect on our business and results of operations** . We are, and will continue to be, reliant in significant part on outside scientists and their third- party research institutions for research and development and early clinical testing of our product candidates. These scientists and institutions may have other commitments or conflicts of interest, which could limit our access to their expertise and adversely affect the timing of ~~the~~ IND filings and our ability to conduct future planned clinical trials. We currently have limited internal research and development capabilities. We conduct independent clinical trials and perform pre- clinical research but we also rely on third- party research institutions for both clinical trial and pre- clinical research. ~~Currently~~ **On November 24 , 2024** MSK **published an abstract at Connective Tissue Oncology Society** ~~is conducting a clinical trial to address relapsed osteosarcoma~~ using DANYELZA **Anti- Gd2 Antibody in an ISS multi- center osteosarcoma trial (Study 15- 096)** . ~~Under~~ **Per** the ~~terms~~ **results** of ~~the MCTA~~ **this trial** , ~~we~~ **the data missed the established end point of 12- month event free survival, or EFS, of 40 %. The underlying EFS response rates were as follows: ● Overall population 14 out of 39 patients – 12- month EFS: 36 % ● 2nd CR: 37 % ● 3rd CR: 33 % Looking into further association between 12- month EFS and GD2 expression ● 5 of 16 GD2 positive patients (31 %) were event free at 12 months69 ● 4 of 8 GD2 positive patients (50 %) with 4 staining intensity were event free at 12 monthsWe believe that this data shows DANYELZA' s potential to serve a high unmet need within osteosarcoma where survival rates have shown little or no improvement in decades. With the current standard of care, 12- months EFS is typically approximately 20 % (as reported in various published reports). We also believe that the data supporting the use of DANYELZA for targeting GD2 is very compelling and worth further development. We** are ~~obligated to pay~~ **considering the advancement of a diagnostic tool** for ~~costs associated with~~ **GD2, which could prove to be a valuable tool for a potential pivotal trial in** this ~~clinical~~ **or other GD2 related indications. There**

**can be no assurance that the data from this** trial **will support further** ~~. We have agreed to fund certain research and~~ development ~~costs under both the MSK License, the MSK CD33 License and the SADA License Agreement. However, the research we have agreed to fund constitutes only a small portion~~ of **DANYELZA for osteosarcoma** ~~the overall research of MSK . Other research being conducted by MSK may receive higher priority than research on the programs we may fund. 75The~~ -- **The** outside scientists who conduct the clinical testing of DANYELZA and our other current product candidates, and who conduct the research and development upon which our product candidate pipeline depends, are not our employees; rather they serve as either independent contractors or the primary investigators under research and other agreements that we have entered into with MSK. Such scientists and collaborators may have other commitments that limit their availability to us. Although our scientific advisors generally agree not to do competing work, if an actual or potential conflict of interest between their work for us and their work for MSK or another entity arises, we may lose their services. These factors could adversely affect the timing of our IND filings and our ability to conduct future planned clinical trials. It is also possible that some of our valuable proprietary knowledge may become publicly known through these scientific advisors if they **were to** breach their confidentiality agreements with us, which would cause competitive harm to, and have a material adverse effect on, our business. Our existing agreements with MSK may be subject to termination by MSK upon the occurrence of certain circumstances including in the event of our insolvency or bankruptcy, if we are convicted of a felony relating to the manufacture, use, or sale of products licensed from MSK or if we fail to pay amounts owed to MSK under the agreements or other types of breach by us of our obligations under the agreements that remain uncured. If MSK terminates the MSK License, the ~~MSK~~ CD33 License, the SADA License Agreement or its other agreements with us, commercialization of any approved product, such as DANYELZA, or the research and development of the relevant product candidates would be suspended, and we would not be able to research, develop, and license our existing and future product candidates as currently contemplated. We may be required to devote additional resources to the development of our product candidates or seek a new collaboration partner, and the terms of any additional collaborations or other arrangements that we establish may not be favorable to us. Switching or adding third parties to conduct our clinical trial would involve substantial costs and delays and require extensive management time and focus, which can materially impact our ability to meet our desired clinical development timelines. DANYELZA and our **other** product candidates, ~~including those~~ **which are all** based on the SADA PRIT Technology, are biologics and the manufacture of DANYELZA and our product candidates, ~~including those based on the SADA PRIT Technology,~~ is **therefore** complex. We, or any of our third- party manufacturers, may encounter difficulties in production, particularly with respect to process development or scaling- up of our manufacturing capabilities. For some reagents, equipment, and materials, we rely or may rely on sole source vendors or a limited number of vendors. Such ~~difficulties~~ **circumstances** may result in an inadequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure. DANYELZA and our **other** product candidates, ~~including those~~ **which are all** based on the SADA PRIT Technology, are biologics and the process of manufacturing them is complex, highly regulated and subject to multiple risks. As a result of the complexities, the cost to manufacture biologics is generally higher than traditional small molecule chemical compounds, and the manufacturing process for biologics is less reliable and is more difficult to reproduce. In addition, manufacture of DANYELZA and our **other** product candidates, ~~including those~~ **which are all** based on the SADA PRIT Technology, requires many reagents, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. Our manufacturing process may be susceptible to product loss or failure due to interruptions in the manufacturing process variability in product characteristics, quality control, contamination, equipment or reagent failure, improper installation or operation of equipment, product testing, vendor or operator error, availability of qualified personnel, logistics and shipping delays as well as compliance with strictly enforced federal, state and foreign regulations. Even minor deviations from normal ~~manufacturing~~ **70manufacturing** processes could result in reduced production yields, product defects, and other supply disruptions. If microbial, viral, or other contaminants are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. No assurance can be given that any stability failures or other issues relating to the manufacture of DANYELZA or our **other** product candidates, ~~including those~~ **which are all** based on the SADA PRIT Technology, will not occur in the future. Further, as a product candidate progresses from pre- clinical studies to late- stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not ~~76achieve~~ -- **achieve** these intended objectives, and any of such changes could cause the product candidate to perform differently and affect the results of planned clinical trials or other future clinical trials. Moreover, as we develop and / or scale- up our manufacturing processes, we expect that we will need to obtain rights to and supplies of certain materials and equipment to be used as part of those processes. We may not be able to obtain rights to such materials on commercially reasonable terms, or at all. In addition, the manufacturing process for any products that we may develop is subject to FDA and other foreign regulatory approval process, and we will need to contract with manufacturers who can meet all applicable FDA, EU and other foreign regulatory requirements on an ongoing basis. If **Patheon / Thermo Fisher is** ~~we, or our CMOs, are~~ unable to reliably produce **the DANYELZA drug** ~~products~~ **product** to specifications acceptable to the FDA, EMA and European Commission or other foreign regulatory authorities, we may not obtain or maintain the approvals we need to **continue** ~~commercialize~~ **commercializing** such products. ~~Even if we obtain regulatory approval for any of our product candidates, there~~ **There** is no assurance that ~~either we or~~ **Patheon / Thermo Fisher** ~~our~~ **or our other** CMOs will be able to manufacture **DANYELZA or our** ~~the~~ **other** ~~approved~~ product **candidates, respectively,** to specifications acceptable to the FDA, EMA and European Commission or other foreign regulatory authorities, to produce ~~it~~ **them** in sufficient quantities to meet ~~the~~ **our clinical and**

**commercial** requirements ~~for the potential launch of the product~~, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product ~~candidate~~ **candidates**, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects. Although we **anticipate seeking FDA approval for DANEYLZA manufacture at the Patheon / Thermo Fisher site in Monza, Italy, and we** are working to develop commercially viable processes **for manufacture of our SADA PRIT product candidates**, our manufacturing capabilities could be affected by cost overruns **, tariffs**, unexpected delays, equipment failures, labor shortages, natural disasters, power failures and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business. ~~We~~ **After the shut- down of Patheon / Thermo Fisher' s Greenville site, we** may ultimately be unable to, among other things, **manufacture DANYELZA at an acceptable cost and / or timetable. We may also be unable to** develop a manufacturing process and distribution network **for our SADA PRIT product candidates** that will, reduce the cost of goods for our product candidates to levels that will allow for an attractive return on investment if and when those product candidates are commercialized. We have entered into strategic collaborations for the development, marketing and commercialization of DANYELZA ~~and omburtamab~~ in certain jurisdictions and may do so in the future for all or some of our product candidates. If those collaborations are not successful, or if we are unable to establish additional collaborations, we may have to alter or delay our development and commercialization plans. In November 2020, we entered into an exclusive license and distribution agreement for DANYELZA and omburtamab with Takeda Israel, a wholly- owned subsidiary of Takeda Pharmaceutical Company Limited covering the State of Israel, West Bank and Gaza Strip. **Any resumption of** ~~The ongoing and rapidly evolving~~ conflict between Israel and Hamas may have a material adverse impact on Takeda Israel' s ability to sell our products and / or collect receivables from customers in the State of Israel as well as on Takeda Israel' s ability to pursue the development, marketing and / or commercialization of DANYELZA in the State of Israel, West Bank and Gaza Strip, which may ultimately have an adverse impact on the amount of royalties we receive pursuant to the Takeda Licensing Agreement. In December 2020, we entered into a distribution agreement for DANYELZA ~~and omburtamab~~ with Swixx BioPharma AG for the Eastern European territories Bosnia & Herzegovina, Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Russia, Serbia, Slovakia and Slovenia. **In February 2025, we entered into** ~~Sanctions issued by the U. S. and~~ **an** ~~other countries against~~ **amendment of our agreement with Swixx to remove** Russia ~~in response to its attack on Ukraine and related counter- sanctions issued by Russia have made it very difficult for us to operate in Russia and may have a material adverse impact on our ability to sell our products and / or collect receivables from~~ **71from** ~~customers in Russia~~ **the covered territories**. In December 2020, we entered into a license agreement for DANYELZA and omburtamab with SciClone Pharmaceuticals International Ltd., or SciClone, for Greater China, including Mainland China, Taiwan, Hong Kong and Macau **. For additional risks relating to our collaborations with entities operating in China, see " Risks related to government regulation: market approval and other legal compliance matters – Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain products or product candidates outside of the United States and require us to develop and implement costly compliance programs "**. In May 2021, we entered into an exclusive distribution agreement with Adium ~~Pharma S. A., or Adium,~~ for Latin America. **In** ~~Finally, in~~ December 2022, we entered into a distribution agreement with WEP ~~Clinical Ltd.~~ in connection with an early access program for DANYELZA in Europe. **In May 2024, we entered into a distribution agreement with INPHARMUS for distribution of DANYELZA in Turkey. In January 2025, we amended our agreement with INPHARMUS to extend the covered territories to the Gulf Coast Countries in the Mediterranean and Persian Gulf. In October 2024, we entered into a distribution agreement with Nobelpharma in Japan.** We may enter into further strategic collaborations for the development, marketing and commercialization of **DANYELZA** ~~all or some of our~~ **or any further** product candidates. Our current and future potential collaborators include large and mid- size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for any further collaborations will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of a number of factors. We have and will for any future collaborations likely have limited control over the amount and timing of resources that our collaborators dedicate to the development, ~~77marketing~~ **marketing** and / or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our current and future potential collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, our current collaborators have and any future collaborators may have, the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms. Our current and any future potential collaborations involving **DANYELZA and any of** our **future** product candidates pose risks to us, including the following: ● collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations; ● collaborators may not perform their obligations as expected; ● collaborators may not pursue development, marketing and / or commercialization of our product candidates or may elect not to continue or renew development, marketing or commercialization programs based on clinical trial results, changes in the collaborator' s strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities; ● collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing; ● collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our drugs or product candidates; ● a collaborator with marketing and distribution rights to one or more drugs may not commit sufficient resources to the marketing and distribution of such drug or drugs; ● disagreements with collaborators, including disagreements over

proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time- consuming and expensive; **72** ● collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation; ● collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; ● we may lose certain valuable rights under circumstances identified in any collaboration arrangement that we enter into, such as if we undergo a change of control; ● we may be restricted under then- existing collaboration agreements from entering into future agreements on certain terms with potential collaborators; ● collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development, marketing and / or commercialization of the applicable product candidates; ● collaborators may learn about our discoveries, data, proprietary information, trade secrets, or compounds and use this knowledge to compete with us in the future; ~~and78~~ -- **and** ● the number and type of our collaborations could adversely affect our attractiveness to potential future collaborators or acquirers. Our current and any future collaboration agreements, if any, may not lead to development or commercialization of product candidates in the most efficient manner, or at all. We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all, if and when we seek to enter into collaborations. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may 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 may not be able to further develop our product candidates or bring them to market and generate revenue from sales of drugs. Risks related to government regulation; market approval and other legal compliance mattersEven if we complete the necessary non- clinical studies and clinical trials, the FDA and comparable foreign regulatory authority approval processes are lengthy, time- consuming, and inherently unpredictable, and we or any of our potential future collaborators may experience significant delays in the clinical development and regulatory approval, if any, for the commercialization of our product candidates. **Additionally, as governments have a change in elected officials, the new administration may change certain approval practices of prior administration.** To date, we have only obtained regulatory approval to market DANYELZA in the United States, **Western** Europe, China, Israel, Brazil and Mexico for R / R high- risk NB in bone and / or bone marrow. We cannot predict when or if, and in which other territories, we, or any of our potential future collaborators, will obtain marketing approval to commercialize DANYELZA or any of our product candidates. The research, testing, manufacturing, labeling, approval, selling, import, export, marketing, and distribution of drug products, including biologics, are subject to extensive regulation by the FDA and other regulatory authorities in the United States and foreign countries. Even if we complete the necessary pre- clinical studies and clinical trials, we will not be permitted to market any biological drug product in the United States or in foreign countries, until we receive a Biologics License from the FDA or foreign equivalent in other countries. Although we have received a Biologics License for DANYELZA for R / R high- risk NB in bone and / or bone marrow, we intend to discuss with the FDA ~~submission~~ **73submission** of additional BLAs for approval of DANYELZA to treat additional indications that currently lack an FDA- approved treatment option. The FDA standard for regular approval of a BLA generally requires two well- controlled Phase 3 studies or one large and robust, well- controlled Phase 3 study in the patient population being studied that provides substantial evidence that a biologic is safe, pure and potent. Phase 3 clinical studies typically involve hundreds of patients, have significant costs and take years to complete. However, product candidates studied for their safety and effectiveness in treating serious or life- threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well- controlled clinical trials establishing that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As is the case with DANYELZA in the United States, as a condition of accelerated approval, the FDA may require a sponsor to perform post- marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug or biologic may be subject to withdrawal procedures by the FDA that are more accelerated than those available for regular approvals. The FDA may ultimately require one or multiple Phase 3 clinical trials prior to approval of any product candidates for which we seek accelerated approval. We have some, but only limited, experience in completing a submission of a BLA to the FDA, or similar approval submissions to comparable foreign authorities. Our BLA for DANYELZA was approved, but we received a CRL for our BLA for omburtamab **and we determined to stop our omburtamab development program** . A BLA must include extensive pre- clinical and clinical data and supporting information to establish that the product candidate is safe, pure, and potent for each desired indication. The BLA must ~~79also~~ -- **also** include significant information regarding the chemistry, manufacturing, and controls for the product, and the manufacturing facilities must complete a successful pre- license inspection. We expect the novel nature of our product candidates and the small size of our target patient populations, to create further challenges in obtaining regulatory approval from the FDA and other regulatory authorities. For example, for product candidates targeting ultra- rare diseases, such as CNS / LM from NB, where the very small patient population makes it difficult or impossible to conduct two traditional, adequate and well- controlled studies, the FDA or comparable foreign regulatory authorities may need to exercise flexibility in approving therapies for such diseases. Even flexibility from the FDA may not be sufficient to obtain approval. For instance, in its CRL for omburtamab, and in our Type A meeting held subsequent to receipt of the CRL, the FDA made recommendations for us to consider in terms of adequate and

well- controlled trial design to demonstrate substantial evidence of effectiveness and a favorable benefit- risk profile **, which was challenging due to the small size of our target patient population** . The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data, and the use of control groups to support licensure. For example, in connection with our BLA for omburtamab, the FDA convened an Advisory Committee that met in October 2022, which voted 16 to 0 that the BLA did not provide sufficient evidence to conclude that omburtamab improves overall survival among the target patient population. The opinion of this and any other Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure **of** our product candidates based on the completed clinical trials, such as was the case for omburtamab. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive, and lengthy, and approval may not be obtained. The process of obtaining marketing approvals, both in the United States, the European Union and elsewhere, is a lengthy, expensive and uncertain process. It may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Securing marketing approval requires the submission of extensive pre- clinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate' s safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA, EMA and the European Commission or other regulatory authorities have substantial discretion and may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use. ~~Any~~ **74Any** marketing approval we ultimately obtain may be limited or subject to restrictions or post- approval commitments that render the approved product not commercially viable. In addition, clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to: ● obtaining regulatory approval to begin a trial, if applicable; ● the availability of financial resources to begin and complete the planned trials; ● reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; ● obtaining approval at each clinical trial site by an Institutional Review Board or IRB or positive opinions from Ethics Committees; ● recruiting suitable patients to participate in a trial in a timely manner; ● having patients complete a trial or return for post- treatment follow- up; ● clinical trial sites deviating from trial protocol, not complying with GCPs, or dropping out of a trial; ~~80~~ ● addressing any patient safety concerns that arise during the course of a trial; ● addressing any conflicts with new or existing laws or regulations; ● adding new clinical trial sites; ● manufacturing qualified materials under cGMPs for use in clinical trials; ● impact of pandemics or other public- health emergencies; ● impact of **any resumption** ~~the Russian invasion~~ of **conflict** ~~Ukraine; ● impact of the state of war~~ between Israel and Hamas, and the related risk of a larger conflict; or ● inspection of clinical trial sites and manufacturing facilities by regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials and is affected by many factors. See the risk factor above " — If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected. " for additional information on risks related to patient enrollment. Further, a clinical trial may be suspended or terminated by us, the IRBs or Ethics Committees for the institutions in which such trials are being conducted, the Data Monitoring Committee for such trial, or the FDA or other 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 the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate potential future product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue. Our third- party research institution collaborators may also experience similar difficulties in completing ongoing clinical trials and conducting future clinical trials of product candidates. Many of the factors that cause, or lead to, a ~~delay~~ **75delay** in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Our product candidates could fail to receive marketing approval for many reasons, including the following: ● the FDA, EMA, European Commission or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; ● we may be unable to demonstrate to the satisfaction of the FDA, EMA, European Commission or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication; ● the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA, European Commission or comparable foreign regulatory authorities for approval; ● we may be unable to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks; ● the FDA, EMA, European Commission or comparable foreign regulatory authorities may disagree with our interpretation of data from pre- clinical studies or clinical trials; ~~81~~ ● the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA or other submission or to obtain marketing approval in the United States, the EU or elsewhere; ● the FDA, European Commission, national competent authorities of EEA countries or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third- party manufacturers with which we contract for clinical and commercial supplies; ● the FDA, or comparable foreign regulatory authorities may fail to approve any companion diagnostics, or the legal manufacturer may fail to CE mark companion diagnostics, which is an acronym for the French " Conformite Europeenne " that ~~certifies that a product has met~~ **documents the manufacturer' s assessment according to which the companion diagnostic complies with the requirement of** EU ~~health, safety, and environmental requirement~~ **legislation governing in vitro diagnostic medical devices** , that may be required in connection with approval of our therapeutic product

candidates; and ● the approval policies or regulations of the FDA, European Commission or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. This lengthy approval process as well as the unpredictability of clinical trial results resulted in our failure to obtain marketing approval to market omburtamab. The same factors may also result in a failure for us to obtain marketing approval to market any of our other product candidates, which would further significantly harm our business, results of operations and prospects. In addition, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted drug application may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional pre- clinical studies, clinical trials, toxicology or other in vivo or in vitro data to support the initiation of other studies and testing. In addition, varying interpretations of the data obtained from pre- clinical studies and clinical trials could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we, or any collaborators we may have in the future, ultimately obtain may be limited or subject to restrictions or post approval commitments that render the approved drug not commercially viable. ~~Any~~ **76Any** delay in obtaining or failure to obtain required approvals could materially adversely affect our ability or that of any collaborators we may have to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price. The EMA, the European Commission or comparable foreign regulatory authorities, may disagree with our regulatory plans, including our plans to seek conditional marketing authorization, and we may fail to obtain regulatory approval of DANYELZA from the European Commission, or our other product candidates, which would prevent DANYELZA, or our other product candidates from being marketed abroad. Any approval we are granted for our product candidates in the United States, such as the approval of DANYELZA, would not assure approval of our product candidates in foreign jurisdictions. In order to market and sell our drugs in the European Union and many other jurisdictions, we, and any collaborators we may have in the future, must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. On April 27, 2021 we submitted a MAA, to the EMA for omburtamab for the treatment of pediatric patients with CNS / LM from NB. In December 2022, the EMA' s CHMP, adopted a negative opinion recommending a refusal of the MAA. CHMP determined that it was not possible to conclude on the effectiveness of omburtamab as the main study did not have a randomized comparator. **On April 12, 2023, the European Commission adopted a decision refusing the marketing authorization for omburtamab.** We **determined to stop** ~~are assessing the implications of the negative opinion and~~ our ~~plans for the~~ omburtamab **development** program. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside of the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside of the United States, it is required that the drug be approved for reimbursement before the drug can be ~~82approved --~~ **approved** for sale in that country. We, and any collaborators we may have in the future, may not obtain approvals from regulatory authorities outside of the United States on a timely basis, if at all. Approval by the FDA, such as the approval of DANYELZA, does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside of the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. As part of its marketing authorization process, the European Commission may grant a " conditional " marketing authorization in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional marketing authorization for a medicinal product if it is demonstrated that all of the following criteria are met: ● the risk- benefit balance of the medicinal product is positive; ● it is likely that the applicant will be in a position to provide the comprehensive clinical data; ● the medicinal product fulfills an unmet medical need; and ● the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. The conditional marketing authorization is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional marketing authorization can be converted into a traditional marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the marketing authorization will cease to be renewed. Although we may seek a conditional marketing authorization for one or more of our product candidates by the European Commission, the EMA or the European Commission may ultimately not agree that the requirements for such conditional marketing authorization have been satisfied. ~~Our~~ **77Our** clinical trial results may also not support approval, whether accelerated approval, conditional marketing authorizations, or regular approval. The results of pre- clinical and clinical studies may not be predictive of the results of later- stage clinical trials, and product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through pre- clinical studies and initial clinical trials. Failure to obtain regulatory approval to market any of our product candidates outside of the US would significantly harm our business, results of operations, and prospects. We may seek Breakthrough Therapy Designation, or BTD, for one or more of our product candidates. We may not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process. BTD is intended to expedite the development and review of products that treat serious or life- threatening diseases when 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. The designation of a product candidate as a breakthrough therapy provides potential benefits that include more frequent meetings with the FDA to discuss the development plan for the product candidate and ensure collection of appropriate data needed to support approval; more frequent written correspondence from the FDA about such things as the design of the proposed clinical trials and use of biomarkers; intensive guidance on an efficient drug development program, beginning as early as Phase 1; organizational

commitment involving senior managers; and eligibility for rolling review and priority review. ~~83In June 2017, 131I-omburtamab received BTD for the treatment of pediatric patients with R / R NB who have CNS / LM from NB.~~ We may seek BTD for some or all of our other product candidates, but we may never receive another BTD, or, if received, such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures. BTD does not change the standards for product approval nor assure ultimate approval by the FDA. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Our product candidates may not be able to obtain or maintain Orphan Drug Designation, or ODD, or Rare Pediatric Disease Designation, or RPDD. Regulatory authorities in some jurisdictions, including the United States and the European Union, 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 an indication with a patient population of fewer than 200, 000 individuals annually in the United States, or a patient population greater than 200, 000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In August 2016, the FDA granted ODD to 131I- omburtamab for the treatment of NB. In 2013, the FDA granted ODD to DANYELZA for the treatment of NB. In November 2018, the European Commission granted orphan medicinal product designation ~~, or OMPD,~~ for naxitamab for the treatment of NB. **We determined** ~~In February 2017, the European Commission granted orphan medicinal product designation~~ to **stopped the development of** omburtamab ~~for~~ **in November 2024 pursuant to** the ~~treatment of NB~~ **amendment license agreement with MSK.** . In the United States, ODD entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user- fee waivers. In addition, if a product that has ODD subsequently receives the first FDA approval for the disease for which it has such designation, the product may be entitled to orphan drug exclusivity. Orphan drug exclusivity in the United States provides that the FDA may not approve any other applications, including a full BLA, to market the same drug for the same indication for seven years, except in limited circumstances. The corresponding exclusivity period is 10 years in Europe, and can be reduced to six years if a drug no longer meets the criteria for ODD or if the drug is sufficiently profitable so that market exclusivity is no longer justified. ~~The~~ **78The** Rare Pediatric Disease Priority Review Voucher Program, or PRV Program, is intended to incentivize pharmaceutical sponsors to develop drugs for rare pediatric diseases. A sponsor who obtains approval of a BLA for a rare pediatric disease may be eligible for a PRV, under this program, which may be redeemed by the owner of such PRV to obtain priority review for a marketing application. A PRV is fully transferrable and can be sold to any sponsor, who in turn can redeem the PRV for priority review of a marketing application in six months, compared to the standard timeframe of approximately 10 months. A drug that receives RPDD before ~~September 30~~ **December 20** , 2024, will continue to be eligible for a PRV if the drug is approved by the FDA before September 30, 2026 ~~. If development of omburtamab continues and the BLA for omburtamab is not approved prior to September 30, 2026, regardless of whether it meets the criteria for a rare pediatric disease PRV, it will not be eligible for a PRV~~ . Even if we obtain ODD or RPDD for any of our product candidates in the future, we may not be able to maintain such status or enjoy the anticipated associated benefits. We may not be the first to obtain marketing approval of any product candidate that has ODD for the orphan- designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan- designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we, or any future collaborators, obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product from ~~84competition~~ -- **competition** because different drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety 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 or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. ODD neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. Even if we, or any collaborators we may have in the future, obtain marketing approvals for our product candidates, the terms of approvals and ongoing regulation of our drugs could require substantial expenditure of resources and may limit how we, or they, manufacture and market our drugs, which could materially impair our ability to generate revenue. Once marketing approval has been granted, as it was for DANYELZA in the United States, an approved drug and its manufacturer and marketer are subject to ongoing review and extensive regulation. The accelerated approval of DANYELZA is subject to certain post-marketing requirements and commitments, including a confirmatory post- marketing trial of clinical benefit, that must be completed in order to convert the BLA to full approval and prevent withdrawal of the license by FDA. The confirmatory post-marketing clinical trial required by the FDA to verify and to further characterize the clinical benefit is our ongoing Study 201, which ~~will~~ **is required to** enroll a minimum of 80 evaluable patients ~~and~~ **with evaluable disease, with a minimal follow- up of 12 months from the onset of Complete Response / Partial Response, which is equivalent to at least a total 122 patients in Study 201. The study will** report ~~overall rate of response, or~~ ORR, ~~duration of response, or~~ DOR, ~~progression free survival, or~~ PFS ~~,~~ and ~~overall survival, or~~ OS. The ORR is the primary endpoint for the study, DOR is the secondary endpoint **,** and PFS and OS are secondary endpoints in long- term follow- up. We **have enrolled 109 patients, and we** anticipate completing the study ~~no later than~~ by March 31, 2027. Other post- marketing requirements associated with the approval of DANYELZA include submissions of safety and other post- marketing information and reports, registration and listing requirements, 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. We, and any collaborators we may have in the future, must also comply with requirements concerning advertising and promotion for any of our product candidates for which we or they obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the drug' s approved labeling. Thus, we, and any collaborators we may have in the future, may not be able to promote any drugs we develop for indications or uses for which they are not approved. The FDA and comparable foreign regulatory authorities may also impose requirements for costly post- marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a drug. For example, the approval may be subject to limitations on the indicated uses for which the drug may be marketed or to the conditions of approval, including the requirement to implement a Risk Evaluation and Mitigation Strategy, or comparable foreign ~~strategies~~ **79strategies** , which could include requirements for a restricted distribution system. Manufacturers of approved drugs and those manufacturers' facilities are also required to comply with extensive FDA and comparable foreign regulatory requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, our contract manufacturers, our future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA and comparable foreign regulatory authorities to monitor and ensure compliance with cGMPs. Accordingly, assuming we, or our potential future collaborators, receive marketing approval for one or more of our product candidates, we, and our potential future collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we, and our future potential collaborators, are not able to comply with post- approval regulatory requirements, we, and our potential future collaborators, could have the marketing approvals for our drugs withdrawn by regulatory authorities and our, or our potential future collaborators', ability to market any future drugs could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post- approval regulations may have a negative effect on our operating results and financial condition. ~~85DANYELZA~~ -- **DANYELZA** and any of our product candidates for which we, or our potential future collaborators, obtain marketing approval in the future will be subject to substantial penalties if we, or they, fail to comply with regulatory requirements or if we, or they, experience unanticipated problems with our drugs following approval. DANYELZA and any of our product candidates for which we, or our potential future collaborators, obtain marketing approval in the future, will be subject to continual review by the FDA and other regulatory authorities. The FDA and other agencies, including the Department of Justice, or the DOJ, as well as comparable foreign regulatory authorities closely regulate and monitor the post- approval marketing and promotion of drugs to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and comparable foreign regulatory authorities impose stringent restrictions on manufacturers' communications regarding off- label use and if we, or our potential future collaborators, do not market any of our product candidates for which we, or they, receive marketing approval for only their approved indications, we, or they, may be subject to warnings or enforcement action for off- label marketing. Violation of the Federal Food, Drug and Cosmetic Act, or FDCA, and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state healthcare fraud and abuse laws and state consumer protection laws. ~~In~~ **Radioactive materials are subject to additional oversight by agencies such as the Nuclear Regulatory Commission and the Environmental Protection Agency which add complexity to compliance efforts for products containing these materialsIn** addition, later discovery of previously unknown adverse events or other problems with our drugs or their manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including: ● litigation involving patients taking our drug; ● restrictions on such drugs, manufacturers or manufacturing processes; ● restrictions on the labeling or marketing of a drug; ● restrictions on drug distribution or use; ● requirements to conduct post- marketing studies or clinical trials; ● warning letters or untitled letters; **80** ● withdrawal of the drugs from the market; ● refusal to approve pending applications or supplements to approved applications that we submit; ● recall of drugs; ● fines, restitution or disgorgement of profits or revenues; ● suspension, variation or withdrawal of marketing approvals; ● damage to relationships with any potential collaborators; ● restrictions on coverage by third- party payors; ● unfavorable press coverage and damage to our reputation; ● refusal to permit the import or export of drugs; ~~86~~ ● drug seizure; or ● injunctions or the imposition of civil or criminal penalties. Current and future legislation, or changes in existing FDA and other government regulations and policies, may increase the difficulty and cost for us and our potential future collaborators to maintain or obtain potential marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain. In the United States and some foreign jurisdictions, there have been and continue to be a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities and affect our ability, or the ability of our potential future collaborators, to profitably sell any drugs for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we, or our potential future collaborators, may receive for any approved drugs. 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 for DANYELZA, and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the Affordable Care Act, or ACA, substantially

changed the way healthcare is financed by both governmental and private insurers. New laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. We cannot predict whether these challenges will continue or other proposals will be made or adopted, or what impact these efforts may have on us. Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the price of drugs under Medicare and reform government program reimbursement methodologies for drug products. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could ~~limit~~ **81limit** the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and / or the level of reimbursement physicians receive for administering any approved product we might bring to market. For example, on August 16, 2022, ~~President Biden signed~~ the Inflation Reduction Act of 2022, or IRA, **was signed** into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the " donut hole " under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost and creating a new manufacturer discount program. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $ 1. 2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation' s automatic reduction to several government programs. This includes aggregate reductions of Medicare ~~87payments~~ -- **payments** to providers up to two percent (2 %) per fiscal year, which went into effect in April 2013 and will remain in effect until 2032 unless additional Congressional action is taken. Some states are also considering legislation and ballot initiatives that would control the prices and coverage and reimbursement levels of drugs, including laws to allow importation of pharmaceutical products from lower cost jurisdictions outside the U. S. and laws intended to impose price controls on state drug purchases. We expect healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for DANYELZA and any other approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our drug candidates or additional pricing pressures. The cost of prescription pharmaceuticals in the United States has also been the subject of considerable discussion in the United States, and members of Congress and the Administration have stated that they will address such costs through new legislative and administrative measures. The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of our product candidates to that of other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired. Legislative and regulatory proposals have also been made to expand post- approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of DANYELZA or our other approved products, if any, may be. In addition, increased scrutiny by the Congress of the FDA' s approval process may significantly delay or prevent marketing approval, as well as subject us and any future collaborators to more stringent drug labeling and post- marketing testing and other requirements. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States **, particularly in light of the recent U. S. Presidential and Congressional elections,** or abroad. As an example, the regulatory landscape related to clinical trials in the EU has ~~evolved~~ **82evolved** . The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR permits trial sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment of some elements of the application by all EU Member States in which the trial is to be conducted, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State' s decision is communicated to the sponsor through a centralized EU portal, the Clinical Trial Information System, or CTIS. The CTR ~~provides~~ **contemplates** a three- year transition period **that ended** ~~. The extent to which ongoing clinical trials will be governed by the CTR varies. For clinical trials in relation to which an application for approval was made~~ on ~~the basis of the Clinical Trials Directive before~~ January 31, ~~2023, the CTD will continue to apply on a transitional basis until January 31,~~ 2025. ~~By that~~ **Since this** date, all **new or** ongoing trials **are** ~~will become~~ subject to the provisions of the CTR. ~~The~~ **Compliance with the** CTR **requirements by us** ~~will apply to clinical trials from an~~ **and**

~~earlier date if the related clinical trial application was made on the basis of the CTR or~~ **our** ~~if the clinical trial~~ **third- party service providers, such** ~~has~~ **as CROs** ~~already transitioned to the CTR framework before January 31~~, ~~2025~~ **may impact our development plans**. In addition, on April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation **and on April 10, 2024, the Parliament adopted its related position**. If adopted in the form proposed, the ~~recent~~ European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a decrease in data and market exclusivity opportunities for our product candidates in the EU and make them open to generic or biosimilar competition earlier than is currently the case with a related reduction in reimbursement status. ~~88If~~ **If** we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted. Government price controls or other changes in pricing regulation could restrict the amount that we are able to charge for DANYELZA or any of our other product candidates that may be approved in the future, which would adversely affect our revenue and results of operations. We expect that coverage and reimbursement of pharmaceutical products may be increasingly restricted both in the U. S. and internationally. The escalating cost of health care has led to increased pressure on the health care industry to reduce costs. In particular, drug pricing by pharmaceutical companies has come under increased scrutiny and continues to be subject to intense political and public debate in the U. S. and abroad. Government and private third- party payors have proposed health care reforms and cost reductions. A number of federal and state proposals to control the cost of health care, including the cost of drug treatments, have been made in the U. S. Specifically, there have been several recent U. S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. For example, the IRA, among other things, (i) directs the U. S. Department of Health and Human Services, or HHS, to negotiate the price of certain high- expenditure, single- source ~~drugs and~~ biologics **that have been on the market for at least 11 years and** covered under Medicare, and subject ~~drug~~ manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated " maximum fair price " for such ~~drugs and~~ biologics under the law, and (ii) imposes rebates with respect to certain **products** ~~drugs and biologics~~ covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented ~~. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations~~, although the Medicare drug price negotiation program is currently subject to legal challenges. ~~It is currently unclear how~~ **These provisions began to take effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced** the ~~IRA~~ **agreed- upon prices of the first ten drugs that were subject to price negotiation, which take effect in January 2026. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products** will **become subject** ~~be implemented but is likely~~ to ~~have a significant impact on~~ the ~~pharmaceutical industry~~ **Medicare Drug Price Negotiation Program**. ~~Further, in response to the Biden administration' s October 2022 executive order, on February 14, 2023,~~ HHS ~~released a report outlining three new models for testing by the Centers for Medicare & Medicaid Services Innovation Center which~~ will **select up** ~~be evaluated on their ability~~ to **fifteen additional products covered under Part D for negotiation in 2025** ~~lower the cost of drugs, promote accessibility, and improve quality of care~~. ~~It is unclear whether the models~~ **Each year thereafter, more Part B and Part D products** will **become subject to** ~~be utilized in any health reform measures in~~ the **HHS price negotiation program** ~~future. In some international markets, the government controls the pricing, which can affect the profitability of drugs~~. On December 7, 2023, ~~the Biden administration announced~~ an initiative to control the price of prescription drugs through the use of march- in rights under the Bayh- Dole Act **was announced**. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March- In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march- in rights. While march- in rights have not previously been exercised, it is uncertain if that will continue under the new framework. ~~Current~~ **83Current** government regulations and possible future legislation regarding health care may affect coverage and reimbursement for medical treatment by third- party payors, which may render DANYELZA or our other product candidates, if approved, not commercially viable or may adversely affect our anticipated future revenues and gross margins. In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies **, which can affect the profitability of drugs and biologics**. For example, the EU provides options for EU Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product, it may refuse to reimburse a product at the price set by the manufacturer or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Many EU Member States also periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in the EU Member States will continue to propose and implement cost- containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and / or branded products available through parallel import to keep healthcare costs down. ~~89Moreover~~ **Moreover**, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost- effectiveness of our products to other available therapies. This Health Technology Assessment (" HTA ") of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal

impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. In December 2021, Regulation No 2021 / 2282 on HTA amending Directive 2011 / 24 / EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and will apply as of January 2025, is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation foresees a three- year transitional period and will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e. g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected. We cannot predict the extent to which our business may be affected by these or other potential future legislative or regulatory developments **, particularly in light of the recent U. S. Presidential and Congressional elections** . However, future price controls or other changes in pricing regulation or negative publicity related to the pricing of pharmaceutical drugs generally could restrict the amount that we are able to charge for any our future products, which would adversely affect our anticipated revenue and results of operations. Our relationships with healthcare providers, physicians and third- party payors are subject to applicable anti- kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties, including criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. Our relationships with healthcare providers, physicians and third-party payors are subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign ~~governments~~ **84governments** in which we conduct our business. Our current and future arrangements with healthcare providers, physicians and third- party payors and patients may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute DANYELZA and other our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following: ● Anti-Kickback Statute — the federal healthcare anti- kickback statute prohibits, among other things, persons 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 or arranging of, any good or service, for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; ● False Claims Act — the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing ~~90or~~ **or** concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per- claim penalties; ● HIPAA — the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; 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 in order to have committed a violation; ● HIPAA Privacy Provisions — as amended by the Health Information Technology for Economic and Clinical Health Act (“ HITECH ”) and its implementing regulations, HIPAA also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouse as well as their business associates and subcontractors that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms and technical safeguards, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, and HIPAA, as amended, requires notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information; ● Transparency Requirements — the federal legislation commonly referred to as the Physician Payments Sunshine Act, enacted as part of the Affordable Care Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, therapeutic biologics and medical supplies reimbursable under Medicare, Medicaid, and Children’ s Health Insurance Programs to report annually to the Department of **HHS** ~~Health and Human Services~~ information related to certain payments and other transfers of value, including consulting fees, travel reimbursements, research grants, and other payments or gifts ~~with values~~ over ~~$ 10~~ **the de minimis value threshold** made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), other healthcare providers (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; ● FDCA — the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices; and ● Analogous State and Foreign Laws — analogous state and foreign fraud and abuse laws and regulations, such as state **and foreign** anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers. ~~Outside~~ **85Outside** the United States, interactions between pharmaceutical companies and health care professionals are also governed by strict laws, such as national

anti- bribery laws of European countries, national sunshine rules, regulations, industry self- regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. Some state and foreign laws require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the government and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information. Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations involve substantial costs. It is possible that interpretation of healthcare laws and regulations will vary across jurisdictions, and that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, ~~91imprisonment~~ -- **imprisonment** , exclusion of drugs from government- funded healthcare programs, such as Medicare and Medicaid, or comparable foreign programs, and the curtailment or ~~restructuring~~ **business realignment** of our operations. We have established internal policies and procedures to mitigate our compliance risks. However, no assurance can be given that such policies and procedures will be adequate to ensure compliance with applicable laws and regulations. Moreover, although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management' s attention from the operation of our business, even if our defense is successful. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, it may be costly to us in terms of money, time and resources, and they may be subject to criminal, civil or administrative sanctions, including exclusions from government- funded healthcare programs. We are subject to stringent and evolving U. S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences. In the ordinary course of business, we and our collaborators and third- party providers may collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, such as proprietary and confidential business data, trade secrets, intellectual property, and data we collect about trial participants in connection with our clinical trials. Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of sensitive information by us and on our behalf. In the United States, federal, state, and local laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act), govern the collection, use, disclosure and protection of health- related and other personal data and could apply to our operations or the operations of our collaborators and third- party providers. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH, which imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA. In the past few years, numerous U. S. states — including California, Virginia, Colorado, Connecticut, and Utah — have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal information. ~~As~~ **86As** applicable, such rights may include the right to access, correct, or delete certain personal information, and to opt- out of certain data processing activities, such as targeted advertising, profiling, and automated decision- making. The exercise of these rights may impact our business and ability to provide our products and services. These state laws also allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020, collectively the CCPA, applies to personal information of consumers, business representatives, and employees who are California residents and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for fines of up to $ 7, 500 per intentional violation and allows private litigants affected by certain data breaches to seek to recover potentially significant statutory damages. While the CCPA and many of these state laws also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties ~~upon~~ **with** whom we ~~rely~~ **work** . ~~We~~ **Similar laws are being considered in several other states, as well as the federal and local levels, and we** expect more states to pass similar laws in the future. Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union' s General Data Protection Regulation, or EU GDPR, the United Kingdom' s GDPR, or UK GDPR, Brazil' s General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or LGPD) (Law No. 13, 709 / 2018), and China' s Personal Information Protection Law, or PIPL, impose strict requirements ~~92for~~ -- **for** processing personal data. In particular, the EU GDPR applies to any company established in the European Economic Area, or EEA, and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The obligations from the EU GDPR and UK GDPR, together referred to as GDPR, may include limiting personal data processing to only what is necessary for specified, explicit, and legitimate purposes; requiring a legal basis for personal data processing; complying with specific requirements to process health- related data; requiring the appointment of a data

protection officer in certain circumstances; increasing transparency obligations to data subjects; requiring data protection impact assessments in certain circumstances; limiting the collection and retention of personal data; increasing rights for data subjects; formalizing a heightened and codified standard of data subject consents; requiring the implementation and maintenance of technical and organizational safeguards for personal data; mandating notice of certain personal data breaches to the relevant supervisory authority (ies) and affected individuals; and mandating the appointment of representatives in the UK and / or the EU in certain circumstances. Under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR (17. 5 million British Pounds under the UK GDPR) or 4 % of annual global revenue, in each case, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross- border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and UK have significantly restricted the transfer of personal data to the United States and other countries whose data privacy laws they generally believe are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross- border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EU' s standard contractual clauses, the UK' s International Data Transfer Agreement / Addendum, and the EU- U. S. Data Privacy Framework and the UK extension thereto (which allows for transfers for relevant U. S.- based organizations who self- certify compliance and participate in the Framework), these mechanisms may be subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally- compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data ~~out~~ **87out** of Europe for allegedly violating the EU GDPR' s cross- border data transfer limitations. In addition to data privacy and security laws, we are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the CCPA, require our customers to impose specific contractual restrictions on their service providers. We publish privacy policies, marketing materials and other statements, such as confirmation of compliance with certain certifications or self- regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences. Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. In addition, these obligations may require us to change our business model. ~~93We~~ **We** may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties ~~on~~ **with** whom we ~~rely~~ **work** may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties ~~on which~~ **with whom** we ~~rely~~ **work** fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e. g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class- action claims and mass arbitration demands); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management' s attention; additional reporting requirements and / or oversight; bans on processing personal data **(including clinical trial data)** ; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become more active in bringing privacy- related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); interruptions or stoppages of data collection needed to train our algorithms; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations. If our information technology systems or data, or those of third parties ~~upon which~~ **with whom** we ~~rely~~ **work** , are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences. In the ordinary course of our business, we and the third parties upon which we process proprietary, confidential, and sensitive data, including personal data (such as health- related data), intellectual property and trade secrets (collectively, sensitive information). Cyber- attacks, malicious internet- based activity, online and offline fraud, and other

similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties ~~upon which~~ **with whom** we ~~rely~~ **work** , including our current and future CROs, CMOs, other contractors and consultants. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer " hackers, " threat actors, " hacktivists, " organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation- states, and nation- state- supported actors. Some actors now engage and are expected to continue to engage in cyber- attacks, including without limitation nation- state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other ~~major~~ **88major** conflicts, we, the third parties ~~upon which~~ **with whom** we ~~rely~~ **work** , and our customers may be vulnerable to a heightened risk of these attacks, including retaliatory cyber- attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. We and the third parties ~~upon which~~ **with whom** we ~~rely~~ **work** are subject to a variety of evolving threats, including but not limited to social- engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial- of- service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply- chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, telecommunications failures, earthquakes, fires, floods, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent – particularly for companies like ours in the medical field – and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. ~~94Remote~~ -- **Remote** work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program. We rely on third- party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, communication systems, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third- party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third- party service providers fail to satisfy their privacy or security- related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply- chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third- party partners' supply chains have not been compromised. We take steps to detect and remediate vulnerabilities, but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These vulnerabilities pose risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties ~~upon~~ **with** whom we ~~rely~~ **work** , including our research partners or collaborators. We may expend significant resources or modify our business activities (including our clinical trial activities or product development) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures or industry- standard or reasonable security measures to protect our information technology systems and sensitive information. ~~While~~ **89While** we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. Applicable data privacy and security obligations may require us **, or we may voluntarily choose,** to notify relevant stakeholders of security incidents, including affected individuals, customers, regulators, and investors **, or to take other actions, such as providing credit monitoring and identify theft protection services** . Such disclosures ~~are~~ **and related actions can be** costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we, or a third party ~~upon~~ **with** whom we ~~rely~~ **work** , experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and / or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversions of management' s attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our products, deter new customers from using our products, and negatively impact our ability to grow and operate our business. For example, the loss of clinical trial data ~~95from~~ -- **from** completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or disclosure of confidential or proprietary information, further development and commercialization of our product candidates could be delayed. Our contracts may not contain limitations of

liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. In addition, third parties may gather, collect, or infer competitively sensitive information about us from public sources, data brokers, or by other means that could be used to undermine our competitive advantage or market position. Additionally, any sensitive information (including confidential, competitive, proprietary, or personal data) that we input into a third- party generative AI platform could be leaked or disclosed to others, including if sensitive information is used to train the third parties' AI model. Coverage and reimbursement may be limited or unavailable in certain market segments for DANYELZA and our product candidates, which could make it difficult for us to sell DANYELZA and our product candidates profitably. Successful sales of DANYELZA and our product candidates, if approved, depend on the availability of adequate coverage and reimbursement from third- party payors. In addition, because DANYELZA and our product candidates represent relatively new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from DANYELZA or our product candidates. Patients who are provided medical treatment for their conditions generally rely on third- party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance. Government authorities and third- party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third- party payor may depend upon a number of factors, including the third- party payor' s determination that use of a product is: ● a covered benefit under its health plan; **90** ● safe, effective and medically necessary; ● appropriate for the specific patient; ● cost-effective; and ● neither experimental nor investigational. In the United States, no uniform policy of coverage and reimbursement for products exists among third- party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third- party payor is a time- consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost- effectiveness data for the use of our products on a payor- by- payor basis, with no assurance that coverage and adequate reimbursement will be obtained. To date, although a number of third- party providers have established coverage policies and provided reimbursement for DANYELZA, there is no guarantee that third- party providers will establish coverage policies or provided reimbursement for any of our other product candidates, if approved. The reimbursement payment rates for DANYELZA or any other product we commercialize might not be adequate for us to achieve or ~~96sustain~~ -- **sustain** profitability or may require co- payments that patients find unacceptably high. Additionally, third- party payors may not cover, or provide adequate reimbursement for, long- term follow- up evaluations required following the use of our products, if approved. Third- party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost- effectiveness of medical products and services, and imposing controls to manage costs. Our rebate payments may increase, or our prices may be adjusted under value- based purchasing arrangements based on evidence- based measures or outcomes- based measures for a patient or beneficiary based on use of DANYELZA or any other product we commercialize. Patients are unlikely to use our product unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Because our products and product candidates have a higher cost of goods than conventional therapies, and may require long- term follow up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater. Further, coverage policies and third- party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics. To date DANYELZA has been approved for sale in the United States ~~, Israel, China~~ and ~~Brazil only~~ **multiple regions outside of the United States** , but we intend to seek approval to market our products in additional selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we or our partner holding the approval such as Takeda Israel, holding the approval of DANYELZA in Israel will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third- party payors for our product candidates and may be affected by existing and future health care reform measures. We may incur significant liability if enforcement authorities allege or determine that we are engaging in commercial activities or promoting DANYELZA or another product candidate in a way that violates applicable regulations. Physicians have the discretion to prescribe drug products for uses that are not described in the product' s labeling and that differ from those approved by the FDA or other applicable regulatory authorities. Off label uses are common across medical specialties. Although the FDA and other regulatory authorities do not regulate a physician' s choice of treatments, the FDA and other regulatory authorities regulate a manufacturer' s communications regarding off label use and prohibit off label promotion, as well as the dissemination of false or misleading labeling or promotional materials. Manufacturers may not promote drugs for off label uses. Accordingly, we may not promote DANYELZA in the United States for use in any indications other than relapsed / refractory high **-** risk neuroblastoma in bone and / or bone marrow. The FDA and other regulatory and enforcement authorities actively enforce laws and regulations prohibiting ~~promotion~~ **91promotion** of off label uses and the promotion of products for which marketing approval has not been obtained. A company that is found to have improperly promoted off label uses may be subject to significant liability, which may include civil and administrative remedies as well as criminal sanctions.

Notwithstanding regulations related to product promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non- misleading, and non- promotional scientific exchange concerning their products. We intend to engage in medical education activities and communicate with healthcare providers in compliance with all applicable laws and regulatory guidance. Due to the nature of radioactive isotopes in radioimmunotherapy product candidates, the product shelf life is limited and susceptible to spoilage and / or loss, which could adversely affect our business, financial condition and operating results. Our radioimmunotherapy product candidates have a very limited shelf life once radiolabeled with radioactive elements. For commercial manufacture and supply these product candidates require reliable transportation and radiolabeling production facilities located **near** ~~in close proximity to~~ our final customers to avoid spoilage, damage and / or ~~97loss~~ -- **loss** . The failure of third parties with whom we contract to **safely and compliantly** deliver these product candidates within the scope of their limited shelf lives could result in the loss of a given shipment and the sales associated with it. Any delay in shipment results in a loss of the radioactive dose **because** ~~as a result~~ of radioactive decay, with the risk that the entire useful dose may be lost. Moreover, since each order is made individually and delivered with dedicated transportation in compliance with local regulations applicable to the handling of radioactive materials, we do not have readily available replacements to substitute for a lost delivery if circumstances beyond our control, such as delays or problems caused by inclement weather or a failure in the transportation system operated by third parties that we hire, prevent the timely delivery of a batch, or if the receiving facility fails to distribute the ordered batch in a timely fashion in accordance with specifications. Such losses or failures could have a material adverse effect on our business, financial condition and results of operations. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous, radioactive and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain products or product candidates outside of the United States and require us to develop and implement costly compliance programs. We currently have operations in the United States and Denmark and we maintain relationships with CMOs in the United States as well as other parts of Europe for the manufacture of our product candidates. If we further expand our operations outside of the United States, we must comply with numerous laws and regulations in each new jurisdiction in which we plan to operate. The creation and implementation of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required. No assurance can be given that our compliance policies and procedures are or will be sufficient or that our directors, ~~officers~~ **92officers** , employees, representatives, consultants and agents have not engaged and will not engage in conduct for which we may be held responsible, nor can we assure you that our business partners have not engaged and will not engage in conduct that could materially affect their ability to perform their contractual obligations to us or even result in our being held liable for such conduct. The FCPA prohibits any U. S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti- bribery provisions of the FCPA are enforced primarily by the DOJ. The Securities and Exchange Commission, or SEC, is involved with enforcement of the books and records provisions of the FCPA. ~~98Compliance~~ -- **Compliance** with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Similar laws in other countries, such as the U. K. Bribery Act 2010, may apply to our operations. Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non- U. S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain drugs and product candidates outside of the United States, which could limit our growth potential and increase our development costs **. In addition, certain Chinese biotechnology companies and contract development and manufacturing organizations may become subject to trade restrictions, sanctions, other regulatory requirements or proposed legislation by the U. S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially having an adverse impact on our development and commercialization efforts and potential revenues, including potential payments to us based on regulatory and commercial activities in China. For example, the recently proposed BIOSECURE Act introduced in the U. S. House of Representatives, as well as a substantially similar bill in the U. S. Senate, target U. S. government**

**contracts, grants, and loans for entities that use equipment and services from certain named Chinese biotechnologies companies and authorizes the U. S. government to name additional Chinese biotechnology companies of concern. If these bills become law, or similar laws are passed, they would have the potential to severely restrict the ability of companies to work with certain Chinese biotechnology companies of concern without losing the ability to contract with, or otherwise receive funding from, the U. S. government. Such disruption could have adverse effects on the development and commercialization of our product candidates and products, and our business and financial results** . The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA or other export control, anti- corruption, anti- money laundering and anti- terrorism laws or regulations can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U. S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long- term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U. S. exchanges for violations of the FCPA' s accounting provisions. ~~Risks~~ **93Risks** related to our intellectual propertyOur success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection. Our commercial success will depend in large part on obtaining and maintaining proprietary rights including patent, trademark and trade secret protection of our products, product candidates and related proprietary technologies, their respective components, formulations, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third- party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our products, product candidates and related proprietary technologies is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. The patenting 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. In addition, we may not be able to pursue or obtain patent protection in all relevant markets. 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. Our pending and future patent applications may not result in issued patents that protect our product candidates or related technologies, in whole or in part. In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing product candidates or products and related technologies. We currently depend on proprietary technology licensed from MSK and MIT and may depend on other third- party licensors in the future. If we lose our existing licenses or are unable to acquire or license additional proprietary rights from MSK, MIT or other third parties, we may not be able to continue developing our products. We currently in- license certain intellectual property from MSK and MIT. In the future we may in- license intellectual property from other licensors. We rely on certain of these licensors to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them. We have limited control over these activities or any other intellectual property that may be related to our in- licensed intellectual property. For example, we cannot be certain that such activities by these licensors have been or will be conducted in compliance with ~~99applicable~~ -- **applicable** laws and regulations or will result in valid, enforceable or sufficient patents and other intellectual property rights. We have limited control over the manner in which our licensors may initiate an infringement proceeding against a third- party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves. The growth of our business may depend in part on our ability to acquire or in- license additional proprietary rights. For example, our programs may involve additional product candidates that may require the use of additional proprietary rights held by third parties. Our products or product candidates may also require specific formulations to work effectively and efficiently. These formulations may be covered by intellectual property rights held by others. We may develop products containing our compounds and pre- existing pharmaceutical compounds. These pharmaceutical compounds may be covered by intellectual property rights held by others. We may be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our products or product candidates. Such diagnostic test or tests may be covered by intellectual property rights held by others. We may not own, or may have to share, the intellectual property rights obtained in collaboration with any other party, or intellectual property rights obtained relating to improvements of in- licensed products or processes. We may be unable to acquire or in- license any relevant third- party intellectual property rights that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third- party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license under such intellectual property rights, any such license may be non- exclusive, which may allow our competitors to access the same ~~technologies~~ **94technologies** licensed to us. Additionally, we sometimes collaborate with academic and other institutions, such as MSK, to accelerate our pre- clinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution' s rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third- party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer. The

licensing and acquisition of third- party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third- party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates, products and related proprietary technologies. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire. We are a party to license agreements with MSK, MIT and others, pursuant to which we in- license key patent and patent applications for our product candidates, products and related proprietary technologies. These existing licenses impose various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations or otherwise materially breach a license agreement, our licensors may have the right to terminate the license, in which event we would not be able to develop or market the products covered by such licensed intellectual property. In addition, any claims asserted against us by our licensors may be costly and time- consuming, divert the attention of key personnel from business operations or otherwise have a material adverse effect on our business. ~~100Uncertainty~~ --- **Uncertainty** as to the issuance, scope, validity, enforceability and value of patents, and the potential for future changes in patent and other intellectual property protections, may result in inadequate protection of our as well as in- licensed intellectual property or may result in alleged or actual infringement of the intellectual property rights of third parties. The patent position of pharmaceutical and biotechnology companies generally is highly uncertain and involves complex legal and factual questions for which many legal principles remain unresolved. In recent years patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights and in- licensed patent rights are highly uncertain. Our pending and future patent applications and in- licensed patent applications may not result in patents being issued in the United States or in other jurisdictions which protect our products or product candidates or related technologies 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 and in- licensed patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the 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 be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. In addition, the U. S. Patent and Trademark Office, or USPTO, might require that the term of a patent issuing from a pending patent application be disclaimed and limited to the term of another patent that is commonly owned or names a common inventor. As a result, the issuance, scope, validity, enforceability and commercial value of our as well as in- licensed patent rights are highly uncertain. Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and in- licensed patent applications and the enforcement or defense of the issued patents. In March 2013, under the Leahy- Smith America Invents Act, or America Invents Act, the United States moved from a " first- to- invent " to a " first- to- file " system. Under a " first- to- file " system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U. S. ~~patent~~ **95patent** law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post- grant review system. The effects of these changes are currently unclear as the USPTO only recently developed new regulations and procedures in connection with the America Invents Act and many of the substantive changes to patent law, including the " first- to- file " provisions, only became effective in March 2013. In addition, the courts have yet to address many of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. During examination of our own as well as our in- licensed patent applications third parties may present observations or submit patents, published patent applications or other prior art which may affect the patentability of the claimed inventions. The costs for obtaining patent protection may be increased significantly by the need for appeal proceedings or oral proceedings, which may also result in a patent not being issued. We may become involved in opposition, interference, derivation, post- grant review, inter partes review, ex- parte re- examination or other proceedings challenging our patent rights or the patent rights of others, and the outcome of any proceedings are highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our and in- licensed patent rights, allow third parties to commercialize our products, product candidates and related technologies 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. Intellectual property rights do not necessarily address all potential threats. Even if our owned or in- licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non- infringing manner. The issuance of a patent is not conclusive as ~~101to~~ **to** its scope, validity or enforceability, and our owned and in- licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the patent claims of our owned or in- licensed patents being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our products, product candidates and technology. 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 and in- licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example: ● others may be able to make or use compounds that are similar to the pharmaceutical compounds used in our products or product candidates but that are not covered by the claims of our patents; ● the APIs in our current products or product candidates may eventually become commercially available in generic drug products, and no patent protection may be available with regard to formulation, method of manufacture or method of use; ● we may not be able to prevent parallel importation of products into the U. S., EU member states and / or other jurisdictions, which may reduce our profit margin; ● we or our licensors, as the case may be, may fail to meet our obligations to the U. S. government in regard to any in- licensed patents and patent applications funded by U. S. government grants, leading to the loss of patent rights; **96** ● we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions; ● others may independently develop similar or alternative technologies or duplicate any of our products or product candidates and proprietary technologies; ● it is possible that our owned or in- licensed pending patent applications will not result in issued patents; ● it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents; ● we may not be able to obtain patent term extensions or supplementary protection certificates covering our products; ● it is possible that others may circumvent our owned or in- licensed patents; ● it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our product candidates, products or technologies similar to ours; ● the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States; ● the claims of our owned or in- licensed issued patents or patent applications, if and when issued, may not cover our product candidates or products; ~~102~~ ● our owned or in- licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties; ● the inventors of our owned or in- licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors; ● we have engaged in scientific relationships in the past, such as with MSK, and expect to continue to do so with MSK and / or other third parties in the future. Such third parties may develop adjacent or competing products to ours that are outside the scope of our licensed patents and / or the respective research collaboration / agreement with such third parties; ● we may not develop additional proprietary technologies for which we can obtain patent protection; ● it is possible that products, product candidates or diagnostic tests we develop may be covered by third parties' patents or other proprietary rights; or ● the patents of others may have an adverse effect on our business. In addition, during the course of business we have decided not to pursue certain products or processes and we may do so again in the future. If it is later determined that our activities, product or product candidates infringed the intellectual property of any third- party, we may be liable for damages, enhanced damages or subjected to an injunction, any of which could have a material adverse effect on our business. We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect, and we have limited control over the protection of trade secrets used by our licensors, collaborators and suppliers. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may ~~unintentionally~~ **97unintentionally** or willfully disclose our information to competitors or use such information to compete with us. Moreover, our competitors may independently develop equivalent knowledge, methods and know- how. If our confidential or proprietary information is divulged to or acquired by third parties, including our competitors, our competitive position in the marketplace will be harmed and this would have a material adverse effect on our business. If any of our owned or in- licensed patents are found to be invalid or unenforceable, or if we are otherwise unable to adequately protect our rights, it could have a material adverse impact on our business and our ability to commercialize or license our technology products and product candidates. Likewise, our current owned patents and patents in- licensed from MSK relating to our proprietary technologies and our product candidates comprise patents that are expected to expire on various dates from 2026 through 2042, without taking into account any possible patent term adjustments, extensions or supplementary protection. Upon the expiration of our current patents, we may lose the right to exclude others from practicing the relevant inventions. The expiration of these patents could also have a similar material adverse effect on our business, results of operations, financial condition and prospects. We own or in- license pending patent applications from MSK and others covering our proprietary technologies or our product candidates that if issued as patents are expected to expire from 2031 through 2041, without taking into account any possible patent term adjustments, extensions or supplementary protections. However, no assurance can be given that the USPTO or relevant foreign patent offices will grant any of these patent applications. Even if granted, we may fail to obtain patent term extensions or supplementary protection certificates covering our products. We may incur substantial costs **because** ~~as a result~~ of litigation or other proceedings relating to patents, and we may be unable to protect our rights to our product candidates, products and technologies. If we or our licensors choose to go to court to stop a third- party from using the inventions claimed in our owned or in- licensed patents, that third- party may ask the court to rule that the patents are invalid and / or should not be enforced against that third- party. These lawsuits are expensive and would consume time and other resources even if we or they, as ~~103the~~ **the** case may be, were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we or they, as the case may be, do not have the right to stop others from using the inventions. There is also a risk that, even if the validity of these patents is upheld, the court will refuse to stop the third- party on the ground that such third- party' s activities do not infringe our owned or in- licensed patents. In addition, the U. S. Supreme Court has changed some legal principles that affect patent applications, granted patents and assessment of the eligibility or validity of these patents. As a consequence, issued patents may be found to contain

invalid claims according to the newly revised eligibility and validity standards. Some of our owned or in- licensed patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in proceedings before the USPTO, or during litigation, under the revised criteria which could also make it more difficult to obtain patents. Similar considerations pertain to patents granted outside of the United States, for which the validity, enforceability and / or scope of protection may be influenced by changing national and / or international legal principles. We, or our licensors, may not be able to detect infringement against our owned or in- licensed patents, as the case may be, which may be especially difficult for manufacturing processes or formulation patents. Even if we or our licensors detect infringement by a third party of our owned or in- licensed patents, we or our licensors, as the case may be, may choose not to pursue litigation against or settlement with the third party. If we, or our licensors, later sue such third party for patent infringement, the third party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us or our licensors to enforce our owned or in- licensed patents, as the case may be, against such third party. If another party questions the patentability of any of our claims in our owned or in- licensed U. S. patents, the third party can request that the USPTO review the patent claims such as in an inter partes review, ex parte re- exam or post- grant review proceedings. These proceedings are expensive and may result in a loss of scope of some claims or a loss of the entire patent. In addition to potential USPTO review proceedings, we may become a party to patent opposition proceedings in the European Patent Office, or EPO, or similar proceedings in other foreign patent offices, where either our owned or in- licensed foreign patents are challenged. The costs of these opposition or similar proceedings could be substantial, and such oppositions may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result at the USPTO, EPO or other patent office may result in the loss of our right to ~~exclude~~ **98exclude** others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our business. We may incur substantial costs **because** ~~as a result~~ of litigation or other proceedings relating to intellectual property rights other than patents, and we may be unable to protect our rights to our product candidates, products and technologies. We may rely on trade secrets and confidentiality or nondisclosure agreements to protect our proprietary technology and know- how, especially where we do not believe patent protection is appropriate or obtainable. Where we enter into agreements imposing confidentiality or nondisclosure obligations upon employees or third parties to protect our proprietary technology and know- how, these confidentiality obligations may be breached or may not provide meaningful protection for our trade secrets or proprietary technology and know- how. Furthermore, despite the existence of such confidentiality and nondisclosure agreements, or other contractual restrictions, we may not be able to prevent the unauthorized disclosure or use of our confidential proprietary information or trade secrets by consultants, vendors, former employees or current employees. In addition, adequate remedies may not be available in the event of an unauthorized access, use, or disclosure of our trade secrets or know- how. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets effectively or to the same extent as the laws of the United States. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Third parties may obtain knowledge of our trade secrets through independent development or other access by legal means. The occurrence of such events could limit or preclude our ability to produce or sell our products in a competitive manner or otherwise have a material adverse effect on our business. ~~104If~~ **If** we are sued for infringing patents or other intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation may have a material adverse effect on our business. Our commercial success depends upon our ability to develop, manufacture, market and sell our products or product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields relating to our product candidates or products. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert that our products or product candidates infringe others' patent rights. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates or products, technologies or methods. In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology related to our products or product candidates, technology covered by our owned and in- licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may affect technology covered by our owned and in- licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. If another party has filed a U. S. patent application on inventions similar to those owned by or in- licensed to us, we or, in the case of in- licensed technology, the licensor may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. If we or one of our licensors is a party to an interference proceeding involving a U. S. patent application on inventions owned by or in- licensed to us, we may incur substantial costs, divert management' s time and expend other resources, even if we are successful. ~~There~~ **99There** is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. We may be subject to, or threatened with litigation by third parties having patent or other intellectual property rights alleging that our product candidates or products and / or proprietary technologies infringe, misappropriate or violate their intellectual property rights. If a third- party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to: ● infringement and

other intellectual property claims, which, regardless of merit, may be expensive and time- consuming to litigate and may divert our management' s attention from our core business; ● substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party' s rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner' s attorneys' fees; ● a court prohibiting us from developing, manufacturing, marketing or selling our product candidates or products, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do; ● if a license is available from a third party, it may not be offered on reasonable terms and may require that we pay substantial royalties, upfront fees and other amounts, and / or grant cross- licenses to intellectual property rights for our products; and ● redesigning our products or product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time. ~~105Some~~ **Some** of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. We may choose to challenge the patentability of claims in a third party' s U. S. patent by requesting that the USPTO review the patent claims in an ex- parte re- exam, inter partes review or post- grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party' s patent in patent opposition proceedings in the EPO, or other foreign patent office. The costs of these opposition proceedings could be substantial, and such proceedings may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates or products or proprietary technologies. We may not be able to protect our intellectual property rights with patents throughout the world. Filing, prosecuting and defending patents on all of our products or product candidates throughout the world would be prohibitively expensive. Competitors may use our technology 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 have patent protection but where enforcement is not as strong as in the United States. These products may compete with our products or product candidates in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, ~~which~~ **100which** could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Obtaining and maintaining our patent protection depends upon 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. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent prosecution process and following the issuance of a patent. Our failure to comply with such requirements could result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case if our patent were in force, which would have a material adverse effect on our business. Failure to secure trademark registrations could adversely affect our business. If we do not successfully register our trademarks, we may encounter difficulty in enforcing, or be unable to enforce, our trademark rights against third parties, which could adversely affect our business and our ability to effectively compete in the marketplace. When we file registration applications for trademarks relating to our products or product candidates, those applications may be rejected, and registered trademarks may not be obtained, maintained or enforced. During trademark registration proceedings in the United States and foreign jurisdictions, we may receive rejections. We are given an opportunity to respond to those rejections, but we may not be able to overcome such rejections. In addition, in the United States Patent and Trademark Office and in comparable agencies in many foreign jurisdictions, third parties may oppose pending trademark registration applications or seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademark registrations may not survive such proceedings. ~~106In~~ **In** addition, any proprietary name we use, such as DANYELZA, or propose to use with any of our products or product candidates in the United States must be approved by the FDA, regardless of whether we have registered, or applied to register, the proposed proprietary name as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest, which may have a material adverse effect on our business. We rely on our trademarks, trade names, service marks, domain names and logos, as appropriate, to market our brands and to build and maintain brand recognition. We rely on trademark protections to protect our business and our products and services. We generally seek to register and continue to register and renew, or secure by contract where appropriate, trademarks, trade names and service marks as they are developed and used, and reserve, register and renew domain names as appropriate. Our registered trademarks or unregistered trademarks, trade names or service marks may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. Effective trademark protection may not be available or may not be sought in every country in which our products are made available and contractual disputes may

affect the use of marks governed by private contract. Similarly, not every variation of a domain name may be available or be registered, even if available. We may not be able to protect our rights to these trademarks, trade names, service marks and domain names, which we need to build brand name recognition in our markets of interest. And while we seek to protect the trademarks we use in the United States and in other countries, we may be unsuccessful in obtaining registrations and / or otherwise protecting these trademarks. If that were to happen, we may be prevented from using our names, brands and trademarks unless we enter into appropriate royalty, license or coexistence agreements. Over the long- term, if we are unable to establish name recognition based on our trademarks, ~~trade~~ **101trade** names, service marks and domain names, then we may not be able to compete effectively, resulting in a material adverse effect on our business. Risks related to employee matters and managing growthWe depend heavily on our executive officers. Our future success depends on our ability to retain our senior management and other key executives and to attract, retain and motivate qualified personnel. The loss of their services could materially harm our business **. We currently have limited internal research and development capabilities. We conduct independent clinical trials and perform pre- clinical research, but we also rely on third- party research institutions for both clinical trials and pre- clinical research** . We are highly dependent on the members of our executive management as well as the other principal members of our management and scientific teams. Our agreements with any of them do not prevent them from terminating their employment with us at any time. In ~~April 2022 we announced the departure of our then Chief Executive Officer and in~~ October 2023, we announced ~~additional management transitions, including~~ the appointment of a new President and Chief Executive Officer and transition of our President and Interim Chief Executive Officer to Chief Business Officer **. In March 2024, we announced the resignation of our Executive Vice President, Chief Financial Officer, Secretary and Treasurer, which resignation became effective in July 2024 when his successor commenced employment with us in July 2024** . We cannot assure you that **these management changes or** any **future** management ~~change~~ **changes , or any other changes that we have or may make with respect to our workforce,** will not have an adverse impact on our business operations. The loss of the services of members of our executive management ~~team~~ **and other functions** and the failure to find appropriate replacements in a timely fashion could impede the achievement of our research, development and commercialization objectives. ~~Our President and Chief Executive Officer, Michael Rossi, joined us in November 2023.~~ It is important to our success that ~~Mr. Rossi, as well as~~ any ~~other~~ key employees ~~that~~ **who have recently joined us or who will** join us in the future ~~,~~ quickly adapt to and excel in their new roles. If they are unable to do so, our business and financial results could be materially adversely affected. Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel remains critical to our success. We currently conduct a significant portion of our operations in the New York City metropolitan area, in a region that is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel is intense and the turnover rate can be high, which may limit our ability to ~~107hire~~ **hire** and retain highly qualified personnel on acceptable terms or at all. We expect that we will need to recruit talent from outside of our region, and doing so may be costly and difficult. To induce valuable employees to join and remain at our company, in addition to salary and cash incentives, we have provided, and intend to continue to provide, stock option and / or restricted stock grants that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in the fair market value of our capital stock that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, these employment agreements provide for at- will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain " key person " insurance for any of our executives or other employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. We may **not realize the expected benefits from our recent business realignment and workforce reduction and we may incur additional costs implementing it or other difficulties. 102In January 2025, we announced a business realignment plan designed to optimize our operations by aligning dedicated internal resources to two business units, with the goal of increasing operational flexibility and speed, and accelerating clinical development within our radiopharmaceutical platform. Pursuant to the plan, we now have two business units, one that is focused on expanding market access to DANYELZA and progressing the clinical and commercial development of naxitamab in other indications and for potential label expansion, and another that is focused on progressing the radiopharmaceutical platform, including the SADA PRIT technology platform and our early- stage pipeline, with a shared general administrative function. In connection with this business realignment, we expect a reduction in our current workforce by up to approximately 13 %, which we expect will be completed by the first half of 2026. However, the changes to our operating structure and the reduction in workforce may yield unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond our intended reduction- in- force, a reduction in morale among our remaining employees, and the risk that we may not achieve the anticipated benefits, all of which may have an adverse effect on our commercialization efforts, development activities, and results of operations or financial condition. As a result of the reduction in workforce and realignment plan, we expect to incur business alignment expenses of up to approximately $ 2. 6 million, consisting predominantly of severance benefits of approximately $ 2. 1 million and acceleration of stock- based compensation of up to approximately $ 0. 5 million. We recognized $ 1. 5 million of these business realignment expenses in the year ended December 31, 2024, and we anticipate that there expenses will impact our results of operations during the first quarter of 2025, as well, and that the cash payments will occur through the first half of 2026. We may also incur other charges, costs, future cash expenditures or impairments not currently contemplated due to events that may occur because of, or in connection with, our new operating structure and reduction in the workforce. If we discover that the reductions in the workforce will make it difficult for us to pursue new**

**opportunities and initiatives and require us to hire qualified replacement personnel, this may require us to incur additional and unanticipated costs and expenses. Furthermore, the separation of our operations may make it more difficult to achieve synergies between our commercial and development activities. If we are unable to efficiently integrate our expertise and resources across both business units, we may not fully realize the potential benefits of our SADA-PRIT platform, and the commercialization of DANYELZA may be negatively impacted. It is possible that our management may need to divert a disproportionate amount of its attention away from our day- to- day strategic and operational activities and devote a substantial amount of time to managing these organizational changes. Moreover, there is no assurance we will be successful in our pursuit of any of our goals. Our failure to successfully accomplish any of the above activities and / or realize the stated goals of our business realignment may have a material adverse impact on our business, financial condition, and results of operations. We may** need to increase the size of our organization in the future, and we may experience difficulties managing growth. If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be adversely affected. We may need to expand the size of our organization in the future. The growth we may experience in the future may provide challenges to our organization, requiring us to also rapidly expand other aspects of our business, including our manufacturing operations. Rapid expansion in personnel may result in less experienced people producing and selling our products, which could result in unanticipated costs and disruptions to our operations. If we cannot scale and manage our business appropriately, our potential growth may be impaired and our financial results will suffer. ~~Risks~~ **103Risks** related to our common stockOur executive officers, directors and principal stockholders have ownership of a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval. As of February ~~22~~ **25**, ~~2024~~ **2025**, our executive officers ~~,~~ **and** directors ~~and our stockholders, who own more than 5 % of our outstanding common stock in the aggregate beneficially,~~ own shares representing approximately ~~22~~ **19**. ~~6~~ **8** % of our common stock. As a result, if these stockholders were to choose to act together, they would be able to exert significant influence over all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they chose to act together, would have significant influence over the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire. Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management or members of our board of directors. Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which a stockholder might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions: ● establish a classified board of directors such that not all members of the board are elected at one time; ~~108~~ ● allow the authorized number of our directors to be changed only by resolution of our board of directors; ● limit the manner in which stockholders can remove directors from the board; ● establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors; ● require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent; ● limit who may call stockholder meetings; ● authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a " poison pill " that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and ● require the approval of the holders of at least 75 % of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, or DGCL, which prohibits a person who owns in excess of 15 % of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15 % of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. ~~Our~~ **104Our** ability to use our net operating loss carryforwards and certain other tax attributes may be limited. Our ability to utilize our net operating loss carry- forwards and certain other tax attributes depends on many factors, including our future income, which cannot be assured, and the impact of any tax reform legislation or proposals. Under current law, U. S. federal net operating loss carryforwards generated in tax years beginning before January 1, 2018 may be carried forward for 20 tax years. U. S. federal net operating loss carryforwards generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such net operating loss carryforwards is limited to 80 % of taxable income. It is uncertain if and to what extent various states will conform to U. S. federal income tax law. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an " ownership change " (generally defined as a greater than 50 percentage point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three- year period), an annual limitation is imposed on the corporation' s use of its change net operating loss carry-forwards and certain other pre- change tax attributes to offset its post- change taxable income or taxes. Based on our analysis of our Section 382 ownership changes through December 31, ~~2022~~ **2023**, we believe that it is more likely than not that none of our net operating loss carryforwards will expire because of existing limitations under Section 382 of the Code, due to the large size of such limitations. We may experience Section 382 ownership changes in the future as a result of subsequent shifts in our equity ownership, many of which are outside our control. State net operating loss carryforwards may be similarly limited, and there may be periods during which the use of such net operating loss carryforwards is suspended or otherwise limited, which

could accelerate or permanently increase our state taxes owed. Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition, or results of operations. New income, sales and use, or other tax laws or regulations could be enacted at any time, and existing tax laws and regulations could be interpreted, modified, or applied adversely to us. These events could require us to pay additional taxes on a prospective or retroactive basis, as well as penalties, interest, and other costs for past amounts ~~109deemed~~ --- **deemed** to be due. New laws, or laws that are changed, modified, or interpreted or applied differently also could increase our compliance, operating, and other costs, as well as the costs of our products. **For example** ~~Recent legislation in the United States~~ , ~~commonly referred to as~~ the Inflation Reduction Act, enacts a 15 % minimum tax on the adjusted financial statement income of certain large U. S. corporations for tax years beginning after December 31, 2022, as well as a 1 % excise tax on stock repurchases made by public corporations after December 31, 2022. Further, the Tax Cuts and Jobs Act of 2017 ~~, or the Tax Act, enacted many significant changes to U. S. tax laws, some of which were further modified by the Coronavirus Aid, Relief, and Economic Security Act, and may be modified in the future by the current or a future presidential administration. Among other changes, the Tax Act~~ amended the Code to require that certain research and experimental expenditures be capitalized and amortized over five years if incurred in the United States or fifteen years if incurred in foreign jurisdictions for tax years beginning after December 31, 2021. Although the U. S. Congress has considered legislation that would defer, modify, or repeal the capitalization and amortization requirement, there is no assurance that such changes will be made. If the requirement is not deferred, repealed, or otherwise modified, it may increase our cash taxes and effective tax rate. In addition, it is uncertain if and to what extent various states will conform to current federal law, or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net operating losses and other deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses could have a material impact on the value of our deferred tax assets and could increase our future tax expense. Because we do not anticipate paying any cash dividends on our capital stock for the foreseeable future, capital appreciation, if any, of our common stock will be the source of gain associated with investment in our common stock. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain associated with investment in our common stock for the foreseeable future. ~~Future~~ **105Future** sales of common stock by us or our stockholders may cause substantial dilution to our existing stockholders and have an adverse effect on the then prevailing market price of our common stock. Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Sales of our common stock may be made by holders of our public float or by holders of restricted securities in compliance with the provisions of Rule 144 of the Securities Act of 1933, or the Securities Act. There were ~~43~~ **45** , ~~777~~ **218** , ~~105~~ **177** shares of common stock outstanding as of February ~~22~~ **25** , ~~2024~~ **2025** . In addition, we have issued stock options and other equity awards under our equity compensation plans. The shares underlying these awards are registered on a registration statement on Form S- 8. As a result, upon vesting, these shares can be freely exercised, as applicable, and sold in the public market upon issuance, subject to volume limitations applicable to affiliates. We have also registered ~~14~~ **16** , ~~278~~ **025** , ~~887~~ **771** shares of our common stock that we may issue under our equity compensation plans as of February ~~22~~ **25** , ~~2024~~ **2025** , and we plan to increase that number further. Also, in general under Rule 144, a non- affiliated person who has satisfied a six- month holding period in a company registered under the Exchange Act, as amended, may, sell their restricted common stock without volume limitation, so long as the issuer is current with all reports under the Exchange Act in order for there to be adequate common public information. Affiliated persons may also sell their common shares held for at least six months, but affiliated persons will be required to meet certain other requirements, including manner of sale, notice requirements and volume limitations. Non- affiliated persons who hold their common shares for at least one year will be able to sell their common stock without the need for there to be current public information in the hands of the public. Future sales of shares of our public float or by restricted common stock made in compliance with Rule 144 may have an adverse effect on the then prevailing market price, if any, of our common stock. ~~110We~~ **We** may issue additional shares of our common stock or securities convertible into our common stock from time to time in connection with a financing, acquisition, investments or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and cause the trading price of our common stock to decline. We currently have on file with the SEC a shelf registration statement, which allows us to offer and sell certain registered securities, such as common stock, preferred stock, debt securities, warrants and units, from time to time pursuant to one or more offerings at prices and terms to be determined at the time of sale. We may sell common stock, convertible securities or other equity or debt securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity or debt securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders. Our amended and restated certificate of incorporation designates the state courts in the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against us and our directors, officers and employees. Our amended and restated certificate of incorporation 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 the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) is the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or employees to our company or our stockholders, any action asserting a claim against us arising pursuant to any provision of the DGCL or our amended and restated certificate of incorporation or amended and restated bylaws, or any action asserting a claim against us governed by the internal

affairs doctrine. This exclusive forum provision may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find ~~favorable~~ **106favorable** for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our sales of our common stock by us, our insiders or other stockholders. The price of our common stock has been and is likely to be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock. Also, the volatility of our stock price may adversely affect our ability to attract equity funding in the future on reasonable terms or at all. Our stock price has been and is likely to be volatile. The stock market in general and the market for pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. Since our common stock began trading on The Nasdaq Global Select Market on September 22, 2018, our stock has traded at prices as low as $ 2. 70 per share and as high as $ 55. 22 per share through February ~~22~~ **25** , ~~2024~~ **2025** . In the last 12 months, our stock has traded at prices as low as $ ~~2~~ **5** . ~~83~~ **47** per share and as high as $ ~~17~~ **20** . ~~01~~ **90** per share through February ~~22~~ **25** , ~~2024~~ **2025** . As a result of this volatility, investors in our common stock may not be able to sell their shares at or above the prices they paid. Further, as a result of this volatility it may be difficult for us to attract new equity investments, including additional public offerings of our common stock, on terms we consider reasonable, or at all. The market price for our common stock may be influenced by many factors, including: ● our ability to successfully ~~launch~~ **grow or maintain sale of DANYELZA** and commercialize ~~DANYELZA and~~ any other product candidates, if approved; ● the timing and results of clinical trials of any of our product candidates; ● regulatory actions with respect to our products or product candidates or our competitors' products and product candidates; ● the success of existing or new competitive products or technologies; ~~111~~ ● announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments; ● establishment or termination of collaborations for our products and product candidates or development programs; ● failure or discontinuation of any of our development programs; ● results of clinical trials of product candidates of our competitors; ● regulatory or legal developments in the United States and other countries; ● developments or disputes concerning patent applications, issued patents or other proprietary rights; ● the recruitment or departure of key personnel; ● the level of revenues and expenses related to any of our products, product candidates or development programs; ● the results of our efforts to discover, develop, acquire or in- license additional product candidates or products; ● our ability to accurately forecast demand for our products, actual or anticipated changes in forecasts of financial performance, or changes in development timelines; **107** ● announcement or expectation of additional financing efforts; ● sales of our common stock by us, our insiders or other stockholders; ● variations in our financial results or those of companies that are perceived to be similar to us; ● changes in estimates or recommendations by securities analysts, if any, that cover our stock; ● changes in the structure of healthcare payment systems; ● market conditions and investor sentiment in the pharmaceutical and biotechnology sectors; ● general economic, industry and market conditions, such as an increased rate of inflation, increased cost of goods, supply- chain disruptions and uncertain global financial markets, and geopolitical events ~~,~~ ~~such as the conflict between Ukraine and Russia and related sanctions~~ ; and ● the other factors described in this " Risk Factors " section. In the past, securities class- action litigation has often been instituted against companies following periods of volatility in the price of their common stock. For example, following volatility in the price of our common stock following the ODAC meeting in October 2022, one of our stockholders filed a putative class action lawsuit in the federal district court for alleged violations of the Securities Exchange Act of 1934, as amended. Litigation could result in substantial costs and divert our management' s attention and resources, which could have a material and adverse effect on our financial condition, business, and the per share trading price of our common stock. ~~112We~~ **We have been named** , **and may in the future be named, as defendants in lawsuits or other legal proceedings that could result in substantial costs and divert management' s attention. As described elsewhere in this report NOTE 9 — LICENSE AGREEMENTS AND COMMITMENTS in the notes to the consolidated financial statements included in Item 8. Financial Statements and Supplementary Data, we and** our Chief Business Officer and Vice Chairman Mr. Thomas Gad, and our former Chief Executive Officer ~~,~~ Dr. Claus Juan Møller San Pedro, **were** ~~have been named as defendants in a lawsuit that could result in substantial costs and divert management' s attention, and we have also been named in other lawsuits. Any of these lawsuits could result in substantial costs and divert management' s attention. As described elsewhere in this report in " Part II, Item 1 — Legal Proceedings, " we and our Chief Business Officer and Vice Chairman Mr. Thomas Gad, and our former Chief Executive Officer Dr. Claus Juan Møller San Pedro, have been~~ named as defendants in a class- action lawsuit **alleging** ~~that alleges~~ that we and the individuals named in the lawsuit violated Sections 10 (b) and / or 20 (a) of the Exchange Act and Rule 10b- 5 promulgated thereunder. **We are** ~~Further, as~~ also **from time to time subject to** ~~described elsewhere in this report in " Part II, Item 1 — Legal~~ **legal** ~~Proceedings~~ **proceedings arising out of our business and / or operations** ~~, " on February 8, 2023, Jeffrey Hazelton, a purported Y- mAbs stockholder, filed a putative stockholder derivative action~~ . ~~These complaints seek~~ **Such legal proceedings may involve product liability claims, shareholder lawsuits and other claims by third parties, and employment claims made by our current or former employees. Such proceedings may result in substantial costs and may divert management' s attention and resources, may negatively impact our reputation and may lead to additional legal proceedings, investigations or claims** , among other things, **which may harm our business** ~~unspecified damages, and reasonable costs and expenses, including attorneys' fees. As of the date of this report, we are unable to predict the outcome of these matters~~ . Although we have insurance, it provides for a substantial retention of liability and is subject to limitations and may not cover a significant portion, or any, of the expenses or liabilities we may incur or be subject to in connection with the ~~class- action lawsuit or other~~ litigation to which we are party. Moreover, any conclusion of ~~these~~ **a** ~~matters~~ **matter** in a manner adverse to us and for which we incur substantial costs or damages not covered by our directors' and officers' liability insurance would have a material adverse effect on our financial condition and business. In addition, ~~the~~ litigation has caused and will continue to cause our management and board of directors to divert time and attention ~~to the litigation~~ and could adversely impact our reputation and further divert management and our board of directors' attention and resources from other priorities, including the execution of our business

plan and strategies that are important to our ability to grow our business and advance our product candidates, any of which could have a material adverse effect on our business. ~~In addition, additional lawsuits may be filed, the conclusion of which in a manner adverse to us and for which we incur substantial costs or damages not covered by our directors' and officers' liability insurance would have a material adverse effect on our financial condition and business. General~~ **108General** risk factorsOur business, financial condition and results of operations have been and may in the future be adversely affected by pandemics or similar health crises, macroeconomic conditions **, including escalating trade tensions,** and by geopolitical events ~~, including the global conflict resulting from the invasion of Ukraine by Russia, and sanctions related thereto, which resulted in the suspension of our clinical trial and regulatory activities in Russia, and the state of war between Israel and Hamas~~ . Our financial condition, results of operations, business and cash flow may be negatively affected by general conditions in the global economy and in the global financial markets and uncertainty about economic stability. The global economy has experienced extreme volatility and disruptions, including as a result of the COVID- 19 pandemic, **inflationary conditions and escalating trade tensions,** as well as from international conflicts, terrorism or other geopolitical events ~~, such as the Russian invasion of Ukraine, and related sanctions and other economic disruptions or concerns~~ . Sanctions imposed by the United States and other countries in response to such conflicts, may also adversely impact the financial markets and the global economy, and the economic countermeasures by the affected countries or others could exacerbate market and economic instability. **Moreover** ~~On February 24~~ , ~~2022, Russia initiated significant military action against Ukraine. In response,~~ the ~~United States and~~ **new Trump administration has recently imposed tariffs on** certain **U. S. imports, and China and** other countries ~~imposed significant sanctions~~ **have responded with retaliatory tariffs on certain U. S. exports. We cannot predict what effects these tariffs** and ~~trade actions against Russia and could impose further sanctions~~ **potential additional tariffs will have on our business. However** , **these tariffs and other** trade restrictions ~~, and other retaliatory actions if the conflict continues or worsens. It is not possible to predict the broader consequences of the conflict, including related geo- political tensions, and the measures and retaliatory actions that will be taken by the United States and other countries in respect thereof, as well as any countermeasures or retaliatory actions Russia may take in response, are likely to cause regional instability and geo- political shifts and could materially adversely affect global trade, currency exchange rates, regional economies, and the global economy. While it is difficult to anticipate the ultimate impact of any of the foregoing on our company in particular, the conflict and actions taken in response to the conflict has caused us to terminate our clinical trials and suspend our regulatory activities to obtain marketing authorization for DANYELZA in Russia although we may still provide drug to be used on a compassionate use basis. Additional actions that we or others may take in response to the conflict~~ could increase our **operating** costs, **reduce** ~~disrupt our supply chain, impair our ability to raise or~~ **our gross margins** ~~access additional 113capital when needed on acceptable terms, if at all,~~ or otherwise ~~adversely affect~~ **negatively impact** our ~~business,~~ financial ~~condition, and~~ results ~~of operations. For additional detail regarding this conflict, see the risk factor above " — Russia' s invasion of Ukraine and ancillary developments may have an adverse effect on our business. " In addition, on October 7, 2023, Hamas militants infiltrated Israel' s southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Following the attack, Israel' s security cabinet declared war against Hamas. It is currently not possible to predict the duration or severity of the ongoing conflict, whether it will develop into a wider conflict or its effects on our business, operations and financial conditions. The ongoing conflict is rapidly evolving and developing and may have a material adverse impact on Takeda Israel' s ability to sell our products and / or collect receivables from customers in the State of Israel pursuant to the Takeda Licensing Agreement as well as on Takeda Israel' s ability to pursue the development, marketing and / or commercialization of DANYELZA in the State of Israel, West Bank and Gaza Strip, which may ultimately have an adverse impact on the amount of royalties we receive pursuant to the Takeda Licensing Agreement~~ . There can be no assurance that further deterioration in credit and financial markets, global banking stability, and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for any product candidates we may develop and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could impair our ability to achieve our growth strategy, could harm our financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that our current or future service providers, manufacturers or other collaborators may not survive such difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. We cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. If we engage in future acquisitions, partnerships, or other strategic transactions, this may increase our capital requirements, dilute our stockholders if we issue equity securities, cause us to incur debt or assume contingent liabilities, and subject us to other risks. We may evaluate various acquisitions, partnerships or other strategic transactions, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including: ● increased operating expenses and cash requirements; ● the assumption of additional indebtedness or contingent liabilities; ● the issuance of our equity securities; ● assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integration; ● the diversion of our management' s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition; **109** ● retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships; ● risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; ~~and114~~ **and** ● our inability to generate revenue from acquired technology and / or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one- time expenses and

acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, which could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. We expect our operating results to fluctuate in future periods, which may adversely affect our stock price. Our operating results have fluctuated in the past, and we believe they will continue to do so in the future. Our operating results may fluctuate due to the level of success of our commercial efforts, as well as the variable nature of our operating expenses as a result of the timing and magnitude of expenditures. In one or more future periods, our results of operations may fall below the expectations of securities analysts and investors. In that event, the market price of our common stock could decline. A variety of risks associated with operating our business internationally, including through collaboration partners, could materially adversely affect our business. We have obtained and plan to continue to seek regulatory approval of our product candidates outside of the United States. We also have existing commercialization collaborations in certain territories outside the United States such as with SciClone, Takeda Israel, Swixx Biopharma AG, Adium ~~,~~and WEP ~~Clinical Ltd. Takeda Israel obtained regulatory approval for DANYELZA in Israel in August 2022 and we obtained regulatory approval for DANYELZA in China in December 2022~~ . In ~~May~~ **addition, we have entered into distribution agreement with INPHARMUS and Nobelpharma in** ~~2023~~ **2024** ~~, we obtained regulatory approval for DANYELZA in Brazil and in September 2023, we obtained regulatory approval for DANYELZA in Mexico~~ . Accordingly, we and our existing and potential collaborators in jurisdictions outside the US, are subject to additional risks related to operating in foreign countries, including: ● differing regulatory requirements in foreign countries; ● unexpected changes in tariffs **and escalating trade tensions** , trade barriers, price and exchange controls, and other 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 taxes, including local transfer pricing regulations and withholding of payroll taxes; ● foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; ● difficulties staffing and managing foreign operations; ● workforce uncertainty in countries where labor unrest is more common than in the United States; ● potential liability under the FCPA, or OFAC, Anti- Money Laundering Program as required by the Bank Secrecy Act and its implementing regulations, or comparable foreign laws; **110** ● challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; ~~115~~ ● production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and ● business interruptions resulting from geo- political actions, including war and terrorism. These and other risks associated with our current and planned international operations may materially adversely affect our ability to attain or maintain profitable operations. Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses. Our operations, and those of our third- party research institution collaborators, CROs, CMOs, suppliers, other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, droughts, floods, hurricanes, typhoons, fires, extreme weather conditions, climate change events, medical epidemics, terrorist activities, wars or other armed conflicts, geopolitical tensions ~~, such as the ongoing conflict between Russia and Ukraine~~ and related sanctions **,** and the ~~state~~ **potential resumption** of ~~war~~ **the conflict** between Hamas and Israel and a potential larger conflict, cyber security attacks and other natural or man- made disasters or business interruptions, for which we are predominantly self- insured, and other severe hazards or global health crises, such as an outbreak of Ebola or COVID- 19, or other actual or threatened epidemic, pandemic, outbreak and spread of a communicable disease or virus, in the countries where we operate or plan to sell our products, if approved, could adversely affect our operations and financial performance. In addition, we rely on our third- party research institution collaborators for conducting research and development of our product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third- party manufacturers to produce and process DANYELZA, and our ~~other~~ product candidates. Our ability to obtain **commercial supplies of DANYELZA and** clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man- made or natural disaster or other business interruption **, and we anticipate that our ability to obtain commercial and clinical supplies of DANYELZA will be interrupted in connection with the transition of production of DANYELZA drug product from our supplier Patheon / Thermo Fisher' s manufacturing facility in Greenville, North Carolina to its manufacturing facility in Monza, Italy. See " We rely on third parties to manufacture DANYELZA for commercial and clinical supply and our product candidates, including our antibody constructs based on the SADA PRIT Technology, for our ongoing and planned pre- clinical studies and clinical studies. Our business could be harmed if third parties fail to provide us enough DANYELZA or our other product candidates, including our antibody constructs based on the SADA PRIT Technology, or fail to do so at acceptable quantities, quality levels or prices or fail to maintain adequate compliance with CMC guidelines of the FDA and comparable foreign regulatory authorities. Our third- party manufacturers have in the past and may in the future experience manufacturing difficulties, and any such difficulties could harm our business. " elsewhere in this Part I., Item 1A.** . Damage or extended periods of interruption to our third- party collaborators', including MSK' s, corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Although we intend to maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption. The ultimate extent of the impact of any epidemic, pandemic or other global health crisis, such as COVID- 19, on our business, financial condition and results of operations will depend on future developments which are highly uncertain and cannot be predicted, including new information that may emerge concerning the duration and severity of such epidemic, pandemic or other global health crisis, actions taken to contain or prevent their further spread and the pace of global economic recovery following

containment of the spread. ~~If~~ **111If** product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates. We face an inherent risk of product liability as a result of the sale of DANYELZA and clinical testing of our product candidates and will face an even greater risk if we commercialize more products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during use, clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: ● decreased demand for our products; ● injury to our reputation; ~~116~~ ● withdrawal of clinical trial participants and inability to continue clinical trials; ● initiation of investigations by regulators; ● costs to defend the related litigation; ● a diversion of management' s time and our resources; ● substantial monetary awards to trial participants or patients; ● product recalls, withdrawals or labeling, marketing or promotional restrictions; ● exhaustion of any available insurance and our capital resources; ● the inability to commercialize any product candidate; ● loss of any potential future revenue; and ● a decline in our share price. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of DANYELZA or any product candidates we develop, alone or with collaborators. The amount of clinical trial and product liability insurance coverage that we may obtain, may not be adequate, we may be unable to maintain such insurance, or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise. Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, ~~reckless~~ **112reckless** and negligent conduct that fails to: comply with the regulations of the FDA, the EU and other similar foreign regulatory requirements; provide true, complete and accurate information to the FDA, the EMA, the European Commission, and other similar foreign regulatory bodies; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. As we have obtained FDA approval of DANYELZA and have begun commercializing DANYELZA in the United States, our exposure under such laws has increased significantly, and our costs associated with compliance with such laws have increased significantly and are likely to continue to increase. These laws impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission (s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other parties, 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 ~~117protecting~~ --- **protecting** us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these 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, including the imposition of significant fines or other sanctions. We may be subject to claims that our licensors, employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their former employers or their clients. As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace. The increasing use of social media platforms presents new risks and

challenges. Social media is increasingly being used to communicate about our drug, clinical development programs, and the diseases our drug and drug candidates are being developed to treat, and we are utilizing what we believe is appropriate social media in connection with our commercialization efforts for DANYELZA and we intend to do the same for our future products, if approved. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical study or to report an alleged adverse event, or AE. When such disclosures occur, there is a risk that we fail to monitor and comply with applicable AE reporting obligations or we may not be able to defend our business or the public' s legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our ~~investigational~~ **113investigational** products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or incur other harm to our business. If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline. The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our business downgrades their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline. ~~118If~~ **If** we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely consolidated financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our common stock. We qualified as a smaller reporting company and as a non- accelerated filer for the years ended December 31, **2024 and** 2023 ~~and 2022~~ **, respectively** . As a public company we are required to provide management' s attestation on internal controls pursuant to Section 404 of the Sarbanes- Oxley Act. However, as a non- accelerated filer, we are not required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm in this Annual Report on Form 10- K for the fiscal year ended December 31, ~~2023~~ **2024** . Our inability to operate controls effectively could cause material weaknesses in our internal control over financial reporting in the future, could have a material adverse impact on our company and consolidated financial statements and we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock. In addition, we may in the future be required to provide Section 404 of the Sarbanes- Oxley Act, or Section 404, reports by our independent registered public accounting attesting to the effectiveness of our internal control over financial reporting. An adverse report could have a material adverse impact on our company and consolidated financial statements, investor confidence in us and, as a result, the value of our common stock. The rules governing the standards that must be met for management and, when applicable, our independent registered public accounting firm to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. In connection with our and our independent registered public accounting firm' s evaluations of our internal control over financial reporting, we may need to upgrade systems, including information technology, implement additional financial and management controls, reporting systems, and procedures, and hire additional accounting and finance staff. 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 conducted by us or our independent registered public accounting firm may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated 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 common stock. Internal control deficiencies could also result in a restatement of our financial results in the future. We could become subject to stockholder or other third- party litigation, as well as investigations by the SEC, the Nasdaq Global Select Market, or other regulatory authorities, which could require additional financial and management resources and could result in fines, trading suspensions, payment of damages or other remedies. Further, any delay in compliance with the auditor attestation provisions of Section 404, if and when applicable, could subject us to a variety of administrative sanctions, including ineligibility for short- form resale registration, action by the SEC and the suspension or delisting of our common stock, which could reduce the trading price of our common stock and could harm our business. **114** ~~We will continue to incur costs associated with satisfying our obligations as public company, and our management is required to devote substantial time to new compliance initiatives. As a public company, we continue to incur significant legal, accounting and other expenses. In addition, the Sarbanes- Oxley Act and rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time- consuming and costly. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance. 119~~