Risk Factors Comparison 2024-02-28 to 2023-02-28 Form: 10-K

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Our business is subject to a number of risks and uncertainties, including those risks discussed at length below. These risks include, among others, the brief bulleted list of our principal risk factors set forth below that make an investment in our company speculative or risky. You are encouraged to carefully review our full discussion of the material risk factors relevant to an investment in our business, which follows the brief bulleted list of our principal risk factors set forth below: Risks Related to Our Business: ● We **have a history** ~~are substantially dependent on the success~~ of ~~our product candidates~~ **operating losses; we expect to continue to incur losses** and **we may never** ~~cannot guarantee that these product candidates will successfully complete development, receive regulatory approval, or~~ be **profitable** ~~successfully commercialized~~ ; ● We may **need** ~~encounter substantial delays in our clinical trials or may not be able to conduct our clinical trials on the timelines we expect and we may be required to conduct~~ additional ~~clinical trials~~ **financing to fund** ~~or~~ **our operations** ~~modify current or future clinical trials based on feedback we receive from the FDA; ● It may take longer~~ and ~~cost more to~~ complete **the development of** ~~our clinical trials than we project, or~~ **our various product candidates and commercialization of our products, and if** we **are** ~~may not be able~~ **unable to obtain such financing, we may be unable** to complete ~~them~~ **the development** ~~at all; ● Our clinical trials may fail to demonstrate adequately the safety and efficacy~~ of our product candidates ~~, which would prevent or delay regulatory approval~~ and commercialization **of our products. Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates** ; ● The manufacture of our **products and** product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development, quality control, or scaling- up of our manufacturing capabilities. If we, or any of our third- party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients ~~, if approved,~~ could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure; ● Cell- based therapies and biologics rely on the availability of **biological raw materials (including live cells), chemicals and agents used for manufacturing,** reagents, specialized equipment, and other specialty materials, which may not be available to us on acceptable terms or at all. For ~~some~~ **each** of these ~~reagents, equipment, and materials~~ , we rely or may rely on **treatment sites, limited manufacturers,** sole source vendors **,** or a limited number of vendors, which could impair our ability to manufacture and supply our products ~~; ● We collaborate with governmental, academic and corporate partners to improve and develop TIL therapies for new indications for use in combination with other therapies and to evaluate new TIL manufacturing methods, the results of which, because the manufacturing processes are not within our control, may be incorrect or unreliable; ● We may need additional financing to fund our operations and complete the development and commercialization of our various product candidates, and if we are unable to obtain such financing, we may be unable to complete the development and commercialization of our product candidates. Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates; ● We are subject to extensive regulation, which can be costly, time consuming and can subject us to unanticipated delays; even if we obtain regulatory approval for some of our products, those products may still face regulatory difficulties; ● We are required to pay substantial royalties and lump sum benchmark payments under our license agreements with the NIH, Moffitt, Novartis, and Cellectis, and we must meet certain milestones to maintain our license rights~~ ; ● Because our current products represent, and our other potential product candidates will represent novel approaches to the treatment of disease, there are many uncertainties regarding the development, the market acceptance, third- party reimbursement coverage and the commercial potential of our product candidates; ● No assurance can be given that the Gen 2 manufacturing process **or other processes** we have selected will be FDA- compliant ~~,~~ **or** more efficient and **will** lower the cost to manufacture TIL products; ● We face significant competition from other biotechnology and pharmaceutical companies and from non- profit institutions; ● **Our projections regarding the market opportunities for our products and product candidates may not be accurate, and the actual market for our products and product candidates may be smaller than we estimate; ● We may be unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell our products and product candidates, if they are approved, and as a result, we may be unable to generate significant product revenues; ● If our products or product candidates do not achieve broad market acceptance, the revenues that we generate from their sales will be limited; ● Our products and product candidates may face competition sooner than anticipated; ● As a condition of approval, the FDA may require that we implement various post- marketing requirements and conduct post-marketing studies, any of which would require a substantial investment of time, effort, and money, and which may limit our commercial prospects; ● We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth; ● We may rely on third parties to perform many essential services for any products that we commercialize, including services related to distribution, government price reporting, customer service, accounts receivable management, cash collection, and adverse event reporting. If these third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to commercialize our current or future products will be significantly impacted and we may be subject to regulatory sanctions; ● We may be unable to successfully or sufficiently expand our manufacturing capacity to meet demand for our products; ● We depend on the success of our product candidates and cannot guarantee that these product candidates will successfully complete development, receive regulatory approval, or be successfully commercialized; ●** Development of a product candidate intended for use in combination with an already approved product may present more or different challenges than development of

a product candidate for use as a single agent; ● A Fast Track product designation, **BTD,** ~~Breakthrough Therapy designation~~ or other designation to facilitate product candidate development may not lead to faster development or a faster regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval; ● While lifileucel has received ~~Orphan Drug Designation, or~~ ODD ~~,~~ for melanoma stages IIB- IV and for cervical cancer patients with tumors greater than 2 cm, there is no guarantee that we will be able to maintain this designation, receive these designations for any of our other product candidates, or receive or maintain any corresponding benefits, including periods of exclusivity; **33** ● ~~As a condition of approval,~~ **We may encounter substantial delays in our clinical trials or may not be able to conduct our clinical trials on the timelines we expect and we may be required to conduct additional clinical trials or modify current or future clinical trials based on feedback we receive from** the FDA **; ● It** may **take longer and** ~~require that we implement various post~~ **cost** ~~- marketing requirements and conduct post- marketing studies~~ **more to complete our clinical trials than we project** , ~~any~~ **or we may not be able to complete them at all; ● Our clinical trials may fail to demonstrate adequately the safety and efficacy** of **our product candidates,** which would **prevent** ~~require a substantial investment of time, effort, and money, and which may limit our~~ - **or** ~~commercial prospects~~ **delay regulatory approval and commercialization** ; ● We **are required** ~~may be unable~~ to ~~establish effective marketing~~ **pay substantial royalties** and ~~sales capabilities~~ **lump sum benchmark payments under** ~~or~~ **our** ~~enter into~~ **license or acquisition** agreements with ~~third parties to market and sell our product candidates, if they~~ - **the NIH** ~~are approved~~ , **Moffitt** ~~and as a result~~ , **Novartis, Clinigen, and Cellectis, and** we ~~may be unable~~ **must meet certain milestones** to ~~generate product revenues~~ **maintain our license rights** ; ● ~~If~~ **We rely on and collaborate with governmental, academic, and corporate partners** ~~our~~ - **or** ~~product candidates do~~ **agencies to approve, improve, and develop TIL cell therapies for new indications for use in combination with other therapies and to evaluate new TIL manufacturing methods, the results of which, because the manufacturing processes are** not **within our control** ~~achieve broad market acceptance~~ , **and may** ~~the revenues that we generate from their sales will~~ be ~~limited~~ **incorrect or unreliable** ; ● Our business could be adversely affected by the effects of health epidemics, including ~~the recent spread of~~ the COVID- 19 pandemic, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations. The COVID- 19 pandemic could materially affect our operations, including at our headquarters in San Carlos, California and at our manufacturing facility in Philadelphia, Pennsylvania, which ~~are currently~~ **have previously been** subject to state executive orders and shelter- in- place orders, and at our clinical trial sites, as well as the business or operations of our other manufacturers, **contract research organizations, or** CROs **,** or other third parties with whom we conduct business ~~; ● We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth~~ ; ● We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability, ~~an~~ ongoing military ~~conflict~~ **conflicts** between Russia and Ukraine **and Israel and Hamas** and record inflation. Our business, financial condition and results of operations could be materially adversely affected by any negative impact on the global economy and capital markets resulting from the conflict in Ukraine **and the Middle East** , geopolitical tensions or record inflation; ● Climate change or legal, regulatory or market measures to address climate change may negatively affect our business, results of operations, cash flows and prospects; **and** ● Environmental, social and governance matters may impact our business and reputation ~~; and ● We may rely on third parties to perform many essential services for any products that we commercialize, including services related to distribution, government price reporting, customer service, accounts receivable management, cash collection, and adverse event reporting. If these third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to commercialize our current or future product candidates will be significantly impacted and we may be subject to regulatory sanctions~~ . Risks Related to Government Regulation: **● We are subject to extensive regulation, which can be costly, time consuming and can subject us to unanticipated delays; even after obtaining regulatory approval for some of our products and / or product candidates, those products and / or product candidates may still face regulatory difficulties;** ● The FDA regulatory approval process is lengthy and time- consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates; ● Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions; ● Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates profitably; ~~and36~~ -- **and** ● Governments outside the U. S. tend to impose strict price controls, which may adversely affect our revenues, if any. The summary risk factors described above should be read together with the text of the full risk factors below in this section entitled " Risk Factors " and the other information set forth in this Annual Report on Form 10- K, including our consolidated financial statements and the related notes, as well as in other documents that we file with the SEC. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations and future growth prospects. ~~Risks~~ **34Risks** Related to Our ~~BusinessWe~~ **BusinessRisks Related to Our Financial Position and Need for Additional CapitalWe** have a history of operating losses; we expect to continue to incur losses and we may never be profitable. We are a ~~clinical~~ **commercial** - stage ~~biotechnology~~ **biopharmaceutical** company **pioneering a transformational approach to treating** ~~focused on the development and commercialization of novel~~ cancer **by** ~~immunotherapy products designed to harness~~ **harnessing** the **human** ~~power of a patient' s own~~ immune system **' s ability** to ~~eradicate~~ **recognize and destroy diverse** cancer **cells using therapies personalized for each patient** . ~~We do~~ **Until recently, we did** not have products approved for commercial sale and have not generated **significant** revenue from operations. **With the closing of the acquisition of the worldwide rights to Proleukin ® in May 2023, we began to have commercial sales.** As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~1~~ **2** . ~~6~~ **0** billion. In addition, during the year ended December 31, ~~2022~~ **2023** , we incurred a net loss of $ ~~395~~ **444** . ~~9~~ **0** million. **While** ~~Since our inception~~ we ~~have not generated any revenues from operations. We~~ are **beginning**

~~preparing for~~ the commercial launch of our ~~products~~ **product** , ~~if approved~~ **Amtagvi ™** , **we** ~~in 2023. We~~ do not expect to generate any meaningful product sales ~~or royalty revenues~~ until **later in 2024** ~~we have a product approved~~ . We expect to incur significant additional operating losses in the future as we expand our development and clinical trial activities in support of demonstrating the effectiveness of our products. Our ability to achieve long- term profitability is dependent upon obtaining regulatory approvals for our products and successfully commercializing our products alone or with third parties. However, our operations may not be profitable even if any of our products under development are successfully developed and produced and thereafter commercialized. **We may need additional financing to fund our operations and complete the development of our various product candidates and commercialization of our products, and if we are unable to obtain such financing, we may be unable to complete the development of our product candidates and commercialization of our products. Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.** Our ~~For example,we have entered into collaborations with Moffitt,and MDACC to perform clinical trials using TIL products that differ from our products,but the results of these clinical trials,if negative,may adversely impact our stock price and our development plans for our products.Additionally,we may use third party data to analyze,reach conclusions or make predictions or decisions with respect to our product candidates that may be incomplete,inaccurate or otherwise unreliable.We may need additional financing to fund our operations and complete the development and commercialization of our various product candidates,and if we are unable to obtain such financing,we may be unable to complete the development and commercialization of our product candidates.Raising additional capital may cause dilution to our existing stockholders,restrict our operations or require us to relinquish rights to our technologies or product candidates.Our~~ operations have consumed substantial amounts of cash since inception.From our inception to December 31, ~~2022~~ **2023** ,we have an accumulated deficit of $ ~~1~~ **2** . ~~6~~ **0** billion.In addition,our research and development and our operating costs have also been substantial and are expected to increase.For example,in October 2018,we closed an underwritten public offering of our common stock.The net proceeds from the offering,after deducting the underwriting discounts and commissions and other offering expenses payable by us,were $ 236.7 million.In June 2020,we closed another underwritten offering of our common stock.The net proceeds from the offering,after deducting the underwriting discounts and commissions and other offering expenses payable by us,were $ 567.0 million.In **July 2023,we closed another underwritten offering of our common stock.The net proceeds from the offering,after deducting the underwriting discounts and commissions and other offering expenses payable by us,were $ 161.5 million.In** February 2021 **,** we entered into an open market sale agreement,or the ~~First~~ **2021** ~~Sales~~ **Sale** Agreement,with Jefferies LLC **,or Jefferies** ,which provided for the sale of up to $ 350.0 million of our common stock from time to time,which was subsequently increased to $ 500.0 million in ~~50November~~ **November** 2022 upon the execution of an updated open market sale agreement,or the ~~Second~~ **2022** ~~Sales~~ **Sale** Agreement,with Jefferies ~~LLC~~ **.In June 2023,we entered into a new open market sale agreement,or the 2023 Sale Agreement,with Jefferies,which superseded the 2022 Sale Agreement and provided for the sale of up to $ 450.0 million of our common stock from time to time** .As of December 31, ~~2022~~ **2023** ,we had $ ~~478~~ **346** .3 million in cash,cash equivalents ~~and~~ **,** investments **,and restricted cash** ($ ~~231~~ **114** . ~~7~~ **9** million of cash and cash equivalents,$ ~~240~~ **165** . ~~1~~ **0** million in short- term investments,and restricted cash of $ ~~6~~ **66** .4 million).Accordingly **,based on the funds we have available as of the date these consolidated financial statements are issued,which include estimated net proceeds (after deducting underwriting and other offering expenses) of approximately $ 197.1 million from the public offering of our common stock completed on February 22,2024** ,we believe that **we have** ~~our existing cash,cash equivalents and investments will be~~ sufficient **capital** to fund our **anticipated** ~~operations~~ **operating expenses and capital expenditures as planned** for at least the next twelve months ~~from~~ **following** the ~~date~~ **issuance of our consolidated financial statements included in** this Annual Report on Form 10- K ~~is issued~~ .However,in order to complete the development of our ~~current~~ current **product candidates** ~~line of business~~ , and ~~the biotechnology industry~~ in **order** ~~which we operate, makes it difficult~~ to ~~evaluate~~ **effect** our business plan ~~and~~ **, including establishing** our ~~prospects. We~~ **own manufacturing facility, we anticipate that we will** have ~~only a limited operating history in our current line of business on which a decision~~ to **spend more than the funds** ~~invest in our company can be based. The future of our company~~ currently **available** ~~is dependent upon our ability~~ to **us** ~~implement our business plan, as that business plan may be modified from time to time by our management and Board of Directors~~ . **Furthermore** ~~While we believe that we have a reasonable business plan and research and development strategy~~ , **changing circumstances** ~~we have only a limited operating history against which we can test our plans and assumptions, and investors therefore cannot evaluate the likelihood of our success. We face the problems, expenses, difficulties, complications and delays normally associated with a pre- commercial biotechnology company, many~~ **may** ~~of which are beyond our control. Accordingly, our prospects should be considered in light of the risks, expenses and difficulties frequently encountered in the establishment of a new business developing technologies in an industry that is characterized by a number of market entrants and intense competition. Because~~ **cause us** ~~of our size and limited resources, we may not possess the ability~~ to **increase** ~~successfully overcome many of the risks and uncertainties frequently encountered by pre- commercial companies involved in the rapidly evolving field of immunotherapy. If our research and development efforts are successful, we may also face the risks associated with the shift from development to commercialization of new products based on innovative technologies. There can be no assurance that we will be successful in developing our business. We are substantially dependent on the success of our product candidates and cannot guarantee that these product candidates will successfully complete development, receive regulatory approval, or~~ **our** ~~be successfully commercialized. We~~ **spending significantly faster than we** currently **anticipate** ~~have no products approved for commercial sale. We have invested a significant portion of our efforts and financial resources in the development of our current product candidates~~ , ~~including lifileucel, LN- 145, IOV- 4001, IOV- 2001,~~ and ~~IOV- 3001, and expect that~~ we ~~will continue to invest heavily in our current product candidates, as well as in any future product candidates we~~ may ~~develop. Our business depends entirely on the successful development and commercialization of our product candidates, which may never occur. Our ability to generate revenues in the~~

~~future is substantially dependent on our ability to develop, obtain regulatory approval for, and then successfully commercialize our product candidates. We currently generate no revenue from the sale of any products, and we may never be able to develop or commercialize a marketable product. Our product candidates will~~ require additional ~~may require additional~~ capital for the further development **of our product candidates** and commercialization of our ~~product~~ **products** ~~candidates~~ and may need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate.Moreover,our fixed expenses such as rent,minimum payments to our contract manufacturers,and other contractual commitments,including those for our research collaborations,are substantial and are expected to increase in the future. ~~We~~ **35We** will need to obtain additional financing to fund our future operations,including completing the development **of our product candidates** and commercialization of our ~~product~~ **products** ~~candidates~~ .Our future funding requirements will depend on many factors,including,but not limited to:● progress,timing,scope and costs of our ~~clinical trials,~~ clinical ~~and non-~~ **trials, including the ability to timely initiate** clinical ~~development~~ **sites** , **enroll subjects and** ~~regulatory approval, commercial manufacturing~~ **manufacture TIL** ~~arrangements, establishment of a commercial organization, significant marketing efforts, and further investment before 37we generate any revenue from product sales. We cannot assure you that we will meet our timelines for our current or~~ **for treatment for patients in our ongoing, planned and potential** future clinical trials ~~potential future clinical trials~~ ;● time and cost necessary to obtain regulatory approvals that may be required by regulatory authorities to execute clinical trials or commercialize our product;● our ability to successfully commercialize our product candidates,if approved;● our ability to have clinical and commercial product successfully manufactured consistent with FDA and European Medicines Agency,or EMA,regulations;● amount of sales and other revenues from product candidates that we may commercialize,if any,including the selling prices for such potential products and the availability of adequate third- party coverage and reimbursement for patients;● sales and marketing costs associated with commercializing our products,if approved,including the cost and timing of building our marketing and sales capabilities;● cost of building,staffing and validating our own manufacturing facility in the U.S.;● terms and timing of our current and any potential future collaborations,licensing or other arrangements that we have established or may establish;● cash requirements of any future acquisitions or the development of other product candidates;● costs of operating as a public company;● time and cost necessary to respond to technological,regulatory,political and market developments;● costs of filing,prosecuting,defending and enforcing any patent claims and other intellectual property rights;and ● costs associated with any potential business or product acquisitions (such as the ~~anticipated~~ acquisition of Proleukin ®),strategic collaborations,licensing agreements or other arrangements that we may establish.Unless and until we can generate a sufficient amount of revenue,we may finance future cash needs through public or private equity offerings,license agreements,debt financings,collaborations,strategic alliances and marketing or distribution arrangements.Additional funds may not be available when we need them on terms that are acceptable to us,or at all.We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us,we may be required to delay or reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts.Our current license and collaboration agreements may also be terminated if we are unable to meet the payment obligations under those agreements.As a result,we may seek to access the public or private capital markets whenever conditions are favorable,even if we do not have an immediate need for additional capital at that time.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.The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants,such as limitations on our ability to incur additional debt,limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties,we may have to relinquish valuable rights to our technologies or product candidates,or grant licenses on terms unfavorable to us. ~~51Subject~~ **36Subject** to various spending levels approved by our Board of Directors,our management will have broad discretion in the use of the net proceeds from our capital raises,including our **July 2023,** June 2020,October 2018 and January 2018 public offerings and the proceeds from sales pursuant to our " at- the- market " ~~sales~~ **sale** agreement with Jefferies LLC,and may not use them effectively.Our management will have discretion in the application of the net proceeds from our capital raises,including our **July 2023,** June 2020,October 2018,and January 2018 public offerings,and the proceeds from sales pursuant to the ~~First~~ **2023** ~~Sales~~ **Sale** Agreement with Jefferies ~~LLC~~ , which **provides** ~~may be delayed or~~ **for the sale of up to $ 450. 0 million of our common stock from time to time, and our stockholders will** not ~~completed for a~~ **have the opportunity as part of their investment decision to assess whether the net proceeds from our capital raises are being used appropriately. You may not agree with our decisions, and our use of the proceeds from our capital raises may not yield any return to stockholders. Because of the** number **and variability** of ~~reasons~~ **factors that will determine our use of the net proceeds from our capital raises** , ~~including~~ their ultimate use may vary substantially from their currently intended use.Our failure to apply the net proceeds of our capital raises effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return,if any,on our investment of those net proceeds.Stockholders will not have the opportunity to influence our decisions on how to use our net proceeds from our capital raises.Pending their use,we may invest the net proceeds from our capital raises in interest and non-interest- bearing cash accounts,short- term,investment- grade,interest- bearing instruments and U.S.government securities.These temporary investments are not likely to yield a significant return.The use of our net operating loss carryforwards and research tax credits may be limited.Our net operating loss carryforwards and any future research and development tax credits may expire and not be used.As of December 31, ~~2022~~ **2023** ,we had U.S.federal net operating loss carryforwards of approximately $ 1. ~~0~~ **2** billion.Our net operating loss carryforwards arising in taxable years ending on or prior to December 31,2017,will begin expiring in 2027 if we have not used ~~the~~ **them** ~~negative~~ **prior** to that time.Net operating loss carryforwards arising in taxable years ending after December 31,2017,are no longer subject to expiration under the Internal Revenue Code of 1986,as amended,or the

Code.Additionally,our ability to use any net operating loss and credit carryforwards to offset taxable income or tax,respectively,in the future will be limited under Sections 382 and 383 of the Code,respectively,if we have a cumulative change in ownership of more than 50 % within a three- year period.Prior to December 31, ~~2022~~ **2023** ,we ~~have~~ experienced multiple ownership changes.As a result,the federal and state carryforwards associated with the net operating loss and credit deferred tax assets were reduced by the amount of tax attributes estimated to expire during their respective carryforward periods.In addition,since we will need to raise substantial additional funding to finance our operations,we may undergo further ownership changes in the future.Any such annual limitation may significantly reduce the utilization of the net operating loss carryforwards and research tax credits before they expire.Depending on our future tax position,limitation of our ability to use net operating loss carryforwards in states in which we are subject to income tax could have an adverse impact **on our results** of ~~of~~ operations and financial condition.Recently enacted tax reform legislation in the U.S.,changes to existing tax laws,or challenges to our tax positions could adversely affect our business and financial condition.In recent years,various tax legislations were signed into law.On December 22,2017,the Tax Cuts and Jobs Act of 2017,or the Tax Act,was signed into law,making significant changes to the Internal Revenue Code.On March 27,2020,the Coronavirus Aid,Relief,and Economic Security Act,or the CARES Act,was enacted in response **to** the COVID- 19 pandemic. ~~We~~ **Certain** provisions of the CARES Act amend or suspend certain provisions of the Tax Act.For example,the tax relief measures under the CARES Act for businesses include a five- year net operating loss carryback,suspension of annual deduction limitation of 80 % of taxable income from net operating losses generated in a tax year beginning after December 31,2017,changes in the deductibility of interest,acceleration of alternative minimum tax credit refunds,payroll tax relief,and a technical correction to allow accelerated deductions for qualified improvement property.On June 15,2020,Assembly Bill 85 was passed in California which suspended the use of net operating losses and limited the use of credits for certain corporations.Changes to existing federal and state tax laws could adversely impact our business,results of operations and financial position as the impact of recent tax legislation is uncertain. ~~52In~~ **37In** addition,U.S.federal,state and local tax laws ~~are~~ are extremely complex and subject to various interpretations.Although we believe that our tax estimates and positions are reasonable,including our decision to build ~~our~~ **the** iCTC ~~facility~~ at the Navy Yard in Philadelphia in order to take advantage of the site ~~'~~**'** s designation as a Keystone Opportunity Zone,Keystone Opportunity Expansion Zone,or Keystone Opportunity Improvement Zone,or collectively **a** KOZ,which allows incentives for business development,as well as certain other financial incentives provided by the Commonwealth of Pennsylvania,the City of Philadelphia and the Philadelphia Industrial Development Corporation,there can be no assurance that our tax positions will not ~~permitted~~ **be challenged by relevant tax authorities or that we would be successful in any such challenge. Further, challenges** to ~~Philadelphia and the Philadelphia Industrial Development Corporation,there can be no assurance that our tax positions will not be challenged by relevant tax authorities or that we would be successful in any such challenge.Further,challenges to~~ the site' s designation as a KOZ or broader challenges to Pennsylvania' s KOZ program could result in the revocation of the site ~~'~~**'** s designation as a KOZ and the attendant tax advantages associated with such designation.If we are unsuccessful in such a challenge,or if the site ~~'~~**'** s status as a KOZ is revoked,the relevant tax authorities may assess additional taxes,which could result in adjustments to,or impact the timing or amount of,taxable income,deductions or other tax allocations,which may adversely affect our results of operations and financial position. **Risks Related** ~~We are subject~~ to ~~extensive regulation~~ **the Manufacturing and Commercialization of Our Products and Product CandidatesEven though our lead product Amtagvi ™ is approved and commercialized** , ~~which can be costly~~ **we may not become profitable.Our lead product** , ~~time consuming~~ **Amtagvi ™,is initially targeting a small population of refractory patients that suffer from metastatic melanoma.Even with FDA approval of Amtagvi ™,** and ~~can subject us to unanticipated delays;~~ even if we obtain **significant** market **share, because the potential target population** ~~or~~ **for** ~~promote any of our product candidates before~~ **Amtagvi ™ in refractory patients may be small,** we ~~receive~~ **may never achieve profitability without obtaining** regulatory approval ~~from the FDA or~~ **for additional** ~~comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates or regulatory approval that will allow us to successfully commercialize our product candidates. If we do not receive FDA approval with the necessary conditions~~ **indications** to allow successful commercialization, and then..... therapies, including lifileucel for metastatic melanoma . The FDA **often** ~~may also consider its approvals~~ **approves new therapies initially only for use in patients** ~~of competing products, which may alter the treatment landscape concurrently~~ with **relapsed** ~~their review of our~~ **or refractory metastatic disease** ~~BLA filings, and which may lead to changes in the FDA' s review requirements that have been previously communicated to us and our interpretation thereof, including changes to requirements for clinical data or clinical trial design~~ . ~~Such changes could delay~~ **We expect to initially seek** approval **of** ~~or~~ **our** ~~necessitate withdrawal of our BLA filings. Our~~ product candidates **in this setting and** are **currently** susceptible to the risks of failure inherent..... We have a limited history of conducting clinical trials and have no experience as a company..... adversely affect our business. Our reliance on these third parties for development activities will reduce..... trials of our product candidates with small patient populations ~~may not be predictive of~~ **. Since Proleukin ® is an established product and** ~~the~~ **there** ~~results of later- stage clinical trials or the results once the applicable clinical trials~~ are **competing** completed. Preliminary, single cohort,..... may be greater variability in results for products **in development** ~~processed and administered on a patient- by- patient basis~~ , **the success** ~~as anticipated for our product candidates, than for " off~~ - **of Proleukin ®** ~~- the- shelf " products, like many other drugs. There~~ is ~~typically~~ **closely tied to Amtagvi ™** ~~an~~ **and** extremely high rate of attrition from the..... plan to test our product candidates for use with other **cell therapies. An** ~~oncology products, the design, implementation, and interpretation of the clinical trials necessary for marketing~~ approval ~~may be more complex than if we were developing our product candidates alone. In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or~~ **for** ~~foreign regulatory authorities will interpret the results as we do, and more clinical trials could be required before we submit our product candidates for approval. To the extent that the results of the clinical trials are not satisfactory to the FDA or foreign regulatory authorities for support of~~ a **marketed** ~~marketing application, we may be required to expend significant resources, which may not~~

~~be available to us, to conduct additional clinical trials in support of potential approval of our~~ product ~~candidates. We have reported preliminary results for clinical trials of our product candidates~~ , ~~including TIL for the treatment of metastatic melanoma, cervical cancer, and head and neck cancers. These preliminary results, which include assessments of efficacy~~ such as ~~44ORR~~ **Proleukin ®** , **may be withdrawn by the FDA or another regulatory agency and disrupt both Proleukin ® and Amtagvi ™ because of their codependency. Additionally, Proleukin ® revenues** are **dependent upon continued use** ~~subject to substantial risk of change due to small sample sizes and may change as patients are evaluated or as additional patients are enrolled~~ in ~~these~~ **manufacturing and** clinical **settings by Iovance** ~~trials. These outcomes may be unfavorable, deviate from our earlier reports, and / or delay or prevent regulatory approval or commercialization of our product candidates, including candidates for which we have reported preliminary efficacy results. In clinical trials where a staged expansion is expected, such as studies using a Simon' s two stage design, these outcomes may result in the failure to meet an~~ **and** ~~initial efficacy threshold for the first stage. Furthermore,~~ other measures of efficacy for these clinical trials..... staff, as toxicities resulting from personalized cell therapy **companies** ~~are not normally encountered in the general patient population and by medical personnel. Any of these occurrences may harm our business, financial condition and prospects significantly~~ . The manufacture of our **products and** product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development, quality control, or scaling- up of our manufacturing capabilities. If we, or any of our third- party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients ~~, if approved,~~ could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure. Our **products and** product candidates are biologics and the process of manufacturing our products is complex, highly regulated and subject to multiple risks. The manufacture of our **products and** product candidates involves complex processes, including harvesting tumor fragments from patients, isolating the T- cells from the tumor fragments, multiplying the T- cells to obtain the desired dose, and ultimately infusing the T- cells back into a patient **. The complexities of manufacturing cell therapy products require extensive collaboration with treatment centers including the provision of patient tumor tissue for manufacture. Manufacturing is dependent on many factors including quality of the patient tumor tissue, treatment center training, and unique factors specific to autologous cell therapy manufacturing that can jeopardize the product approval, launch, scale, and capacity** . As a result of the complexities, the cost to manufacture biologics is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult to reproduce. Our manufacturing process will be susceptible to product loss or failure due to logistical issues associated with the collection of tumor fragments, or starting material, from the patient, shipping such material to the manufacturing site, shipping the final product back to the patient, and infusing the patient with the product, manufacturing issues associated with the differences in patient starting material, interruptions in the manufacturing process, contamination, equipment failure, assay failures, improper installation or operation of equipment, vendor or operator error, inconsistency in cell growth, meeting pre- specified release criteria, and variability in product characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If for any reason we lose a patient' s starting material, or later- developed product at any point in the process, or if any product does not meet the applicable specifications, the manufacturing process for that patient will need to be restarted, including ~~46resection~~ -- **resection** of the proper amount of tumor fragment **,** and the resulting delay may adversely affect that patient' s outcome. If microbial, viral, environmental or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. ~~Because~~ **38Because** our **products and** product candidates are manufactured specifically for each individual patient, we will be required to maintain a chain of identity **and chain of custody** with respect to the patient' s tumor as it moves from the patient to the manufacturing facility, through the manufacturing process, and back to the patient. Maintaining such ~~a chain~~ **chains** of identity **and chains of custody** is difficult and complex, and failure to do so could result in adverse patient outcomes, loss of product, or regulatory action including withdrawal of our products from the market. Further, as product candidates are developed through preclinical studies to late- stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials or otherwise necessitate the conduct of additional studies. Currently, our **products and** product candidates are manufactured using processes developed or modified by us or by our third- party research institution collaborators that we may not intend to use for more advanced clinical trials or commercialization. ~~We have selected~~ Gen 2 ~~as~~ **is** the **FDA- approved, commercial** manufacturing process for **Amtagvi ™** ~~product registration,~~ and **has been selected for** all ongoing and future company- sponsored clinical trials. Although we believe Gen 2 is a commercially viable process, there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale- up, process reproducibility, stability issues, lot consistency, and timely availability of raw materials. ~~This includes potential risks associated with the FDA not agreeing with all of the details of our validation data or other aspects of our potency assay or assays for Cohort 4 of our C- 144- 01 clinical trial. For example, on October 5, 2020, we announced that we and the FDA were not able to agree on the required potency assays to fully define our TIL therapy, which is required as part of a BLA submission, and that as a result of these developments, our BLA submission was not expected by the end of 2020 and was anticipated instead to occur in 2021. Previously, we reported the submission of assay data to the FDA, and on May 18, 2021, we announced that we had received regulatory feedback from the FDA regarding our potency assays for lifileucel. Following FDA feedback regarding the potency assays for lifileucel, we continued work developing and validating our potency assays and engaged in discussions with the FDA during the second half of 2021 and first quarter of 2022. Based on feedback received from these discussions, we held a pre- BLA meeting in July 2022. We initiated a~~

~~rolling BLA for lifileucel in metastatic melanoma in August 2022, which we plan to complete in the first quarter of 2023. In addition, as previously disclosed, we have begun a confirmatory Phase 3 clinical trial of lifileucel in combination with pembrolizumab in frontline metastatic melanoma in late 2022 which we expect to utilize significant manufacturing capacity.~~ As a result of these challenges, we may experience delays in our clinical development and / or commercialization plans. Furthermore, we may ultimately be unable to reduce the cost of goods for our product candidates to levels that will allow for an attractive return on investment if and when those product candidates are commercialized. In May 2019 we entered into a lease agreement to build a commercial- scale manufacturing facility, the iCTC, in Philadelphia, Pennsylvania for commercial and clinical production of autologous TIL products, including our product ~~candidate lifileucel~~ **Amtagvi ™** . The iCTC is currently manufacturing TIL for our ongoing clinical trials and preparing to provide commercial supply upon potential BLA approval; as of the end of 2021, we had completed the commissioning activities at the iCTC and successfully initiated manufacturing of clinical batches of lifileucel and LN- 145, representing our first internally manufactured TIL product, as we continue our launch readiness activities to supply commercial TIL upon potential BLA approval. We expect our manufacturing facility will provide us with enhanced control of material supply for both clinical trials and the commercial market, enable the more rapid implementation of process changes, and allow for better long- term margins. We ~~are building~~ **have built** capacity to **potentially** treat thousands of cancer patients annually. However, we may not be successful in finalizing the development of our own manufacturing facility or capability. We may establish multiple manufacturing facilities as we expand our commercial footprint to multiple geographies, which may lead to regulatory delays or prove costly. Even if we are successful, our manufacturing capabilities could be affected by cost- overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures, and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business. The manufacture of cell therapy products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of cell therapy products often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, and compliance with strictly enforced federal, state, local and foreign regulations. **The FDA may take a restrictive approach when regulating cell therapy manufacturing facilities that could result in delays, product release challenges, shortages, or capacity restraints.** ~~47Our~~ -- **Our** current manufacturing strategy involves the use of CMOs ~~to supplement~~ **in conjunction with** the manufacturing capacity at the iCTC. Currently our **products and** product candidates are also manufactured by WuXi and **previously by** Moffitt **. Additionally, we partner with American Red Cross, or ARC, to leverage their GMP approved facilities and operate our own facility to produce feeder cells for TIL manufacturing. The process for manufacturing TIL is heavily reliant on the supply of biological raw materials and maintaining a GMP facility capable of supplying our manufacturing facilities with quality cells to make the final product. There are only a limited number of these types of facilities and sources for the materials needed by TIL cell therapy manufacturers. The iCTC and our CMO are aseptic manufacturing facilities that operate clean rooms for the production of TIL cell therapies, which are subject to contamination, labor, occupational safety, regulatory, climate, and environmental risks that could interfere with production** . Any problems or delays we or our CMOs experience in preparing for commercial scale manufacturing of a product **, product** candidate **,** or component **thereof** may result **,** in **the case of product candidates,** a delay in the FDA approval ~~of~~ **thereof or, in** the **case of** ~~product~~ **products ,** ~~candidate or~~ may impair our ability to manufacture commercial quantities or such quantities at an acceptable cost, which could result in the delay, prevention, or impairment of clinical development **of our product candidates** and commercialization of our ~~product~~ **products** ~~candidates~~ and could adversely affect our business. Furthermore, if we or our commercial manufacturers fail to deliver the required commercial quantities of our product candidates on a timely basis and at reasonable costs, we would likely be unable to meet demand for our products and we would lose potential revenues. ~~Moreover~~ **39Moreover** , should we continue to use CMOs, we may not succeed in maintaining our relationships with our current ~~CMOs~~ - **CMO** or establishing relationships with additional or alternative CMOs. Our **products and** product candidates may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing for us and willing to do so. If our CMOs should cease manufacturing for us, we would experience delays in obtaining sufficient quantities of our product candidates for clinical trials and, if approved, commercial supply. Further, our CMOs may breach, terminate, or not renew these agreements. If we were to need to find alternative manufacturing facilities it would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. The commercial terms of any new arrangement could be less favorable than our existing arrangements and the expenses relating to the transfer of necessary technology and processes could be significant. Reliance on third- party manufacturers entails exposure to risks to which we would not be subject if we manufactured the product candidate ourselves, including: ● inability to negotiate manufacturing and quality agreements with third parties under commercially reasonable terms; ● reduced day- to- day control over the manufacturing process for our product candidates as a result of using third- party manufacturers for all aspects of manufacturing activities; ● reduced control over the protection of our trade secrets and know- how from misappropriation or inadvertent disclosure; ● termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that may be costly or damaging to us or result in delays in the development or commercialization of our **products and / or** product candidates; ~~and~~ ● disruptions to the operations of our third- party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier. **● international or multi- national activities that are related to business activities outside of our scope, but may have an impact on a CMO' s ability to conduct business in a manner consistent with governmental or our regulatory and ethical standards; and ● our ability to synchronize operations and standards to ensure that all aspects of manufacturing are consistent without deviations across facilities.** In addition, the manufacturing process and facilities for any products that we

may develop at the iCTC and or our CMOs is subject to FDA and foreign regulatory authority approval processes, and we or our CMOs will need to meet all applicable FDA and foreign regulatory authority requirements, including ~~cGMPs~~ **cGMP**, on an ongoing basis. The cGMP requirements include quality control, quality assurance, and the maintenance of records and documentation. The FDA and other regulatory authorities enforce these requirements through facility inspections. Manufacturing facilities must submit to pre- approval inspections by the FDA that will be conducted after we submit our marketing applications, including our BLAs, to the FDA. Manufacturers are also subject to continuing regulatory oversight by FDA and other regulatory authorities, including inspections following marketing approval. Further, we, in cooperation with our CMOs, must supply all necessary chemistry, manufacturing, and control documentation for a pre- approval inspection in support of a BLA on a timely basis. There is no guarantee that we or our CMOs will be able to successfully pass all aspects of a pre-approval inspection by the FDA or other foreign regulatory authorities. Our ~~,~~ **manufacturing facilities** or our CMOs' ~~,~~ manufacturing facilities may be unable to comply with our specifications, ~~cGMPs~~ **cGMP**, and with other FDA, state, and foreign regulatory requirements. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of product candidate that may not be detectable in final product testing. If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, or in accordance with the strict regulatory requirements, we may not obtain or maintain the approvals we need to commercialize such products. Even **after obtaining regulatory approval, in the case of our products, and even** if we obtain regulatory approval ~~for any~~ **, in the case** of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Deviations from manufacturing requirements may further require remedial measures that may be costly and / or time-consuming for us or a third party to implement and may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. ~~48Even~~ -- **Even** to the extent we use and continue to use CMOs, we are ultimately responsible for the manufacture of our products and product candidates. A failure to comply with these requirements may result in regulatory enforcement actions against our manufacturers or us, including fines and civil and criminal penalties, which could result in imprisonment, suspension or restrictions of production, ~~injunctions~~ **40injunctions**, delay or denial of product approval or supplements to approved products, clinical holds or termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues with the biologic, refusal to permit the import or export of the products, product seizure, detention, or recall, operating restrictions, suits under the civil False Claims Act, corporate integrity agreements, consent decrees, or withdrawal of product approval. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations **,** and growth prospects. Cell- based therapies and biologics rely on the availability of **biological raw materials (including live cells), chemicals and agents used for manufacturing,** reagents, specialized equipment, and other specialty materials, which may not be available to us on acceptable terms or at all. For ~~some~~ **each** of these ~~reagents, equipment, and materials,~~ we rely or may rely on **treatment sites, limited manufacturers,** sole source vendors or a limited number of vendors, which could impair our ability to manufacture and supply our products. Manufacturing our **products and** product candidates requires **live cells among other biological raw materials, chemicals and agents used for manufacturing.** ~~many~~ **Many** reagents, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for certain materials and equipment used in the manufacture of our product candidates. Some of these suppliers may not have the capacity to support clinical trials and commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill- equipped to support our needs. We also do not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key materials and equipment to support clinical or commercial manufacturing. For ~~some~~ **each** of these **biological raw materials (including live cells), chemicals and agents used for manufacturing,** reagents, equipment, and materials, we rely and may in the future rely on **treatment sites, limited manufacturers,** sole source vendors or a limited number of vendors. An inability to continue to source product from any of these suppliers, which could be due to a number of issues, including regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business. As we continue to develop and scale our manufacturing process, we expect that we will need to obtain rights to and supplies of certain materials and equipment to be used as part of that process. We may not be able to obtain rights to such materials on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such materials or find a suitable substitute, it would have a material adverse effect on our business. Even if we are able to alter our process so as to use other materials or equipment, such a change may lead to a delay in our clinical development and / or commercialization plans. If such a change occurs for product candidate that is already in clinical testing, the change may require us to perform both ex vivo comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials . We will be unable to commercialize..... a timely basis, or at all . Because our current products represent, and our other potential product candidates will represent novel approaches to the treatment of disease, there are many uncertainties regarding the development, the market acceptance, third- party reimbursement

coverage and the commercial potential of our product candidates. Human immunotherapy products are a new category of therapeutics. Because this is a relatively new and expanding area of novel therapeutic interventions, there are many uncertainties related to development, marketing, reimbursement, and the commercial potential for our product candidates. There can be no assurance as to the length of the clinical trial period, the number of patients the FDA will require to be enrolled in the clinical trials in order to establish the safety, efficacy, purity and potency of immunotherapy products, or that the data generated in these clinical trials will be acceptable to the FDA to support marketing approval. The FDA may take longer than usual to come to a decision on any BLA that we submit and may ultimately determine that there is not enough data, information, or experience with our product candidates to support an approval decision. The FDA may also require that we conduct additional post-marketing studies or implement risk management programs, such as REMS until more experience with our product candidates is obtained. Finally, after increased usage, we may find that our product candidates do not have the intended effect or have unanticipated side effects, potentially jeopardizing initial or continuing regulatory approval and commercial prospects. ~~We~~ **41We** may also find that the manufacture of our product candidates is more difficult than anticipated, resulting in an inability to produce a sufficient amount of our product candidates for our clinical trials or, if approved, commercial supply. Moreover, because of the complexity and novelty of our manufacturing process, there are only a limited number of manufacturers who have the capability of producing our product candidates. Should any of our contract manufacturers no longer produce our product candidates, it may take us significant time to find a replacement, if we are able to find a replacement at all. There is no assurance that the approaches offered by our products will gain broad acceptance among doctors or patients or that governmental agencies or third- party medical insurers will be willing to provide reimbursement coverage for proposed product candidates. Moreover, we do not have verifiable internal marketing data regarding the potential size of the commercial market for our product candidates, nor have we obtained current independent marketing surveys to verify the potential size of the commercial markets for our current product candidates or any future product candidates. Since our current product candidates and any future product candidates will represent novel approaches to treating various conditions, it may be difficult, in any event, to accurately estimate the potential revenues from these product candidates. Accordingly, we may spend significant capital trying to obtain approval for product candidates that have an uncertain commercial market. The market for any products that we successfully develop will also depend on the cost of the product. ~~54We~~ **Cell based therapies may take longer to attain insurance coverage, and although we may apply for special government programs and prepare the market for product approval, there is no way to ensure that healthcare providers, insurance companies, or other third parties will reimburse our product at an expeditious rate. Even if we obtain insurance coverage for our product from payors, coverage at treatment centers will require payment for the total cost of care which involves surgery, conditioning chemotherapy, as well as other staffing and hospitalization needs. This will require coordination between authorized treatment centers and other payors including government payors that may only cover a portion of charges. If our treatment centers do not successfully obtain coverage in time, there may be a slow uptake or variable or limited access, if at all, to our therapies. We** do not yet have sufficient information to reliably estimate what it will cost to commercially manufacture our current product candidates, and the actual cost to manufacture these products could materially and adversely affect the commercial viability of these products. Our goal is to reduce the cost of manufacturing and providing our therapies. However, unless we can reduce those costs to an acceptable amount, we may never be able to develop a commercially viable product. If we do not successfully develop and commercialize products based upon our approach or find suitable and economical sources for materials used in the production of our products, we will not become profitable, which would materially and adversely affect the value of our common stock. Our TIL **cell** therapies and our other therapies may be provided to patients in combination with other agents provided by third parties. The cost of such combination therapy may increase the overall cost of therapy and may result in issues regarding the allocation of reimbursements between our therapy and the other agents, all of which may affect our ability to obtain reimbursement coverage for the combination therapy from governmental or private third- party medical insurers. No assurance can be given that the Gen 2 manufacturing process **or other processes** we have selected will be FDA- compliant ~~,~~ **or** more efficient and **will** lower the cost to manufacture TIL products. **We** ~~Pursuant to the CRADA, and in cooperation with our contract manufacturers and potentially other manufacturers, we~~ have developed and are developing improved methods for ~~the~~ generating and selecting autologous TILs, and methods for large- scale production of autologous TILs that are in accord with current cGMP procedures. We have developed a new and more efficient TIL manufacturing process that we believe can be more efficient and cost effective, and in a more automated manner than previous processes. The production and control of the physical and / or chemical attributes of our products in a cGMP facility is subject to many uncertainties and difficulties. **As a novel therapy, TIL manufacturing and product release is complex and must evolve with both industry- wide autologous cell therapy challenges and new regulatory requirements that may result in delays and unexpected denials.** We have never manufactured our adoptive cell therapy product candidate on a commercial scale, nor have our partners. As a result, we cannot give any assurance that the Gen 2 process or any future process that we select will be a manufacturing process that can produce our products in compliance with the applicable regulatory requirements, at a cost or in quantities necessary to make them commercially viable. Moreover, we and our third- party manufacturers will have to continually adhere to current cGMP regulations enforced by the FDA through its facilities inspection program. If our facilities or any of the facilities of these manufacturers cannot demonstrate adequate assurance of compliance with FDA standards during a pre- approval inspection, the FDA approval of our products will not be granted. In complying with cGMP and foreign regulatory requirements, we and any of our third- party manufacturers will be obligated to expend time, money and effort in production, record- keeping and quality control to assure that our products meet applicable specifications and other requirements. If we or any of our third- party manufacturers fail to comply with these requirements, we may be subject to regulatory action. No assurance can be given that we will be able to develop such a manufacturing process, or that our partners will thereafter be able to establish and operate such a production facility. **42Our business entails a significant risk of product liability.** If product liability lawsuits are brought

against us, **whether or not meritorious,** we may incur substantial liabilities and may be required to limit **or halt** commercialization of our **products and / or** product candidates. We face an inherent risk of product liability as a result of the clinical testing **and manufacture** of our product candidates **for human trials,** and ~~will~~ **we currently** face an even greater risk ~~if~~ **as** we commercialize ~~any~~ **products and engage in the quality testing and release of** products. For example, we may be sued if our **products and / or** product candidates cause ~~or~~ **,** are perceived **, or alleged** to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing **,** or sale **, whether or not trial participants or patients are predisposed to adverse outcomes. Furthermore, if physicians and / or hospitals are not sufficiently trained in the use of our products or therapies, whether clinical or commercialized, they may misuse or ineffectively use our products or related products for our therapies, which may result in unsatisfactory patient outcomes or patient injury** . Any such product liability claims may include allegations of defects in manufacturing, defects in design, **defects in quality control measures,** a failure to warn of dangers inherent in the product, negligence, strict liability **, and /** or a breach of warranties. Claims could also be asserted under state consumer protection acts. Large judgements have also been awarded in class action lawsuits based on therapeutics that had unanticipated side effects. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit **or halt** commercialization of our **products and / or** product candidates. Even **a** successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: ● decreased **or interrupted** demand for our **products and / or** product candidates; ● injury to our reputation; ● withdrawal of clinical trial participants or sites and potential termination of clinical trial sites or entire clinical programs; ● initiation of investigations by regulators **(including investigation of the safety and effectiveness of our products, our manufacturing processes and facilities, or our marketing programs)** , refusal to approve marketing applications or supplements, **warnings,** and withdrawal or **other** ~~limitation~~ **limitations** ~~of~~ **on** product approvals; ● costs to **prepare for and** defend the related litigation; ● a diversion of management' s time and our resources; ● substantial monetary awards to clinical trial participants or patients; ● product recalls, withdrawals **,** or **restrictions on** labeling, marketing **,** or ~~promotional~~ **promotions** ~~restrictions~~ ; ● loss of revenue; ● significant negative media attention; ~~55~~ ● decrease in the price of our stock and overall value of our company; ● exhaustion of our available insurance coverage and our capital resources; **and /** or ● the **delay or** inability to commercialize our product candidates **or achieve adequate revenue from our products** . Our inability to obtain sufficient product liability insurance at an acceptable cost **and / or scope of coverage** to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Our insurance policies may also have various exclusions **and / or deductibles** , and we may be subject to a product liability **or bodily injury** claim for which we have no coverage **or for which the insurance carrier disputes the scope of coverage** . ~~While~~ **Furthermore, any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or the inability to secure coverage in the future. Although** we **currently** have **product liability** ~~obtained clinical trial~~ insurance **that we believe is appropriate** for our ~~Phase 2 clinical trials~~ **stage of development, we may need to obtain higher levels to cover marketing any of our approved products. In addition** , we may have to pay amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. **We anticipate that we will need to increase our insurance coverage as we commence additional clinical trials and as we commercialize product candidates that have been or may be approved. If we determine that it is prudent to increase our product liability coverage, we may be unable to obtain such increased coverage on acceptable terms, or at all. The market for insurance coverage is increasingly expensive, and the costs of insurance coverage will increase as our clinical programs and commercialization efforts increase in size. Furthermore,** ~~Even~~ **even** if our agreements with ~~any future~~ corporate collaborators entitle us to indemnification against **product liability** losses, such indemnification may not be available or adequate should any claim arise. ~~We~~ **Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources, adversely affect or eliminate the prospects for commercialization or sales of a product that is the subject of any such claim, and could have a material adverse effect on our business, financial condition, results of operations, and growth prospects. 43We** face significant competition from other biotechnology and pharmaceutical companies and from non- profit institutions. Competition in the field of cancer therapy is intense and is accentuated by the rapid pace of technological development. Research and discoveries by others may result in breakthroughs which may render our products obsolete even before they generate any revenue. There are products that are approved and currently under development by others that could compete with the products that we are developing. Many of our potential competitors have substantially greater research and development capabilities and approval, manufacturing, marketing, financial and managerial resources and experience than we do. Our competitors may: ● develop safer, more convenient or more effective immunotherapies and other therapeutic products; ● develop therapies that are less expensive or have better reimbursement from private or public payors; ● reach the market more rapidly, reducing the potential sales of our products; or ● establish superior proprietary positions. Due to the promising clinical therapeutic effect of competitor therapies in clinical exploratory trials, we anticipate substantial direct competition from other organizations developing advanced T- cell therapies targeting patients who have received prior anti- PD- 1 / PD- L1 therapies. In particular, we expect to compete with other new therapies for our lead indications developed by companies such as Agenus, BeyondSpring, Bristol- Myers Squibb, Merck, Nektar Therapeutics, Checkmate Pharmaceuticals, Daiichi Sankyo, Eisai, Exelixis, Moderna, ~~Mirati Therapeutics,~~ OncoSec Medical, Replimune, Regeneron Pharmaceuticals, ~~Seagen~~ **Pfizer** , and Genmab. We also may compete with other TIL **cell** therapies in development by companies such as Instil Bio, Achilles Therapeutics, KSQ Therapeutics, Obsidian Therapeutics, Immatics, TILT Biotherapeutics, WindMIL Therapeutics, GRIT Biotechnology, Lyell Immunopharma, Cellular Biomedicine Group, and others. We also may compete with therapies based on genetically engineered T- cell receptors rendered reactive against tumor- associated antigens prior to their administration to patients, as well as TIL **cell** therapies that are designed to be

specific to neoantigens, including products developed by Adaptimmune Therapeutics, Alaunos Therapeutics, Intima Bioscience, Marker Therapeutics, Turnstone Biologics, Neogene, and others. To date, these technologies have been primarily applicable to hematologic malignancies, but their application in solid tumor indications may create competition with us. We may also face competition from immunotherapy treatments offered by companies such as Amgen, AstraZeneca, Bristol- Myers Squibb, Merck, Pfizer, Regeneron Pharmaceuticals, Roche, and BioNTech. We may also face competition from novel IL- 2 treatments in development by Alkermes, Werewolf, Nektar Therapeutics, Merck, Sanofi, Neoleukin Therapeutics and others. Many of these companies and our other current and potential competitors have substantially greater research and development capabilities and financial, scientific, regulatory, manufacturing, marketing, sales, human resources, and experience than we do. Many of our competitors have several therapeutic products that have already been developed, approved and successfully commercialized, or are in the process of obtaining regulatory approval for their therapeutic products in the U. S. and internationally. Our competitors may obtain regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in competitors establishing a strong market position before we are able to enter the market. Universities and public and private research institutions in the U. S. and Europe are also potential competitors. For example, a Phase 3 M14TIL clinical trial comparing TIL to standard ipilimumab in patients with metastatic melanoma is currently being conducted in Europe by the Netherlands Cancer Institute, the Copenhagen County Herlev University Hospital, and the University of Manchester. Results from the M14TIL clinical trial were presented at the European Society for Medical Oncology Congress in September 2022. While these universities and public and private research institutions primarily have educational objectives, they may develop proprietary technologies that lead to other FDA approved therapies or that secure patent protection that we may need for the development of our technologies and products. ~~56Our~~ -- **Our** lead product ~~candidate lifileucel~~ **Amtagvi ™** is ~~a~~ **an approved** therapy for the treatment of metastatic melanoma and ~~metastatic cervical~~ **a candidate for the treatment of other** ~~cancer~~ **cancers** . Currently, there are numerous companies that are developing various alternate treatments for melanoma and ~~cervical~~ **other** ~~cancer~~ **cancers** , including patients that have progressed after prior treatment with checkpoint inhibitors and chemotherapy. Accordingly, ~~lifileucel~~ **Amtagvi ™** faces significant competition in the melanoma and ~~cervical~~ **other** cancer treatment space from multiple companies. Even **after** ~~if we obtain~~ **obtaining** regulatory approval for ~~lifileucel~~ **Amtagvi ™** , the availability and price of our competitors' products could limit the demand and the price we are able to charge for our therapies. We may not be able to implement our business plan if the acceptance of our products is inhibited by price competition or the reluctance of physicians to switch from other methods of treatment to our product, or if physicians switch to other new therapies, drugs or biologic products or choose to reserve our product for use in limited circumstances. ~~Mergers~~ **44Mergers** and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. ~~We~~ **Our projections regarding the market opportunities for our products and product candidates may not be accurate, and the actual market for our products and product candidates may be smaller than we estimate. Our projections of both the number of people who have the advanced cancers we** are ~~dependent~~ **targeting as well as the subset of people with metastatic or unresectable cancers and who have the potential to benefit from treatment with our products or product candidates are based** on **our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research by** third parties **, and may prove** to ~~support~~ **be incorrect. Further, new studies** ~~our~~ - **or approvals of new therapeutics may change** ~~research, development and manufacturing activities and, therefore, are subject to~~ the ~~efforts~~ **estimated incidence or prevalence** of these **cancers. The number of** ~~parties~~ - **patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our products** and **product candidates may be limited** ~~our~~ - **or** ~~ability~~ **may not be amenable** to **treatment** ~~successfully collaborate~~ with ~~these third parties. As a result of our current strategy to outsource most of our manufacturing, we rely very heavily on third parties to perform for us the manufacturing of~~ our products ~~for~~ - **or product candidates and may** ~~our clinical trials. We~~ also ~~license a portion of our technology from others. We intend to rely upon our contract manufacturers to produce large quantities of materials needed for clinical trials and potentially product commercialization. Third party manufacturers may not~~ be **limited by the cost of** ~~able to meet our needs with respect to timing, quantity or~~ **our treatments and the reimbursement** ~~quality. If we are unable to contract for a sufficient supply~~ of ~~needed materials on acceptable terms, or if we should encounter delays or difficulties in our relationships with manufacturers, our clinical testing may be delayed, thereby delaying the~~ **those treatment costs by** ~~submission of products for regulatory approval or the market introduction and subsequent sales of our products. Any such delay may lower our revenues and potential profitability. In addition, in order to supplement our own efforts to improve TIL manufacturing and develop TIL therapies in new indications in clinical trials, we currently work and collaborate with government and academic research institutions, medical institutions and corporate partners such as the NCI, Moffitt, Cellectis, Yale University, the Ohio State University, and Novartis. We also intend to continue to enter into additional~~ third- party **payors** ~~collaborative agreements in the future~~ . ~~However, we may not be able to successfully negotiate any additional collaborative arrangements. If established, these relationships may not be scientifically or~~ **For instance** ~~commercially successful~~ , ~~or may be unable~~ **we expect Amtagvi ™** to ~~enroll~~ **initially target a small** ~~patients~~ - **patient population that suffers from metastatic melanoma** ~~, which has occurred in one of our prior collaborations~~ . **Even** The success of these and future collaborations..... These disagreements can be difficult to resolve if ~~neither of the parties has final decision- making authority under the collaboration agreement. With regard to future collaboration efforts,~~ we ~~face~~ **obtain** significant **market share** ~~competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for collaboration will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and,~~

~~an evaluation by the proposed collaborator of a number of similar or~~ **for our products or product candidates, because** ~~unique factors. Collaborations with biopharmaceutical companies and other~~ -- **the** ~~third parties often~~ **potential target populations** are **small** ~~terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation. Any collaboration may pose a number of risks~~ , **we** ~~including the following: ● collaborators~~ may **never** ~~not perform their obligations as expected; ● collaborators may not pursue development and commercialization of any product candidates that~~ achieve **profitability without obtaining** regulatory approval ~~or~~ **for** may elect not to continue or renew..... of product candidates, might lead to additional responsibilities for us with respect to product....., may be lost if the indication **indications** for which we develop our designated product..... the commercial prospects of our product candidates . We may be unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell our **products and** product candidates, if they are approved, and as a result, we may be unable to generate **significant** product revenues. We currently have a small commercial team focused on our commercial strategy, but we do not have a **large** commercial infrastructure for the marketing, sale, and distribution of biopharmaceutical products. **In** ~~If approved, in~~ order to commercialize our products, we must build our marketing, sales, and distribution capabilities or make arrangements with third parties to perform these services, which will take time and require significant financial expenditures and we may not be successful in doing so. Even if we are able to effectively establish a sales force and develop a marketing and sales infrastructure, our sales force and marketing teams may not be successful in commercializing our current or future product candidates. To the extent we rely on third parties to commercialize any products for which we obtain regulatory approval, we would have less control over their sales efforts, and could be held liable if they failed to comply with applicable legal or regulatory requirements. **In addition to marketing our product, we will need to establish authorized treatment centers that will be able to obtain patients from the broader community and provide access to our therapies. Even if we are able to obtain approval for a product candidate, we may not be able to approve enough treatment centers for the provision of our product to a broad patient population. Additionally, certain areas do not have hospitals with the facilities to safely administer our therapy. Accordingly, we may only be able to launch our products with a limited number of treatment centers, which could ultimately reduce the uptake of our products. Although we have a team allocated to authorize and monitor our treatment centers, substantial resources and investment from us and each treatment center may be required. Additionally, the treatment center onboarding process can be complicated and requires extensive training, technical equipment, and coordination of processes. Once authorized, treatment centers will be required to ensure that their training, facilities, and treatment capabilities are adequately maintained.** We have ~~no~~ **limited** prior experience in the marketing, sale, and distribution of biopharmaceutical products, and there are significant risks involved in the building and managing of a commercial infrastructure. The establishment and development of commercial capabilities, including a comprehensive healthcare compliance program, to market any products we may develop will be expensive and time consuming and could delay any product launch, and we may not be able to successfully develop this capability. We, or our collaborators, will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, manage, and retain marketing, sales and commercial support personnel. In the event we are unable to develop a commercial infrastructure, we may not be able to commercialize our current or future product candidates, which would limit our ability to generate product revenues. Factors that may inhibit our efforts to commercialize our current or future **products and** product candidates and generate **significant** product revenues include: ● if the COVID- 19 pandemic continues or reoccurs it may negatively impact our ability to establish commercial operations, educate and interact with healthcare professionals, and successfully launch our product on a timely basis; **45** ● the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe our current or future product candidates; ● our inability to effectively oversee a geographically dispersed sales and marketing team; ● the costs and time associated with the initial and ongoing training of sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions; ● an inability to secure adequate coverage and reimbursement by government and private health plans; ● the clinical indications for which the products are approved and the claims that we may make for the products; ● limitations or warnings, including distribution or use restrictions, contained in the products' approved labeling; ● any distribution and use restrictions imposed by the FDA or to which we agree as part of a mandatory REMS or voluntary risk management plan; ● liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements; ● the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and ● unforeseen costs and expenses associated with creating an independent sales and marketing organization or engaging a contract sales organization. ~~60If~~ **If our products** ~~our~~ **or** product candidates do not achieve broad market acceptance, the revenues that we generate from their sales will be limited. ~~We have~~ **Until the closing of the Proleukin ® acquisition in May 2023, we had** never commercialized a product candidate for any indication. Even ~~if~~ **after** our **products and** product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third- party payors, and others in the medical community. If any **product or** product candidate for which we obtain regulatory approval does not gain an adequate level of market acceptance, we may not generate significant product revenues or become profitable. Market acceptance of our **products and** product candidates by the medical community, patients, and third- party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients and patients may be reluctant to switch from existing therapies even when new and potentially more effective or safer treatments enter the market. Efforts to educate the medical community and third- party payors on the benefits of our **products and** product candidates may require significant resources and may not be successful. If any of our **products or** product candidates ~~is approved but~~ does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of any of our **products and** product candidates will depend on a number of factors, including: ● the efficacy of our **products and** product candidates; ● the prevalence and

severity of adverse events associated with such **products or** product candidates; ● the clinical indications for which the products are approved and the approved claims that we may make for the products; ● limitations or warnings contained in the approved product' s FDA- required labeling, including potential limitations or warnings for such products that may be more restrictive than other competitive products; ● changes in the standard of care for the targeted indications for such **products and** product candidates; ● the relative difficulty of administration of such **products and** product candidates; ● cost of treatment versus economic and clinical benefit in relation to alternative treatments or therapies; ● the availability of adequate coverage or reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid; ● the extent and strength of our marketing and distribution of such **products and** product candidates; ● the safety, efficacy, and other potential advantages over, and availability of, alternative treatments already used or that may later be approved for any of our intended indications; ● distribution and use restrictions imposed by the FDA with respect to such **products and** product candidates or to which we agree as part of a mandatory risk evaluation and mitigation strategy or voluntary risk management plan; ● the timing of market introduction of such **products and** product candidates, as well as competitive products; ● our ability to offer such **products and** product candidates for sale at competitive prices; ● the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; ● the extent and strength of our third- party manufacturer and supplier support; ● the approval of other new products for the same indications; ● adverse publicity about the product or favorable publicity about competitive products; ~~and~~ **and46** ● potential product liability claims. Our efforts to educate the medical community and third- party payors on the benefits of our **products and** product candidates may require significant resources and may never be successful. Even if the medical community accepts that our **products and** product candidates are safe and effective for their approved indications, physicians and patients may not immediately be receptive to such **products or** product candidates and may be slow to adopt them as an accepted treatment of the approved indications. If our current or future **products and** product candidates are approved but do not achieve an adequate level of acceptance among physicians, patients, and third- party payors, we may not generate meaningful revenues from our product candidates, and we may not become profitable. Our **products and** product candidates may face competition sooner than anticipated. The enactment of the BPCIA created an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as " interchangeable " based on its similarity to an existing brand product. Under the BPCIA, the FDA cannot make an approval of an application for a biosimilar product effective until 12 years after the original branded product was approved under a BLA. Certain changes, however, and supplements to an approved BLA, and subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest, or other related entity do not qualify for the 12- year exclusivity period. ~~61Our~~ -- **Our products and** product candidates may qualify for the BPCIA' s 12- year period of exclusivity. However, there is a risk that the FDA will not consider our **products and** product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Additionally, this period of regulatory exclusivity does not block companies pursuing regulatory approval via their own traditional BLA, rather than via the abbreviated pathway. Changes may also be made to this exclusivity period as a result of future legislation as there has been ongoing efforts to reduce the period of exclusivity. Even if we receive a period of BPCIA exclusivity for our first licensed product, if subsequent products do not include a modification to the structure of the product that impacts safety, purity, or potency, we may not receive additional periods of exclusivity for those products. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non- biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. Medicare Part B encourages use of biosimilars by paying the provider the same percentage of the reference product, average sale price, or ASP as a mark- up, regardless of which product is reimbursed. It is also possible that payors will give reimbursement preference to biosimilars even over reference biologics absent a determination of interchangeability. We will need to obtain FDA approval of any proposed proprietary branded product names, and any failure or delay associated with such approval may adversely affect our business. Any name we intend to use for our **products and** product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U. S. Patent and Trademark Office, or USPTO. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims or contributes to an overstatement of efficacy. If the FDA objects to any of our proposed proprietary product names, we may be required to adopt alternative names for our **products and / or** product candidates. If we adopt alternative names, we would lose the benefit of any existing trademark applications for such **product and / or** product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our **products and** product candidates **We** will need to grow the size and capabilities of our organization,and we may experience difficulties in managing this growth.Our operations are dependent upon the services of our executives and our employees who are engaged in research and development.The loss of the services of our executive officers or senior research personnel could delay our product development programs and our research and development efforts.In order to develop our business in accordance with our business plan,we will have to hire additional qualified personnel,including in the areas of research,manufacturing,clinical trials management,regulatory affairs,and sales and marketing.We are continuing our efforts to recruit and hire the necessary employees to support our planned operations in the near term. ~~For~~ **64For** example,we continue to recruit **for** a new Chief Executive Officer.However,competition for qualified employees among companies in the biotechnology and biopharmaceutical industry is intense,and no assurance can be given that we will be able attract,hire,retain and motivate the highly skilled

employees that we need.Future growth will impose significant added responsibilities on members of management,including:● identifying,recruiting,integrating,maintaining,and motivating additional employees;● managing our internal development efforts effectively,including the clinical and FDA review process for our product candidates,while complying with our contractual obligations to contractors and other third parties;and ● improving our operational,financial and management controls,reporting systems,and procedures.Our future financial performance and our ability to commercialize our product candidates will depend,in part,on our ability to effectively manage any future growth,and our management may also have to divert a disproportionate amount of its attention away from day- to- day activities in order to devote a substantial amount of time to managing these growth activities.We currently rely,and for the foreseeable future will continue to rely,in substantial part on certain independent organizations,advisors and consultants to provide certain services.There can be no assurance that the services of these independent organizations,advisors and consultants will continue to be available to us on a timely basis when needed,or that we can find qualified replacements.In addition,if we are unable to effectively manage our outsourced activities or if the quality,compliance or accuracy of the services provided by consultants is compromised for any reason,our clinical trials may be extended,delayed,or terminated,and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business.There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms,if at all.If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors,we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and,accordingly,may not achieve our research,development,and commercialization goals on a timely basis,or at all. ~~We may~~ . Our internal computer systems, or those used by our contract research organizations or other contractors or consultants, may fail or suffer security breaches. Despite the implementation of security measures, our internal computer systems and those of our contract research organizations and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized and authorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event was to occur and cause interruptions in our operations, it could result in a disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for a product candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of any product candidates could be delayed **. We maintain a specialized information technology system for tracking chain of custody and chain of identity for TIL cell therapy patients. Like other autologous cell therapies, this is extremely important for patient safety and is a requirement outlined in our BLA submission. This requires us to store and maintain patient specific health information. The risks associated with storing patient health and personal data may increase cyber threats and regulatory accountability and scrutiny. Although we have industry- standard secure systems and maintain privacy controls, there is a possibility that incidents compromising this information can occur. In addition to the regulatory and civil litigation risks, failure to maintain this data correctly could result in loss of patients or impair our ability to deliver patient care** . We are dependent on information technology, systems, infrastructure and data. We are dependent upon information technology systems, infrastructure and data. The multitude and complexity of our computer systems make them inherently vulnerable to service interruption or destruction, malicious intrusion and random attack. Likewise, data privacy or cybersecurity breaches by third parties, employees, contractors or others may pose a risk that sensitive data, including our intellectual property, trade secrets or personal information of our employees, patients, or other business partners may be exposed to unauthorized persons or to the public. Cyberattacks are increasing in their frequency, sophistication and intensity. The Russia- Ukraine conflict may also increase cybersecurity risks on a global basis. Cyberattacks could include the deployment of harmful malware, denial- of- service, ransomware, social engineering and other means to affect service reliability and threaten data confidentiality, privacy, integrity and availability. Our business and technology partners face similar risks, and any security breach of their systems could adversely affect our security posture. While we have invested, and continue to invest, in the protection of our data and information technology infrastructure, there can be no assurance that our efforts, or the efforts of our partners and vendors, will prevent service interruptions, or identify breaches in our systems, that could adversely affect our business and operations and / or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us. In addition, our liability ~~insurance~~ **63insurance** may not be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other cybersecurity related breaches. ~~62Our~~ -- **Our** business could be adversely affected by the effects of health epidemics, including ~~the continued spread of~~ the COVID- 19 pandemic, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations. The COVID- 19 pandemic could materially affect our operations, including at our headquarters in San Carlos, California, at our manufacturing facility in Philadelphia, Pennsylvania, **which have previously been subject to state executive orders and shelter- in- place orders,** and at our clinical trial sites, as well as the business or operations of our other manufacturers, **contract research organizations, or** CROs **,** or other third parties with whom we conduct business. Our business could be adversely affected by health epidemics in regions where we have offices, manufacturing facilities, concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of clinical trial sites, third party manufacturers and CROs upon whom we rely. For example, starting in December 2019, a novel strain of coronavirus ~~(“~~ **, or** COVID- 19 **, ”)** ~~was reported to have surfaced in Wuhan, China and has~~ spread to multiple countries, including the U. S. and several European countries. In March 2020, the World Health Organization declared COVID- 19 a global pandemic and the U. S. declared the COVID- 19 pandemic a national emergency. Similarly, during that time, the State of California declared a state of emergency related to the spread of the COVID- 19 pandemic and the health officers of six San Francisco Bay Area counties, including San Mateo County where our headquarters in San Carlos is located, issued shelter- in- place orders. In addition, on

March 19, 2020, the Governor of California and the State Public Health Officer and Director of the California Department of Public Health ordered all individuals living in the State of California to stay at their place of residence for an indefinite period of time (subject to certain exceptions to facilitate authorized necessary activities) to mitigate the impact of the COVID- 19 pandemic. Throughout 2020 and 2021, similar executive orders were issued by state and local governments, and states of emergency had been declared at the state and local level in most jurisdictions throughout the U. S. As recently as April 2022, ports and airports in Shanghai, China have been closed due to another outbreak of COVID- 19, resulting in a lockdown of the city and disruption to export and import activities. In the U. S., many of these executive orders have been rescinded, however, the Company remains vigilant and continues to monitor the ongoing COVID- 19 pandemic closely to determine if additional actions are required. Quarantines, shelter- in- place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to the COVID- 19 pandemic or other infectious diseases could impact personnel at third- party manufacturing facilities in the U. S. and other countries, or the availability or cost of materials, which would disrupt our supply chain. In addition, our clinical trials may be affected by the COVID- 19 pandemic. Clinical site initiation, patient enrollment and patient monitoring may be delayed due to prioritization of hospital resources toward the COVID- 19 pandemic. Some sites may no longer be available to see patients for clinical trials. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Patients may also miss follow- up visits after receiving our therapies during our clinical trials, which may or may not be rectified by future patient visits and which may result in the exclusion of data from such patients from the clinical trial data. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to the virus that causes the COVID- 19 pandemic and adversely impact our clinical trial operations. The COVID- 19 pandemic may also affect our ability to recruit treatment- naïve patients into our clinical trials, because those patients may be more likely to seek standard of care therapies available at local treatment centers rather than enroll in a clinical trial at a larger hospital. We continue to monitor the impact, if any, of the COVID- 19 pandemic on our current and future operations, including our regulatory filing timelines and strategy as well as our preparation for commercial launch. Despite the wide- spread availability of COVID- 19 vaccines, it is unclear the extent to which the COVID- 19 pandemic (including future variants) will impact our business, results of operations, financial condition and our future strategic plans as future developments of the outbreak are highly uncertain and cannot be predicted. New information is constantly emerging concerning the severity of COVID- 19 and the actions to contain COVID- 19 or treat its impact, among others. As the COVID- 19 pandemic continues for an extended period of time, ~~and with~~ **any restrictions regarding** travel ~~,~~ **and** face to face interactions ~~, and~~ **or constraints on** resources ~~are not allowed or are severely limited~~ , either by us or our contractors, including our CMOs, **may negatively impact** our regulatory strategy ~~, BLA filing timelines,~~ or commercial launch preparations ~~may be negatively impacted~~ . The COVID- 19 pandemic may also impact the FDA and their ability to timely review our regulatory filings and conduct the pre- approval inspections necessary for ultimate approval of BLA. We cannot predict at this time whether and how FDA operations may be impacted at relevant times for our planned regulatory submissions. ~~63Our~~ **64Our** failure to comply with international data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. European Union, or EU, member states and other foreign jurisdictions, including Switzerland, the United Kingdom and Canada, have adopted data protection laws and regulations which impose significant compliance obligations on us. Moreover, the collection and use of personal health data in the EU, which was formerly governed by the provisions of the EU Data Protection Directive, was replaced with the EU General Data Protection Regulation, or the GDPR, in May 2018. The 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 GDPR also imposes strict rules on the transfer of personal data out of the EU to the U. S., provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to € 20 million or 4 % of the annual global revenues of the noncompliant company, whichever is greater. The GDPR requirements apply not only to third- party transactions, but also to transfers of information between us and our subsidiaries. The implementation of the GDPR has increased our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may in the future be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management' s attention and increase our cost of doing business. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. If we fail to comply with the data protection laws in any EU member country or other jurisdiction, the data protection authority of such country or other jurisdiction may, in addition to fines, impose sanctions on us, which may include a prohibition that prevents us from transferring and / or processing personal data of data subjects from such country or other jurisdiction for a duration determined by the sanctioning authority. Our inability to transfer and / or process personal data of data subjects could preclude us from conducting clinical trials of our products in the EU member country or other jurisdiction for the duration of the sanction. Our inability to conduct clinical trials in the EU member country or other jurisdiction for the duration of the sanction may delay and increase the cost of development of our products, with a material adverse effect on our business. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the U. S., the EU and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business. Our failure to comply with state and / or national data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. There are numerous other laws and legislative and regulatory initiatives at the federal and state levels addressing privacy and security concerns, and some state privacy laws apply more broadly than the Health Insurance Portability and Accountability Act, or HIPAA, and associated regulations. For example, California recently enacted legislation, the California Consumer Privacy Act, or CCPA, which went

into effect January 1, 2020, and was recently amended and expanded by the California Privacy Rights Act, or CPRA, which will take effect on January 1, 2023. The CCPA and CPRA, among other things, create new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also created a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for certain information collected as part of clinical trials as specified in the law, it may regulate or impact our processing of personal information depending on the context. It remains unclear what, if any, additional modifications will be made to the CPRA by the California legislature or how it will be interpreted. Therefore, the effects of the CCPA and CPRA are significant and will likely require us to modify our data processing practices and may cause us to incur substantial costs and expenses to comply. We will need to grow the size..... timely basis, or at all. If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks. We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including: ● increased operating expenses and cash requirements; ● the assumption of additional indebtedness or contingent liabilities; ● the issuance of our equity securities; **65** ● assimilation of operations, intellectual property and products of an acquired company or product, including difficulties associated with integrating new personnel; ● the diversion of our management' s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition; ● retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships; ● risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and ● our inability to generate revenue from acquired technology and / or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs. Depending on the size and nature of future strategic acquisitions, we may acquire assets or businesses that require us to raise additional capital or to operate or manage businesses in which we have limited experience. Making larger acquisitions that require us to raise additional capital to fund the acquisition will expose us to the risks associated with capital raising activities. Acquiring and thereafter operating larger new businesses will also increase our management, operating and reporting costs and burdens. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one- time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. In addition, even if we are able to pursue certain strategic acquisition opportunities, ~~65such as the anticipated acquisition of Proleukin ®,~~ we cannot guarantee that such acquisitions may completed in a timely manner, if at all, or that all conditions necessary to consummate such transactions will be satisfied, including the receipt of all required regulatory approvals. We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability, ~~an~~ ongoing military ~~conflict~~ **conflicts** between Russia and Ukraine ~~,~~ **and Israel and Hamas** and record inflation. Our business, financial condition and results of operations could be materially adversely affected by any negative impact on the global economy and capital markets resulting from the ~~conflict~~ **conflicts** in Ukraine **and the Middle East** , geopolitical tensions or record inflation. U. S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions and the start of the military conflict between Russia and Ukraine. On February 24, 2022, a full- scale military invasion of Ukraine by Russian troops was reported. Although the length and impact of the ongoing military conflict is highly unpredictable, the conflict in Ukraine could lead to market disruptions, including significant volatility in commodity prices, credit and capital markets, as well as supply chain interruptions, which has led to record inflation globally. We are continuing to monitor inflation, the situation in Ukraine and global capital markets and assessing the potential impacts on our business. The global economy has been, and may continue to be, negatively impacted by Russia' s invasion of Ukraine. As a result of Russia ~~'~~ **'** s invasion of Ukraine, the U. S., the European Union, the United Kingdom, and other G7 countries, among other countries, have imposed substantial financial and economic sanctions on certain industry sectors and parties in Russia. Broad restrictions on exports to Russia have also been imposed. These measures include: (i) comprehensive financial sanctions against major Russian banks; (ii) additional designations of Russian individuals with significant business interests and government connections; (iii) designations of individuals and entities involved in Russian military activities; and (iv) enhanced export controls and trade sanctions limiting Russia ~~'~~ **'** s ability to import various goods. Russian military actions and the resulting sanctions could continue to adversely affect the global economy and financial markets and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds. ~~Further~~ **In addition** , **on October 7, 2023, Hamas militants and members of** ~~there~~ **other terrorist organizations infiltrated Israel' s southern border from the Gaza Strip and conducted a series of terror attacks on civilian and military targets. Thereafter, Hamas launched extensive rocket attacks on Israeli population and industrial centers located along the Israeli border with the Gaza Strip. Shortly following the attack, Israel' s security cabinet declared war against Hamas and launched an aerial bombardment of various targets within the Gaza Strip. The Israeli government subsequently called for the evacuation of over one million residents of the northern part of the Gaza Strip and began a ground invasion of the Gaza Strip. It is possible that other terrorist and / or regional organizations will join the hostilities as well, including Hezbollah in Lebanon, and Palestinian military organizations in the West Bank, resulting in a widening of the conflict. The intensity and duration of Israel' s current war against Hamas is difficult to predict as** are **such war' s economic implications on the global economy. There are also** current geopolitical tensions with China. Recently, the Biden administration has signed multiple executive orders regarding China. One particular executive order titled Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, ~~Safe~~ **66Safe** , and Secure American Bioeconomy signed on

September 12, 2022 will likely impact the pharmaceutical industry to encourage U. S. domestic manufacturing of pharmaceutical products. **Moreover, there have been Congressional legislative proposals, such as the recent bill titled the Biosecure Act, to discourage contracting with Chinese companies on the development or manufacturing of pharmaceutical products.** Any additional executive ~~orders~~ **action, legislative action** or potential sanctions with China could materially impact our current manufacturing partners **and our agreements with them, including our MSA with WuXi. For example, in February 2024, the chair and ranking member of the House Select Committee on the Chinese Communist Party, Representatives Mike Gallagher and Raja Krishnamoorthi, respectively, along with Senators Gary Peters and Bill Haggerty sent a letter to the Biden administration requesting that both WuXi AppTec Co., Ltd., WuXi' s parent company, and the affiliated WuXi Biologics be added to the Department of Defense' s Chinese Military Companies List (1260H list), the Department of Commerce' s Bureau of Industry and Security Entity List, and the Department of Treasury' s Non- SDN Chinese Military- Industrial Complex Companies List. While the Biden administration has yet to take action on this letter, adding either or both previously mentioned WuXi entities on any or all of the aforementioned lists could materially impact our MSA with WuXi** . Although our business has not been materially impacted by the ongoing military ~~conflict~~ **conflicts** between ~~Russian~~ **Russia** and Ukraine **or Israel and Hamas** , geopolitical tensions, or record inflation to date, it is impossible to predict the extent to which our operations, or those of our suppliers and manufacturers, will be impacted in the short and long term, or the ways in which the conflict may impact our business. The extent and duration of the ~~conflict~~ **conflicts** in Ukraine **and the Middle East** , geopolitical tensions, record inflation, sanctions and resulting market disruptions are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described herein. We **are exposed** ~~may rely on third parties~~ to **fluctuations in currency exchange rates** ~~perform many essential services for any products~~ that **could negatively impact our financial results and cash flows. With the acquisition of Proleukin ® in May 2023, a portion of our business will be conducted outside the United States. Furthermore,** we ~~commercialize~~ **are required to make certain future payments under the Proleukin ® acquisition agreement that are denominated in non- US dollars** , including ~~services related~~ **a milestone payment** to **Clinigen upon** ~~distribution, government price reporting, customer service, accounts receivable management, cash collection, and adverse event reporting. If these~~ -- **the approval** ~~third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to commercialize our current or future product candidates will be significantly impacted and we may be subject to regulatory sanctions. We may retain third- party service providers to perform a variety~~ of **lifileucel in melanoma** ~~functions related to the sale and distribution of our current or future product candidates, key aspects of which will be out of our direct control. These service providers may provide key services related to distribution, customer service, accounts receivable management, and cash collection. If we retain a service provider, we would substantially rely on it~~ as well as **future deferred consideration and earnout payments based on Proleukin ® sales. As such, we face exposure to adverse movements in foreign currency exchange rates, including movements in foreign currency for** ~~other~~ -- **the** ~~third~~ **future milestone payment. These exposures may change over time as business practices evolve, and they could have a material adverse impact on our results of operations, financial position, and cash flows. Our primary exposure to movements in foreign currency exchange rates currently relates to non** - ~~party providers that perform services for us~~ **U. S. dollar denominated sales in Europe** , ~~including entrusting our inventories of products to their~~ -- **the** ~~care~~ **United Kingdom,** and **Asia, and non** ~~handling. If these third~~ - **U** ~~party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter physical or natural damage at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired and we may be subject to regulatory enforcement action~~ . **S** ~~In addition, we may engage third parties to perform various other services for us relating to adverse event reporting, safety database management, fulfillment of requests for medical information regarding our product candidates and related services~~ . **dollar denominated operating expenses** ~~If the quality or accuracy of the data maintained by these service providers is insufficient, or these third parties otherwise fail to comply with regulatory requirements related to adverse event reporting, we could be subject to regulatory sanctions. 66Additionally, we may contract with a third- party to calculate~~ and **certain assets** ~~report pricing information mandated by various government programs. If a third party fails to timely report or adjust prices as required or errs in calculating government pricing information from transactional data in our financial records, it could impact our discount~~ and ~~rebate liability~~ **liabilities in** ~~, and potentially subject us to regulatory sanctions or~~ **our operating subsidiaries** ~~False Claims Act lawsuits~~ . Climate change or legal, regulatory or market measures to address climate change may negatively affect our business, results of operations, cash flows and prospects. We believe that climate change has the potential to negatively affect our business and results of operations, cash flows and prospects. We are exposed to physical risks (such as extreme weather conditions or rising sea levels), risks in transitioning to a low- carbon economy (such as additional legal or regulatory requirements, changes in technology, market risk and reputational risk) and social and human effects (such as population dislocations and harm to health and well- being) associated with climate change. These risks can be either acute (short- term) or chronic (long- term). The adverse impacts of climate change include increased frequency and severity of natural disasters and extreme weather events such as hurricanes, tornados, wildfires (exacerbated by drought), flooding, and extreme heat. Extreme weather and sea- level rise pose physical risks to our facilities as well as those of our suppliers. Such risks include losses incurred as a result of physical damage to facilities, loss or spoilage of inventory, and business interruption caused by such natural disasters and extreme weather events. Other potential physical impacts due to climate change include reduced access to high- quality water in certain regions and the loss of biodiversity, which could impact future product development. These risks could disrupt our operations and ~~its~~ supply ~~chain~~ **chains** , which may result in increased costs. New legal or regulatory requirements may be enacted to prevent, mitigate, or adapt to the implications of a changing climate and its effects on the environment. These regulations, which may differ across jurisdictions, could result in us being subject to new or expanded carbon pricing or taxes, increased compliance costs, restrictions on greenhouse gas emissions, investment in new technologies, increased carbon disclosure and

transparency, upgrade of facilities to meet new building codes, and the redesign of utility systems, which could increase our operating costs, including the cost of electricity and energy used by us. Our supply chain would likely be subject to these same transitional risks and would likely pass along any increased costs to us. ~~Environmental~~ **67Environmental** , social and governance matters may impact our business and reputation. Governmental authorities, non- governmental organizations, customers, investors, external stakeholders and employees are increasingly sensitive to environmental, social and governance, or ESG, concerns, such as diversity and inclusion, climate change, water use, recyclability or recoverability of packaging, and plastic waste. This focus on ESG concerns may lead to new requirements that could result in increased costs associated with developing, manufacturing and distributing our products. Our ability to compete could also be affected by changing customer preferences and requirements, such as growing demand for more environmentally friendly products, packaging or supplier practices, or by failure to meet such customer expectations or demand. While we strive to improve our ESG performance, we risk negative stockholder reaction, including from proxy advisory services, as well as damage to our brand and reputation, if we do not act responsibly, or if we are perceived to not be acting responsibly in key ESG areas, including equitable access to medicines and vaccines, product quality and safety, diversity and inclusion, environmental stewardship, support for local communities, corporate governance and transparency, and addressing human capital factors in our operations. If we do not meet the ESG expectations of our investors, customers and other stakeholders, we could experience reduced demand for our products, loss of customers, and other negative impacts on our business and results of operations. Risks Related to Government ~~RegulationThe~~ **RegulationWe** ~~tax allocations,which may adversely affect our results of operations and financial position.We~~ are subject to extensive regulation,which can be costly,time consuming and can subject us to unanticipated delays;even **after** ~~if we obtain~~ **obtaining** regulatory approval for some of our products **and / or product candidates** ,those products **and / or product candidates** may still face regulatory difficulties.Our **products,** potential products,cell processing and manufacturing activities,are subject to comprehensive regulation by the FDA in the U.S.and by comparable authorities in other countries.The process of obtaining FDA and other required regulatory approvals,including foreign approvals,is expensive and often takes many years and can vary substantially based upon the type,complexity and novelty of the products involved.In addition,regulatory agencies may lack experience with our technologies and products,which may lengthen the regulatory review process,increase our development costs and delay or prevent their commercialization. ~~No~~ **Prior to Amtagvi ™,no** adoptive cell therapy using TIL ~~has~~ **had** been approved for marketing by the FDA.Consequently,there is no precedent for the successful commercialization of products based on our technologies.In addition,we have had only limited experience in filing and pursuing applications necessary to gain regulatory approvals,which may impede our ability to obtain timely FDA approvals,if at all.We have ~~initiated~~ **completed** the process for FDA approval for one adoptive cell therapy product.We will not be able to commercialize any of our potential products until we obtain FDA approval,and so any delay in obtaining,or inability to obtain,FDA approval would harm our business.If we fail to comply with regulatory requirements at any stage,whether before or after marketing approval is obtained,we may face a number of regulatory consequences,including refusal to approve pending applications,license suspension or revocation,withdrawal of an approval,imposition of a clinical hold or termination of clinical trials,warning letters,untitled letters,modification of promotional materials or labeling,provision of corrective information,imposition of post- market requirements **,** including the need for additional testing,imposition of distribution or other restrictions under a REMS,product recalls,product seizures or detentions,refusal to allow imports or exports,total or partial suspension of production or distribution,FDA debarment,injunctions,fines,consent decrees,corporate integrity agreements,debarment from receiving government contracts,and new orders under existing contracts,exclusion from participation in federal and state healthcare programs,restitution,disgorgement,or civil or criminal penalties,including fines and imprisonment,and adverse publicity,among other adverse consequences.Additionally,we may not be able to obtain the labeling claims necessary or desirable for the promotion of our products **or product candidates** .We may also be required to undertake post- marketing trials.In addition,if we or others identify side effects after any of our adoptive cell therapies are on the market,or if manufacturing problems occur,regulatory approval may be withdrawn,and reformulation of our products may be required. **The** ~~We may not be able~~ FDA regulatory approval process is lengthy and time- consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates. We **completed** ~~have recently commenced~~ our first submission of a rolling BLA to the FDA for lifileucel in ~~August~~ **March** ~~2022~~ **2023** ~~and expect to complete the~~ **. The FDA accepted our** BLA ~~submission~~ **for AmtagviTM for patients with advanced melanoma** in **May** ~~the first quarter of~~ 2023 **and granted lifileucel Priority Review. The FDA originally assigned November 25, 2023 as the target action date for a decision under PDUFA, however, the FDA recently reassigned February 24, 2024 as the revised target action date** . A BLA must include extensive preclinical and clinical data and supporting information to establish the product candidate' s safety and effectiveness for each desired indication. Our BLA ~~submission~~ **submissions** and ~~current~~ expected timelines for our ~~lifileucel~~ product ~~candidate~~ **candidates** ~~for the treatment of metastatic melanoma~~ are based on our interpretation of communications received from the FDA to date regarding ~~this~~ **each** product candidate and are ~~subject~~ **68subject** to revision if additional communications are received from the FDA. ~~67Following our End~~ **As such, we may experience delays with FDA approval** of ~~Phase~~ **additional BLAs. We have announced our intention to conduct registrational trials for both advanced NSCLC and cervical cancer with our LN- 145 and lifileucel product candidates, respectively. These trials, which we refer to as IOV- LUN- 202 Cohorts 1 and** 2 ~~meeting with the FDA~~ in **the case** ~~June 2019, we increased enrollment in Cohort 1~~ of ~~our ongoing~~ **advanced NSCLC and** C- 145- 04 ~~clinical trial of TIL therapy lifileucel to at least 75 patients of the appropriate population to address the expected sample size in anticipation of a BLA submission in 2021. Additionally, the patient population was defined per the discussion with FDA as patients who have progressed following initial systemic therapy for recurrent or metastatic disease which include many of the more advanced patients enrolled to date. In January 2021, we announced that~~ Cohort 2 ~~of~~ **in** the ~~C~~ **case of cervical cancer, are currently underway and have been the subject of formal FDA meetings and communications. For instance, on December 22, 2023, the FDA placed a clinical hold on the IOV- LUN- 202 trial in**

response to a recently reported Grade 5 (fatal) serious adverse event potentially related to the non- myeloablative lymphodepletion pre- conditioning regimen, and we have paused enrollment and the LN - 145 **treatment regimen for new patients in IOV** - ~~04~~ **LUN- 202 during the** clinical **hold** ~~trial had completed enrollment and that the landscape of care for cervical cancer patients had changed because of a recent FDA approval for pembrolizumab in the frontline cervical cancer setting. In August 2022 we announced that following FDA discussions and feedback on a registration strategy to address the shift in frontline standard of care, we reopened Cohort 2 of the ongoing C- 145- 04 clinical trial to enroll additional patients. The expanded Cohort 2 is intended to support a BLA submission in cervical cancer following progression on or after chemotherapy and PD- 1 therapy~~ . Our current beliefs regarding the registration pathway for the lifileucel **and LN- 145** product ~~candidate~~ **candidates** in **these indications** ~~metastatic cervical cancer~~ are based on our interpretation of communications with the FDA to date and our efforts to address such communications, which may be incorrect. Our statements that the clinical trial may support a BLA submission also assume that our as- adjusted clinical trial has addressed the additional requests and feedback by the FDA. Further, enrollment in ~~this~~ **these** clinical ~~trial~~ **trials** may need to be further adjusted based on future feedback from the FDA, changes in the competitive environment, or other regulatory agency input. Protocol revisions may have an adverse effect on the results reported to date. Changes to implement an independent review committee and assay validation and implementation, and the data within ~~this~~ **these** clinical ~~trial~~ **trials** may not ultimately be supportive of product approval, all of which could result in significant delays to our currently anticipated timeline for development and approval of lifileucel **and LN- 145** product ~~candidate~~ **candidates** or prevent ~~its~~ **their** approval ~~for the treatment of cervical cancer~~ . A BLA must also include significant information regarding the chemistry, manufacturing and controls for the product. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA has limited experience with commercial development of cell therapies for cancer. We may also not be able to successfully utilize the BTD ~~or RMAT designations~~ **designation** we have received for metastatic cervical cancer ~~and advanced melanoma, respectively,~~ to successfully complete the development and commercialization of ~~lifileucel~~ **AmtagviTM for such indication** . We may not be able to reach agreement with **the** FDA on an interpretation of outcomes from our meetings, including meetings we have held with **the** FDA in relation to our C- 145- 04 ~~and C- 144- 01~~ clinical ~~trials~~ **trial** and future meetings ~~. For example, on October 5, 2020, we reported the submission of additional potency assay data to the FDA, and at the same time, we also announced that we had reached agreement with the FDA on the minimum duration of follow up for Cohort 4 to support our BLA submission for lifileucel in the treatment of metastatic melanoma. In May 2021, we announced that we had received regulatory feedback from the FDA regarding our potency assays for lifileucel. Following FDA feedback, we continued our work developing and validating our potency assays and engaged in discussions with the FDA during the second half of 2021 and the first quarter of 2022. Based on the FDA feedback we received from these discussions, we held a pre- BLA meeting in July 2022, and initiated a rolling BLA for lifileucel in metastatic melanoma in August 2022, which we plan to complete in the first quarter of 2023~~ . In addition, as previously disclosed, Iovance ~~plans to open~~ **began startup activities for** a confirmatory Phase 3 clinical trial **, TILVANCE- 301,** of lifileucel in combination with pembrolizumab in frontline metastatic melanoma in late 2022. The FDA previously granted Fast Track Designation for lifileucel in combination with pembrolizumab for the treatment of immune checkpoint inhibitor naïve metastatic melanoma. However, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained. We may also experience delays, including delays arising from the need to increase enrollment, in completing planned clinical trials for a variety of reasons, including delays related to: ● the availability of financial resources to commence and complete the planned clinical trials; ● reaching agreement on acceptable contract terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites; ● obtaining approval at each clinical trial site by an independent IRB, or central IRB; ● recruiting suitable patients to participate in a clinical trial; ● having patients complete a clinical trial or return for post- treatment follow- up; ● clinical trial sites deviating from clinical trial protocol or dropping out of a clinical trial; ● adding new clinical trial sites; ● manufacturing sufficient quantities of qualified materials under ~~cGMPs~~ **cGMP** and applying them on a subject- by- subject basis for use in clinical trials; or ● timely implementing or validating changes to our manufacturing or quality control processes and methods needed to address FDA feedback. ~~68We~~ **We** could also encounter delays if there are unresolved ethical issues associated with physicians enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such clinical trials are being conducted by the FDA or other regulatory authorities, or recommended for suspension or termination by DSMBs due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, including as a result of genetic editing methods, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience ~~termination~~ **69termination** of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions. In order to market and sell our products outside the U. S., we or our third- party collaborators may be required to obtain **or maintain** separate marketing approvals and comply with numerous and varying regulatory requirements. Obtaining and maintaining regulatory approval of our 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. Approval policies and requirements may vary among jurisdictions. 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 U. S., including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U. S., 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 intend to charge for our products is also subject to approval. We or our collaborators may not be able to file for regulatory approval of our product candidates in international jurisdictions or obtain approvals from regulatory authorities outside the U. S. on a timely basis, if at all **. The FDA or other regulatory agencies may also withdraw approval for previously approved products** . We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the U. S. have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. 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 will be harmed. We are, and if we receive regulatory approval of our product candidates, will continue to 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 our product candidates. Any regulatory approvals that we receive for our product candidates will require ongoing surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS to approve our 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. The FDA may also require post-approval Phase 4 studies. Moreover, the FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may withdraw approval, require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product' s indicated uses or marketing, or impose ongoing requirements for potentially costly post- approval studies or post- market surveillance. Any such restrictions could limit sales of the product. In addition, we, our contractors, and our collaborators are and will remain responsible for FDA compliance, including requirements related to product design, testing, clinical trials and preclinical studies approval, manufacturing processes and quality, labeling, packaging, distribution, adverse event and deviation reporting, storage, advertising, marketing, promotion, sale, import, export, submissions of safety and other post- marketing information and reports such as deviation reports, establishment registration, product listing, annual user fees, and recordkeeping for our product candidates. ~~69We~~ **We** and any of our collaborators, including our contract manufacturers, could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with regulatory requirements. Application holders must further notify the FDA, and depending on the nature of the change, obtain FDA pre- approval for product and manufacturing changes. The cost of compliance with post- approval regulations may have a negative effect on our operating results and financial condition. ~~Later~~ **70Later** discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, that the product is less effective than previously thought, problems 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, distribution, or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls; ● restrictions on the labeling of our product candidates, including required additional warnings, such as black box warnings, contraindications, precautions, and restrictions on the approved indication or use; ● modifications to promotional pieces; ● changes to product labeling or the way the product is administered; ● liability for harm caused to patients or subjects; ● fines, restitution, disgorgement, warning letters, untitled letters, or holds on or termination of clinical trials; ● refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals; ● product seizure or detention, or refusal to permit the import or export of our product candidates; ● injunctions or the imposition of civil or criminal penalties, including imprisonment; ● FDA debarment, debarment from government contracts, and refusal of future orders under existing contracts, exclusion from federal healthcare programs, consent decrees, or corporate integrity agreements; ● regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the biologic; ● **FDA restrictions on manufacturing or distribution if there is an inability to trace the source of a problem due to the nature of cell therapy; ● withdrawal of regulatory approvals for the Proleukin ® product; ●** reputational harm; or ● the product becoming less competitive. Any of these events could further have other material and adverse effects on our operations and business and could adversely impact our stock price and could significantly harm our business, financial condition, results of operations, and prospects. 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 our 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 U. S. 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, be subject to other regulatory enforcement action, and we may not achieve or sustain profitability. If we fail to comply with federal and state healthcare and promotional laws, including fraud and abuse and information privacy and security laws, we could face substantial penalties and our business, financial condition, results of operations, and prospects

could be adversely affected. As a biopharmaceutical company, we are subject to many federal and state healthcare laws, including the federal AKS, the federal civil and criminal FCA, the civil monetary penalties statute, the Medicaid Drug Rebate statute and other price reporting requirements, the Veterans Health Care Act of 1992, the federal Health Insurance Portability and Accountability Act of 1996 (as amended by the Health Information Technology for Economics and Clinical Health Act), the Foreign Corrupt Practices Act of 1977, the Patient Protection and Affordable Care Act of 2010, and similar state laws. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid, or other third- party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. If we do not comply with all applicable fraud and abuse laws, we may be subject to enforcement by both the federal government and the states in which we conduct our business. Laws and regulations require calculation and reporting of complex pricing information for prescription drugs, and compliance will require us to invest in significant resources and develop a price reporting infrastructure or depend on third parties to compute and report our drug pricing. Pricing reported to CMS must be certified. Non- compliant activities expose us to FCA risk if they result in overcharging agencies, underpaying rebates to agencies, or causing agencies to overpay providers. ~~70If~~ **71If** we or our operations are found to be in violation of any federal or state healthcare law, or any other governmental regulations that apply to us, we may be subject to penalties, including civil, criminal, and administrative penalties, damages, fines, disgorgement, debarment from government contracts, refusal of orders under existing contracts, exclusion from participation in U. S. federal or state health care programs, corporate integrity agreements, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including but not limited to, exclusions from participation in government healthcare programs, which could also materially affect our business. In particular, if we are found to have impermissibly promoted any of our product candidates, we may become subject to significant liability and government fines. We, and any of our collaborators, must comply with requirements concerning advertising and promotion for any of our product candidates for which we or they obtain marketing approval. Promotional communications with respect to therapeutics are subject to a variety of legal and regulatory restrictions and continuing review by the FDA, Department of Justice, Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress, and the public. When the FDA or comparable foreign regulatory authorities issue regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product is approved. If we are not able to obtain FDA approval for desired uses or indications for our products and product candidates, we may not market or promote our products for those indications and uses, referred to as off- label uses, and our business may be adversely affected. We further must be able to sufficiently substantiate any claims that we make for our products including claims comparing our products to other companies' products and must abide by the FDA' s strict requirements regarding the content of promotion and advertising. While physicians may choose to prescribe products for uses that are not described in the product' s labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, we are prohibited from marketing and promoting the products for indications and uses that are not specifically approved by the FDA. These off- label uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the U. S. generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by biopharmaceutical companies concerning off- label use. The FDA and other agencies actively enforce the laws and regulations regarding product promotion, particularly those prohibiting the promotion of off- label uses, and a company that is found to have improperly promoted a product may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off- label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed. Thus, we and any of our collaborators will not be able to promote any products we develop for indications or uses for which they are not approved. In the U. S., engaging in the impermissible promotion of our products, following approval, for off- label uses can also subject us to false claims and other litigation under federal and state statutes, including fraud and abuse and consumer protection laws, which can lead to civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which we promote or distribute therapeutic products and do business through, for example, corporate integrity agreements, suspension or exclusion from participation in federal and state healthcare programs, and debarment from government contracts and refusal of future orders under existing contracts. These false claims statutes include the federal civil False Claims Act, which allows any individual to bring a lawsuit against a biopharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims or causing others to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. These False Claims Act lawsuits against manufacturers of drugs and biologics have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements, up to $ 3. 0 billion, pertaining to certain sales practices and promoting off- label uses. In addition, False Claims Act lawsuits may expose manufacturers to follow- on claims by private payors based on fraudulent marketing practices. This growth in litigation has increased the risk that a biopharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If we or our future collaborators do not lawfully promote our approved products, if any, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations and prospects. ~~71Although~~

72Although an effective compliance program can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with applicable federal and state fraud laws may prove costly. 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. Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates profitably. In both domestic and foreign markets, sales of our product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third- party payors. Such third- party payors include government health programs such as Medicare and Medicaid, managed care providers, private health insurers, and other organizations. In addition, because our product candidates represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from our product candidates. Patients who are provided medical treatment for their conditions generally rely on third- party payors to reimburse all or part of the costs associated with their treatment. Obtaining coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Government authorities and third- party payors decide which drugs and treatments they will cover and the amount of reimbursement. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. If reimbursement is not available, or is available only to limited levels, our product candidates may be competitively disadvantaged, and we, or our collaborators, may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us, or our collaborators, to establish or maintain a market share sufficient to realize a sufficient return on our or their investments. Alternatively, securing favorable reimbursement terms may require us to compromise pricing and prevent us from realizing an adequate margin over cost. 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. Obtaining coverage and reimbursement approval of a product from a government or other third- party payor is a time- consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co- payments that patients find unacceptably high. Moreover, the factors noted above have continued to be the focus of policy and regulatory debate that has, thus far, shown the potential for movement towards permanent policy changes; this trend is apt to continue, and may result in more or less favorable impacts on pricing. Patients are unlikely to use our product candidates unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our product candidates. In the U. S., 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. As a result, the coverage determination process is often a time- consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Prices paid for a drug also vary depending on the class of trade. Prices charged to government customers are subject to price controls, including ceilings, and private institutions obtain discounts through group purchasing organizations. Net prices for drugs may be further reduced by mandatory discounts or rebates required by government healthcare programs and demanded by private payors. It is also not uncommon for market conditions to warrant multiple discounts to different customers on the same unit, such as purchase discounts to institutional care providers and rebates to the health plans that pay them, which reduces the net realization on the original sale. ~~72In~~ **73In** addition, federal programs impose penalties on manufacturers of drugs marketed under an NDA or BLA, in the form of mandatory additional rebates and / or discounts if commercial prices increase at a rate greater than the Consumer Price Index- Urban, and these rebates and / or discounts, which can be substantial, may impact our ability to raise commercial prices. Regulatory authorities and third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability or that of our collaborators to sell our product candidates profitably. These payors may not view our products, if any, as cost- effective, and coverage and reimbursement may not be available to our customers, or those of our collaborators, or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. Cost control initiatives could cause us, or our collaborators, to decrease, discount, or rebate a portion of the price we, or they, might establish for products, which could result in lower than anticipated product revenues. If the realized prices for our products, if any, decrease or if governmental and other third- party payors do not provide adequate coverage or reimbursement, our prospects for revenue and profitability will suffer. Moreover, the recent and ongoing series of congressional hearings relating to drug pricing has presented heightened attention to the biopharmaceutical industry, creating the potential for political and public pressure, while the potential for resulting legislative or policy changes presents uncertainty. Assuming coverage is approved, the resulting reimbursement payment rates might not be adequate. If payors subject our product candidates to maximum payment amounts or impose limitations that make it difficult to obtain reimbursement, providers may choose to use therapies which are less expensive when compared to our product candidates. Additionally, if payors require high copayments, beneficiaries may decline prescriptions and seek alternative therapies. We may need to conduct post- marketing studies in order to demonstrate the cost- effectiveness of any future products to the satisfaction of hospitals and other target customers and their third- party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Our future products might not ultimately be considered cost- effective. Adequate third- party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development. Third- party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition,

third- party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. We, and our collaborators, cannot be sure that coverage will be available for any product candidate that we, or they, commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U. S. An inability to promptly obtain coverage and adequate payment rates from both government- funded and private payors for any our product candidates for which we obtain marketing approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition. There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. 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 our product candidates if we obtain regulatory approval; ● our ability to set a price that we believe is fair for our products; ● 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. 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. A particular challenge for our product candidates arises from the fact that they will primarily be used in an inpatient setting. Inpatient reimbursement generally relies on stringent packaging rules that may mean that there is no separate payment for our product candidates. Additionally, data used to set the payment rates for inpatient admissions is usually several years old and would not take into account all of the additional therapy costs associated with the administration of our product candidates. If special rules are not created for reimbursement for immunotherapy treatments such as our product candidates, hospitals might not receive enough reimbursement to cover their costs of treatment, which will have a negative effect on their adoption of our product candidates. ~~73We~~ **74We** are subject to new legislation, regulatory proposals, and healthcare payor initiatives that may increase our costs of compliance, and adversely affect our ability to market our products, obtain collaborators, and raise capital. In the U. S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities, and affect our ability, or the ability of our collaborators, to profitably sell any products for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or our collaborators, may receive for any approved products. Since enactment of the Patient Protection and Affordable Care Act, as amended ~~(~~ **, or** the ~~"~~ ACA **, ")** ~~in~~ 2010, in both the U. S. 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 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 on April 1, 2013, and were to remain in effect until 2024. The Bipartisan Budget Act of 2015 extended the 2 % sequestration to 2025. In January 2013, the American Taxpayer Relief Act of 2012, or ATRA, was approved which, among other things, reduced Medicare payments to several providers, with primary focus on the hospital outpatient setting and ancillary services, 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. On January 20, 2017, the ~~new~~ **Trump** administration signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices, and, for that reason, some final regulations have yet to take effect. In December 2017, Congress repealed the individual mandate for health insurance required by the ACA and could consider further legislation to repeal other elements of the ACA. At the end of 2017, CMS promulgated regulations that reduce the amount paid to hospitals for outpatient drugs purchased under the 340B program, and some states have enacted transparency laws requiring manufacturers to report information on drug prices and price increases. In June 2021, the Supreme Court issued its opinion in California v. Texas, upholding the constitutionality of the ACA. Additional federal and state healthcare reform measures may be adopted in the future that may result in more rigorous coverage criteria, increased regulatory burdens and operating costs, decreased net revenue from our pharmaceutical products, decreased potential returns from our development efforts, and additional downward pressure on the price that we receive for any approved drug. **There is also an increasing focus on the price of drugs, both at the state and federal levels, and it is likely that additional pricing controls will be enacted and could harm our business, financial condition and results of operations. For instance, states such as California have begun enacting transparency laws aimed at curbing drug price increases and with the change in administration it is possible that President Biden may issue executive orders with the potential to change a number of prior executive branch actions on drug pricing. We continue to monitor the potential impact of proposals and recently enacted legislation to lower prescription drug costs at the federal and state level. For example, the Inflation Reduction Act, or the IRA, was signed into law in August 2022 by President Biden, which makes significant changes to how drugs are covered and paid for under the Medicare program, including the creation of financial penalties for drugs whose prices rise faster than the rate of inflation, redesign of the Medicare Part D program to require manufacturers to bear more of the liability for certain drug benefits, and government price- setting for certain Medicare Part D drugs, starting in 2026, and Medicare Part B drugs starting in 2028. We are evaluating what effect, if any, the IRA may have on our business.** Any reduction in

reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. Legislative and regulatory proposals may also be made to expand post- approval requirements and restrict sales and promotional activities for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance, or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA' s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post- marketing testing and other requirements. In addition, there have been a number of other policy, legislative and regulatory proposals aimed at changing the pharmaceutical industry. The U. S. government, state legislatures and foreign governmental entities have shown significant interest in implementing cost containment programs to limit the growth of government- paid healthcare costs, including price controls, restrictions on reimbursement ~~and~~ **75and** coverage and requirements for substitution of generic products for branded prescription drugs. Adoption of government controls and measures and tightening of restrictive policies in jurisdictions with existing controls and measures, could exclude or limit our product candidates from coverage and limit payments for pharmaceuticals. ~~Under the Biden Administration' s Build Back Better Agenda, for example, Medicare negotiation of prescription drug costs with biopharmaceutical companies is proposed to lower prescription drug costs~~ We continue to monitor the potential impact of these and other proposals to lower prescription drug costs at the federal and state level. ~~74At~~ **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. We are unable to predict the future course of federal or state healthcare legislation in the U. S. directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The ACA and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations. Governments outside the U. S. tend to impose strict price controls, which may adversely affect our revenues, if any. In international markets, reimbursement and health care payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some countries, particularly the countries of the EU and the United Kingdom, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of our product candidate to other available therapies. There can be no assurance that our products will be considered cost- effective by third- party payors, that an adequate level of reimbursement will be available, or that the third- party payors' reimbursement policies will not adversely affect our ability to sell our products profitably. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially. Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and / or negligent conduct that fails to: comply with the laws of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the U. S. and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the U. S., our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission (s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. We have adopted a Code of Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct 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 comply with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our, or our employees', consultants', collaborators', contractors', or vendors' business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, compliance agreements, withdrawal of product approvals, and curtailment of our operations, among other things, any of which could ~~adversely~~ **76adversely** affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the U. S. will also likely subject us to

foreign equivalents of the healthcare laws mentioned above, among other foreign laws. ~~75Risks --~~ **Risks** Related to Our Intellectual PropertyWe may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, or lawsuits accusing our products of patent infringement, which could be expensive, time- consuming and unsuccessful. Competitors may infringe the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may be enjoined from manufacturing, use, and marketing our products, or may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Periodic maintenance fees on any issued patent are due to be paid to the U. S. Patent and Trademark Office, or USPTO, and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business. We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights. The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial. Some of our competitors may be better able to sustain the costs of complex patent litigation because they have substantially greater resources. If there is litigation against us, we may not be able to continue our operations. Should third parties file patent applications or be issued patents claiming technology also used or claimed by us, we may be required to participate in interference proceedings in the USPTO to determine priority of invention. We may be required to participate in interference proceedings involving our issued patents and pending applications. We may be required to cease using the technology or to license rights from prevailing third parties as a result of an unfavorable outcome in an interference proceeding. A prevailing party in that case may not offer us a license on commercially acceptable terms. Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO. If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and / or unenforceable. In patent litigation in the U. S., defendant counterclaims alleging invalidity and / or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the U. S. or abroad, even outside the context of litigation. Such mechanisms include re- examination, post grant review, and equivalent proceedings in foreign jurisdictions (e. g., opposition proceedings). For example, on November 24, 2021, an opposition proceeding was initiated in the European Patent Office against our European Patent No. 3601533 B1. This opposition proceeding, or any similar proceedings that may arise in the U. S. or foreign jurisdictions, could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant or third ~~party~~ **77party** were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business. ~~76If~~ **If** we are unable to protect our proprietary rights, we may not be able to compete effectively or operate profitably. Our success is dependent in part on maintaining and enforcing the patents and other proprietary rights that we have licensed and may develop, and on our ability to avoid infringing the proprietary rights of others. Certain of our intellectual property rights are licensed from another entity, and as such the preparation and prosecution of these patents and patent applications was not performed by us or under our control. Furthermore, patent law relating to the scope of claims in the biotechnology field in which we operate is still evolving and, consequently, patent positions in our industry may not be as strong as in other more well- established fields. The patent positions of biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. The issuance of a patent is not conclusive as to its validity or enforceability and it is uncertain how much protection, if any, will be given to the patents we have licensed from the NIH, Moffitt, or MDACC if any of these parties, or we, attempt to enforce the patents and / or if they are challenged in court or in other proceedings, such as oppositions, which may be brought in foreign jurisdictions to challenge the validity of a patent. A third party may challenge the validity or enforceability of a patent after its issuance by the Patent Office. It is possible that a competitor may successfully challenge our patents or that a challenge will result in limiting their coverage. Moreover, the cost of litigation to uphold the validity of patents and to prevent infringement can be substantial. If the outcome of litigation is adverse to us, third parties may be able to use our patented invention without payment to us. Moreover, it is possible that competitors may infringe our patents or successfully avoid the patented technology through design innovation. To stop these activities, we may need to file a lawsuit. These lawsuits

are expensive and would consume time and other resources, even if we were successful in stopping the violation of our patent rights. In addition, there is a risk that a court would decide that our patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of our patents were upheld, a court would refuse to stop the other party on the grounds that its activities are not covered by, that is, do not infringe, our patents. Should third parties file patent applications, or be issued patents claiming technology also used or claimed by our licensor (s) or by us in any future patent application, we may be required to participate in interference proceedings in the USPTO to determine priority of invention for those patents or patent applications that are subject to the first- to- invent law in the U. S., or may be required to participate in derivation proceedings in the USPTO for those patents or patent applications that are subject to the first- inventor- to- file law in the U. S. We may be required to participate in such interference or derivation proceedings involving our issued patents and pending applications. We may be required to cease using the technology or to license rights from prevailing third parties as a result of an unfavorable outcome in an interference proceeding or derivation proceeding. A prevailing party in that case may not offer us a license on commercially acceptable terms. We cannot prevent other companies from licensing most of the same intellectual properties that we have licensed or from otherwise duplicating our business model and operations. Certain intellectual properties that we are using to develop TIL- based cancer therapy products were licensed to us by the NIH. The issued or pending patents that the NIH licensed to us are exclusive, and specific with respect to melanoma, breast, HPV- associated, bladder and lung cancers. No assurance can be given that the NIH has not previously licensed, or that the NIH hereafter will not license to other biotechnology companies some or all of the non- exclusive technologies available to us under the NIH License Agreement. In addition, one pending U. S. patent application in the NIH License Agreement is not owned solely by the NIH. No assurance can be given that NIH' s co- owner of the certain pending U. S. patent application in the NIH License Agreement has not previously licensed, or that the co- owner thereafter will not license, to other biotechnology companies some or all of the technologies available to us. Co- ownership of these intellectual properties will create issues with respect to our ability to enforce the intellectual property rights in courts and will create issues with respect to the accountability of one entity with respect to the other. Since the NCI, Moffitt, MDACC, and others already use TIL **cell** therapy for the treatment of metastatic melanoma and other indications, their methods and data are also available to third parties, who may want to enter into our line of business and compete against us. Other than the Gen 2 manufacturing process, we currently do not own any exclusive rights on our entire product portfolio that could be used to prevent third parties from duplicating our business plan or from otherwise directly competing against us. While additional technologies that may be developed under our CRADA may be licensed to us on an exclusive basis, no assurance can be given that our existing exclusive rights and will be sufficient to prevent others from competing with us and developing substantially similar products. ~~77The~~ **78The** use of our technologies could potentially conflict with the rights of others. Our potential competitors or others may have or acquire patent rights that they could enforce against us. If they do so, then we may be required to alter our products, pay licensing fees or cease activities. If our products conflict with patent rights of others, third parties could bring legal actions against us or our collaborators, licensees, suppliers or customers, claiming damages and seeking to enjoin manufacturing, use and marketing of the affected products. If these legal actions are successful, in addition to any potential liability for damages (including treble damages and attorneys' fees for willful infringement), we could be required to obtain a license to continue manufacturing, promoting the use or marketing the affected products. We may not prevail in any legal action and a required license under the patent may not be available on acceptable terms or at all. We have conducted ~~an~~ extensive freedom- to- operate, or FTO, analyses of the patent landscape with respect to our lead product candidates. Although we continue to undertake FTO analyses of our manufacturing processes, our lead TIL products, and contemplated future processes and products, because patent applications do not publish for 18 months, and because the claims of patent applications can change over time, no FTO analysis can be considered exhaustive. Furthermore, patent and other intellectual property rights in biotechnology remains an evolving area with many risks and uncertainties. As such, we may not be able to ensure that we can market our product candidates without conflict with the rights of others. Changes in U. S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products. As is the case with other cell therapy and biopharmaceutical companies, our success is dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry ~~involve~~ **involves** both technological and legal complexity, and is therefore costly, time- consuming and inherently uncertain. In addition, the U. S. has recently enacted and is currently implementing wide- ranging patent reform legislation. Recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U. S. Congress or the USPTO may impact the value of our patents. We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world. We have limited intellectual property rights outside the U. S. 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 U. S. can be less extensive than those in the U. S. 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 U. S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U. S., or from selling or importing products made using our inventions in and into the U. S. 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 U. S. 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, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, 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. ~~78We~~ **79We** may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties. We have received confidential and proprietary information from third parties and our employees and contractors. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against or pursue these claims. For example, we are currently engaged in litigation involving counterclaims that we have brought relating to theft of certain of our trade secrets, breach of confidentiality, and related counterclaims. Even if we are successful in resolving these claims, litigation could result in substantial ~~cost~~ **costs** and be a distraction to our management and employees. Risks Related to Our SecuritiesOur officers, directors and principal stockholders own a substantial percentage of our stock and will be able to exert significant control over matters subject to stockholder approval. Our officers, directors, and principal stockholders currently beneficially own a substantial portion of our outstanding voting stock. Therefore, these stockholders have the ability and may continue to have the ability to influence our corporate decision making. Given current ownership levels, these stockholders may be able to determine some or all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control or influence elections of directors, amendments to our certificate of incorporation or bylaws, or approval of any merger, sale of assets, or other major corporate transaction. This level of control may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders. Our stock price may be volatile, and our stockholders' investment in our stock could decline in value. The market price of our common stock is likely to be volatile and could fluctuate widely in response to many factors, including but not limited to: ● volatility and instability in the capital markets due to the COVID- 19 pandemic; ● announcements of the results of clinical trials by us, our collaborators, or our competitors, or negative developments with respect to similar products, including those being developed by our collaborators; ● developments with respect to patents or proprietary rights; ● announcements of technological innovations by us or our competitors; ● announcements of new products or new contracts by us or our competitors; ● actual or anticipated variations in our operating results due to the level of development expenses and other factors; ● changes in financial estimates by equities research analysts and whether our earnings meet or exceed such estimates; ● conditions and trends in the pharmaceutical, biotechnology and other industries; ● receipt, or lack of receipt, of funding in support of conducing our business; ● regulatory developments within, and outside of, the U. S.; ● litigation or arbitration; ● general volatility in the financial markets; ● general economic, political and market conditions and other factors; and ● the occurrence of any of the risks described in this Annual Report on Form 10- K. You may experience future dilution as a result of future equity offerings or other equity issuances. We may have to raise additional capital in the future. To raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may be lower than the current price per share of our common stock. In addition, investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by investors in prior offerings. Any such issuance could result in substantial dilution to our existing stockholders. ~~79Future~~ **80Future** sales of our common stock in the public market could cause our stock price to fall. Our stock price could decline as a result of sales of a large number of shares of our common stock or the perception that these sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. As of December 31, ~~2022~~ **2023**, we had ~~187~~ **256**, ~~812~~ **135**, ~~072~~ **715** shares of common stock outstanding. In addition, we had ~~20~~ **25**, ~~876~~ **589**, ~~978~~ **659** shares of common stock equivalents that would increase the number of common stock outstanding if these instruments were exercised or converted to purchase common stock based on vesting requirements of stock options and common stock issuable through purchases of employee stock purchase plan, or upon the conversion of preferred stock. The issuance and subsequent sale of the shares underlying these common stock equivalents could depress the trading price of our common stock. On June 10, 2019, our certificate of incorporation was amended to increase the number of authorized shares of our common stock, ~~par value $ 0. 000041666,~~ from 150, 000, 000 shares to 300, 000, 000 shares, which was approved by our stockholders on that date **. On June 16, 2023, our certificate of incorporation was amended to increase the number of authorized shares of our common stock from 300, 000, 000 to 500, 000, 000 shares, which amendment was approved by our stockholders on June 6, 2023**. In addition, in the future, we may issue additional shares of common stock or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. For example, in ~~June~~ **July** ~~2020~~ **2023**, we issued ~~19~~ **23**, ~~475~~ **000**, ~~806~~ **000** shares of common stock in connection with an underwritten public offering, and we may offer additional shares under our automatic shelf registration statement in the future. Future issuances may result in substantial dilution to our existing

stockholders and could cause our stock price to decline. If equities or industry analysts do not publish research or reports about our company, or if they issue adverse or misleading opinions regarding us or our stock, our stock price and trading volume could decline. Although we have research coverage by equities analysts, if coverage is not maintained, the market price for our stock may be adversely affected. Our stock price also may decline if any analyst who covers us issues an adverse or erroneous opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet analysts' expectations. If one or more analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline and possibly adversely affect our ability to engage in future financings. 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. As a result, we could become subject to sanctions or investigations by regulatory authorities and / or stockholder litigation, which could harm our business and have an adverse effect on our stock price. As a public reporting company, we are subject to various regulatory requirements, including the Sarbanes- Oxley Act of 2002, which requires our management to assess and report on our internal controls over financial reporting. Nevertheless, in future years, our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls that we would be required to remediate in a timely manner to be able to comply with the requirements of Section 404 of the Sarbanes- Oxley Act each year. If we are not able to comply with the requirements of Section 404 of the Sarbanes- Oxley Act each year, we could be subject to sanctions or investigations by the SEC, Nasdaq or other regulatory authorities which would require additional financial and management resources and could adversely affect the market price of our common stock. In addition, material weaknesses in our internal controls could result in a loss of investor confidence in our financial reports. We are, and in the future may be, subject to federal or state securities or related legal actions that could adversely affect our results of operations and our business. Federal and state securities and related legal actions may result in substantial costs and divert our management' s attention from other business concerns, which could seriously harm our business or affect our reputation. We may not be successful in defending future claims and cannot provide assurance that insurance proceeds will be sufficient to cover any costs or liability under such claims. For example, on December 11, 2020, a purported stockholder derivative complaint was filed by plaintiff Leo Shumacher against us, as nominal defendant, and then current directors, as defendants, in the Court of Chancery in the State of Delaware ~~(~~**, or** the ~~"~~Court ~~")~~. The complaint alleges breach of fiduciary duty and a claim for unjust enrichment in connection with alleged excessive compensation of certain of our non- executive directors and seeks unspecified damages on behalf of our company. The parties have agreed to a proposed ~~settlement~~ **81settlement** , which was submitted to the Court on June 15, 2022. The parties continue to work toward settlement ~~80after~~ -- **after** a hearing on November 17, 2022, where the Court required additional steps to be taken by the parties before it will determine whether final approval will be given to the settlement. The outcome of this and other future litigation is uncertain. Our Board of Directors could issue one or more additional series of preferred stock without stockholder approval with the effect of diluting existing stockholders and impairing their voting and other rights. Our certificate of incorporation, as amended, authorizes the issuance of up to 50, 000, 000 shares of " blank check " preferred stock (of which only 17, 000 shares were issued as Series A Convertible Preferred Stock and 11, 500, 000 shares were issued as Series B Convertible Preferred Stock) with designations, rights and preferences as may be determined from time to time by our Board of Directors. Our Board of Directors is empowered, without stockholder approval, to issue one or more series of preferred stock with dividend, liquidation, conversion, voting or other rights which could dilute the interest of, or impair the voting power of, our common stockholders. The issuance of a series of preferred stock could be used as a method of discouraging, delaying or preventing a change in control. For example, it would be possible for our Board of Directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to effect a change in control of our company. We do not anticipate paying cash dividends for the foreseeable future, and therefore investors should not buy our stock if they wish to receive cash dividends. We have never declared or paid any cash dividends or distributions on our common stock. We currently intend to retain our future earnings to support operations and to finance expansion and, therefore, we do not anticipate paying any cash dividends on our common stock in the foreseeable future. Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result. There are provisions in our certificate of incorporation, as amended, and amended and restated bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change in control was considered favorable by you and other stockholders. For example, our Board of Directors has the authority to issue up to 38, 483, 000 additional shares of preferred stock and to fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change in control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders. In addition, we are subject to the anti- takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock. Our certificate of incorporation, as amended, designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our certificate of incorporation, as amended, provides that, subject to limited exceptions, the Court of Chancery of the State of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for (1)

any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or agents to us or our stockholders, creditors or other constituents, (3) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation, as amended, or our amended bylaws, or (4) any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our certificate of incorporation described above. This choice of forum provision may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage such lawsuits against us and our directors, officers, and employees. Further, this choice of forum provision does not preclude or contract the scope of exclusive **82** ~~federal or concurrent jurisdiction for any actions brought under the Securities Act or the Exchange Act. Section 27 81~~