Risk Factors Comparison 2024-03-05 to 2023-03-08 Form: 10-K

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

Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Annual Report as well as our other public filings with the Securities and Exchange Commission. Risks Related to our Financial Position and Need for Additional Capital We have incurred losses from operations since our inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future. We may never achieve or sustain profitability. We are a clinical stage biopharmaceutical company with limited operating history. All the product candidates we are developing will require substantial additional development time and resources before we or our partners would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We have incurred losses from operations in each year since our inception, including net losses of $ **3. 6 million and $** 29. 1 million ~~and $ 28. 7 million~~ for the **years** ~~twelve months~~ ended December 31, **2023 and** 2022 ~~and 2021~~, respectively. At December 31, ~~2022~~ **2023**, we had an accumulated deficit of $ ~~236~~ **240**. ~~9~~ **5** million. We expect to continue to incur substantial expenses as we expand our development activities and advance our clinical programs. To become and remain profitable, we or our partners must succeed in developing product candidates, obtaining regulatory approval for them, and manufacturing, marketing and selling those products for which we or our partners may obtain regulatory approval. We or they may not succeed in these activities, and we may never generate revenue from product sales that is significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with pharmaceutical and biological product development, we are unable to predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. In addition, our expenses could increase if we are required by the FDA or comparable foreign regulatory authorities to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any product candidates. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, develop other product candidates or continue our operations. We will require substantial additional financing to achieve our goals, and failure to obtain additional financing when needed could force us to delay, limit, reduce or terminate our drug development efforts. There is substantial doubt as to our ability to continue as a going concern. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We expect our current level of research and development expenses to ~~increase~~ **decrease** in ~~2023~~ **2024 with** ~~primarily due to~~ the ~~continued~~ **completion of** enrollment of the ENVASARC trial ~~and Phase 1 / 2 clinical trial of YH001~~ in ~~combination with envafolimab in certain sarcoma subtypes~~ **Q1 2024, however this is based on our current expectations which are subject to change**. At December 31, ~~2022~~ **2023**, we had cash and cash equivalents totaling $ ~~17~~ **8**. ~~5~~ **6** million, of which $ 0. 1 million is pledged as collateral for our obligations under our corporate headquarters facility lease. Based upon our current operating plan, we believe that our cash and cash equivalents as of December 31, ~~2022~~ **2023** will be sufficient to fund **the current requirements of working capital and other financial commitments, including** our operating **lease obligations,** ~~expenses and capital requirements~~ into mid- ~~2023~~ **2024**. We will need additional funding to complete the development and commercialization of product candidates, including envafolimab and YH001. In addition, in December 2019 **,** we entered into a collaboration and clinical trial agreement with 3D Medicines and Alphamab **,** and in October 2021, we entered into a collaborative development and commercialization agreement with Eucure and Biocytogen. Under these agreements, we are responsible for various portions of the costs to conduct clinical trials, among other development obligations. We will need additional funds to advance the development of these programs and meet our cost- sharing obligations, and these requirements may be substantial depending on how many programs are selected for development and the stage of development each program reaches. As more fully discussed in Note 1 to ~~our~~ **the audited** consolidated financial statements included in this Annual Report, the uncertainties around our ability to obtain additional funding raise substantial doubt regarding our ability to continue as a going concern for a period of 12 months following the date these accompanying consolidated financial statements were issued. Regardless of our expectations, ~~changing~~ circumstances beyond our control, including the effects of **adverse** macroeconomic and geopolitical developments ~~, such as the COVID- 19 pandemic, rising inflation rates and the ongoing conflict between Ukraine and Russia~~ may cause us to consume capital more rapidly than we currently anticipate. For example, our clinical trials may encounter technical, enrollment or other difficulties or we could encounter difficulties obtaining clinical trial material or other supplies that could increase our development costs more than we expect. **We** ~~In addition, we may continue to incur substantial legal expenses in connection with our on- going dispute with I- Mab, including in connection with enforcing and collecting any award from the arbitration process. In any event, we~~ will require additional capital prior to completing clinical development, filing for regulatory approval, or commercializing any product candidates. In December **2020, as amended in March** 2022, we entered into ~~a~~ **the Capital** ~~non-~~ **on DemandTM Sales** ~~- recourse financing agreement~~ **Agreement** (**as amended,** the ~~Investment~~ **Sales** Agreement) with ~~certain investors~~ **JonesTrading Institutional Services LLC** (**JonesTrading** ~~collectively the Investors~~) ~~pursuant to which the Investors will pay us a maximum aggregate amount (Maximum Capital) equal to $ 30. 0 million or a lesser amount based on the amount awarded (the Award), if any, to us in connection with our ongoing arbitration proceeding with I- Mab (the Arbitration). Of the Maximum Capital, (i) $ 3. 5 million (the Initial Capital) was paid to us shortly after execution, (ii) 25 % will be paid to us within 15 business days of issuance of an Award, subject to the Award size exceeding a prespecified threshold and satisfaction of other conditions set forth in the Investment Agreement, and (iii) the remainder will be paid to us in tranches over a multi-~~

~~year period, subject again to the Award size exceeding a prespecified threshold and satisfaction of other conditions set forth in the Investment Agreement. While the Investment Agreement provides us with access to additional capital under certain circumstances, we cannot predict the outcome of the arbitration and are unable to estimate whether the Award will meet or exceed the prespecified threshold required in the Investment Agreement. If the Award does not meet or exceed the prespecified threshold, we may not have access to additional capital under the Investment Agreement. In December 2020, as amended in March 2022, we entered into a Sales Agreement with JonesTrading~~ pursuant to which we could sell from time to time, at our option, up to an aggregate of $ 50. 0 million of shares of our common stock through JonesTrading, as sales agent or principal, $ ~~45~~ **41** . ~~7~~ **5** million of which remains available for sale as of December 31, ~~2022~~ **2023 . In May 2023, we and Lincoln Park Capital Fund, LLC (Lincoln Park) entered into the LPC Purchase Agreement, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Lincoln Park is committed to purchase up to an aggregate of $ 26. 0 million of shares of our common stock from time to time and at our sole discretion over the term of the LPC Purchase Agreement, $ 25. 0 million of which remains available for sale as of December 31, 2023** . While the Sales Agreement **and LPC Purchase Agreement** ~~provides~~ **provide** us with an additional option to raise capital through issuances and sales of our common stock, there can be no guarantee that we will be able to sell shares under the Sales **Agreement and LPC Purchase** Agreement in the future, or that any sales will generate sufficient proceeds to meet our capital requirements. In particular, **sales of our common stock made pursuant to the Sales Agreement, if any, will be made on the Nasdaq Capital Market under our effective registration statement on Form S- 3, subject to limitations on the amount of securities we may sell within any 12 month period, by means of ordinary brokers' transactions at market prices. Moreover,** JonesTrading is under no obligation to sell any shares of our common stock that we may request to be sold under the Sales Agreement from time to time. If sales are made under the Sales Agreement **and LPC Purchase Agreement** , our existing stockholders may experience dilution and such sales, or the perception that such sales are or will be occurring, may cause the trading price of our common stock to decline **, and may make it tougher for us to raise additional financing** . Attempting to secure additional financing may divert our management from our day- to- day activities, which may adversely affect our ability to develop product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. **For example, if we do not achieve the primary endpoint of our ENVARSAC Phase 2 pivotal trial, we may not continue development of envafolimab as a single agent in UPS / MFS, which would likely adversely our ability to raise additional financing and could significantly impact our ability to continue as a going concern and negatively impact our stock price and operations.** As a result of **adverse** macroeconomic and geopolitical developments, such as **recent** ~~the COVID- 19 pandemic~~ and ~~actions taken to slow its spread~~ **potential future bank failures, health epidemics** , ongoing military conflict between Ukraine and Russia **, the recent state of war between Israel and Hamas and the related risk of a larger regional conflict** , actual or anticipated changes in interest rates, economic inflation and the responses by central banking authorities to control such inflation, the global credit and financial markets have experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets deteriorate further, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly delay, scale back or discontinue the development ~~or commercialization~~ of product candidates or otherwise significantly curtail, or cease, operations. If we are unable to pursue or are forced to delay our planned drug development efforts due to lack of financing, it would have a material adverse effect on our business, financial condition, operating results and prospects. Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to product candidates on unfavorable terms to us. We may seek additional capital through a variety of means, including through equity offerings and debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to product candidates, or grant licenses on terms that are not favorable to us. ~~The RGC Loan Agreement contains restrictions that limit~~ **We are currently authorized to issue 60. 0 million shares of** our **common stock** ~~flexibility in operating our business~~ . We may be required to **increase** ~~make a prepayment or~~ **our authorized shares in order to raise additional capital. Issuances of** ~~repay the outstanding indebtedness earlier than we expect if a prepayment event or~~ **our shares of common stock following** an ~~event~~ **increase in authorized shares would result in further dilution to our existing stockholders. For instance, our cash and cash equivalents are sufficient to fund the current requirements** of ~~default occurs~~ **working capital and other financial commitments** , including ~~a material adverse change with respect to us, which could have a materially adverse effect on~~ our ~~business~~ **operating lease obligations, into mid- 2024** . In ~~September 2022, as amended December 2022, we entered into a loan and security agreement (~~ the **absence of additional capital, we do not anticipate being able to** ~~RGC Loan Agreement) with Runway Growth Finance Corp. (RGC or the Lender) that provides~~ **provide final response assessment data including duration** ~~a term loan commitment in an aggregate principal amount~~ of **response** ~~up to $ 35. 0 million~~ in **all patients from** ~~three~~ -- **the ENVASARC trial** ~~tranches: (i) a Term A loan~~ in ~~an aggregate principal amount of $ 10. 0 million, with~~ the **second half** ~~full amount funded on the closing~~ of ~~the RGC Loan Agreement and repaid in January 2023 in connection with the execution of our arbitration financing arrangement; (ii) a Term B loan in an aggregate principal amount of up to $ 15. 0 million to be funded in one or more disbursements at our request on or prior to June 30,~~ 2024 ~~, subject to certain conditions being met; and (iii) a Term C loan in an aggregate principal amount of up to $ 10. 0 million that may be disbursed in a single disbursement in the lender' s sole discretion upon our~~ **or complete** ~~request at any time from closing of~~ the

Phase 2 trial of TRC102 in ~~RGC Loan Agreement through and including December 31, 2024~~ **2025** ~~. Pursuant to the December 2022 amendment (the RGC Loan Amendment): (i) we repaid all amounts of principal and accrued but unpaid interest in respect of the Term A Loan (as defined in the RGC Loan Agreement) on January 3~~ , ~~2023 without the obligation for us to pay the final payment fee or the prepayment fee described in the RGC Loan Agreement; (ii) on or before March 31, 2023, at our request, if we have raised at least $ 25. 0 million in net cash proceeds from certain equity or debt transactions (including amounts raised in connection with our arbitration financing arrangement) prior to making such request, Lender will loan to us an~~ **and therefore may** ~~aggregate principal amount of $ 10. 0 million, with the full amount funded in a single disbursement; (iii) we will not issue an additional warrant to Lender in connection with the loan, if any, described in clause (ii) above; and (iv) Lender' s security interest in specific collateral will be subordinated to the arbitration financing investors' security interest in the specific collateral. If the loan described in clause (ii) above is not made by March 31, 2023, the RGC Loan Agreement will terminate on that date, and we will~~ not be ~~obligated~~ **able** to ~~pay~~ **complete our trials on** the ~~prepayment fee described in~~ **current timelines or at all. If we are not able to raise additional funds on a timely basis, we may be forced to delay, reduce** the ~~RGC Loan Agreement but the final payment fee described in the RCG Loan Agreement~~ **scope of, or eliminate one or more of our planned operating activities or otherwise significantly curtail or cease operations. Any delay or inability to pursue our planned activities likely** will ~~become immediately due and payable. The RGC Loan Agreement contains various covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things: • convey, sell, lease or otherwise dispose of certain parts of our business or property; • merge or consolidate with another entity; • incur or assume certain debt; • incur certain types of liens on our assets; • make changes to certain collateral accounts or fall below a prespecified amount of liquidity; • pay dividends or make other distributions to our stockholders; • make certain loans or investments; • enter into material transactions with affiliates; and • voluntarily repay or prepay certain indebtedness. The restrictive covenants of the RGC Loan Agreement could cause us to be unable to pursue business opportunities that we or our stockholders may consider beneficial. A breach of any of these covenants could result in an event of default under the RGC Loan Agreement. An event of default will also occur upon the occurrence of, among other things, a material adverse~~ **adversely** ~~effect~~ **affect** ~~on our business, operations, properties, assets or condition (financial or otherwise), which could potentially include receipt of negative results in clinical trials, a material impairment in the perfection or priority of the lien in any collateral or value of such collateral, or a material adverse effect on the prospect of our repayment of any portion of the amounts we owe under the RGC Loan Agreement or in the ability of RGC to enforce its rights and remedies. In the case of a continuing event of default under the RGC Loan Agreement, RGC, on behalf of all lenders, could elect to declare all amounts outstanding to be immediately due and payable, proceed against the collateral in which we granted a security interest under the RGC Loan Agreement, or otherwise exercise the rights of a secured creditor. Amounts outstanding under the RGC Loan Agreement are secured by substantially all of our assets, excluding intellectual property, which is subject to a negative pledge arrangement. Should an event of default or continuing event of default occur or if RGC elects to exercise its rights or remedies in accordance with the RGC Loan Agreement, including accelerating any payments or proceeding against any collateral, it would have a material adverse effect on~~ our business, financial condition, ~~results of operations~~ and ~~prospects~~ **stock price. The continued low trading price of our common stock (with a closing price of $ 0. 181 per share on February 29, 2024) presents a significant challenge to our ability to raise additional funds** . Risks Related to Clinical Development and Regulatory Approval of Product Candidates If ~~the response rate~~ **our ENVASARC Phase 2 pivotal trial does not achieve its primary endpoint, we may not continue development** of envafolimab as a single agent ~~or in combination with ipilimumab~~ in UPS / MFS ~~is not significantly higher than existing therapies, our~~ **or obtain regulatory** ~~strategy of pursuing accelerated approval of envafolimab on ORR as the primary endpoint could delay or prevent the~~ approval of envafolimab in UPS / MFS. We are initially developing envafolimab in refractory UPS / MFS, where the PD- (L) 1 inhibitors given as single agents ~~or in combination with ipilimumab~~ demonstrated response rates which were significantly higher than the response rate demonstrated by the **FDA-** approved treatment Votrient or chemotherapy in UPS / MFS. **Nine of 80 responses (11. 25 %) by blinded independent central review (BICR) are needed to satisfy the primary endpoint of the trial which is to statistically exceed the known 4 % ORR of Votrient for patients with refractory UPS or MFS. In December 2023, we announced that the ENVASARC trial had enrolled more than 70 of the 80 planned patients in cohort C of single agent envafolimab treatment. Additional safety and efficacy data were reviewed for 46 patients enrolled into cohort C who were the subject of the September IDMC review. For patients that completed a minimum of 12 weeks of efficacy evaluations and the ORR was 15 % by investigator review and 8. 7 % by BICR. Median duration of response by BICR remains greater than six months.** If the response rate of envafolimab as a single agent ~~or in combination with ipilimumab~~ in UPS / MFS ~~is~~ **by BICR does** not **exceed 11. 25 %** ~~significantly higher than Votrient or other chemotherapy~~ , **we will not achieve** ~~our strategy of pursuing accelerated approval of envafolimab on ORR as~~ the primary endpoint ~~will be unlikely to succeed, which could delay or~~ **for** ~~prevent the approval~~ **our Phase 2 pivotal trial and may not continue development** of envafolimab **as a single agent** in UPS / MFS ~~. Our plan to develop~~ **or obtain regulatory approval of** envafolimab in ~~combination with ipilimumab and YH001 in combination with~~ **UPS / MFS. Any discontinuation by us of our development of** envafolimab ~~exposes us~~ **as a single agent in UPS / MFS would likely adversely impact our ability** to **raise** additional **financing** ~~risks. We intend to develop envafolimab in combination with ipilimumab~~ and **could significantly impact** ~~to develop YH001 in combination with envafolimab, and may in the future develop other product candidates in combination with other approved therapies or~~ **our ability** ~~therapies in development. Patients may not be able~~ to ~~tolerate envafolimab~~ **continue as a going concern, cause a decline in** ~~or~~ **our stock price and adversely affect** ~~any of our other product candidates in combination with ipilimumab, YH001 or~~ **our operations** ~~other therapies or dosing of envafolimab in combination with ipilimumab, YH001 or other therapies may have unexpected consequences~~ . Even if ~~any of~~ **we demonstrate sufficient responses in the ENVARSAC trial, the FDA** ~~our~~ **or other regulatory agencies may not agree** ~~product candidates were to receive marketing approval or be commercialized for use in combination~~ with **our clinical development plan and**

require ~~other existing therapies, we would continue to be subject to the risks~~ that **we conduct** ~~the FDA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition~~ **additional** ~~, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own products being removed from the market or being less successful commercially. Additionally, if the third- party providers of therapies or therapies in development used in combination with our product candidates are unable to produce sufficient quantities for~~ clinical trials **to support** ~~or~~ **our regulatory submissions** ~~for commercialization of our product candidates~~, **including that we conduct more than one pivotal trial in order to gain approval. Any such additional trials would significantly delay** ~~or~~ **our clinical** ~~if the cost of combination therapies are prohibitive, our~~ development ~~and commercialization efforts would be impaired~~, ~~which would have an adverse effect on our business, financial condition, results~~ **result** ~~of~~ **in additional costs to us, may significantly impact our ability to continue as a going concern and could adversely impact our stock price and** operations ~~and prospects~~. Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development. Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Even if product candidates demonstrate favorable results in ongoing or planned Phase 1 and 2 clinical trials, many product candidates fail to show desired safety and efficacy traits in late-stage clinical trials despite having progressed through earlier trials. In addition to the potential lack of safety or efficacy of product candidates, clinical trial failures may result from a multitude of factors including flaws in trial design, manufacture of clinical trial material, dose selection and patient enrollment criteria, or differences in determination of progression events by investigators compared to central radiographic reviewers. With respect to envafolimab and YH001, while results of trials conducted by others outside of the United States have been promising, they may not be predictive of results in U. S. trials due to differences in trial design, target indications, patient populations, availability of alternative treatments and other factors. Based upon the recommendation of the IDMC following an interim analysis of data from the ENVASARC trial, we have proceeded in the trial using a dose of envafolimab that is twice the dose administered to the first patients in the trial. While dosing at higher levels has shown promising results in other trials outside of the United States, we cannot be certain that we will observe similar results in the ENVASARC trial, including whether the higher dose will result in tolerability issues that were not encountered with the lower dose. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we or our partners may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. If patients drop out of our trials, miss scheduled doses or follow- up visits or otherwise fail to follow trial protocols, or if our trials are otherwise disrupted due to ~~COVID- 19 actions taken to slow its spread or~~ adverse macroeconomic and geopolitical developments, such as **recent and potential future bank failures,** the ongoing military conflict between Ukraine and Russia **or the recent state of war between Israel and Hamas and the related risk of a larger regional conflict**, the integrity of data from our trials may be compromised or not accepted by the FDA or other regulatory authorities, which would represent a significant setback for the applicable program. If any product candidate is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our stock price would be materially and adversely affected. Interim, topline and preliminary data from preclinical studies and clinical trials may change as more data become available, and are subject to audit and verification procedures that could result in material changes in the final data. We and our collaboration partners publicly disclose from time to time, interim, topline or preliminary data from preclinical studies and clinical trials, which is based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change as more data become available. We and our collaboration partners may also announce topline data following the completion of a preclinical study or clinical trial, which may be subject to change following a more comprehensive review of the data related to the particular study or trial. We and our collaboration partners also make assumptions, estimations, calculations and conclusions as part of the analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. In addition, the manner in which clinical data and results are reported may differ depending on the jurisdiction in which a trial is conducted or between us and our collaboration partners. As a result, the interim, topline or preliminary results that we or our collaboration partners report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the previously published preliminary data. As a result, interim, topline and preliminary data should be viewed with caution until the final data are available. Adverse differences between previous preliminary or interim data and future interim or final data could significantly harm our business prospects. From time to time, we or our collaboration partners may also disclose interim data from clinical trials. Interim data from clinical trials 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 or as patients from clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us, our collaboration partners, or by our competitors could result in volatility in the price of our common stock. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product, our company in general and our common stock. In addition, the information we or our collaboration partners choose to publicly disclose regarding a particular study or

clinical trial is based on what is typically extensive information, and you or others may not agree with what we or our collaboration partners determine to be material or otherwise appropriate information to include in such disclosure, and any information we or our collaboration partners determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, topline, or preliminary data that is reported for our product candidates differ from future or more comprehensive data, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates, our business, operating results, prospects or financial condition may be harmed. Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales. We may experience delays in clinical trials of product candidates. Our ongoing and planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including: • inability to raise funding necessary to initiate or continue a trial; • delays in obtaining regulatory approval to commence a trial; • delays in reaching agreement with the FDA on final trial design; • adverse findings in toxicology studies, including chronic toxicology studies; • imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities; • delays in reaching agreement on acceptable terms with prospective clinical trial sites; • delays in obtaining required institutional review board approval at each site; • delays in recruiting suitable patients to participate in a trial; • delays in enrollment caused by the availability of alternative treatments; • delays in having patients complete participation in a trial or return for post- treatment follow- up; • clinical sites dropping out of a trial to the detriment of enrollment; • time required to add new clinical sites; or • delays in our ability to acquire sufficient supply of clinical trial materials. For example, the FDA may require additional or different data in order to move forward with a BLA submission for envafolimab for patients with local advanced, unresectable or metastatic UPS and MFS, which could ultimately delay regulatory approval and could have a material adverse effect on our business. In addition, ~~the COVID- 19 pandemic has~~ **adverse macroeconomic and geopolitical developments have** impacted clinical trials broadly, including our own with some sites pausing enrollment or not completing all assessments specified in the protocol, and some patients choosing not to enroll or continue participating in ongoing trials. We and our collaborators may continue to experience delays in site initiation and patient enrollment, failures to comply with trial protocols, delays in the manufacture of product candidates for clinical testing, supply chain disruptions and other difficulties in starting or competing our clinical trials due to ~~the COVID- 19 pandemic and other~~ macroeconomic and geopolitical developments. If initiation or completion of our ongoing or planned clinical trials are delayed for any of the above reasons or other reasons, our development costs may increase, our approval process could be delayed and our ability to commercialize product candidates could be materially harmed, which could have a material adverse effect on our business. Our product candidates or those of our partners may cause adverse events or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance. Adverse events (AEs) caused by product candidates or other potentially harmful characteristics of product candidates could cause us, our partners, including Eucure, Biocytogen, 3D Medicines, Alphamab or the NCI, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. Envafolimab has produced AEs consistent with other inhibitors of the PD- L1 and PD- 1 pathways, including rare fatal immune related toxicities ~~. Only a single related serious adverse event was reported in 36 patients in the ENVASARC interim efficacy data review in December 2022~~ . Based on the August 9, 2021 data cutoff from the YH001 Phase 1 dose escalation clinical trial being conducted in Australia, no dose limiting toxicities had occurred and a single related serious adverse event of grade 3 colitis was reported, which led to treatment discontinuation. Phase 1 or Phase 2 clinical trials of TRC102 conducted to date have generated AEs related to the trial drug, some of which have been serious. The most common AE identified in our clinical trials of TRC102 has been anemia. There can be no assurance that AEs associated with product candidates will not be observed. As is typical in drug development, we have a program of ongoing toxicology studies in animals for clinical stage product candidates and cannot provide assurance that the findings from such studies or any ongoing or future clinical trials will not adversely affect our clinical development activities. Further, if any approved products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution; • regulatory authorities may require the addition of labeling statements, such as warnings or contraindications; • we may be required to change the way the product is administered or conduct additional clinical trials; • we could be sued and held liable for harm caused to patients; or • our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing product candidates. The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for product candidates, our business will be substantially harmed. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate' s clinical development and may vary among jurisdictions. For example, for certain oncology indications where the FDA has traditionally granted approval to therapies that can demonstrate progression- free survival, the agency may later require us to demonstrate overall survival, which would greatly extend the time and increase the capital required to complete clinical development. We have not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. Product candidates could fail to receive regulatory approval for many reasons, including the following: • the FDA or comparable foreign regulatory authorities may disagree with the design, scope or implementation of our clinical trials; • we may

be unable to demonstrate to the satisfaction of the FDA 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 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 or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; • the data collected from clinical trials of product candidates may not be sufficient to support the submission of a BLA or a New Drug Application (NDA), or other submission or to obtain regulatory approval in the United States or elsewhere; • the FDA 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; and • the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change significantly in a manner rendering our clinical data insufficient for approval. This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market product candidates, which would harm our business, results of operations and prospects significantly. In addition, even if we were to obtain approval, regulatory authorities may approve any product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post- marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could harm the commercial prospects for our product candidates or those of our partners. We have not previously submitted a marketing application, or any similar drug approval filing to the FDA or any comparable foreign authority for any product candidate, and we cannot be certain that any product candidates will be successful in clinical trials or receive regulatory approval. Further, product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more product candidates, our revenue will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such product candidates, if approved. Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could negatively impact our business. The ability of the FDA to review and approve proposed clinical trials or new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA' s ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA' s ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. ~~Separately~~ **More recently** , in response to the global COVID- 19 pandemic, in March 2020, the FDA announced its intention to postpone most foreign and domestic inspections of manufacturing facilities ~~. In July 2020, the FDA restarted on- site inspections on a risk- based basis. Regulatory authorities outside the United States have~~ and **such delays continued** ~~may adopt similar restrictions or~~ **for several months** ~~other policy measures in response to the COVID- 19 pandemic~~ . If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. We may attempt to secure approval from the FDA through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post- marketing requirements, the FDA may seek to withdraw accelerated approval. We may in the future seek accelerated approval for one or more of our product candidates, including envafolimab in UPS / MFS. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life- threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor' s agreement to conduct, in a diligent manner, additional post- approval confirmatory studies to verify and describe the drug' s clinical benefit. If such post- approval studies fail to confirm the drug' s clinical benefit, the FDA may withdraw its approval of the drug. In addition, the FDA currently requires pre- approval of promotional materials for accelerated approval products, once approved. If we decide to submit an application for accelerated approval for our product candidates, there can be no assurance that such submission or application will be accepted or that any

expedited development, review or approval will be granted on a timely basis, or at all. **In the event we do not receive accelerated approval, the related development costs associated with our product candidates will increase and the related timelines will be delayed.** The FDA could require us to conduct further studies prior to considering our application or granting approval of any type **and may require us to have a confirmatory trial to verify the clinical benefit of the product candidate underway and partially or fully enrolled before granting approval. Even if we receive accelerated approval from the FDA, it will be subject to rigorous post marketing requirements, including the completion of confirmatory post market clinical trials, submission to the FDA of periodic progress reports on confirmatory trials, and submission to the FDA of all promotional materials prior to their dissemination. The FDA could seek to withdraw accelerated approval for multiple reasons, including if we fail to conduct any required post market study with due diligence; a post market study does not confirm the predicted clinical benefit; other evidence shows that the product is not safe or effective under the conditions of use; or we disseminate promotional materials that are found by the FDA to be false and misleading. Under the Consolidated Appropriations Act for 2023, the FDA may use expedited procedures to withdraw any product for which we receive accelerated approval if our confirmatory trials fail to verify the purported clinical benefits** . A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidates would result in a longer time period to commercialization of such product candidate, if any, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace. We may not receive fast track designation for our product candidates from the FDA, or fast track designation may not actually lead to a faster development or regulatory review or approval process. Fast track designation provides increased opportunities for sponsor meetings with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed. A new drug or biologic is eligible for fast track designation if it is intended to treat a serious or life- threatening disease or condition and the drug demonstrates the potential to address unmet medical needs for the disease or condition. While the FDA did grant us fast track designation for the development of envafolimab for patients with locally advanced, unresectable or metastatic UPS and MFS who have progressed on one or two prior lines of chemotherapy, it has broad discretion whether or not to grant this designation for our other product candidates. Even if we believe another particular product candidate is eligible for this designation, we cannot assure you that the FDA will grant it. Further, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. We may be unsuccessful in our efforts to obtain orphan drug designations (ODDs) from the FDA for product candidates, and even if these designations are obtained, we may not ultimately realize the potential benefits of ODD. Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 people in the United States, or a patient population of greater than 200, 000 people in the United States, but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan drugs do not require prescription drug user fees with a marketing application, may qualify the drug development sponsor for certain tax credits, and may be eligible for a market exclusivity period of seven years. In **October 2020, the FDA granted ODD for TRC102 for the treatment of patients with malignant glioma, including glioblastoma and in** June 2021, we received ODD for envafolimab for the treatment of soft tissue sarcoma subtypes ~~and in October 2020, the FDA granted ODD for TRC102 for the treatment of patients with malignant glioma, including glioblastoma~~ . Generally, if a drug with an ODD subsequently receives the first marketing approval for the indication for which it has such designation, the drug may be entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same orphan designated indication for that time period. The applicable period is seven years in the United States, which may be extended by six months, in the case of product candidates that have complied with the respective regulatory agency' s agreed upon pediatric investigation plan. Orphan drug exclusivity may be lost if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. In addition, even after a drug is granted orphan exclusivity and approved, the FDA can subsequently approve another drug for the same condition before the expiration of the seven- year exclusivity period 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. In addition, if an orphan designated product receives marketing approval for an indication broader than or different from what is designated, such product may not be entitled to orphan exclusivity. Even though the FDA has granted ODD, if we receive approval for a modified or different indication, our current orphan designations may not provide us with exclusivity. ODD does not convey any advantage in, or shorten the duration of, the regulatory review or approval process. Also, regulatory approval for any product candidate may be withdrawn, and other product candidates may obtain approval before us and receive orphan drug exclusivity, which could block us from entering the market. For example, 3D Medicines has U. S. ODD for envafolimab for the treatment of BTC, an indication that is outside the scope of our current license agreement with 3D Medicines. Orphan drug exclusivity also may not effectively protect us from competition because different drugs can be approved for the same condition and the same drug can be approved for different conditions before the expiration of any orphan drug exclusivity period. If orphan drug exclusivity is lost and we were unable to successfully enforce any remaining patents covering our eligible product candidates, we could be subject to generic competition earlier than we anticipate. In addition, if a subsequent drug is approved for marketing for the same or a similar indication as any product candidates that receive marketing approval, we may face increased competition and lose market share regardless of orphan drug exclusivity. Although we intend to seek breakthrough therapy designation for envafolimab for the treatment of soft tissue sarcoma subtypes, such designation may not be granted, and even if granted this may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood that envafolimab will receive marketing approval in the United States. A breakthrough therapy is defined as a therapy that is intended, alone or in combination with one or more

other therapies, to treat a serious or life- threatening disease or condition, and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For therapies that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Therapies designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. Although we intend to seek breakthrough therapy designation for envafolimab for the treatment of soft tissue sarcoma, we may not be granted such designation and even if designated this may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood that envafolimab will receive marketing approval in the United States. In addition, if granted breakthrough therapy designation, the FDA may later decide that envafolimab no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Obtaining and maintaining regulatory approval of product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of product candidates in other jurisdictions. Obtaining and maintaining regulatory approval of product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as studies or trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we would intend to charge for our products is also subject to approval. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and / or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates or those of our partners will be harmed. Even if we receive regulatory approval of product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with product candidates. Any product candidates for which we receive regulatory approvals will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a Risk Evaluation and Mitigation Strategy (REMS) in order to approve product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves product candidates, the manufacturing processes, labeling, packaging, distribution, AE reporting, storage, advertising, promotion, import, export and recordkeeping for product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, establishment registration and drug listing, as well as continued compliance with regulatory requirements for current good manufacturing practices (cGMPs) , and current good clinical practices (cGCPs) , for any clinical trials that we conduct post- approval. Although physicians, in the practice of medicine, may prescribe an approved drug for unapproved indications, pharmaceutical companies are prohibited from promoting uses that are not approved by the FDA as reflected in the product' s approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with the labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses of approved pharmaceutical products, and a company that is found to have improperly promoted off- label may be subject to significant liability. Later discovery of previously unknown problems with product candidates, including AEs of unanticipated severity or frequency, or with our third party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things: • restrictions on the marketing or manufacturing of product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls; • fines, warning letters or holds on clinical trials; • refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of existing approvals; • product seizure or detention, or refusal to permit the import or export of product candidates; and • injunctions or the imposition of civil or criminal penalties. The FDA' s and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of product candidates. 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 or abroad. 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 and we may not achieve or sustain profitability. Risks Related to Our Reliance on Third Parties We and our partners rely on third party manufacturers to make product candidates, and any failure by a third party manufacturer may delay or impair our ability to complete clinical trials or commercialize our product candidates. Manufacturing drugs and biologics is complicated and is tightly regulated by regulatory authorities, including the FDA and foreign equivalents. We currently rely on third party manufacturers to supply us with drug substance for preclinical and clinical trials. Moreover, the market for contract manufacturing services for drug products is highly cyclical, with periods of relatively abundant capacity alternating with periods in which there is little available capacity. If our need for contract manufacturing services increases during a period of industry- wide tight capacity, we may not be able to access the required capacity on a timely basis or on commercially viable terms, which could result in delays in

initiating or completing clinical trials or our ability to apply for or receive regulatory approvals. We rely on other third parties for drug substance and to perform additional steps in the manufacturing process, including filling into vials, shipping and storage. For our clinical stage pipeline programs, there can be no guarantee that lack of clinical supplies will not force us or our partners to delay or terminate any ongoing or planned clinical trials. We expect to continue to rely on third party manufacturers for any drug required for commercial supply and do not intend to build our own manufacturing capability. Successfully transferring complicated manufacturing techniques to contract manufacturing organizations and scaling up these techniques for commercial quantities is costly, time consuming and subject to potential difficulties and delays. With respect to envafolimab, pursuant to the Envafolimab Collaboration Agreement, 3D Medicines and Alphamab have agreed to manufacture and supply, or to arrange for a third party manufacturer to manufacture and supply, envafolimab to us at pre- negotiated prices that vary based on clinical or commercial use. With respect to YH001, Eucure has agreed to manufacture and supply, or to arrange for a third party manufacturer to manufacture and supply, YH001 to us for clinical trials pursuant to the terms of a clinical supply and quality agreement to be separately negotiated, but we cannot guarantee that we will successfully negotiate and enter into the contemplated clinical supply and quality agreement or do so on commercially favorable terms. We do not have any long- term supply agreements for the manufacture of product candidates and cannot guarantee that any third party manufacturer would be willing to continue supplying drug product for clinical trials or commercial sale at a reasonable cost or at all. In addition, manufacturing agreements are often subject to early termination by the third party manufacturer under certain circumstances. The facilities used by our current or future third party manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit a BLA or an NDA to the FDA. While we work closely with our third party manufacturers on the manufacturing process for product candidates, we generally do not control the implementation of the manufacturing process of, and are completely dependent on, our third party manufacturers for compliance with cGMP regulatory requirements and for manufacture of both drug substances and finished drug products. If our third party manufacturers or those of our collaborators cannot successfully manufacture material that conforms to applicable specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we may experience delays in initiating planned clinical trials and we may not be able to secure or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers or other third party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or commercialize product candidates. We depend in part on NCI and other third party sponsors to advance clinical development of TRC102. If these third party sponsors ceased their support for our product candidates, our ability to advance clinical development of product candidates could be limited and we may not be able to pursue the number of different indications for our product candidates that are currently being pursued. NCI is currently sponsoring and funding multiple clinical trials involving TRC102. In addition, Case Western has sponsored and funded two separate clinical trials involving TRC102. The advancement of TRC102 depends in part on the continued sponsorship and funding of clinical trials by these organizations, as our resources and capital would not be sufficient to conduct these trials on our own. None of these third party sponsors are obligated to continue sponsorship or funding of any clinical trials involving our product candidates and could stop their support at any time. If these third party sponsors ceased their support for our product candidates, our ability to advance clinical development of product candidates could be limited and we may not be able to pursue the number of different indications for our product candidates that are currently being pursued. Even if these third party sponsors continue to sponsor and fund clinical trials of our product candidates, our reliance on their support subjects us to numerous risks. For example, we have limited control over the design, execution or timing of their clinical trials and limited visibility into their day- to- day activities, including with respect to how they are providing and administering our product candidates. If a clinical trial sponsored by a third party has a failure due to poor design of the trial, errors in the way the clinical trial is executed or for any other reason, or if the sponsor fails to comply with applicable regulatory requirements or if there are errors in the reported data, it could represent a major set- back for the development and approval of our product candidates, even if we were not directly involved in the trial and even if the clinical trial failure was not related to the underlying safety or efficacy of the product candidate. In addition, these third party sponsors could decide to de- prioritize clinical development of our product candidates in relation to other projects, which could adversely affect the timing of further clinical development. We are also subject to various confidentiality obligations with respect to the clinical trials sponsored by third party sponsors, which could prevent us from disclosing current information about the progress or results from these trials until the applicable sponsor publicly discloses such information or permits us to do so. This may make it more difficult to evaluate our business and prospects at any given point in time and could also impair our ability to raise capital on our desired timelines. We are dependent on 3D Medicines and Alphamab with respect to certain aspects of our development of envafolimab for the treatment of sarcoma in North America and on Eucure and Biocytogen with respect to certain aspects of our development of YH001 for the treatment of certain sarcoma subtypes in North America. The failure to maintain these collaboration and clinical trial agreements, the failure of 3D Medicines, Alphamab, Eucure or Biocytogen to perform their obligations under the agreements, or the actions of 3D Medicines, Alphamab, Eucure or Biocytogen or their other partners with respect to envafolimab and YH001 in other indications or outside North America could negatively impact our business. Pursuant to the terms of our collaboration and clinical trial agreement with 3D Medicines and Alphamab, we were granted an exclusive license to develop and commercialize envafolimab for sarcoma in North America. Pursuant to the terms of our collaborative development and commercialization agreement with Eucure and Biocytogen, we were granted an exclusive (including with respect to Eucure and its affiliates), nontransferable, license to develop and commercialize YH001 in North America for the treatment of multiple human indications, including the Initial Indications or one or more of the Substitute Indications, which may be substituted for Initial Indications at our discretion. While we are generally responsible for

clinical development, 3D Medicines and Alphamab are responsible for certain critical activities associated with envafolimab and Eucure and Biocytogen are responsible for certain critical activities associated with YH001, including, as applicable, the manufacture and supply of envafolimab and YH001, CMC activities and prosecution and enforcement of intellectual property rights. We have limited control over the amount and timing of resources that 3D Medicines, Alphamab, Eucure and Biocytogen will dedicate to their respective efforts, and their failure to perform their obligations would impair our ability to develop envafolimab for sarcoma in North America and YH001 for certain sarcoma subtypes in North America. In addition, we have very limited influence or control over 3D Medicines', Alphamab' s, Eucure' s or Biocytogen' s (or their respective other partners') activities with respect to the development and commercialization of envafolimab and YH001 in non- licensed indications or indications outside of North America, even though these activities could have a significant impact on the development and commercialization of envafolimab for sarcoma in North America and YH001 for certain sarcoma subtypes in North America. For example, Eucure may pursue clinical trials for YH001 in North America outside of the Initial Indications or Substitute Indications, and also within the Initial Indications or Substitute Indications as part of a combination therapy of YH001 and an additional Eucure product, any of which could have a significant impact on the development and commercialization of YH001 for sarcoma in North America. Additionally, adverse events in clinical trials outside of the United States could cause the FDA to put clinical trials of envafolimab or YH001 in the United States on hold, and negative results of clinical trials of envafolimab in other indications may cast doubt as to the likelihood of positive results of clinical trials in UPS / MFS or other sarcoma indications. We are subject to a number of other risks associated with these collaboration and clinical trial agreements, including: • we and our corporate partners could disagree as to future development plans which could delay initiation of clinical trials or stop a future clinical trial; • there may be disputes between us and our corporate partners, including disagreements regarding the terms of the collaboration and clinical trial agreement, that may result in the delay of or failure to achieve development, regulatory and commercial objectives and / or costly litigation or arbitration that diverts our management' s attention and resources; • our corporate partners may not provide us with timely and accurate information regarding development progress and activities outside of sarcoma and North America, which could adversely impact our ability to report progress to our investors and may cause us to make ill- informed decisions with respect to our own development efforts; • our corporate partners may not properly maintain or defend the intellectual property rights licensed to us in North America or may undertake activities that invite litigation that could jeopardize or invalidate the intellectual property rights licensed to us or expose us to potential litigation; and • our corporate partners are responsible for conducting CMC activities for envafolimab and YH001 and may not conduct such activities at the quality level required to seek FDA approval. If we have disagreements with our corporate partners, if they do not perform their obligations under the collaboration and clinical trial agreements or there are negative events with respect to envafolimab or YH001 outside of the licensed indications or North America, there could be material adverse consequences to our ability to successfully develop and commercialize envafolimab and YH001 in North America or to the value of envafolimab and YH001 to us. ~~Our~~ **Any such consequences would likely adversely impact our** ability to **raise additional financing** ~~realize value from any product candidates developed under our agreements with I- Mab will depend in part on I- Mab' s activities and willingness to fund future development and the timing and outcome of our dispute with I- Mab of which we cannot predict the outcome~~ and could **significantly impact** ~~materially adversely affect~~ our ability to **continue** ~~operate our business and financial results. Pursuant to the terms of our strategic collaboration and clinical trial agreements with I- Mab, we are largely responsible for clinical development activities and I- Mab is responsible for pre- clinical development and manufacturing activities. Consequently, our ability to realize value or generate any revenues from the development of product candidates in collaboration with I- Mab will depend in part on I- Mab' s willingness and ability to successfully complete pre- clinical development and manufacturing activities, in addition to funding agreed- upon portions of the costs of clinical development. We have limited control over the amount and timing of resources that I- Mab will dedicate to its respective efforts, and have limited rights in the event that I- Mab determines to cease development or manufacturing activities or funding for any product candidate under the collaboration. We could also encounter disagreements with I- Mab over the timing and scope of development or manufacturing of any product candidates or payments owed under the collaboration or which, if any, BsAb product candidates are selected for development. For example, in March 2020, I- Mab issued a press release announcing a strategic partnership with Kalbe Genexine Biologics (KG Bio), whereby KG Bio received what the press release described~~ as a ~~right of first negotiation outside North America for TJ004309 for up to $ 340 million in potential payments to I- Mab. In March 2020, we also learned that I- Mab had entered into two license and collaboration agreements with ABL Bio in July 2018 (ABL Bio License 1 and ABL Bio License 2). Under ABL Bio License 1, I- Mab granted to ABL Bio exclusive, worldwide (excluding Greater China), royalty- bearing rights to develop and commercialize a BsAb using certain monoclonal antibody sequences. Under ABL License 2, I- Mab and ABL agreed to collaborate to develop three PD- L1- based bispecific antibodies by using ABL Bio' s proprietary BsAb technology and commercialize them in their respective territories, which, collectively, include China, Hong Kong, Macau, Taiwan and South Korea, and other territories throughout the rest of the world if both parties agree to do so in such other territories during the performance of the agreement. In June 2020, I- Mab commenced an arbitration proceeding under the Rules of Arbitration of the ICC before the Tribunal after we invoked contractual dispute resolution provisions asserting that I- Mab had breached its contractual obligations concerning two strategic collaboration and clinical trial agreements with us entered into in November 2018. Those strategic collaboration and clinical trial agreements relate to the development of TJ004309 and five of I- Mab' s proprietary bispecific antibody product candidates to be nominated by I- Mab within a five- year period for development and commercialization in North America. We filed counterclaims in the arbitration seeking to recover over $ 200 million in damages from I- Mab based on I- Mab' s breaches of the two strategic collaboration and clinical trial agreements. In 2021, I- Mab sent us notices purporting to terminate the TJ004309 Agreement, which would result in I- Mab owing us a prespecified termination fee of $ 9. 0 million. However, I- Mab does not have an option to terminate the TJ004309 Agreement without cause until the ongoing~~ -- **going concern** ~~Phase 1 clinical trial of~~

~~TJ004309 is " Complete, " as that term is defined in the TJ004309 Agreement, and we responded by disputing the basis for I- Mab' s termination. In March 2021, I- Mab filed a lawsuit in the Delaware Court of Chancery seeking a variety of relief including an~~ **and** ~~order of specific performance requiring us to comply with I- Mab' s purported termination of the TJ004309 Agreement. In May 2021, the Delaware Court of Chancery stayed the lawsuit in favor of arbitration. The Tribunal held a hearing on the merits in February 2022, and final post- hearing briefs were submitted by us and I- Mab in May 2022. On November 8, 2022, the Tribunal invited the parties to submit additional, limited briefing on two discrete issues by December 9, 2022. Following that submission, the parties submitted their respective cost submissions for attorney fees reimbursement in January 2023. The Tribunal did not indicate when it expects to render its final decision; however, it did note that it was far along in its deliberations and preparation of a final award. We expect the Tribunal to render its final decision in the first quarter of 2023. Under the applicable rules of the arbitration, the prevailing party may be awarded attorneys' fees at the Tribunal' s discretion. The claims under the arbitration are complex; accordingly, we cannot predict the outcome of the arbitration, which could materially adversely affect our ability to operate our business and our financial results, and we are unable to estimate the amount of recovery or~~ **our stock price** ~~damages, if any, that may be awarded by the Tribunal. The dispute with I- Mab has caused, and could continue to cause, us to incur significant costs, as well as distract our management over an~~ **and operations** ~~extended period. Until these disputes are concluded, we will be unable to provide a timeline as to when or if we will file an IND for a BsAb under the Bispecific Agreement. Furthermore, our ability to license bispecific product candidates from I- Mab may be more limited than we previously believed~~ . We may not be successful in establishing and maintaining additional collaborations, which could adversely affect our ability to develop and commercialize our existing product candidates or to leverage our clinical development capabilities. A part of our strategy is to strategically evaluate and, as deemed appropriate, enter into additional licensing and collaboration agreements, including potentially with major biotechnology or pharmaceutical companies. In particular, we are actively seeking additional corporate partnerships in which we would share in the cost and risk of clinical development and commercialization of innovative product candidates of third parties. We face significant competition in seeking appropriate partners, and the negotiation process is time- consuming and complex. In order for us to successfully partner our product candidates, potential partners must view these product candidates as having the requisite potential to demonstrate safety and efficacy and as being economically valuable in light of the terms that we are seeking and other available products for licensing by other companies. With respect to additional partnerships whereby we would develop third party product candidates, we will need to identify promising product candidates where the owner of the development and commercial rights could benefit from our clinical development capabilities ~~. Under our collaboration and clinical trial agreement with I- Mab for TJ004309, we are prohibited from developing other biologic product candidates targeting the same indications for which TJ004309 is being developed, which increases our reliance on the success of I- Mab' s activities with respect to TJ004309 and could limit our ability to collaborate with others with respect to biologic product candidates in certain indications~~ . Even if we are successful in our efforts to establish new collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. Any inability or delay in entering into new collaboration agreements related to our product candidates, in particular in foreign countries where we do not have and do not intend to establish significant capabilities, could delay the development and commercialization of our product candidates and reduce their market potential. If we are unable to enter into additional collaborations that leverage our clinical development capabilities, we may be forced to reduce these capabilities, which could lower the value of our company and make it less likely that third parties will seek to collaborate with us to develop their product candidates. We rely on third parties to conduct preclinical studies and clinical trials of product candidates, and if they do not properly and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for product candidates. We do not have our own capabilities to perform preclinical testing of product candidates, and therefore rely entirely on third party contractors and laboratories to conduct these studies for us. In addition, while we intend to continue designing, monitoring and managing our clinical trials of product candidates using our clinical operations and regulatory team, we still depend upon independent investigators and collaborators, such as universities and medical institutions, to conduct our clinical trials at their sites under agreements with us. We will compete with many other companies for the resources of these third- party contractors, laboratories, investigators and collaborators, and the initiation and completion of our preclinical studies and clinical trials may be delayed if we encounter difficulties in engaging these third parties or need to change service providers during a preclinical study or clinical trial. We control only certain aspects of the activities conducted for us by the third parties on which we currently rely and on which we will rely in the future for our preclinical studies and clinical trials. Nevertheless, we are responsible for ensuring that each of our clinical trials and certain of our preclinical studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. With respect to clinical trials, we and these third parties are required to comply with cGCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable cGCP 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 clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the cGCP regulations. In addition, our clinical trials must be conducted with product candidates produced under cGMPs 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 or state health care laws, including, among others, fraud and abuse, false claims, privacy and security, and physician payment transparency laws.

Any third parties conducting our preclinical studies and clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical development programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. 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 protocols or regulatory requirements or for other reasons, our preclinical studies and clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize product candidates. As a result, our financial results and the commercial prospects for our product candidates or those of our partners would be harmed, our costs could increase and our ability to generate revenue could be delayed. Switching or adding third parties to conduct our preclinical studies and clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines. Risks Related to Our Intellectual Property If we are unable to obtain or protect intellectual property rights related to our product candidates, we may not be able to compete effectively. We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates. If we do not adequately protect our intellectual property, competitors may be able to use our technologies which could do harm to our business and affect our ability to be profitable. In particular, our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates. Additionally, we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. The patent applications that we own or in- license may fail to result in issued patents with claims that cover our product candidates in the United States or in other countries. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Any disclosure or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, eroding our competitive position in our market. The patent position of biotechnology companies is generally uncertain because it involves complex legal and factual considerations in a legal framework that is constantly evolving. The standards applied by the United States Patent and Trademark Office (USPTO) **,** and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology patents. There is a substantial amount of prior art in the biotechnology and pharmaceutical fields, including scientific publications, patents and patent applications. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found. We may be unaware of prior art that could be used to invalidate an issued patent or prevent our pending patent applications from issuing as patents. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. If patent applications we hold or have in- licensed with respect to our product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patents or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidate that we may develop. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to a product candidate. For applications filed before March 16, 2013, or patents issuing from such applications, an interference proceeding can be provoked by a third party, or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the claims of our applications and patents. As of March 16, 2013, the United States transitioned to a " first- to- file " system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. The change to " first- to- file " from " first- to- invent " is one of the changes to the patent laws of the United States resulting from the Leahy- Smith America Invents Act **(** ~~, or~~ the Leahy- Smith Act ~~,~~ **)** signed into law on September 16, 2011. Among some of the other significant changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the USPTO. It is not yet clear, what, if any, impact the Leahy- Smith Act will have on the operation of our business. However, the Leahy- Smith 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. Patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant and, in addition, may be challenged before national courts at any time. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. Furthermore, due to the patent laws of a country, or the decisions of a patent examiner in a country, or our own filing strategies, we may not obtain patent coverage for all our product candidates or methods involving these product candidates in the parent patent application. In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally

20 years after it is filed. Various extensions may be available; however, the life of a patent and the protection it affords is limited. If we encounter delays in obtaining regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic and biosimilar products. Obtaining and enforcing patents is expensive and time- consuming, and we may not be able to file and prosecute all necessary or desirable patent applications or maintain and / or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner ~~, including delays as a result of the COVID- 19 pandemic impacting our or our licensors' operations~~ . Any loss of patent protection could have a material adverse impact on our business. We may be unable to prevent competitors from entering the market with a product that is similar to or the same as our products. We depend on our licensors to prosecute and maintain patents and patent applications that are material to our business. Any failure by our licensors to effectively protect these intellectual property rights could adversely impact our business and operations. * Specific to the development of YH001 in North America, we hold an exclusive (including with respect to Eucure and its affiliates), nontransferable, license to develop and commercialize YH001 in North America for the treatment, through administration of YH001 by intravenous or subcutaneous means, of multiple human indications, including the Initial Indications or one or more of the Substitute Indications, which may be substituted for Initial Indications at our discretion. As it relates to the development of envafolimab for the treatment of sarcoma in North America, we hold an exclusive license from 3D Medicines and Alphamab to any and all intellectual property rights, including patents, copyrights, trademarks and know- how, claiming or covering envafolimab. We also hold a non-exclusive license for the conduct of clinical trials in the EU in support of the development of envafolimab for the treatment of sarcoma in North America ~~. Regarding the development of TJ004309 in North America, we hold a non- exclusive license from I- Mab to any and all intellectual property rights, including patents, copyrights, trademarks and know- how, claiming or covering any pharmaceutical composition or preparation comprising or containing TJ004309~~ . As a licensee of third parties, we rely on these third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under some of our license agreements. We have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. Third party claims of intellectual property infringement or misappropriation may prevent or delay our development and commercialization efforts. Our commercial success depends in part on us and our partners not infringing the patents and proprietary rights of third parties. There is a substantial amount of litigation and other proceedings, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, reexamination and review proceedings before the USPTO and corresponding foreign patent offices. Numerous U. S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we and our partners are developing and may develop our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization. There may be third party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates, that we failed to identify. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until issued as patents. Except for the preceding exceptions, patent applications in the United States and elsewhere are generally published only after a waiting period of approximately 18 months after the earliest filing. Therefore, patent applications covering our product candidates or methods of use of our product candidates could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use or manufacture of our product candidates. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving that a patent is invalid is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Also, in proceedings before courts in Europe, the burden of proving invalidity of the patent usually rests on the party alleging invalidity. Third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. If any third party patents were held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture or methods for treatment, the holders of any such patents would be able to block our ability to develop and commercialize the applicable product candidate until such patent expired or unless we or our partner obtain a license. These licenses may not be available on acceptable terms, if at all. Even if we or our partner were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we or our partner could be prevented from commercializing a product, or be forced to cease some aspect of

our business operations, if, as a result of actual or threatened patent infringement claims, we or our partner are unable to enter into licenses on acceptable terms. Parties making claims against us or our partner may obtain injunctive or other equitable relief, which could effectively block our or our partner' s ability to further develop and commercialize one or more of our product candidates. Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Third parties may submit applications for patent term extensions in the United States and / or supplementary protection certificates in the EU member states seeking to extend certain patent protection which, if approved, may interfere with or delay the launch of one or more of our products. We may face a claim of misappropriation if a third party believes that we inappropriately obtained and used trade secrets of such third party. If we are found to have misappropriated a third party' s trade secrets, we may be prevented from further using such trade secrets, limiting our ability to develop our product candidates, and we may be required to pay damages. During the course of any patent or other intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our product candidates or intellectual property could be diminished. Accordingly, the market price of our common stock may decline. We may become involved in lawsuits to protect or enforce our inventions, patents or other intellectual property or the patent of our licensors, which could be expensive and time consuming. Competitors may infringe our intellectual property, including our patents or the patents of our licensors. In addition, one or more of our third party collaborators may have submitted, or may in the future submit, a patent application to the USPTO without naming a lawful inventor that developed the subject matter in whole or in part while under an obligation to execute an assignment of rights to us. As a result, we may be required to file infringement or inventorship claims to stop third party infringement, unauthorized use, or to correct inventorship. This can be expensive, particularly for a company of our size, and time- consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction against an infringer are not satisfied. An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing. Interference, derivation or other proceedings brought at the USPTO or any foreign patent authority may be necessary to determine the priority or patentability of inventions with respect to our patent applications or those of our licensors or collaborators. Litigation or USPTO proceedings brought by us may fail. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party, or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Even if we are successful, domestic or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or collaborators, to prevent misappropriation of our trade secrets, confidential information or proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed. We have in- licensed a portion of our intellectual property, and, if we fail to comply with our obligations under these arrangements, we could lose such intellectual property rights or owe damages to the licensor of such intellectual property. We are a party to a number of license agreements that are important to our business, and we may enter into additional license agreements in the future. ~~YH001 and associated intellectual property have been licensed from Eucure and Biocytogen, envafolimab~~ **Envafolimab** and associated intellectual property have been licensed from 3D Medicines and Alphamab ~~,~~ and ~~TJ004309~~ **YH001** and associated intellectual property have been licensed from ~~I- Mab~~ **Eucure and Biocytogen** . Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If there is any conflict, dispute, disagreement or issue of non- performance between us and our licensing partners regarding our rights or obligations under the license agreements, including any such conflict, dispute or disagreement arising from our failure to satisfy payment or diligence obligations under any such agreement, we may owe damages, our licensor may have a right to terminate the affected license, and our and our partners' ability to utilize the affected intellectual property in our drug development efforts, and our ability to enter into collaboration or marketing agreements for a product candidate, may be adversely affected **. The failure of our partners to meet their contractual obligations to us could adversely affect our business. Our reliance on our partners poses a number of additional risks, including the risk that they may not perform their contractual obligations to us to our standards, in compliance with applicable legal or contractual requirements, in a timely manner or at all; they may not maintain the confidentiality of our proprietary information; and disagreements or disputes could arise that could cause delays in, or termination of, the research, development or commercialization of product candidates or result in litigation or arbitration. Litigation, arbitration or adversarial proceedings may be prolonged and might**

result in substantial costs and may divert management' s attention and resources, which might seriously harm our business, reputation, overall financial condition and operating results . We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States and in some cases may even force us to grant a compulsory license to competitors or other third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from 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 could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate; and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. In addition, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in domestic and foreign intellectual property laws. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various non- U. S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non- compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and this circumstance would have a material adverse effect on our business. Risks Related to Commercialization of Product Candidates Even if we obtain regulatory approval of product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers, third party payors and others in the medical community. Factors that will influence whether product candidates are accepted in the market include: • the clinical indications for which product candidates are approved, if any; • physicians, hospitals, cancer treatment centers and patients considering product candidates as a safe and effective treatment; • the potential and perceived advantages of product candidates over alternative treatments; • the prevalence and severity of any side effects; • product labeling or product insert requirements of the FDA or other regulatory authorities; • limitations or warnings contained in the labeling approved by the FDA or other regulatory authorities; • the timing of market introduction of product candidates as well as competitive products; • the cost of treatment in relation to alternative treatments; • the availability of coverage and adequate reimbursement by governmental and commercial third party payors; • the willingness of patients to pay out- of- pocket in the absence of coverage by governmental and commercial third party payors; • relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and • the effectiveness of our sales and marketing efforts. If, for any of these or other reasons, product candidates fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers, third party payors or others in the medical community, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete. Off- label use of approved drugs could adversely impact peak sales of our product candidates if approved, including Keytruda' s off- label use in UPS / MFS. While no PD- (L) 1 treatments are currently FDA approved in UPS / MFS or any other sarcoma subtype, Keytruda (pembrolizumab, marketed by Merck & Co.) has a compendia listing in UPS and is reimbursed for off- label use in UPS. The off- label use of Keytruda in UPS / MFS may adversely affect the peak net sales of envafolimab in UPS / MFS and other sarcoma subtypes, if envafolimab is approved by the FDA and commercialized in the United States. Similarly, while no CTLA- 4 therapy is approved by the FDA for the treatment of soft tissue sarcoma, if YH001 is approved, it may nevertheless compete with the currently marketed CTLA- 4 inhibitor ipilimumab (Yervoy, marketed by Bristol Myers Squibb), which is approved by the FDA in multiple indications other than soft tissue sarcoma. We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize product candidates. We face competition both in the United States and internationally, including from major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Competition may increase further as a

result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop, or achieve earlier patent protection, regulatory approval, product commercialization and market penetration than we do. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing product candidates against competitors. Under the terms of our license agreement with Case Western, we obtained an exclusive, worldwide license to certain patents, know- how and other intellectual property controlled by Case Western related to TRC102. Despite our exclusive license, Case Western retained the right to grant non- exclusive licenses to third parties in the same field of use as our exclusive license as a means to settle any intellectual property disputes Case Western may have in the future with such third parties. While Case Western has not made us aware of any present intent to exercise this right, there can be no guarantee that Case Western will not do so in the future or that it would not grant such a non- exclusive license to a competitor of ours seeking to develop and commercialize a product that is identical to TRC102 in the same field of use that we are pursuing. If this were to occur, and we did not have other intellectual property outside of the Case Western license agreement to prevent competitive products for the same indications, we may face competition much earlier than we currently anticipate and the value of TRC102 may decline substantially. Even if we are successful in achieving regulatory approval to commercialize a product candidate faster than our competitors, we may face competition from " biosimilars " due to the changing regulatory environment. In the United States, the Biologics Price Competition and Innovation Act created an abbreviated approval pathway for biological products that are demonstrated to be " highly similar, " or " biosimilar, " to or " interchangeable " with an FDA- approved biological product. This pathway could allow competitors to reference data from biological products already approved after 12 years from the time of approval. Future FDA standards or criteria for determining biosimilarity and interchangeability, and FDA discretion to determine the nature and extent of product characterization, non- clinical testing and clinical testing on a product- by- product basis, may further facilitate the approval of biosimilar products and their ability to compete with our product candidates or those of our partners. In addition, companies may be developing biosimilars in other countries that could compete with our products. If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. Any such event or further changes in the law could decrease the period for which we have exclusivity and consequently negatively impact our business and competitive position. Expiration or successful challenge of our applicable patent rights could also trigger competition from other products, assuming any relevant exclusivity period has expired. Finally, as a result of the expiration or successful challenge of our patent rights, we could face litigation with respect to the validity and / or scope of patents relating to our competitors' products. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize. Coverage and reimbursement may be limited or unavailable in certain market segments for product candidates, which could make it difficult for us to sell product candidates profitably. Successful sales of our product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third party payors. In addition, because our product candidates and those of our partners represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from these 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. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance. Government authorities and other third party payors, such as commercial 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, but not limited to, the third party payor' s determination that use of a product is: • a covered benefit under its health plan; • 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. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. 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 supporting scientific, clinical and cost- effectiveness data to each payor separately for the use of our products, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement rates might not be adequate for us to achieve or sustain profitability or may require co- payments that patients find unacceptably high. Patients are unlikely to use product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of product candidates. Further, coverage policies and third- party payor reimbursement rates may change at any time. Therefore, 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. We intend to seek approval to market product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for product candidates, we 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 product candidates will depend significantly on the availability of coverage and adequate reimbursement from third party payors for product candidates. Healthcare legislative reform measures may have a material adverse effect on our business and results of operations. Third party payors, whether domestic or foreign, or governmental or commercial, and governments are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the Patient Protection and Affordable

Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the ACA, was enacted in the United States. Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017 (Tax Act) includes a provision which repealed, effective January 1, 2019, the tax- based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the " individual mandate. " Additionally, on June 17, 2021 the U. S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the " individual mandate " was repealed by Congress. Further, prior to the U. S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (the IRA) **,** 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 through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the ACA and our business. 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 payments to providers up to 2 % per fiscal year, which went into effect in April 2013 and, due to subsequent legislative changes to the statute will remain in effect until ~~2031~~ **2032** unless additional Congressional action is taken ~~. However, COVID- 19 pandemic relief legislation suspended the 2 % Medicare sequester from May 1, 2020 through March 31, 2022. Under current legislation, the actual reduction in Medicare payments will vary from 1 % in 2022 to up to 4 % in the final fiscal year of this sequester~~ . In January 2013, former U. S. President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. There has been heightened governmental scrutiny over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In July 2021, the Biden administration released an executive order, " Promoting Competition in the American Economy, " with multiple provisions aimed at prescription drugs. In response to Biden' s executive order, on September 9, 2021, the Department of Health and Human Services **(** ~~, or~~ HHS ~~,~~ **)** released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single- source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and 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 ~~will~~ take effect progressively starting in fiscal year 2023, although ~~they~~ **the** ~~may be~~ **Medicare drug price negotiation program is currently** subject to legal challenges. It is currently unclear how the IRA will be implemented but **it** is likely to have a significant impact on the pharmaceutical industry **. In addition, 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 Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, 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. 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** . At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing **. For example, on January 5, 2024, the FDA approved Florida' s Section 804 Importation Program (SIP) proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs** . Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may

adversely affect our future profitability. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and / or impose price controls may adversely affect: • the demand for product candidates, if we obtain regulatory approval; • our ability to set a price that we believe is fair for our products; • our ability to obtain market acceptance in the medical community; • our ability to generate revenue and achieve or maintain profitability; • the level of taxes that we are required to pay; and • the availability of capital. We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business in the future, or the effect any future legislation or regulation will have on us. If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business. If any product candidates are approved for commercialization, we expect that we or our partners will be subject to additional risks related to entering into international business relationships, including: • different regulatory requirements for drug approvals in foreign countries; • different payor reimbursement regimes, governmental payors or patient self- pay systems and price controls; • reduced protection for intellectual property rights; • unexpected changes in tariffs, trade barriers and regulatory requirements, including the significant sanctions and export controls imposed against Russia, Russian banks and certain Russian individuals by the United States, United Kingdom and EU, along with others; • 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 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; • workforce uncertainty in countries where labor unrest is more common than in the United States; • production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and • business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires. If we or our partners outside of the United States are unable to successfully manage these risks associated with international operations, the market potential for our product candidates or those of our partners outside the United States will be limited and our results of operations may be harmed. Risks Related to Our Business and Industry If we fail to develop, acquire or in- license other product candidates or products, our business and prospects will be limited. We do not have internal new drug discovery capabilities or a technology platform with which to develop novel product candidates. Unless we develop or acquire these capabilities or a technology platform, our only means of expanding our product pipeline will be to acquire or in- license product candidates that complement or augment our current targets, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. In addition, part of our corporate strategy is to leverage our existing internal clinical development and regulatory capabilities by entering into collaborations where we conduct development activities related to third party product candidates in exchange for commercialization and payment rights, such as our collaborations with Eucure and Biocytogen with respect to YH001 ~~,~~ **and** 3D Medicines and Alphamab with respect to envafolimab ~~, and I- Mab with respect to TJ004309 and potential BsAb candidates~~ . Identifying, selecting and acquiring or licensing promising product candidates requires substantial technical, financial and human resources. Efforts to do so may not result in the actual development, acquisition or license of a particular product candidate, potentially resulting in a diversion of our management' s time and the expenditure of our resources with no resulting benefit ~~. With respect to TJ004309, if I- Mab licenses rights to TJ004309 to a third party, while we would be entitled to receive varying portions of royalty and non- royalty payments from I- Mab, we would have no further rights to develop, commercialize or realize value from TJ004309~~ . With respect to envafolimab, 3D Medicines and Alphamab retain certain rights to reacquire the rights for sarcoma in North America in connection with an arm' s length sale to a third party of the rights to develop and commercialize envafolimab in North America for all indications. While we and 3D Medicines and Alphamab must negotiate in good faith and agree to fair compensation be paid to us for the value of and opportunity represented by the reacquired rights, we cannot guarantee that any compensation paid to us would adequately cover our investments in the program, the present value of the rights to us or our opportunity costs as a result of having advanced the program prior to reacquisition. Also, in the event that envafolimab is first approved in North America for sarcoma and within three years of the commercial launch of envafolimab in North America for sarcoma 3D Medicines and Alphamab replace us as the party responsible for commercialization, and we do not co- market envafolimab for sarcoma in North America, then 3D Medicine and Alphamab will be required to compensate us for our costs associated with preparing for and conducting commercial activities. However, we may not be able to agree with 3D Medicines and Alphamab on adequate compensation and cannot guarantee that any agreed- upon compensation would adequately cover our investments in commercializing envafolimab in North America or our lost opportunity costs in pursuing commercialization. If we are unable to retain existing product candidates and add additional product candidates to our pipeline, we may not be able to execute on an important part of our business strategy and our long- term business and prospects will be limited. **If we are unable to successfully out- license our CRO- independent PDP, our business could materially suffer. We have developed and out-licensed our CRO- independent PDP for the design, conduct and administration of clinical trials and related research and development activities, including activities relating to regulatory filings, submissions and approvals. Currently, we have only granted a non- exclusive and non- transferable license of our CRO- independent PDP to one licensee. However, we may not be able to identify additional suitable partners. If we are unable to identify suitable partners for our CRO-independent PDP or if we are required to enter into agreements with such partners on unfavorable terms, our business and prospects could materially suffer.** We and our partners are subject to extensive federal, state, and foreign regulation, and our failure to comply with healthcare laws could harm our business. Although we do not currently have any products on the market, we and our partners are subject to healthcare regulation and enforcement by the federal government and the states and foreign jurisdictions in which we conduct our business. The healthcare laws that may affect our ability to operate include: • the **U. S.** ~~federal~~ **Federal** ~~anti~~ **Anti** ~~-~~ ~~kickback~~ **Kickback** ~~statute~~ **Statute** , which applies to our business activities, including our

research, marketing practices, educational programs, pricing policies and relationships with healthcare providers, by prohibiting, among other things, knowingly and willfully soliciting, receiving, offering or providing any remuneration (including any bribe, kickback or rebate) directly or indirectly, overtly or covertly, in cash or in kind, intended to induce or in return for the purchase or recommendation of any good, facility item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare or Medicaid programs; • federal civil and criminal false claims laws, including the federal False Claims Act, and federal civil monetary penalty law that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other governmental healthcare programs that are false or fraudulent, or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; • the federal Health Insurance Portability and Accountability Act of 1996 **(** ~~, or~~ HIPAA **)** , which created federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, imposes certain regulatory and contractual requirements on covered entities, and their business associates **and subcontractors** that create, receive, maintain or transmit individually identifiable health information for or on their behalf, as well as their covered subcontractors, regarding the privacy, security and transmission of individually identifiable health information; • federal " sunshine " requirements imposed by the ACA on certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program (with certain exceptions) to report annually to ~~CMS~~ **the Centers for Medicare & Medicaid Services** information regarding any payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as nurse practitioners and physicians assistants), and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members; and • state or foreign law equivalents of each of the above federal laws that may apply to items or services reimbursed by any third party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require the reporting of information relating to drug and biologic pricing; state and local laws that require the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. It is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened certain of these laws. For example, the ACA, among other things, amended the intent requirement of the federal anti- kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them to have committed a violation. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti- kickback statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. We are also subject to laws and regulations governing data privacy and the protection of health- related and other personal information. These laws and regulations govern our processing of personal data, including the collection, access, use, analysis, modification, storage, transfer, security breach notification, destruction and disposal of personal data. There are foreign and state law versions of these laws and regulations to which we are currently and / or may in the future, be subject. For example, the collection and use of personal health data in the EU is governed by the General Data Protection Regulation **(** ~~, or~~ the EU GDPR **)** . The EU GDPR, which is wide- ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third party processors in connection with the processing of personal data. The EU GDPR also imposes strict rules on the transfer of personal data out of the EU to the United States, provides an enforcement authority and imposes large monetary penalties for noncompliance. The EU GDPR requirements apply not only to third party transactions, but also to transfers of information within our company, including employee information. The EU GDPR and similar data privacy laws of other jurisdictions place significant responsibilities on us and create potential liability in relation to personal data that we or our third party vendors process, including in clinical trials conducted in the United States and EU. In addition, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EU and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, significant administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, imprisonment, exclusion from governmental health care programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability. The use of product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates or those of our partners. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may

result in: • impairment of our business reputation; • withdrawal of clinical trial participants; • costs due to related litigation; • distraction of management' s attention from our primary business; • substantial monetary awards to patients or other claimants; • the inability to commercialize product candidates; and • decreased demand for product candidates, if approved for commercial sale. We currently carry product liability insurance covering our clinical trials with limits we believe are customary for other companies in our field and stage of development. Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business. Our ability to use our net operating loss **(NOL)** carryforwards and certain other tax attributes may be limited. As of December 31, ~~2022~~ **2023**, we had federal and California NOL carryforwards of $ ~~194~~ **190**. ~~3~~ **2** million and $ ~~144~~ **146**. ~~5~~ **9** million, respectively. ~~The~~ **Certain of the** federal and California NOL carryforwards will begin to expire in 2030 and 2033, respectively, if not utilized. The federal NOL generated after 2017 of $ ~~111~~ **106**. ~~1~~ **9** million will carryforward indefinitely, but the deductibility of such federal NOLs is limited to 80 % of taxable income. As of December 31, ~~2022~~ **2023**, we also had federal research and development and Orphan Drug tax credit carryforwards of $ ~~13~~ **15**. ~~7~~ **1** million and California research and development tax credit carryforwards of $ 3. ~~0~~ **3** million. The federal research and development and Orphan Drug tax credit carryforwards will begin expiring in 2031 and 2036, respectively, if not utilized. The California research credit will carry forward indefinitely under current law. Under Sections 382 and 383 of Internal Revenue Code of 1986, as amended (Code), if a corporation undergoes an " ownership change, " the corporation' s ability to use its pre- change NOLs and other pre-change tax attributes, such as research tax credits, to offset its post- change income and taxes may be limited. In general, an " ownership change " occurs if there is a cumulative change in our ownership by " 5 % shareholders " that exceeds 50 percentage points over a rolling three- year period. Similar rules may apply under state tax laws. We believe we have experienced certain ownership changes in the past and have reduced our deferred tax assets related to NOLs and research and development tax credit carryforwards accordingly. In the event we experience one or more ownership changes as a result of future transactions in our stock, then we may be further limited in our ability to use our NOLs and other tax assets to reduce taxes owed on the net taxable income that we earn in the event that we attain profitability. Any such limitations on the ability to use our NOLs and other tax assets could adversely impact our business, financial condition and operating results in the event that we attain profitability. In addition, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. New or future changes to tax laws could materially adversely affect us. New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Act enacted many significant changes to the U. S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) **,** modified certain provisions of the Tax Act and the recently enacted IRA, includes provisions that will impact the U. S. federal income taxation of corporations, including imposing a minimum tax on the book income of certain large corporations and an excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act, the IRA or any newly enacted federal tax legislation. The impact of such legislation and any future changes in tax laws on holders of our common stock is also uncertain and could be adverse. If we fail to attract and keep senior management and key clinical operations and regulatory personnel, we may be unable to successfully develop product candidates and execute our business strategy. We are highly dependent on members of our senior management, including Charles Theuer, M. D., Ph. D., our President and Chief Executive Officer. Our clinical development strategy and ability to directly manage or oversee our on- going and planned clinical trials are also dependent on the members of our clinical operations and regulatory team. The loss of the services of any of these persons could impede the development of product candidates and our ability to execute our business strategy. We may be particularly impacted by the unexpected loss of employees due to our small employee base and limited ability to quickly shift responsibilities to other employees in our organization. We do not maintain " key person " insurance for any of our executives or other employees. Recruiting and retaining other qualified employees for our business, including scientific, quality assurance and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue, making recruitment and retention competitive. ~~This competition~~ **Competition** ~~has become exacerbated by the increase in employee resignations currently taking place throughout the United States as a result of the COVID- 19 pandemic, which is commonly referred to as the " great resignation. " We may also experience employee turnover as a result of the ongoing " great resignation. " As a result, competition~~ for skilled personnel is intense, particularly in the San Diego, California area, and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. The inability to recruit or loss of the services of any executive or key employee could impede the progress of our development and strategic objectives. In response to competition, rising inflation rates and labor shortages, we may need to adjust employee cash compensation, which would affect our operating costs and our margins, or equity compensation, which would affect our outstanding share count and cause dilution to existing ~~shareholders~~ **stockholders**. Unfavorable U. S. and global economic conditions could adversely affect our business, financial

condition or results of operations. Our results of operations could be adversely affected by general conditions in the U. S. and global economies, the U. S. and global financial markets and adverse macroeconomic and geopolitical developments. U. S. and global market and economic conditions have been, and continue to be, disrupted and volatile due to many factors, including the ~~ongoing~~ **recent** COVID- 19 pandemic, material shortages and related supply chain challenges, **recent and potential future bank failures,** geopolitical developments such as the conflict between Ukraine and Russia **or the recent state of war between Israel and Hamas and the related risk of a larger regional conflict** , and higher inflation rates and the responses by central banking authorities to control such inflation, among others. General business and economic conditions that could affect business, financial condition or results of operations include fluctuations in economic growth, debt and equity capital markets, liquidity of the global financial markets, the availability and cost of credit, investor and consumer confidence, and the strength of the economies in which we, our collaborators, our manufacturers and our suppliers operate. A severe or prolonged global economic downturn could result in a variety of risks to our business. For example, inflation rates, particularly in the United States, have increased recently to levels not seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital on acceptable terms, if at all. In addition, the U. S. Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks. Risks of a prolonged global economic downturn are particularly true in Europe, which is undergoing a continued severe economic crisis. A weak or declining economy could also strain our suppliers and manufacturers, possibly resulting in supply and clinical trial disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. Additionally, financial markets around the world experienced volatility following the invasion of Ukraine by Russia in February 2022. In response to the invasion, the United States, United Kingdom and EU, along with others, imposed significant new sanctions and export controls against Russia, Russian banks and certain Russian individuals and may implement additional sanctions or take further punitive actions in the future. The full economic and social impact of the sanctions imposed on Russia (as well as possible future punitive measures that may be implemented), as well as the counter measures imposed by Russia, in addition to the ongoing military conflict between Ukraine and Russia, which could conceivably expand into the surrounding region, remains uncertain; however, both the conflict and related sanctions have resulted and could continue to result in disruptions to trade, commerce, pricing stability, credit availability and / or supply chain continuity in both Europe and globally, and has introduced significant uncertainty into global markets. In particular, the Russia- Ukraine conflict has contributed to rapidly rising costs of living (driven largely by higher energy prices) in Europe and other advanced economies. Further, ~~a weak or declining~~ **rising tensions between China and Taiwan, the ongoing conflict in Israel and surrounding areas, the attacks on marine vessels traversing the Red Sea and the ongoing military conflict between Russia and Ukraine have created volatility in the global capital markets and may have further global** ~~economy~~ **economic consequences, including disruptions of the global supply chain which** could strain our suppliers, manufacturers and collaborators, possibly resulting in additional supply disruption for our product candidates and delays to our clinical trials. As a result, our business and results of operations may be adversely affected by the ongoing conflict between Ukraine and Russia, particularly to the extent it escalates to involve additional countries, further economic sanctions or wider military conflict. If economic conditions in Europe and other key markets for our business and the business of our suppliers, manufacturers and collaborators remain uncertain or deteriorate further ~~, including as a result of the COVID- 19 pandemic or otherwise~~ , we could experience adverse effects on our business, financial condition or results of operations. Risks Related to Our Common Stock The market price of our common stock may be highly volatile, and our stockholders may not be able to resell their shares at a desired market price and could lose all or part of their investment. Even though our common stock trades on the Nasdaq Capital Market, we cannot assure you that an active, liquid trading market for our shares will develop or persist. Our stockholders may not be able to sell their shares quickly or at a recently reported market price if trading in our common stock is not active. The trading price of our common stock has been, and is likely to continue to be, volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following: • adverse results or delays in clinical trials; • inability to obtain additional funding; • any delay in submitting a BLA or an NDA for any product candidates and any adverse development or perceived adverse development with respect to the FDA' s review of that marketing application; • failure to successfully develop and commercialize product candidates; • changes in laws or regulations applicable to product candidates; • changes in the structure of healthcare payment systems; • inability to obtain adequate product supply for product candidates, or the inability to do so at acceptable prices; • adverse regulatory decisions; • introduction of new products or technologies by our competitors; • failure to meet or exceed product development or financial projections we provide to the public; • failure to meet or exceed the estimates and projections of the investment community; • the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community; • announcements of significant acquisitions, collaborations, joint ventures or capital commitments by us or our competitors; • failure to **enter into new, or** maintain our **existing,** collaboration and clinical trial agreements; • failure of 3D Medicines or Alphamab to perform their obligations under our collaboration and clinical trial agreements, or the actions of 3D Medicines or Alphamab or their other partners with respect to envafolimab in other indications or outside North America; • failure of Eucure and Biocytogen to perform their obligations under our collaborative development and commercialization agreement, or the actions of Eucure or Biocytogen or their other partners with respect to YH001 in other indications or outside North America, or within North America in combination with other Eucure product candidates; • disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; • ~~the results of our dispute with I- Mab; •~~ additions or departures of key scientific or management personnel; • significant lawsuits, including patent or stockholder litigation; • changes in the market valuations of similar companies; • the impact of macroeconomic and geopolitical events, such as general political, health and

economic conditions, including ~~the COVID- 19 pandemic~~ **recent and potential future bank failures** , economic slowdowns, recessions, inflation, rising interest rates and tightening of credit markets on our business; • sales of our common stock by us or our stockholders in the future, in particular any sales by significant stockholders or our affiliates; and • trading volume of our common stock. In addition, the stock market in general, and the Nasdaq Capital Market in particular, have experienced extreme price and volume fluctuations, and we have in the past experienced volatility that has been unrelated or disproportionate to our operating performance. From January 1, ~~2022~~ **2023** through ~~March 3~~ **February 29** , ~~2023~~ **2024** , the closing price of our common stock has ranged between $ ~~1~~ **0** . ~~22~~ **1322** and $ ~~3~~ **2** . ~~00~~ **06** per share. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. If we fail to continue to meet all applicable listing requirements, our common stock may be delisted from the Nasdaq Capital Market, which could have an adverse impact on the liquidity and market price of our common stock. Our common stock is currently listed on the Nasdaq Capital Market, which has qualitative and quantitative listing criteria. If we are unable to meet all of the Nasdaq **Stock Market LLC (Nasdaq)** continued listing requirements and at least one of the Nasdaq continued listing standards in the future, including if the closing bid price for our common stock falls below $ 1. 00 per share for 30 consecutive trading days **(the Minimum Bid Price Requirement)** , or if we are unable to maintain at least $ 2. 5 million in stockholders' equity or a market capitalization of at least $ 35 **. 0** million, Nasdaq could determine to delist our common stock. For example, on ~~December 30~~ **June 8** , ~~2022~~ **2023** , we received ~~a letter~~ **letters (the Notices)** from the **Listing Qualifications staff (the Staff) of the** Nasdaq ~~Stock Market LLC (Nasdaq)~~ notifying us that **(i)** for 30 consecutive business days **preceding** ~~prior to~~ the date of ~~such letter~~ **the Notices** , the market value of our common stock was less than $ 35. 0 million, which ~~did~~ **does** not meet the requirement for continued listing on the Nasdaq Capital Market, as required by Nasdaq Listing Rule 5550 (b) (2) (the ~~"~~ Market Value Rule ~~"~~) **, and (ii) we failed to satisfy the Minimum Bid Price Requirement. In accordance with Nasdaq Listing Rule 5810 (c) (3) (C) and Nasdaq Listing Rule 5810 (c) (3) (A), Nasdaq had provided us with 180 calendar days, or until December 5, 2023, to regain compliance with the Market Value Rule and the Minimum Bid Price Requirement** . On ~~January 20~~ **December 6** , 2023, **we received written notice (the Delisting Notice) from** Nasdaq ~~notified~~ **notifying** us that we had **not** regained compliance with the Market Value Rule ~~because~~ **(and we did not satisfy any of the** ~~the~~ **other** ~~market value of~~ **applicable financial and liquidity standards) or the Minimum Bid Price Requirement. Consequently, Nasdaq had determined that** our common stock **would be scheduled** ~~was $ 35. 0 million or~~ **for** ~~greater for~~ **delisting and suspended at** the ~~ten consecutive~~ **opening of** business ~~days~~ **on December 15, 2023 unless we requested an appeal of this determination on or before December 13, 2023. On December 12, 2023, we submitted a request for an oral appeal hearing before a Hearings Panel (the Panel). The hearing is scheduled to occur on March 7, 2024. Accordingly, the delisting and suspension of trading of our common stock will be stayed pending the issuance of the Panel' s final written decision. There can be no assurance that a favorable decision will be obtained** from **the Panel or that** ~~January 5, 2023 to January 19, 2023. Although~~ we ~~have~~ **will be successful in maintaining the listing of our common stock on the Nasdaq Capital Market. If we** ~~regained~~ -- **regain** compliance with **the Market Value Rule and the Minimum Bid Price Requirement,** Nasdaq **will provide us with written confirmation and close the matter. If we fail to satisfy the Nasdaq requirements for** continued listing ~~requirements~~ . ~~if we fail to satisfy another Nasdaq requirement for continued listing, Nasdaq staff could provide notice that~~ our common stock may become subject to delisting. If that were to happen, we may not be able to regain compliance. If we cannot regain compliance after any such notice and if our common stock is delisted by Nasdaq, it could lead to a number of negative implications, including an adverse effect on the price of our common stock, increased volatility in our common stock, reduced liquidity in our common stock, the loss of federal preemption of state securities laws and greater difficulty in obtaining financing. In addition, delisting of our common stock could deter broker- dealers from making a market in or otherwise seeking or generating interest in our common stock, could result in a loss of current or future coverage by certain sell- side analysts and might deter certain institutions and persons from investing in our securities at all. Delisting could also cause a loss of confidence of our collaborators, vendors, suppliers and employees, which could harm our business and future prospects. **There can be no assurance that our appeal of the delisting determination will be successful or that we will be successful in maintaining the listing of its common stock on the Nasdaq Capital Market.** Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall. We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity 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 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. We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock. We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future ~~. Additionally, the RGC Loan Agreement contains covenants that restrict our ability to pay dividends or make other distributions. Any return to stockholders will therefore be limited to the appreciation of their stock~~ . Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management. Some provisions of our charter documents and Delaware law may have anti- takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include: • authorizing the issuance of " blank check " preferred stock, the terms of which may be established and shares of

which may be issued without stockholder approval; • limiting the removal of directors by the stockholders; • creating a staggered board of directors; • prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; • eliminating the ability of stockholders to call a special meeting of stockholders; and • establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings. 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 **(Board)** , which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our ~~board~~ **Board** ~~of directors~~ . This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us. Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information. In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know- how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our development processes that involve proprietary know- how or information that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary processes, in part, by entering into confidentiality agreements with our employees, consultants, and outside scientific advisors, contractors and collaborators. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, or outside scientific advisors might intentionally or inadvertently disclose our trade secret information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. General Risk Factors We are subject to stringent and evolving U. S. and foreign laws, regulations ~~,~~ **and** rules, contractual obligations **, industry standards** , 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; fines and penalties; disruptions of our business operations, reputational harm; loss of revenue or profits; and other adverse business consequences. In the ordinary course of business, we 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, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, sensitive third- party data, business plans, transactions, and financial information (collectively, sensitive data). 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, contractual requirements, and other obligations relating to data privacy and security. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act), and other similar laws (e. g., wiretapping laws). **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 data. As applicable, such rights may include the right to access, correct, or delete certain personal data, 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. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws 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~~ **data** 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** ~~civil penalties~~ for noncompliance (up to $ 7, 500 per **intentional** violation) and allows private litigants affected by certain data breaches to recover significant statutory damages. ~~In addition~~ **Although the CCPA exempts some data processed in the context of clinical trials** , ~~it~~ **the CCPA increases compliance costs and potential liability with respect to** ~~the~~ **other personal data we maintain about** California **residents** ~~Privacy Rights Act of 2020 (CPRA), expands the CCPA' s requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the law~~ . ~~Other states, such as Virginia and Colorado, have also passed comprehensive privacy laws, and similar~~ **Similar** laws are being considered in several other states, as well as at the federal and local levels **and we expect more states to pass similar laws in the future** . **While** ~~These~~ **these states, like the CCPA, also exempt some data processed in the context of clinical trials, these** developments ~~may~~ further complicate compliance efforts, and increase legal risk and compliance costs for us ~~and~~ **,** the third parties upon ~~which~~ **whom** we rely. Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union' s General Data Protection Regulation (EU GDPR) and the United Kingdom' s GDPR (UK GDPR) impose strict requirements for processing personal data **.** For example, under the ~~EU~~ GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million **under the EU GDPR, 17. 5 million pounds sterling under the UK GDPR or, in each case,** Euros or 4 % of annual global revenue, 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 European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes 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 EEA **'** ~~and UK'~~ 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 to relevant U. S.- based organizations who self- certify compliance and participate in the Framework)** , these mechanisms are 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 of Europe for allegedly violating the GDPR' s cross- border data transfer limitations. Obligations related to data privacy and security are quickly changing becoming increasingly stringent, and creating regulatory uncertainty Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and 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. 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 upon whom we rely may fail to comply with such obligations. If we or the third parties upon which we rely 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); additional reporting requirements and / or oversight; bans on processing personal data; and orders to destroy or not use personal data. **In particular, plaintiffs have become increasingly 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 clinical trials); 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 our operations. If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to interruptions to our operations such as our clinical trials; regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences. ~~.~~ In the ordinary course of our business, we and the third parties upon which we rely, process sensitive data, and, as a result, we and the third parties upon which we rely face a variety of evolving threats, including, but not limited to ransomware attacks, which could cause security incidents. Cyber- attacks, malicious internet- based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties upon which we rely. 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 conflicts, we and the third parties upon which we rely 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 services. We and the third parties upon which we rely 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 (such as 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, telecommunications failures, earthquakes, fires, floods, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent 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. 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. Additionally, 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. Third party sites that take part in clinical trials we sponsor or third parties that are also sponsoring clinical trials involving our product candidates or those of our partners, such as NCI and Case Western, face similar threats and any security breach of their systems could adversely affect us. Security breaches could be particularly harmful to our business due to our reliance on internal clinical development functions and systems to conduct our clinical trials. For example, for clinical trials that we conduct, we rely on third party hosted software to manage the resulting clinical data. While the third party vendor is obligated to back up our clinical data on its servers, we do not independently back up our clinical data, and a loss of our clinical data by the third party vendor could result in delays in our development programs, cause us to breach our obligations to our third party collaborators, and significantly increase our costs to recover or reproduce the data. ~~Any of~~ **Our ability to monitor** ~~the~~ **these** ~~previously identified~~ **third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If** ~~or~~ **our** ~~similar threats could cause~~ **third- party sites or other service providers experience** a security incident or other interruption ~~that~~ **, we** could ~~result in unauthorized, unlawful,~~ **experience adverse consequences. While we may be entitled to damages if** ~~or~~ **our** ~~accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the~~ third ~~parties upon which we rely. A~~ **- party sites or service providers fail to satisfy their privacy or** security **- related** ~~incident or other interruption could disrupt our ability (and that of third parties upon which we rely) to provide our clinical development activities. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Additionally, certain data privacy and security~~ obligations **to** ~~may require~~ us **, any award may be insufficient** to **cover** ~~implement and maintain specific security measures or~~ **our damages,** ~~industry- standard or reasonable security measures to protect our~~ **or** ~~information technology systems and sensitive data~~ **we may be unable to recover such award** . While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps to detect **, mitigate,** and remediate vulnerabilities **in our information systems (such as our hardware and / or software, including that of third parties upon which we rely)** , but we may not be able to detect and remediate all vulnerabilities **in a timely manner** 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~~ **Unremediated** vulnerabilities pose material 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 data or our information technology systems, or those of the third parties upon which we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon which we rely) to provide our clinical development activities. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Additionally, 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 data.** Applicable data privacy and security obligations may require us to notify relevant stakeholders **, including affected individuals, customers, regulators, and investors,** of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon which we rely) 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 data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; **diversion of management 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 services, deter new customers from using our services, and negatively impact our ability to grow and operate our business. 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 to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls 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. Other business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses. Our operations, and those of our contractors, consultants and collaborators, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man- made disasters or business interruptions, for which we are predominantly self- insured. To the extent our collaborators are unable to comply with their obligations under our agreements with them or they are otherwise unable to complete or are delayed in completing development activities due to business disruptions, our ability to advance development in the United States may become impaired. In addition, NCI may be affected by government shutdowns in the United States or withdrawn funding, which may lead to suspension or termination of ongoing NCI- sponsored clinical development of our product candidates. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. In addition, our ability and the ability of our partners to obtain clinical supplies of product candidates could be disrupted if the operations of our third party manufacturers are affected by a man- made or natural disaster or other business interruption. Our corporate headquarters are located in San Diego, California near major earthquake faults and fire zones. The ultimate impact on us and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster **. We are regularly subject to general litigation and other claims, which could have an adverse effect on our business and results of operations. We are regularly subject to general litigation and other claims that arise in the ordinary course of our business. The outcome and impact of such litigation cannot be predicted with certainty, but regardless of the outcome, these proceedings can have an adverse impact on us because of legal costs, diversion of management resources and other factors. While the results of these claims have not historically had a material effect on us, we may not be able to defend ourselves adequately against these claims in the future, and these proceedings may have a material adverse impact on our financial condition or results of operations. We may also be subject to intellectual property claims, which are extremely costly to defend, could require us to pay significant damages, and could limit our ability to use certain technologies in the future. Companies in the biopharmaceutical industry are frequently subject to litigation based on allegations of infringement or other violations of intellectual property rights. Third- party intellectual property rights may cover significant aspects of our technologies or business methods or block us from expanding our offerings. Any intellectual property claim against us, with or without merit, could be time consuming and expensive to settle or litigate and could divert the attention of our management. Litigation regarding intellectual property rights is inherently uncertain due to the complex issues involved, and we may not be successful in defending ourselves in such matters. Many potential litigants, including some patent- holding companies, have the ability to dedicate substantial resources to enforcing their intellectual property rights. Any claims successfully brought against us could subject us to significant liability for damages, and we may be required to stop using technology or other intellectual property alleged to be in violation of a third party' s rights. We also might be required to seek a license for third- party intellectual property. Such a license may be unavailable or may require us to pay significant royalties or submit to unreasonable terms, which would increase our operating expenses. We may also be required to develop alternative non- infringing technology, which could require significant time and expense. If we cannot license or develop technology for any allegedly infringing aspect of our business, we would be forced to limit our service and may be unable to compete effectively. Any of these results could harm our business** . We are at risk of securities class action litigation. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management' s attention and resources, which could harm our business. Our employees, independent contractors, principal investigators, consultants, vendors and commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading. We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors and commercial partners may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct or unauthorized activities that violate: • FDA regulations, including those laws that require the reporting of true, complete and accurate information to the FDA; • manufacturing standards; • federal and state fraud and abuse laws and other healthcare laws; • laws governing the conduct of business abroad; or • laws that require the reporting of true and accurate financial information or data. Additionally, these parties may fail to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third 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 protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. 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 civil, criminal and administrative penalties, damages, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other U. S. federal healthcare programs, contractual damages, integrity oversight and reporting obligations, reputational

harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. We may encounter difficulties in managing our growth and expanding our operations successfully. As we seek to advance product candidates through clinical trials and commercialization, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with additional third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with partners, consultants, suppliers and other third parties. Future growth will impose significant added responsibilities on members of our management, including having to divert a disproportionate amount of its attention away from day- to- day operating activities to implement and manage future growth. Our future financial performance and our ability to commercialize product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and, if necessary, sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company. If our third party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages. Our development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States and abroad governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' 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, including through obligations to indemnify our third party manufacturers, 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. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our development and production efforts or those of our third party manufacturers, which could harm our business, prospects, financial condition or results of operations. ~~68~~