Risk Factors Comparison 2025-03-04 to 2024-03-21 Form: 10-K

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

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward- looking statements we have made in this Annual Report on Form 10- K and those we may make from time to time. You should carefully consider the risks described below, in addition to the other information contained in this Annual Report on Form 10- K and our other public filings. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations. Risks Associated with Our Business Our business is subject to a number of risks of which you should be aware before making a decision to invest in our common stock. These risks are more fully described in this " Risk Factors " section, including the following: • We have incurred significant losses since our inception. We expect to incur losses ~~over~~ **for** the **foreseeable future** ~~next several years~~ and may never achieve or maintain profitability. • We have a limited operating history and no history of completing any clinical trial or commercializing **any** ~~products~~ **product**, which may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability. • We will need substantial additional funding to meet our financial obligations and to pursue our business objectives **, including the clinical development of AXN- 2510 / IMM2510**. If we are unable to raise capital when needed, we could be forced to delay further development of our ~~technologies or~~ product candidates **, including AXN- 2510 / IMM2510,** or ~~to~~ curtail our planned operations and the pursuit of our growth strategy. • ~~All of~~ **Our lead product candidate, AXN- 2510 / IMM2510, as well as** our **other** product candidates **,** are currently in **early- stage** ~~preclinical~~ --- **clinical** development ~~and potential investigator- initiated clinical stage~~. If we are unable to successfully develop, receive regulatory approval for and commercialize **AXN- 2510 / IMM2510,** ~~our~~ **or successfully develop any other** product candidates ~~for the indications we seek~~, or experience significant delays in doing so, our business will be harmed ~~. • Because our Collaboration Product and any future product candidates developed from our CoStAR platform represent novel approaches to the treatment of disease, there are many uncertainties regarding the development, market acceptance, third- party reimbursement coverage and commercial potential of our product candidates. • We do not currently have any active clinical trials. We may derive results for our Collaboration Product from open- label investigator- initiated trials led by our collaborator in China. IITs are conducted by principal investigators; our role in the trials and access to the clinical results and data are limited and there is no assurance that the clinical data from our collaborator- led IITs will be accepted or considered by the FDA, or other comparable regulatory authorities~~. • The regulatory approval processes of the **U. S. Food and Drug Administration, or** FDA, **Medicines and Healthcare Products Regulatory Agency, or** MHRA, **European Medicines Agency, or** EMA, and comparable foreign authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain required regulatory approval for our product candidates, our business will be substantially harmed. • Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials. Our product candidates may not have favorable results in **later** clinical trials, if any, or receive regulatory approval ~~. • Negative public opinion of TIL therapies, the dynamically evolving competitive landscape for our target indications or increased regulatory scrutiny of cell therapy using TILs may adversely impact the development of and commercial strategy for our product candidates, our plans for investing in manufacturing readiness for regulatory filings and the success of our current and future product candidates. • As an organization, we are early in the process of potentially conducting our first collaborator- led IITs and have no prior experience in a similar collaboration, in conducting IITs in China, or in completing clinical trials, and may be unable to complete clinical trials for any product candidates we may develop, including our Collaboration Product. • We may not be successful in our efforts to build a pipeline of additional product candidates either internally or by identifying and licensing- in or otherwise acquiring novel product candidates on commercially attractive terms~~. • Biologics are complex and difficult to manufacture. We ~~have experienced~~ **intend to rely on ImmuneOnco Biopharmaceuticals (Shanghai) Inc.** , **or ImmuneOnco** ~~and may in the future experience~~ , **in China to** ~~manufacturing~~ **manufacture** ~~problems that result in delays in~~ **clinical supplies of AXN- 2510 / IMM2510, and to produce preclinical and clinical supply of** ~~the~~ **other** ~~development or commercialization of our~~ product candidates **and we intend to rely** ~~or otherwise harm our business. We may experience new manufacturing challenges by relying~~ on ~~collaborators or other~~ third parties **to produce commercial supplies of any approved product. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates** ~~for~~ **or** ~~manufacturing capabilities~~ **any approved products or such quantities at** ~~and~~ **an** ~~expertise~~ **acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts**. • **We have, and we may in the future, engage in strategic transactions to acquire or in- license additional new product candidates or technologies, and we may not be successful in developing and commercializing any product candidates we acquire or in- license, including AXN- 2510 / IMM2510. The licensing or acquisition of third- party intellectual property rights is competitive, and if we are unable to identify suitable candidates for such transactions on a timely basis or on commercially reasonable terms, it would negatively impact our ability to develop and commercialize product candidates and present significant distractions to our management.** The treatable populations for our product candidates may be smaller than we or third parties currently project, which may affect the addressable markets for our product candidates. • We face significant competition from other biotechnology and pharmaceutical companies **,** and from non- profit institutions, **which may** ~~and our operating results~~ **result** ~~will suffer if~~ **in others discovering, developing or commercializing products before or more successfully than** we **do** ~~fail to compete effectively~~. • If we **or our licensors** are unable to obtain ~~or~~ **and maintain sufficient patent** ~~protect~~ **protection for**

~~intellectual property rights related to any of~~ our product candidates, ~~we may~~ **or if the scope of the patent protection is** not ~~be able~~ **sufficiently broad, third parties, including our competitors, could develop and commercialize products similar or identical** to ~~compete effectively in our~~ **ours** ~~market~~ **, and our ability to commercialize our product candidates may be adversely affected** . • Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain. • We are subject to a variety of stringent and evolving U. S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and data security, and our actual or perceived failure to comply with them could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits and other adverse business consequences. Risks Related to our Financial Position and Capital Needs Since our inception, we have incurred significant net losses, and we expect to continue to incur significant expenses and operating losses for the foreseeable future. Our net losses were $ ~~156~~ **74** . 1 million and $ ~~223~~ **156** . ~~2~~ **1** million for the years ended December 31, **2024 and** 2023 ~~and 2022~~ , respectively. As of December 31, ~~2023~~ **2024** , we had an accumulated deficit of $ ~~581~~ **655** . ~~0~~ **1** million. We have financed our operations with $ 719. 0 million in net proceeds raised in our initial public offering and private placements of convertible preferred stock to date ~~, as well as $ 82. 8 million from our construction loan~~ . We have no products approved for commercialization and have never generated any revenue from product sales. All of our product candidates are in preclinical development **or early** ~~and potential investigator- initiated~~ **stage** clinical ~~stage~~ **development** . We expect to continue to incur significant expenses and operating losses over the next several years. We expect that it could be ~~several~~ **many** years, if ever, before we have a commercialized product. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will continue to be significant as we: • pursue ~~our~~ **clinical development of AXN- 2510 / IMM2510 and undertake other development efforts pursuant to the license and** collaboration ~~and~~ **agreement with ImmuneOnco, or IO Collaboration Agreement; •** seek to potentially license- in or otherwise acquire **additional** new product candidates, as well as potentially initiate and complete clinical trials of **new** product candidates ~~; • continue to advance the preclinical and clinical development of product candidates and our preclinical and discovery programs, including in our CoStAR platform~~ ; • seek regulatory approval for any product candidates that successfully complete clinical trials; • ~~continue to develop our product candidate pipeline; •~~ scale up our clinical and regulatory capabilities; • rely on collaborators or other third parties to manufacture current good manufacturing practices, or cGMP, material for clinical trials or potential commercial sales; • establish a commercialization infrastructure and **develop** ~~scale up~~ internal and external manufacturing and distribution capabilities to commercialize any product candidates for which we may obtain regulatory approval; • adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products; • maintain, expand and protect our intellectual property portfolio; • hire clinical, manufacturing quality control, regulatory, manufacturing and scientific and administrative personnel; • add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and • incur legal, accounting and other expenses in operating as a public company. To date, we have not generated any revenue from product sales. To become and remain profitable, we must succeed in developing and eventually commercializing product candidates that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, obtaining regulatory approval, and manufacturing, marketing and selling any product candidates for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We are only in the preliminary stages of most of these activities and all of our product candidates are in early **-** stage development. We may never succeed in these activities and, even if we do, may never generate any revenue or revenue that is significant enough to achieve profitability. Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain product approvals, diversify our offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment. We are a biopharmaceutical company with a limited operating history. ~~We~~ **Since we** commenced operations in 2019 ~~, and our operations to date have been largely focused on organizing and staffing our company, business planning, raising capital, acquiring our technology and product candidates, acquiring our facilities in Tarzana, California, developing manufacturing capabilities and developing product candidates, including undertaking preclinical studies and initiating clinical trials which were subsequently discontinued. To date~~ , we have not yet demonstrated our ability to successfully complete any clinical trials, obtain regulatory approvals, manufacture a product on a commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. For example, **from late 2022 through 2024,** we implemented several strategic reprioritizations **and restructurings** of our preclinical and clinical development programs and elected to discontinue our ~~ITIL-~~ **TIL** ~~-168~~ development program and our ITIL- 168 and ITIL- 306 clinical trials. As part of these various restructurings, we **have significantly** reduced our ~~U. S.~~ workforce ~~to a team of approximately 15 to lead global business operations, and are in the process of reducing our UK workforce by approximately 61 %~~ . We may experience unforeseen delays or other challenges ~~in implementing our most recent restructuring~~ **as a result of these actions** , which could adversely impact our timelines and operations and, ultimately, our ability to develop product candidates for potential commercialization. We will need to develop clinical, manufacturing, regulatory and commercial capabilities, and we may not be successful in doing so ~~. We will need substantial additional funding to meet our financial obligations and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to delay further development of our technologies or product candidates or curtail our planned operations and the pursuit of our growth strategy~~ . Our operations have consumed substantial amounts of cash since inception. **Developing our in-**

licensed product candidates, including AXN- 2510 / IMM2510, ~~Identifying~~ **identifying** and **potentially** acquiring ~~potential~~ **or in- licensing additional** new product candidates, conducting preclinical testing and clinical trials and developing manufacturing operations for our product candidates is a time- consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. We expect to continue to incur significant expenses and operating losses over the next several years as we conduct clinical trials of our product candidates, **seek to potentially license- in or otherwise acquire additional new product candidates,** initiate future clinical trials of our product candidates, advance our preclinical programs, build our manufacturing capabilities, **and** seek marketing approval for any product candidates that successfully complete clinical trials ~~and advance any of our other product candidates we may develop or otherwise acquire~~ . In addition, our product candidates, if approved, may not achieve commercial success. Our revenue, if any, will be derived from sales of products that we do not expect to be commercially available for a number of years, if at all. If we obtain marketing approval for any product candidates that we develop or otherwise acquire, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. We also expect to continue to incur significant expenses associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to continue our operations. As of December 31, ~~2023~~ **2024** , we had cash, cash equivalents, restricted cash and marketable securities of $ ~~175~~ **115** . ~~0~~ **1** million, which consists of $ ~~9~~ **8** . ~~2~~ **8** million in cash and cash equivalents, $ 1. **8 million of restricted cash and $ 104.** 5 million in ~~restricted cash, $ 141. 2 million in~~ marketable securities ~~and $ 23. 2 million in long- term investments~~ . We believe that our existing cash, cash equivalents **and** ~~, restricted cash,~~ marketable securities ~~and long- term investments~~ will be sufficient to fund our operating expenses and capital requirements beyond 2026. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect ~~. For instance, we may not achieve all the expected cost savings of our current strategic restructuring plan, and we may expend more capital than expected in connection with the 2024 closure of our UK manufacturing and clinical trial operations~~ . Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our development activities, acquisitions of additional product candidates, and changes in regulation. Our future capital requirements will depend on many factors, including: • the scope, progress, ~~costs~~ **cost** and results of ~~our collaborator~~ **clinical development of AXN - 2510 / IMM2510 outside of China** ~~led investigator- initiated trials, or IITs, and discovery, preclinical development, laboratory testing and related activities for our product candidates~~ ; • the **scope, progress, cost and results of our collaboration with ImmuneOnco in China; • the** extent to which we develop, in- license or otherwise acquire ~~other~~ **additional** product candidates and technologies for our product candidate pipeline; • ~~our ability to achieve efficiencies and expected cost reductions in connection with our recent strategic restructuring plans; • the costs and timing of process development and manufacturing scale- up activities associated with our product candidates and other programs as we advance them through preclinical and clinical development; •~~ the number and development requirements of product candidates that we may pursue; • our ability to complete a potential sale ~~or lease~~ of our Tarzana, California facility ~~, as well as subleases of other facilities under lease~~ ; • the costs, timing and outcome of regulatory review of our product candidates; • our cost of human capital as we expand our ~~research and development~~ capabilities ~~and establish a commercial infrastructure~~ ; • the costs and timing of future commercialization activities, including product manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive marketing approval ~~; • the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property- related claims~~ ; • the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval; and • the costs of operating as a public company. We will require additional capital to achieve our business objectives. Additional funds may not be available on a timely basis, on favorable terms, or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long- term business strategy. Further, our ability to raise additional capital may be adversely impacted by worsening global economic conditions and the disruptions to and volatility in the credit and financial markets in the United States and worldwide, including those resulting from the ongoing armed conflicts in Ukraine, and in the Middle East, U. S.- China trade and political tensions, heightened inflation and **fluctuations in** interest ~~rate~~ **rates** ~~increases~~ , recent and potential future bank failures and supply chain disruptions, among other geopolitical and macroeconomic factors. If we are unable to raise sufficient additional capital, we could be forced to delay further development of our technologies or product candidates or curtail our planned operations and the pursuit of our growth strategy. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to technologies or product candidates. **We will need to raise additional capital to support our operations and execute on our business strategy.** Until such time, if ever, as we can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, government or private party grants, debt financings or license and collaboration agreements ~~. Other than our construction loans for the construction and development of our manufacturing facility in Tarzana, California, we do not currently have any other committed external source of funds~~ . 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 of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. For example, the agreements governing our construction loans contain certain affirmative and negative covenants, including maintaining a specified minimum net worth and amount of liquid assets, which could limit our operations. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams or product candidates, grant licenses on terms that may not be favorable to us or commit to future payment streams. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or

future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. We have suffered and in the future could suffer additional losses due to impairment charges, including **if we are** ~~as a result of being~~ unsuccessful in completing a sale ~~or lease~~ of our Tarzana, California manufacturing facility, or, if we are successful, the assets being sold for less than our carrying value. To date, we have recorded significant impairment losses on long- lived assets ~~associated with a sustained decrease in our stock price and the restructuring plan implemented in December 2022 and an extended restructuring plan executed in the first quarter of 2023, for a strategic prioritization of our preclinical and clinical development programs~~. ~~In addition~~ **Most recently**, ~~during~~ **in the** year ended December 31, ~~2023~~ **2024**, ~~due to downward revisions in our internal forecasts made during the year, including future expected cash flows, we determined there were indicators of impairment on our buildings and construction work- in- progress asset groups. As a result, in the year ended December 31, 2023~~, we recorded aggregate ~~restructuring and~~ impairment charges of approximately $ ~~72~~ **7**. ~~0~~ **5** million related to ~~contract termination, asset impairments, severance payments and other employee- related costs. This amount includes our Tarzana, California manufacturing facility that we identified and classified as held for sale, which is reflected at the lower of carrying value or~~ **our** ~~fair value less costs to sell, which resulted in $ 16. 3 million in impairment charges. We also determined that right- of- use assets were impaired, as the~~ restructuring ~~plan~~ **plans** ~~has resulted in a cessation of use for several of our locations under lease, and we recognized an impairment loss of $ 7. 7 million. We currently estimate that we will incur additional charges of up to $ 6. 1 million in connection with the 2024 Plan (as defined and discussed in Note 12 to the financial statements included elsewhere in this Form 10- K), although this estimated amount does not include any non- cash charges associated with stock- based compensation or any charges or costs associated with any potential sale of our Tarzana, California facility and asset impairments, if any. The charges that we currently estimate incurring in connection with the restructuring plan are estimates only and are subject to a number of assumptions, and actual results may differ materially, and we may incur additional costs associated with the restructuring plan~~. We are evaluating opportunities for a potential sale ~~or lease~~ of our Tarzana, California manufacturing site, **which effective July 10, 2024** ~~as~~ **has been** ~~well as subleases of other facilities currently under lease~~ **leased to AstraZeneca Pharmaceuticals LP**; however, we can provide no assurances that we will successfully sell ~~or lease~~ our Tarzana facility ~~or enter into subleases of our other facilities~~, that we will do so in accordance with our expected timeline or that we will recover ~~their~~ **its** carrying value. The process of pursuing the plan to sell ~~, lease or~~ **our Tarzana** ~~sublease these facilities~~ **facility** may be time consuming and disruptive to our business operations, and if we are unable to effectively manage the process, our businesses, financial condition, and results of operations could be adversely affected ~~and may result in additional non- cash impairment charges~~. Any potential transactions, and the related ~~valuations~~ **valuation**, would be dependent upon various external factors beyond our control, including, among others, market conditions, industry trends, interest of third parties, and the availability of financing to potential buyer (s) on reasonable terms. ~~Such impairments or losses have in the past and could in the future materially affect our reported net earnings, business, financial condition, results of operations, cash flows or stock price.~~ Risks Related to the Development of our Product Candidates ~~All of~~ **Our lead product candidate, AXN- 2510 / IMM2510, as well as** our **other** product candidates **,** are currently in **early- stage** ~~preclinical~~ --- **clinical** development ~~and potential investigator- initiated clinical stage~~. If we are unable to successfully develop, receive regulatory approval for and commercialize **AXN- 2510 / IMM2510** ~~our product candidates for the indications we seek~~, or successfully develop any other product candidates, or experience significant delays in doing so, our business will be harmed. We currently have no products approved for commercial sale, and all of our product candidates are currently in early- stage development **, including our lead product candidate AXN- 2510 / IMM2510**. As an organization, we have no prior experience completing any clinical trials ~~or working in a collaborator- led IIT~~; we have limited experience in preparing, submitting and prosecuting regulatory filings and have not previously submitted a biologics license application, or BLA, for any product candidate. Each of our programs and product candidates will require additional preclinical and / or clinical development, regulatory approval, obtaining manufacturing supply, capacity and expertise, building a commercial organization or successfully outsourcing commercialization, substantial investment and significant marketing efforts before we generate any revenue from product sales. We do not have any products that are approved for commercial sale, and we may never be able to develop or commercialize marketable products. Our ability to generate revenue from our product candidates, which we do not expect will occur for several years, if ever, will depend heavily on the successful development, regulatory approval and eventual commercialization of our product candidates. The success of any product candidates that we develop or otherwise may acquire will depend on several factors, including: • timely and successful completion of preclinical studies and clinical trials; • effective INDs from the FDA or comparable foreign applications that allow commencement of our planned clinical trials or future clinical trials for our product candidates; • sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials; • successful enrollment and completion of clinical trials, including under the FDA' s current Good Clinical Practices, or GCPs, and current Good Laboratory Practices; • successful development of, or making arrangements with third- party manufacturers for, our commercial manufacturing processes for any of our product candidates that receive regulatory approval; • receipt of timely marketing approvals from applicable regulatory authorities; • launching commercial sales of products, if approved, whether alone or in collaboration with others; • acceptance of the benefits and use of our products, including method of administration, if approved, by patients, the medical community and third- party payors, for their approved indications; • the prevalence and severity of adverse events experienced with any product candidates; • the availability, perceived advantages, cost, safety and efficacy of alternative therapies for any product candidate, and any indications for such product candidate, that we develop; • our ability to produce any product candidates we develop on a commercial scale; • obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity for our product candidates and otherwise protecting our rights in our intellectual property portfolio; • maintaining compliance with regulatory requirements, including cGMPs, and complying effectively with other procedures; • obtaining and maintaining third- party coverage and adequate reimbursement and patients' willingness to pay out- of- pocket in the absence of such coverage and adequate

reimbursement; and • maintaining a continued acceptable safety, tolerability and efficacy profile of the products following approval. If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize the product candidates we develop, which would materially harm our business. If we do not receive marketing approvals for any product candidate we develop, we may not be able to continue our operations. At any time, we may decide to discontinue the development of, or not to commercialize, a product candidate, such as our decision to discontinue our ITIL- 168 development program. If we terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to allocate those resources to potentially more productive uses. ~~Human immunotherapy products are a new category of therapeutics, and to date, no TIL therapies have been approved by the FDA, MHRA, EMA or other comparable foreign regulatory authorities. 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 trial period, the number of patients the FDA, MHRA, EMA or other regulatory authorities will require to be enrolled in the trials in order to establish the safety, efficacy, purity and potency of immunotherapy products or that the data generated in these trials will be acceptable to such authorities to support marketing approval. Regulatory authorities may take longer than usual to come to a decision on any BLA or other comparable application 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. Regulatory agencies may also require that we conduct additional post- marketing studies or implement risk management programs, such as Risk Evaluation and Mitigation Strategies, or 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. The success of our business depends in part upon our ability to develop engineered TIL therapies using our CoStAR platform, in particular following our recent reprioritization of clinical programs. The CoStAR platform is novel and we have not completed a clinical trial of any product candidate developed using the CoStAR platform. The platform may fail to deliver TIL therapies that are effective in the treatment of cancer. Even if we are able to identify and develop TIL therapies using the CoStAR platform, we cannot assure that such product candidates will achieve marketing approval to safely and effectively treat cancer. If we uncover any previously unknown risks related to our CoStAR platform, or if we experience unanticipated problems or delays in developing our CoStAR product candidates, we may be unable to achieve our strategy of building a pipeline of TIL therapies. We 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. For example, in October 2022 we paused enrollment in our then ongoing clinical trials to conduct manufacturing analysis and implement corrective and preventative actions and we subsequently discontinued our clinical trials. 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. Since our current and 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. We do not yet have sufficient information to reliably estimate what it will cost to commercially manufacture our current or future 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 product candidates. 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 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. We do not currently have any active clinical trials.~~ We may derive results **and data** for ~~our Collaboration Product~~ **AXN- 2510 / IMM2510 and AXN- 27M / IMM27M** from **clinical** ~~open- label investigator- initiated~~ trials led by **ImmuneOnco** ~~our collaborator~~ in China ~~. IITs are conducted by principal investigators~~ ; our role in ~~the~~ **any such** ~~trial~~ **trials** and **our** access to the clinical results and data ~~are~~ **, will be** limited and there is no assurance that the clinical data from **any such trials** ~~our collaborator- led IITs~~ will be accepted or considered by the FDA, or other comparable regulatory authorities. **Pursuant to** ~~We are early in~~ the **IO** ~~process of potentially conducting our first collaborator~~ **Collaboration Agreement, we expect to fund clinical trial (s) of AXN - 2510 / IMM2510** led ~~IITs~~ **by ImmuneOnco** in China. **In addition, ImmuneOnco is pursuing additional clinical trials of AXN- 2510 / IMM2510 and AXN- 27M / IMM27M in China.** While **these** ~~investigator- initiated~~ trials may provide us with clinical data that can inform our future development strategy, we do not have control over the protocols, administration, or conduct of the trials ~~and~~ **or** ~~the~~ **their** compliance **with** ~~of the extensive~~ regulatory requirements **. There is also no assurance** that the **clinical data from any such clinical** trials ~~are subject to~~ **will be accepted or considered by the FDA or other comparable regulatory authorities. Additional risks include procedural delays** , ~~especially~~ **timing issues and difficulties or differences in interpreting data. As a result, our minimal control over the conduct and timing of, and communications with the FDA, the National Medical Products Administration, or NMPA,** with respect to ~~portion~~ **the trials** that ~~needs~~ **ImmuneOnco is conducting expose us** to **additional risks and uncertainties** ~~be performed by third parties. As a result~~ , ~~we~~ **many of which** are **outside** ~~subject to risks associated with the way investigator- initiated trials are conducted. Third parties in such investigator- initiated~~

~~trials may not perform their responsibilities on our anticipated schedule or~~ **our** ~~consistent with clinical trial protocols~~ **control, and the occurrence of which could adversely affect the prospects** ~~or~~ **for** ~~applicable regulations~~ **our product candidates** . Furthermore, any data integrity issues or patient safety issues arising out of any of these trials would be beyond our control, yet could adversely affect our reputation and damage the clinical and commercial prospects for our product candidates. ~~Additional risks include difficulties or delays in communicating with investigators or administrators, procedural delays and other timing issues, and difficulties or differences in interpreting data. As a result, our minimal control over the conduct and timing of, and communications with the FDA, the NMPA and other comparable regulatory authorities regarding investigator- initiated trials expose us to additional risks and uncertainties, many of which are outside our control, and the occurrence of which could adversely affect the prospects for our product candidates.~~ Preclinical studies and clinical trials ~~, including investigator- initiated trials,~~ are expensive, time- consuming, difficult to design and implement and involve an uncertain outcome. Further, we may encounter substantial delays in completing the development of our product candidates. All of our product candidates are in early-stage development and their risk of failure is high. We ultimately ceased our **TIL** clinical trials **after encountering manufacturing and other clinical development challenges and have ceased development** of ~~ITIL~~ **our CoStAR** ~~- 306 after a strategic pivot to the UK. In 2022, we determined not to resume the clinical trial of our former product candidate ITIL -~~ **TIL technology** ~~- 168 after a voluntary pause following the observation of decreased rates of successful manufacturing; there can be no assurance that we will not in the future observe decreased rates of successful manufacture of drug product for our product candidates or other manufacturing issues, which may lead to further delays or failure in the development of our product candidates, greater than expected expenses, or the redesign or restart of our clinical trials. We have not successfully completed a clinical trial and currently have no active clinical trial~~ . The clinical trials and manufacturing of our product candidates are, and the manufacturing and marketing of our products, if approved, will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. In particular, because our product candidates are subject to regulation as biological products, we will need to demonstrate that they are safe, pure and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. Clinical trials are expensive and can take many years to complete, and their outcomes are inherently uncertain. We cannot guarantee that our clinical trials, including our potential collaborator- led ~~IIT~~ **clinical trials** , will be conducted as planned or completed on schedule, if at all. Failure can occur at any time during the clinical trial process. Even if our clinical trials are completed as planned, we cannot be certain that their results will support the safety and effectiveness of our product candidates for their targeted indications or support continued clinical development of such product candidates. Our clinical trials may not be successful. ~~For example, in October 2022 we notified the FDA and other regulatory agencies that an unplanned review of the data for the initial patients that had been dosed with ITIL- 168 in the DELTA- 1 trial was conducted in order to review risk-benefit. This review was inconclusive because the response data were not mature. Subsequently, the Data Safety Monitoring Board' s prespecified review found no safety concerns. We voluntarily paused our clinical trials to conduct an end- to- end analysis of our manufacturing processes, and after an analysis of the potential scenarios to restart and complete a registration-enabling cohort in advanced melanoma in DELTA- 1, we determined to discontinue our ITIL- 168 clinical development program.~~ In addition, even if we successfully complete clinical trials, we cannot guarantee that the FDA, MHRA, EMA or other comparable foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA, MHRA, EMA or other comparable foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. To date, we have not completed any clinical trials required for the approval of any product candidate. We may experience delays in conducting any clinical trials and we do not know whether our clinical trials will begin on time, need to be redesigned, recruit and enroll patients on time or be completed on schedule, or at all. Clinical trials can be delayed suspended or terminated for a variety of reasons, including in connection with: • inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation of clinical trials; • delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials ~~, such as our October 2022 voluntary pause in our clinical trials and the related investigation into our manufacturing processes~~ ; • delays in developing suitable assays for screening patients for eligibility for trials with respect to certain product candidates; • delays in reaching agreement with the FDA, MHRA, EMA or other regulatory authorities as to the design or implementation of our clinical trials; • obtaining regulatory authorization to commence a clinical trial; • reaching an agreement on acceptable terms with clinical trial sites or prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites; • obtaining institutional review board, or IRB, approval at each trial site; • recruiting suitable patients to participate in a clinical trial; • having patients complete a clinical trial or return for post- treatment follow- up; • inspections of clinical trial sites or operations by applicable regulatory authorities, or the imposition of a clinical hold; • clinical sites, CROs or other third parties deviating from trial protocol or dropping out of a trial; • failure to perform in accordance with the applicable regulatory requirements, including FDA' s GCP requirements, or applicable regulatory requirements in other countries; • addressing patient safety concerns that arise during the course of a trial, including occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits; • adding a sufficient number of clinical trial sites; • manufacturing sufficient quantities of product candidate for use in clinical trials; or • suspensions or terminations by IRBs of the institutions at which such trials are being conducted, by the Data Safety

Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities due to a number of factors, including those described above. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates or significantly increase the cost of such trials, including: • we may experience changes in regulatory requirements or guidance, or receive feedback from regulatory authorities that requires us to modify the design of our clinical trials; • clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon development programs; • the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate; • our third- party contractors and collaborators may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • we or ~~investigators~~ **our collaborators** might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks; • the cost of clinical trials of our product candidates may be greater than we anticipate and we may not have funds to cover the costs; • the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; • regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and • any **current or** future collaborators that conduct clinical trials may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may: • incur unplanned costs; • be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all; • obtain marketing approval in some countries and not in others; • obtain marketing approval for indications or patient populations that are not as broad as intended or desired; • obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings or **Risk Evaluation and Mitigation Strategies, or** REMS; • be subject to additional post- marketing testing requirements; • be subject to changes in the way the product is administered; or • have regulatory authorities withdraw or suspend their approval of the product or impose restrictions on its distribution after obtaining marketing approval. We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the DSMB for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. All of our product candidates will require extensive clinical testing before we are prepared to submit a BLA or marketing authorization application, or MAA, for regulatory approval. We cannot predict with any certainty if or when we might complete the clinical development for our product candidates and submit a BLA or MAA for regulatory approval of any of our product candidates or whether any such BLA or MAA will be approved. We may also seek feedback from the FDA, ~~MHRA, EMA~~ or other regulatory authorities on our clinical development program, and such regulatory authorities may not provide such feedback on a timely basis, or such feedback may not be favorable, which could further delay our development programs. We cannot predict with any certainty whether or when we might complete a given clinical trial. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be harmed, and our ability to generate revenues from our product candidates may be delayed or lost. In addition, any delays in our clinical trials could increase our costs, slow down the development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and results of operations. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. We may seek Fast Track designation for our product candidates, and we may be unsuccessful. Even if received, Fast Track designation may not actually lead to a faster review or approval process and does not increase the likelihood that our product candidates will receive marketing approval. We may seek Fast Track designation for our product candidates, and we may be unsuccessful. If a drug or biologic is intended for the treatment of a serious or life- threatening condition and the product demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for FDA Fast Track designation for a particular indication. There is no assurance that the FDA will grant this status to any of our product candidates. If granted, Fast Track designation makes a product eligible for more frequent interactions with FDA to discuss the development plan and clinical trial design, as well as rolling review of the application, which means that the company can submit completed sections of its marketing application for review prior to completion of the entire submission. Marketing applications of product candidates with Fast Track designation may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track designation does not provide any assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track designation at any time if it believes that the designation is no longer supported by data from our clinical development program. The regulatory approval processes

of the FDA, MHRA, EMA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain required regulatory approval for our product candidates, our business will be substantially harmed. The time required to obtain approval or other marketing authorizations by the FDA, MHRA, EMA and comparable foreign authorities is unpredictable, and it typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, and the type and amount of clinical data necessary to gain approval may change during the course of a product candidate' s clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate, and it is possible that we may never obtain regulatory approval for any product candidates we may seek to develop in the future. Neither we nor any current or future collaborator is permitted to market any drug product candidates in the United States until we receive regulatory approval of a BLA from the FDA, and we cannot market them in the European Union until we receive approval for a MAA from the EMA, or in other foreign countries until we receive the required regulatory approval in such other countries. To date, we have had **no** ~~only limited~~ discussions with the FDA ~~, MHRA, and EMA~~ regarding **our** clinical development ~~programs~~ **of AXN- 2510 / IMM2510** or regulatory approval for **AXN- 2510 / IMM2510** ~~any product candidate within the United States, European Union and United Kingdom, respectively~~ . In addition, we have had no discussions with other comparable foreign authorities ~~,~~ regarding clinical development programs or regulatory approval for any product candidate ~~outside of those jurisdictions~~ . Prior to obtaining approval to commercialize any drug product candidate in the United States or abroad, we must demonstrate with substantial evidence from well- controlled clinical trials, and to the satisfaction of the FDA, MHRA, EMA or other comparable foreign regulatory agencies, that such product candidates are safe, pure and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA, MHRA, EMA or other regulatory agency may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or after approval, or it may object to elements of our clinical development programs. Our product candidates could fail to receive regulatory approval for many reasons, including the following: • the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our **or our collaborators'** clinical trials; • we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication; • the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; • we may be unable to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks; • the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third- party manufacturers with which we contract for clinical and commercial supplies; and • the approval policies or regulations of the FDA or comparable foreign authorities may significantly change in a manner rendering our clinical data insufficient for approval. Of the large number of products in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval and marketing authorization process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval and marketing authorization to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects. We have invested a significant portion of our time and financial resources in the development of our clinical and preclinical product candidates. Our business is dependent on our ability to successfully complete preclinical and clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize product candidates in a timely manner. Even if we eventually complete clinical testing and receive approval of a BLA or foreign marketing application for any product candidates, the FDA, MHRA, EMA or the applicable foreign regulatory agency may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-marketing clinical trials. The FDA, MHRA, EMA or the applicable foreign regulatory agency also may approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally request, and the FDA, MHRA, EMA or applicable foreign regulatory agency may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects. In addition, the FDA, MHRA, EMA and other regulatory authorities may change their policies, issue additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained. Success in preclinical ~~studies or earlier~~ **testing and early stage** clinical trials **by ImmuneOnco** ~~may not be indicative of results~~ in **China** ~~future clinical trials. Our product candidates may not have favorable results in later clinical trials, if any, or receive regulatory approval. Success in preclinical testing and any early investigator- initiated clinical trials~~ does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Preclinical tests and Phase 1 and Phase 2 clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in preclinical or animal studies and early clinical trials does not ensure that later large- scale efficacy trials will be successful nor does it predict final results. For example, we may be unable to identify suitable animal disease models for our product candidates, which could delay or frustrate our ability to proceed into clinical trials or obtain marketing approval. Our product candidates may fail to show the desired safety and efficacy in clinical development despite having progressed through preclinical studies and initial clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late- stage clinical trials even after achieving promising results in preclinical testing and earlier- stage clinical trials. Data obtained from preclinical and

clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects. Interim, " top- line " and preliminary results from our clinical trials that we **or our collaborators** announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publish interim, top- line or preliminary results from our clinical trials **or those of our collaborator, ImmuneOnco** . Interim results from clinical trials that we **or ImmuneOnco** may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top- line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary, top- line or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly. We **and ImmuneOnco** also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we **and they** may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top- line results that we **or ImmuneOnco** report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Further, others, including regulatory agencies may not accept or agree with our **or ImmuneOnco' s** assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular development program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed meaningful by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, top- line or preliminary data that we **or ImmuneOnco** report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, product candidates may be harmed, which could significantly harm our business prospects. Our preclinical studies and clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could prevent, delay or limit the scope of regulatory approval of our product candidates, limit their commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates. To obtain the requisite regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are safe, pure and potent for use in each target indication. These trials are expensive and time consuming, and their outcomes are inherently uncertain. Failures can occur at any time during the development process. Preclinical studies and clinical trials often fail to demonstrate safety or efficacy of the product candidate studied for the target indication, and most product candidates that begin clinical trials are never approved. We may fail to demonstrate with substantial evidence from adequate and well-controlled trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that our product candidates are safe and potent for their intended uses. ~~Possible adverse side effects that could occur with treatment with cell therapy products include thrombocytopenia, chills, anemia, pyrexia, febrile neutropenia, diarrhea, neutropenia, vomiting, hypotension, dyspnea, cytokine release syndrome and neurotoxicity.~~ If our product candidates are associated with undesirable effects in preclinical studies or clinical trials or have characteristics that are unexpected, we may decide or be required to perform additional preclinical studies or to halt or delay further clinical development of our product candidates or to limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk- benefit perspective, which may limit the commercial expectations for the product candidate, if approved ~~. These side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from personalized cell therapy, as with our TIL product candidates, are not normally encountered in the general patient population and by medical personnel~~ . If any such adverse events occur, our clinical trials could be suspended or terminated. If we cannot demonstrate that any adverse events were not caused by the drug, the FDA, MHRA, EMA or comparable foreign regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. Even if we are able to demonstrate that all future serious adverse events are not product- related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may harm our business, financial condition and prospects significantly. **In addition, significant adverse events, or the related suspension or termination of ImmuneOnco' s clinical trial of AXN- 2510 / IMM2510 or AXN- 27M / IMM27M in China, could materially harm our ability to develop these product candidates and may significantly harm our business, financial condition and prospects.** If our product candidates are associated with side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses in which the side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective. The FDA, MHRA, EMA, comparable foreign regulatory authorities or an IRB may also require that we suspend, discontinue, or limit our clinical trials based on safety information, or that we conduct additional animal or human studies regarding the safety and efficacy of our product candidates which we have not planned or anticipated. Such findings could further result in regulatory

authorities failing to provide marketing authorization for our product candidates or limiting the scope of the approved indication, if approved. Many product candidates that initially showed promise in early **-** stage testing have later been found to cause side effects that prevented further development of the product candidate. Additionally, if one or more of our product candidates receives marketing approval, and we or others identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including: • regulatory authorities may suspend, withdraw or limit approvals of such product, or seek an injunction against its manufacture or distribution; • regulatory authorities may require additional warnings on the label; • we may be required to create a medication guide outlining the risks of such side effects for distribution to patients or other requirements subject to a REMS; • we may be required to change the way a product is administered or conduct additional trials; • we could be sued and held liable for harm caused to patients; • we may decide to remove the product from the market; • we may not be able to achieve or maintain third- party payor coverage and adequate reimbursement; • we may be subject to fines, injunctions or the imposition of civil or criminal penalties; and • our reputation and physician or patient acceptance of our products may suffer. There can be no assurance that we will resolve any issues related to any product- related adverse events to the satisfaction of the FDA or comparable foreign regulatory agency in a timely manner or at all **, or that ImmuneOnco will resolve any issues related to AXN- 2510 / IMM2510 or AXN- 27M / IMM27M adverse events to the satisfaction of the NMPA** . Moreover, any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects. **As** ~~Negative public opinion of TIL therapies, the dynamically evolving competitive landscape for our target indications or increased regulatory scrutiny of cell therapy using TILs may adversely impact the development of and~~ - **an organization** ~~commercial strategy for our product candidates~~ , **we do not have experience completing** ~~our plans for investing in manufacturing readiness for regulatory filings, and the success of our current and future product candidates. The clinical and commercial success of our TIL therapies will depend in part on public acceptance of the use of cell therapy using TILs. Any adverse public attitudes about the use of TIL therapies may adversely impact our ability to enroll~~ clinical trials ~~. Moreover~~ , ~~our success will depend upon physicians prescribing,~~ and ~~their patients being willing to receive, treatments that involve the use of product candidates we~~ may ~~develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may~~ be **unable to complete** ~~available. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products once approved. Adverse events in our or others'~~ clinical trials **for any** ~~, even if not ultimately attributable to our~~ product candidates **we may** ~~, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates, all of which would have a negative impact on our business and operations. Further, increased government regulation or negative public opinion of TIL therapies, as well as increased competition in the development~~ ---- **develop** ~~of treatments and therapeutics in the indications we are targeting or may target in the future, may force us to revise our business strategy for our product candidates~~ , including **AXN- 2510 / IMM2510** ~~our plans for making investments in our manufacturing capabilities necessary to prepare for required regulatory filings. We may be forced to significantly curtail or abandon our current strategy and may never be able to realize our current business strategy and commercialize our product candidates~~ . We are early in our development efforts for our product candidates and will need to successfully complete clinical trials, including pivotal clinical trials, in order to obtain FDA, MHRA, EMA or comparable foreign regulatory authorities' approval to market any of our product candidates. Carrying out clinical trials and the submission of a successful BLA or MAA is a complicated process. As an organization, we are early in the process of ~~potentially conducting our first collaborator~~ **collaborating with ImmuneOnco on the development of AXN** - **2510 / IMM2510** ~~led IITs in China,~~ and **AXN- 27M / IMM27M and have no experience completing any clinical trial, have limited experience in preparing regulatory submissions and have not previously submitted a BLA or MAA for any product candidate. We do not have a clinical development team. We** have no prior experience **developing bispecific antibodies and** ~~in China or a similar collaboration, or in completing any clinical trial,~~ have ~~limited~~ **no** experience **treating patients with bispecific antibodies** ~~in preparing regulatory submissions and have not previously submitted a BLA or MAA for any product candidate. We also do not have a clinical development team~~ . We have ~~only previously treated patients with our TIL product in a compassionate use program in the United Kingdom with a TIL product that was manufactured using a prior version of the ITIL- 168 manufacturing process, and dosed one patient in our prior clinical trial for ITIL- 306. In addition, we have~~ had ~~limited~~ **no substantive** interactions with the FDA **related to AXN- 2510 / IMM2510** and cannot be certain how many clinical trials of ~~our product candidates~~ **AXN- 2510 / IMM2510** will be required or how such trials should be designed. Consequently, we may be ~~unsuccessful in our collaboration and may be~~ unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to submission of the applicable regulatory applications and approval of **AXN- 2510 / IMM2510, or** any **other** product candidate. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop **, including AXN- 2510 / IMM2510** . Failure to commence or complete, or delays in, our collaboration or planned clinical trials, could prevent us from or delay us in commercializing our product candidates ~~. In addition~~ , **including AXN- 2510 / IMM2510** ~~Collaboration Product for the potential IITs in China will be manufactured by our collaborator using its manufacturing process; we do not currently have rights to use any proprietary aspects of our collaborator' s manufacturing process for any future clinical trial by us of Collaboration Product in the United States or elsewhere~~ . We may experience delays or difficulties in the enrollment and / or retention of patients in clinical trials, which could delay or prevent our receipt of necessary regulatory approvals. Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population and competition for patients eligible for our clinical trials with competitors which may have ongoing clinical

trials for product candidates that are under development to treat the same indications as one or more of our product candidates, or approved products for the conditions for which we are developing our product candidates. Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities. We cannot predict how successful we will be at enrolling subjects in future clinical trials. Subject enrollment is affected by other factors including: • the severity and difficulty of diagnosing the disease under investigation; • the eligibility and exclusion criteria for the trial in question; • the size of the patient population and process for identifying patients; • our ability to recruit clinical trial investigators with the appropriate competencies and experience; • the design of the trial protocol; • the perceived risks and benefits of the product candidate in the trial ~~, including relating to cell therapy approaches~~ ; • the availability of competing commercially available therapies and other competing therapeutic candidates' clinical trials for the disease or condition under investigation; • the willingness of patients to be enrolled in our clinical trials; • the efforts to facilitate timely enrollment in clinical trials; • potential disruptions caused by disease outbreaks, epidemics and pandemics, including difficulties in initiating clinical sites, enrolling and retaining participants, diversion of healthcare resources away from clinical trials, travel or quarantine policies that may be implemented, and other factors; • the patient referral practices of physicians; • the ability to monitor patients adequately during and after treatment; and • the proximity and availability of clinical trial sites for prospective patients. Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Furthermore, we expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we will have limited influence over their performance. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment of such patients in our clinical trials. We may seek orphan drug designation for some of our product candidates, and we may be unsuccessful, or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity, for product candidates for which we obtain orphan drug designation. We may seek orphan drug designation for some or all of our product candidates in specific orphan indications in which there is a medically plausible basis for the use of these product candidates. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, defined as a patient population of fewer than 200, 000 individuals in the United States, or a patient population of 200, 000 or more in the United States where there is no reasonable expectation that the cost of developing and making available the drug or biologic will be recovered from sales in the United States. Orphan drug designation must be requested before submitting a BLA. Although we may seek orphan drug designation for some or all of our product candidates, we may never receive such designations. In the United States, orphan drug designation entitles a party to financial incentives such as tax advantages and user fee waivers. Opportunities for grant funding toward clinical trial costs may also be available for clinical trials of drugs or biologics for rare diseases, regardless of whether the drugs or biologics are designated for the orphan use. In addition, if a drug or biologic with an orphan drug designation subsequently receives the first marketing approval for a particular active ingredient or principal molecular structural features for the indication for which it has such designation, the product is entitled to a seven year period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can ensure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the drug was designated. Even if we obtain orphan drug designation for a product candidate, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing biological products. If we seek orphan drug designation, we may be unsuccessful in obtaining such orphan drug designation for our product candidates. Even if we obtain orphan drug exclusivity for any of our product candidates, we may be unable to maintain the benefits associated with orphan drug designation, or such orphan drug exclusivity may not effectively protect those product candidates from competition because different drugs can be approved for the same condition, and orphan drug exclusivity does not prevent the FDA from approving the same or a different drug in another indication. Even after an orphan drug is granted orphan drug exclusivity and approved, the FDA can subsequently approve a later application for the same drug for the same condition before the expiration of the seven- year exclusivity period if the FDA concludes that the later drug is clinically superior in that it is shown to be safer in a substantial portion of the target populations, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan drug designation. Moreover, orphan drug- exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or that we are unable to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. Breakthrough therapy designation by the FDA for any product candidate may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that the product candidate will receive marketing approval. We may, in the future, apply for breakthrough therapy designation, or the equivalent thereof in foreign jurisdictions (where available), for our product candidates. A breakthrough therapy is defined as a product candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life- threatening disease or condition, and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication

between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Product candidates designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the BLA. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification or it may decide that the time period for FDA review or approval will not be shortened. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and management resources, we must focus on development programs and product candidates that we identify for specific indications. As such, we are currently primarily focused on ~~our potential Collaboration Product~~ **advancing the development of AXN- 2510 / IMM2510** for the treatment of non- small cell lung cancer and potentially licensing- in or otherwise acquiring ~~a~~ **other** new product ~~candidate~~ **candidates** . As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications for these product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs and product candidates for specific indications may not yield any commercially viable products. For example, before **in- licensing AXN- 2510 / IMM2510, our strategy** ~~prioritizing~~ **prioritized** development of ~~our Collaboration Product, our strategy focused primarily on the development of ITIL-~~ **TIL cell therapy products** ~~- 306, which we recently discontinued, and prior to that, ITIL- 168 for the treatment of PD- 1 inhibitor- relapsed or refractory advanced cutaneous melanoma, which we discontinued in 2022~~ . Further, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. We plan to **work with our collaborator, ImmuneOnco, to** conduct clinical trials for ~~our product candidates~~ **AXN- 2510 / IMM2510 and AXN- 27M / IMM27M** outside the United States **, including China** , and the FDA and similar foreign regulatory authorities may not accept data from such trials conducted in locations outside of their jurisdiction. ~~We are~~ **Our subsidiary, Axion Bio, Inc. or Axion Bio, is** party to a collaboration **with ImmuneOnco pursuant to which ImmuneOnco is pursuing clinical trials of AXN- 2510 / IMM2510 and AXN- 27M / IMM27M** in China ~~designed~~ to ~~facilitate more expedited patient enrollment in a Phase 1 IIT with the goal of generating~~ **generate** ~~early~~ clinical data ~~for our Collaboration Product~~ from patients with ~~NSCLC~~ **certain solid tumor cancers, including of AXN- 2510 / IMM2510** in ~~China~~ **non- small cell lung cancer** . In addition, we may choose to conduct other clinical trials outside the United States, including in the **Australia, Canada, Europe, the** United Kingdom ~~, Australia, Canada, Europe~~ or other foreign jurisdictions. The acceptance by the FDA of data from **clinical** ~~an IIT trial~~ **trials** conducted in China or any other clinical trial outside the United States may be subject to certain conditions or may not be accepted at all. In cases where data from clinical trials conducted outside the United States are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U. S. population and U. S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and (iii) the data may be considered valid without the need for an on- site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on- site inspection or other appropriate means. For example, in February 2022, the FDA publicly rebuked an oncology product sponsor for submitting a marketing application with Phase 3 clinical data solely from China and since that time, it has declined to approve other applications that contained primarily China- generated clinical data. Additionally, the FDA' s clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any similar foreign regulatory authority will accept data from trials conducted outside of the United States, including China, or the applicable jurisdiction. If the FDA or any similar foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time- consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction. Our strategy ~~involves in~~ **is currently focused on developing AXN** - ~~licensing~~ **2510** / **IMM2510, which we in- licensed from ImmuneOnco in August 2024. However, we may seek in the future to engage in additional strategic transactions to in- license or** ~~acquiring~~ **acquire** and ~~developing~~ --- **develop additional** therapeutic assets for diseases with significant unmet medical need. We may not be able to continue to identify, in- license or otherwise acquire, and subsequently develop, new product candidates in addition to our current pipeline. The licensing or acquisition of third- party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third- party intellectual property rights or assets that we may consider attractive for further development. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us, and companies that do not perceive us to be competitor may be reluctant to consider licensing to us given our lack of **relevant meaningful** experience ~~beyond TILs~~ **. In addition, the process of identifying new product candidates and technologies that may be available to acquire or in- license and assessing their potential and value is difficult and time- consuming. Even if we identify suitable candidates to acquire or**

in- license, negotiating strategic transactions is time- consuming and may distract our management from focusing on developing our other product candidates . We also may be unable to license or acquire third- party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. Even if we are successful in continuing to build our pipeline, either through internal research and development or through in- licensing or other asset acquisitions, the potential product candidates that we identify may not be suitable for clinical development. For example, product candidates may be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be successfully developed, much less receive marketing approval and achieve market acceptance. **We may not be successful in developing or commercializing the product candidates we have licensed- in, including the product candidates licensed from ImmuneOnco, or any future product candidate we may acquire or in- license.** If we do not successfully develop and commercialize product candidates ~~based upon our approach~~ , we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price. If we do not achieve our plans and projected development goals in the ~~time frames~~ **timeframes** we announce and expect, the commercialization of our products may be delayed. From time to time, we may estimate the timing of the accomplishment of various scientific, clinical, regulatory, manufacturing and other product development goals, which we sometimes refer to as milestones, including in connection with our collaboration **with ImmuneOnco** . These milestones may include the commencement or completion of, and availability of data from, preclinical studies and clinical trials and the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are, and will be, based on a variety of assumptions **. In particular with respect to expected milestones related to our lead product candidate, AXN- 2510 / IMM2510, we are setting timelines and making assumptions for a product candidate that we in- licensed very recently. We have no prior experience developing a bispecific antibody and, accordingly, are making clinical, regulatory, manufacturing and other assumptions related to a bispecific antibody for the first time** . The actual timing of these milestones can vary significantly compared to our estimates, in some cases for reasons beyond our control. We may experience numerous unforeseen events during, or as a result of ~~our current clinical trials or any future~~ clinical trials that we conduct ~~, such as the observed decrease in 2022 of rates of successful manufacturing of ITIL- 168 that resulted in the decision to voluntarily pause our clinical trials and contributed in part to our decision to ultimately discontinue our ITIL- 168 development program,~~ that could delay or prevent our ability to receive marketing approval or commercialize our product candidates **. In addition, failure to meet projected milestones may negatively impact the trading price of our common stock and our ability to raise additional capital on attractive terms or at all** . The market opportunities for any current or future product candidate we develop, if approved, may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small. Any revenue we are able to generate in the future from product sales will be dependent, in part, upon the size of the market in the United States and any other jurisdiction for which we gain regulatory approval and have commercial rights. If the markets or patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, even if approved. Cancer therapies are sometimes characterized as first- line, second- line or third- line, and the FDA often approves new therapies initially only for third- line use. When cancer is detected early enough, first- line therapy, usually chemotherapy, immunotherapy, hormone therapy, surgery, radiation therapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third- line therapies are administered to patients when prior therapy is not effective. We may initially seek approval for ~~ITIL- 306 and any other~~ product candidates we develop as a therapy for patients who have received one or more prior treatments. If we do so, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval potentially as a first- line therapy, but there is no guarantee that any product candidate we develop, even if approved, would be approved for first- line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials. The number of patients who have the types of cancer we are targeting may turn out to be lower than expected. Additionally, the potentially addressable patient population for our current or future product candidates may be limited, if and when approved. Further, even if any of our product candidates are approved by the FDA or comparable foreign regulators, their approved indications may be limited to a subset of the indications that we targeted. Even if we obtain significant market share for any product candidate, if and when approved, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional indications, including to be used as first- or second- line therapy. We may develop ~~our Collaboration Product~~ **AXN- 2510 / IMM2510, AXN- 27M / IMM27M** and future product candidates for use in combination with other therapies or third- party product candidates, which exposes us to additional regulatory risks. We may develop **the** ~~our Collaboration Product~~ **product candidates licensed- in from ImmuneOnco** and future product candidates for use in combination with one or more currently approved cancer therapies. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risk that the FDA, MHRA, EMA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer. We may also evaluate product candidates in combination with one or more other third- party product candidates that have not yet been approved for marketing by the FDA, MHRA, EMA or comparable foreign regulatory authorities. If so, we will not be able to market and sell any product candidate we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval. If the FDA or comparable foreign regulatory authorities do not approve these other biological products or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the biologics we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain approval of or market any such product candidate. ~~The United Kingdom' s~~

~~withdrawal from~~ **Risks Related to the Manufacturing of our Product Candidates Biologics are complex and difficult to manufacture. We intend to rely on ImmuneOnco in China to manufacture clinical supplies of AXN- 2510 / IMM2510, and to produce preclinical and clinical supply of** ~~the~~ **other** ~~European Union may~~ **product candidates and to produce commercial supplies of any approved product. This reliance on third parties increases the risk that we will not** have **sufficient quantities** ~~a negative effect on global economic conditions, financial markets and our business. Following the result~~ of ~~a referendum in 2016, the United Kingdom left the European Union on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed to by the United Kingdom and the European Union, as of January 1, 2021, the United Kingdom is no longer subject to the transition period, or the Transition Period, during which European Union rules continued to apply. A trade and cooperation agreement, or the Trade and Cooperation Agreement, which outlines the post-Transition Period trading relationship between the United Kingdom and the European Union was agreed to in December 2020 and formally entered into force on May 1, 2021. We have research labs located in Manchester, United Kingdom. Further, since a significant proportion of the regulatory framework in the United Kingdom that is applicable to our business and~~ our product candidates ~~is derived from European Union directives and regulations, Brexit has had, and will continue to have, a material impact on the regulatory regime with respect to the importation, approval and commercialization of our~~ **or any approved** ~~product~~ **products** ~~candidates in the United Kingdom or the European Union. For~~ **or such quantities at** ~~example, Great Britain is no longer covered by the centralized procedures for obtaining EU- wide marketing authorizations from the EMA, and a separate marketing authorization will be required to market our product candidates in Great Britain. Any delay in obtaining, or~~ an **acceptable** ~~inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would delay or prevent us from commercializing our product candidates in the United Kingdom and limit our ability to generate revenue and achieve and sustain profitability. While the Trade and Cooperation Agreement provides for the tariff- free trade of medicinal products between the United Kingdom and the European Union, there are additional non- tariff costs~~ **cost** ~~to such trade that did not exist prior to the end of the Transition Period and frequent delays in the transit of goods between the United Kingdom and the European Union. Further, should the United Kingdom diverge from the European Union from a regulatory perspective in relation to medicinal products, tariffs could be put into place in the future, and we may incur expenses in establishing a manufacturing facility in the European Union in order to circumvent such hurdles or incur significant additional expenses to operate our~~ **or** ~~business~~ **quality**, which could ~~significantly and materially harm or~~ delay **, prevent** ~~our~~ **or impair** ~~ability to generate revenues or~~ **our** ~~achieve profitability of our business. Any further changes in international trade, tariff and import / export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non- tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the United Kingdom. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the European Union. Risks Related to the Manufacturing of our Product Candidates The manufacture of biologic products, particularly cell therapy products, is technically complex and necessitates substantial expertise and capital investment. Production difficulties caused by unforeseen events may delay the availability of material for our clinical studies. The manufacturers of pharmaceutical products must comply with strictly enforced cGMP requirements, state and federal regulations, as well as foreign requirements when applicable. Any failure of us or our contract manufacturing organizations to adhere to or document compliance to such regulatory requirements could lead to a delay or interruption in the availability of our program materials for clinical trials or enforcement action from the FDA, MHRA, EMA or comparable regulatory authorities. If we or our manufacturers were to fail to comply with the requirements of the FDA, MHRA, EMA or other regulatory authority, it could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates. Our potential future dependence upon others for the manufacture of our product candidates may also adversely affect our future profit margins and our ability to commercialize any product candidates that receive regulatory approval on a timely and competitive basis. Biological products, particularly cell therapy products, are inherently difficult to manufacture. Our program materials are manufactured using technically complex processes requiring specialized equipment and facilities, highly specific raw materials, cells, and reagents, and other production constraints. Our production process requires a number of highly specific raw materials, cells and reagents with limited suppliers. Even though we aim to have backup supplies of raw materials, cells and reagents whenever possible, we cannot be certain they will be sufficient if our primary sources are unavailable. A shortage of a critical raw material, cell line, or reagent, or a technical issue during manufacturing may lead to delays in clinical~~ development or commercialization **efforts** ~~plans. Any changes in the manufacturing of components of the raw materials we use could result in unanticipated or unfavorable effects in our manufacturing processes, resulting in delays. Delays or failures in the manufacture of cell therapies (whether by us, any collaborator or our third party contract manufacturers) can result in a patient being unable to receive their cell therapy or a requirement to re- manufacture which itself then causes delays in manufacture for other patients. Any delay or failure or inability to manufacture on a timely basis can adversely affect a patient' s outcomes and delay the timelines for our clinical trials. Such delays or failure or inability to manufacture can result from: • a failure in the manufacturing process itself, for example by an error in manufacturing process (whether by us or our third party CMO), equipment or reagent failure, failure in any step of the manufacturing process, failure to maintain a cGMP environment or failure in quality systems applicable to manufacture, sterility failures, contamination during process; • product loss or failure due to logistical issues associated with the collection of a patient' s tumor or other samples, shipping that material to analytical laboratories, and shipping the final product back to the location using cold chain distribution where it will be administered to the patient, manufacturing issues associated with the differences in patient starting materials, inconsistency in cell growth and variability in product characteristics; • a lack of reliability or reproducibility in the manufacturing process itself leading to variability in end manufacture of cell therapy, which may lead to regulatory authorities placing a hold on a clinical trial or~~

~~requesting further information on the process which could in turn result in delays to the clinical trials; • variations in patient starting material or apheresis product resulting in less product than expected or product that is not viable, or that cannot be used to successfully manufacture a cell therapy; • product loss or failure due to logistical issues including issues associated with the differences between patients' white blood cells or characteristics, interruptions to process, contamination, failure to supply patient apheresis material within required timescales (for example, as a result of an import or export hold- up) or supplier error; • inability to obtain viral vector manufacturing slots from CMOs or to have enough manufacturing slots to manufacture cell therapies for patients as and when those patients require manufacture; • inability to procure starting materials or to manufacture starting materials; • loss of or close- down of any manufacturing facility used in the manufacture of our cell therapies, or the inability to find alternative manufacturing capability in a timely fashion; • loss or contamination of patient starting material, requiring the starting material to be obtained again from the patient or the manufacturing process to be re- started; and • a requirement to modify or make changes to any manufacturing process, which may also require comparability testing that delays our ability to make the required modifications or perform any required comparability testing in a timely fashion, require further regulatory approval or require successful tech transfer to CMOs to continue manufacturing. Manufacturing problems may result in a delay in the timelines for our clinical trials. For example, in October 2022 we voluntarily paused enrollment in our clinical trials for ITIL- 168 following a decrease in the rate of successful manufacturing of ITIL- 168, resulting in the inability to dose some patients, and also voluntarily paused enrollment in our Phase 1 trial of ITIL- 306, although no manufacturing failures were observed in this trial. We thereafter resumed our clinical trial for ITIL- 306 prior to our discontinuation of our ITIL- 306 development program. We informed all applicable regulatory agencies of our voluntary pause and no regulatory agency, including the FDA, issued a clinical hold on any of our prior clinical trials, although there can be no assurance that we will not be subject to a clinical hold in the future. We completed an end- to- end analysis of our manufacturing processes and have taken corrective actions to improve the rate of manufacturing success, but there can be no assurance that these actions will be effective or that we will not experience other manufacturing issues in the future~~ . We currently rely, and expect to continue to rely, on third party manufacturers, including **ImmuneOnco** ~~our collaborator for the potential IITs in China,~~ to manufacture and to perform quality testing **for AXN- 2510 / IMM2510** . Reliance on third parties exposes us to risks associated with having reduced control over manufacturing activities, and any disruptions to the operations of our third- party manufacturers, including those caused by conditions unrelated to our business or operations such as bankruptcy of the manufacturer, could materially and adversely affect our business. ~~The~~ **We do not operate manufacturing facilities for the production of clinical or commercial supplies of our product candidates and currently have no supply agreements for the production of any of our product candidates. We have no personnel with experience in manufacturing bispecific antibodies and lack the resources and the capabilities to** manufacture **any** of our ~~TIL~~ product candidates ~~is difficult and complex and we may encounter difficulties in~~ **on any scale, including clinical or commercial scale. We currently plan to rely on third parties for supply of our** ~~production~~ **product** ~~, particularly~~ **candidates and for commercial supply if any of our product candidates are approved for sale. We intend to enter into a supply agreement** with **ImmuneOnco** ~~respect to process development or~~ **for** ~~scaling~~ **supply of AXN- 2510 / IMM2510** ~~out of our manufacturing capabilities. If we encounter such difficulties, our ability to provide supply of our product candidates~~ for **use in** clinical trials ~~or any approved products could be delayed or stopped~~ . **We currently have no agreements** ~~All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for components of our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late- stage clinical trials in the European Union must be manufactured in accordance~~ with ~~cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. 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 our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a BLA or MAA on a timely basis. Our facilities and quality systems and the facilities and quality systems of some or all of our third- party contractors must pass a pre- approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted, and they could put a hold on one or more of our clinical trials if the facilities of our contract development and manufacturing organizations do not pass such audit or inspections. If these facilities do not pass a pre- approval plant inspection, FDA or comparable foreign regulatory authorities' approval of the products will not be granted. The regulatory authorities also may, at any time following approval of a product for sale, inspect or audit our manufacturing facilities or those of our third- party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and / or time- consuming for us or a third party to implement and that 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 harm our business. If we or any of our~~ third- party manufacturers ~~fail to maintain regulatory compliance, the FDA or~~ **for development** ~~comparable foreign regulatory authorities' can impose regulatory sanctions including~~ , ~~among other things, refusal to approve a pending application~~ -- **validation and manufacturing** ~~for a new drug product or biologic product, or revocation~~ of **AXN** ~~a pre- existing approval. As a result,~~ **2510 / IMM2510 to secure the long- term clinical** ~~our~~ **or** ~~business, financial condition and results of operations may be harmed. Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in~~ commercial supply **of AXN- 2510** ~~. An alternative manufacturer would need to be qualified through a~~

~~BLA and~~ / **IMM2510 or** ~~or~~ **for any of our other products candidates** ~~MAA supplement which could result in further delay~~ . **We** ~~The regulatory agencies~~ may **be unable to secure agreements** ~~also require additional studies if a new manufacturer is relied upon~~ for commercial ~~production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines. These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully, if approved. Furthermore, if our suppliers fail to meet contractual requirements, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue. We rely on our collaborator to manufacture our Collaboration Product and intend to utilize third parties to manufacture our future product candidates. Therefore, we are subject to the risk that such third parties may not perform satisfactorily. We rely on our collaboration partner to manufacture our Collaboration Product and intend to rely on outside vendors to manufacture clinical~~ supply **with** ~~of our future product candidates and intend to evaluate potential third- party manufacturing capabilities if necessary to meet further clinical and commercial demand. In the event that we engage~~ third- party manufacturers ~~and they~~ **, or may be unable to** do **so on acceptable terms. The third- party manufacturers may** not successfully carry out their contractual duties ~~, meet expected deadlines or manufacture our~~ **or obligations, the occurrence of which could substantially increase our costs and limit our supply of such** product candidates **. The demand** ~~in accordance with regulatory requirements or~~ **for** ~~if there are disagreements between us and any~~ third- party manufacturer **' s services is very high** , ~~we may be delayed in producing sufficient clinical~~ and ~~commercial supply of~~ **such manufacturers could be subject to market transactions including mergers, acquisitions and other market consolidation transactions that limit their ability to provide products and services to us thereby increasing the time and cost it could take us to manufacture** our product candidates **or** ~~. In such instances, we may need to locate an~~ **any** ~~appropriate replacement~~ **approved products. Even if we are able to establish and maintain arrangements with** third- party **manufacturers, reliance on third- party manufacturers, including ImmuneOnco, entails additional risks, including: • reliance on the third party for regulatory compliance and quality assurance; • the possible breach of the manufacturing agreement by the third party; • the possible diversion of manufacturing capacity to other customers by the third party; • the possible misappropriation of our proprietary information, including our trade secrets and know- how; and • the possible termination or non- renewal of the agreement by the third party at a time that is costly or inconvenient for us. Third- party manufacturers, including ImmuneOnco, may not be able to comply with current cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third- party manufacturers, including ImmuneOnco, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates. Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. In addition, in order to conduct late- stage clinical trials of our product candidates, we will need to have them manufactured in large quantities. Our third- party manufacturers, including ImmuneOnco, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost- effective manner, or at all. Moreover, if our third- party manufacturers, including ImmuneOnco, are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of that product candidate may be delayed or not obtained, which could significantly harm our business. If the third parties, including ImmuneOnco, that we engage to manufacture product for our preclinical tests and clinical trials should cease to continue to do so for any reason, we likely would experience delays in advancing these clinical trials while we identify and qualify replacement suppliers, and we may be unable to obtain replacement supplies on terms that are favorable to us. In addition, if we are not able to obtain adequate supplies of our product candidates or the drug substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively. If our third party manufacturers divert their capacity and / or supply of materials needed for our product candidates, our ability to complete our clinical trials or eventually bring our product candidates to market may be compromised. Further, if manufacturing of our lead product candidate AXN- 2510 / IMM2510 is transferred from ImmuneOnco to another manufacturer for any reason, loss of any of the knowledge transferred relating to AXN- 2510 / IMM2510 may cause us to incur additional transition costs or result in delays in the manufacturing of AXN- 2510 / IMM2510. We rely on ImmuneOnco for the capability to manufacture our lead product candidate, AXN- 2510 / IMM2510, as well as AXN- 27M / IMM27M, and expect to rely on third party manufacturers for any other product candidates we may develop. We plan to enter into a supply agreement with ImmuneOnco for manufacturing of AXN- 2510 / IMM2510, and the termination or ImmuneOnco' s breach of such agreement could require us to find an alternative manufacturer for AXN- 2510 / IMM2510 and delay development and commercialization of AXN- 2510 / IMM2510. Manufacturing of biological compounds is inherently complex, and shifting manufacturing** relationship ~~, which~~ **to another third- party manufacturer takes significant time and resources and** may ~~not be readily available or on acceptable terms, which~~ **result in higher costs and potential inventory issues. Any failure of ImmuneOnco to adequately transfer knowledge to another manufacturer** ~~would~~ **could** ~~cause additional delay or increased expense and would thereby~~ have a material adverse effect on our business ~~, financial condition, results of operations and prospects. Reliance on collaborators and third- party providers may expose us to more risk than if we were to manufacture product candidates ourselves. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our BLA to the FDA. We do not control~~

~~the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as cGMPs for the manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and / or maintain regulatory approval for their manufacturing facilities~~ . In addition, **ImmuneOnco' s manufacturing processes may use materials which** we **may not be able to secure, requiring us to** have ~~no control over the ability of~~ **to develop alternative processes and delay manufacturing. Our reliance on ImmuneOnco and / our~~ or** ~~contract~~ **other third party** manufacturers **exposes** ~~to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. In addition, any failure to achieve and maintain compliance with these laws, regulations and standards could subject~~ us to the risk that ~~we~~ **such manufacturers** may **divert** ~~have to suspend the~~ **their capacity and / or supply of materials needed for our product candidates, compromising our ability to complete our clinical trials or commercialize our product candidates. Large pharmaceutical companies with greater resources, either through acquisitions, market consolidation or otherwise, may be able to obtain privileged access to** manufacturing ~~of~~ **capacity and /** ~~our~~ **or supply of material needed for the manufacture of AXN- 2510 / IMM2510 or our other** product candidates **. If** ~~or~~ **our competitors are able to use their resources to secure preferential access to the supply capacity of** ~~that obtained approvals could be revoked, which would adversely affect our business and reputation. Furthermore,~~ third ~~-~~ party ~~providers may breach existing agreements they have~~ **manufacturers, or if third party manufacturers elect to terminate their contracts** with us **in** ~~because of factors beyond our control. They may also terminate or refuse to renew their agreement because of their own financial difficulties or business priorities, at a time that is costly or otherwise inconvenient for~~ **favor of exclusive contracts with** ~~us. If we were unable to find adequate replacement or another~~ **other larger pharmaceutical companies** ~~acceptable solution in time~~ , **our ability to obtain a supply of AXN- 2510 / IMM2510 or any other product candidates may be impacted resulting in significant delays and higher costs for development and commercialization of our products. We may not be able to complete** our clinical trials ~~could be delayed or our~~ **or market our products at scale without stable partnerships with** ~~commercial activities could be harmed. We currently rely, and expect to continue to rely, on~~ third ~~parties to manufacture ingredients of our product candidates and to perform quality testing and we intend to maintain third~~ party manufacturers **who produce AXN- 2510 / IMM2510** ~~for~~ **or other drug compounds necessary for** ~~these ingredients, as well as to serve as additional sources of~~ our product candidates ~~, which will expose us to risks including: • reduced control for certain aspects of manufacturing activities; • termination or nonrenewal of manufacturing and service agreements with third parties in a manner or at a time that is costly or damaging to us; and • disruptions to the operations of our third- party manufacturers and service providers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or service provider. Any of these events could lead to clinical trial delays or failure to obtain regulatory approval, or impact our ability to successfully commercialize our product candidates. Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of product manufacture. We depend on third- party suppliers for materials that are necessary for the conduct of preclinical studies and expect to rely on third parties for the manufacture of our product candidates for any future clinical trials, and the loss of these third- party suppliers or their inability to supply us with sufficient quantities of adequate materials, or to do so at acceptable quality levels and on a timely basis, could harm our business. Manufacturing our product candidates requires many reagents, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for certain materials and equipment used in the manufacture of our product candidates. For example, we currently use facilities and equipment at external contract manufacturing organizations, or CMOs, as well as supply sources internal to the collaboration for vector supply. Our use of CMOs increases the risk of delays in production or insufficient supplies as we transfer our manufacturing technology to these CMOs and as they gain experience with our supply requirements. 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 of these reagents, equipment, and materials, we rely and may in the future rely on sole source vendors or a limited number of vendors. The supply of the reagents and other specialty materials and equipment that are necessary to produce our product candidates could be reduced or interrupted at any time. In such case, identifying and engaging an alternative supplier or manufacturer could result in delay, and we may not be able to find other acceptable suppliers or manufacturers on acceptable terms, or at all. Switching suppliers or manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines. If we change suppliers or manufacturers for commercial production, applicable regulatory agencies may require us to conduct additional studies or trials. If key suppliers or manufacturers are lost, or if the supply of the materials is diminished or discontinued, we may not be able to develop, manufacture and market our product candidates in a timely and competitive manner, or at all. 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 a 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. These factors could cause the delay of studies or trials, regulatory submissions, required approvals or commercialization of product candidates that we develop, cause us to incur higher costs and prevent us from commercializing our product candidates successfully. Any contamination or interruption in our manufacturing process, shortages of raw materials or failure of our suppliers of reagents to deliver necessary components could result in delays in our clinical development or marketing schedules. Given the nature of cell therapy manufacturing, there is a risk of contamination. Any contamination could adversely affect our ability to produce product candidates on schedule and could, therefore, harm our results of operations and cause reputational damage. Some of the raw materials required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of our product candidates could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could adversely affect our development timelines and our business, financial condition, results of operations and prospects. For example, the 2022 investigation of our manufacturing failures identified a central source of contamination in the cell media. Although we have completed an end- to- end analysis of our manufacturing process and implemented corrective actions to improve our manufacturing process, there can be no assurance that such actions will be effective or that we will not in the future experience contamination issues in our manufacturing process~~ . Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay. As product candidates proceed through preclinical studies to late- stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and product characteristics. Such changes carry the risk that they will not achieve our intended objectives. Any such changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue. In addition, we may be required to make significant changes to our upstream and downstream processes across our pipeline, which could delay the development of our future product candidates. Risks Related to the Commercialization of our Product Candidates Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success. If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including: • the efficacy, safety and potential advantages compared to alternative treatments; • our ability to offer our products for sale at competitive prices; • the convenience and ease of administration compared to alternative treatments; • product labeling or product insert requirements of the FDA, MHRA, EMA or other comparable foreign regulatory authorities, including any limitations or warnings contained in a product' s approved labeling, including any black box warning or REMS; • the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments; • our ability to hire and retain a sales force; • the strength of marketing and distribution support; • the availability of third- party coverage and adequate reimbursement for **our** ~~ITIL- 306 and any other~~ product candidates, once approved; • the prevalence and severity of any side effects; and • any restrictions on the use of our products together with other medications. If we are unable to establish sales, marketing and distribution capabilities for any product candidate that may receive regulatory approval, we may not be successful in commercializing those product candidates if and when they are approved. We do not have sales or marketing infrastructure. To achieve commercial success for any product candidate for which we may obtain marketing approval, we will need to establish a sales and marketing organization. In the future, we expect to build a focused sales and marketing infrastructure to market our product candidates in the United States, if they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to market our products on our own include: • our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel; • the inability of sales personnel to obtain access to physicians in order to educate physicians about our product candidates, once approved; • 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. If we are unable to establish our own sales, marketing and distribution capabilities and are forced to enter into arrangements with, and rely on, third parties to perform these services, our revenue and our profitability, if any, are likely to be lower than if we had developed such capabilities ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will

have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates. Our projections of the number of people who have the diseases we are seeking to treat, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are estimates based on our knowledge and understanding of these diseases. These estimates may prove to be incorrect and new studies may report lower incidence or prevalence estimates of these diseases. The number of patients in the United States, the European Union and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with our product candidates or patients may become increasingly difficult to identify and access, all of which would adversely affect our business, financial condition, results of operations and prospects. Further, even if we obtain approval for our product candidates, the FDA or other regulators may limit their approved indications to more narrow uses or subpopulations within the populations for which we are targeting development of our product candidates. The total addressable market opportunity for our product candidates will ultimately depend upon a number of factors including the diagnosis and treatment criteria included in the final label, if approved for sale in specified indications, acceptance by the medical community, patient access and product pricing and reimbursement. Incidence and prevalence estimates are frequently based on information and assumptions that are not exact and may not be appropriate, and the methodology is forward- looking and speculative. The process we have used in developing an estimated incidence and prevalence range for the indications we are targeting has involved collating limited data from multiple sources. Accordingly, the incidence and prevalence estimates included in this Annual Report on Form 10- K or our other filings with the Securities and Exchange Commission, or the SEC, should be viewed with caution. Further, the data and statistical information used in this Annual Report on Form 10- K or our other filings with the SEC, including estimates derived from them, may differ from information and estimates made by our competitors or from current or future studies conducted by independent sources. Off- label use or misuse of our products may harm our reputation in the marketplace, result in injuries that lead to costly product liability suits, and / or subject us to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with any product. If our product candidates are approved by the FDA, we may only promote or market our product candidates for their specifically approved indications. We will train our marketing and sales force against promoting our product candidates for uses outside of the approved indications for use, known as " off- label uses. " We cannot, however, prevent a physician from using our products off- label, when in the physician' s independent professional medical judgment he or she deems it appropriate. Furthermore, the use of our products for indications other than those approved by the FDA may not effectively treat such conditions. Any such off- label use of our product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our products for these uses for which they are not approved, which could lead to product liability suits that that might require significant financial and management resources and that could harm our reputation. Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the U. S. Federal Trade Commission, the Department of Justice, or the DOJ, the Office of Inspector General of the U. S. Department of Health and Human Services, or HHS, state attorneys general, members of the U. S. Congress, and the public. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign entities and stakeholders. Violations, including actual or alleged promotion of our products for unapproved or off- label uses, are subject to enforcement letters, inquiries, and investigations, and civil and criminal sanctions by the FDA, DOJ, or comparable foreign bodies. Any actual or alleged failure to comply with labeling and promotion requirements may result in fines, warning letters, mandates to corrective information to healthcare practitioners, injunctions, or civil or criminal penalties. Drug development is highly competitive and subject to rapid and significant technological advancements. There are several large and small pharmaceutical companies focused on delivering therapeutics for the treatment of non- small cell lung cancer, ~~ovarian~~ **triple negative breast** cancer, ~~and renal cell carcinoma~~ and other oncology indications we might target in the future. Further, it is likely that additional drugs will become available in the future for the treatment of our target indications. We face competition from segments of the pharmaceutical, biotechnology and other related markets that pursue the development of **immuno-oncology** ~~TIL or other cell~~ therapies for the treatment of solid ~~tumors~~ **tumor** ~~. Achilles~~ **cancers, including Akeso** Therapeutics, ~~Ltd.~~ **ALX Oncology, Arcus Therapeutics** , AstraZeneca plc ~~(Neogene~~ **, Beigene, BioAtla, BioNTech, Biotheus, Bristol Myers, Cullinan** Therapeutics, **Cytomx** ~~B. V.)~~ , ~~Intima Bioscience~~ **Genentech / Roche** , ~~Inc.~~ **Gilead Sciences** , **GlaxoSmithKline** ~~Iovance Biotherapeutics Inc.~~ , ~~KSQ~~ **iTeos** Therapeutics, **Merck** ~~Inc.~~ , **Novartis** ~~Lyell Immunopharma~~ , **Regeneron** ~~Inc.~~ , ~~Obsidian~~ **Sanofi, Shattuck Labs, Summit** Therapeutics, ~~Inc~~ **Werewolf Therapeutics** . **Several pharmaceutical** and ~~Turnstone Biologics Corp~~ **biotechnology companies have established themselves in the market for the treatment of non- small cell lung cancer, or NSCLC, and several additional companies are developing products for the treatment of NSCLC. Currently, the most commonly used treatments for NSCLC are several immuno- oncology drugs and chemotherapies, administered either as monotherapy or in combination with other approved therapeutics. NSCLC treatment regimens vary due to several factors, including genetic mutations and progression of disease. Several medications have been approved by FDA for these treatments, including, but not limited to pembrolizumab, atezolizumab, nivolumab, durvalumab and ipilmumab. There are anti- angiogenic therapies which are approved for the treatment of certain lung cancers, including bevacizumab and ramucirumab** . In addition, ~~we may face competition from companies focused on CAR~~ **there are several targeted therapies that have also been approved, including, but not limited to, osimertinib, adagrasib, and alectinib. Beyond currently approved therapies, several potential therapeutics are in various stages of development and clinical trials for the treatment of NSCLC, including late** - ~~T and TCR- T cell therapies~~ **stage candidates which have recently released Phase III clinical trial data in NSCLC in 2023** , such as **Daiichi Sankyo** ~~Bristol- Myers Squibb, Inc. (Juno Therapeutics, Inc.), Gilead, Inc. (Kite Pharma, Inc.), Immatics N. V.,~~ and ~~Poseida~~

~~Therapeutics, Inc~~ **AstraZeneca' s datopotamab deruxetecan and Johnson & Johnson' s amivantamab and lazertinib** . **Finally,** ~~There~~ **there** are ~~also companies utilizing other cell- based approaches that may be competitive to our product~~ candidates **in various stages of ongoing clinical trials for NSCLC, including Daiichi Sankyo and Merck with patritumab deruxtecan and AstraZeneca' s volrustomig, each currently enrolling in Phase III clinical trials** . Universities and public and private research institutions in the United States and Europe are also potential competitors ~~. For example, a Phase 3 M14TIL 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 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 FDA- approved therapies or secure patent protection that we may need for the development of our technologies and product candidates. Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the United States and in foreign countries. Our current and potential future competitors may also have significantly more experience commercializing drugs, particularly ~~cell therapy~~ **antibody- based therapeutics** and other biological products, that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small number of our competitors. We will face competition from other drugs or from other non- drug products currently approved or that will be approved in the future in the oncology field, including for the treatment of diseases and disorders in the therapeutic categories we intend to target. Therefore, our ability to compete successfully will depend largely on our ability to: • develop and commercialize drugs that are superior to other products in the market; • demonstrate through our clinical trials that our product candidates are differentiated from existing and future therapies; • attract qualified scientific, product development and commercial personnel; • obtain patent or other proprietary protection for our medicines; • obtain required regulatory approvals; • obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third- party payors; and • successfully collaborate with pharmaceutical companies and / or non- profit institutions in the discovery, development and commercialization of new medicines. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any product candidate we develop. The inability to compete with existing or subsequently introduced drugs would have an adverse impact on our business, financial condition and prospects. In addition, the reimbursement structure of approved cell therapies by other companies could impact the anticipated reimbursement structure of our cell therapies, if approved, and our business, financial condition, results of operations and prospects. Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in- license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving regulatory and marketing approval for, or commercializing, drugs before we do, which would have an adverse impact on our business and results of operations. Any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated. If we are successful in achieving regulatory approval to commercialize any biologic product candidate that we develop, it may face competition from biosimilar products. In the United States, our product candidates are regulated by the FDA as biologic products subject to approval under the BLA pathway. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA- licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed by the FDA. During this 12- year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor' s own preclinical data and data from adequate and well- controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have an adverse effect on the future commercial prospects for our biological products. There is a risk that any of our product candidates approved as a biological product under a BLA would not qualify for the 12- year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. 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. If competitors are able to obtain marketing approval for biosimilars referencing our candidates, if approved, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and potential adverse consequences. The success of our product candidates will depend significantly on coverage and adequate reimbursement or the willingness of patients to pay for these therapies. We believe our success depends on obtaining and maintaining coverage and adequate reimbursement for our product candidates and the extent to which patients will be willing to pay out- of- pocket for such products, in the absence of reimbursement for all or part of the cost. In the United States and in other countries, 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. The availability of coverage and adequacy of reimbursement for our products by third- party payors, including government health care programs (e. g., Medicare, Medicaid, TRICARE), managed care providers, private health insurers, health maintenance organizations, and other organizations is essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates. Third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a payor- by- payor basis. One payor' s determination to provide coverage for a drug product does not assure that other payors will also provide coverage, and adequate reimbursement. The principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within ~~the U. S. Department of Health and Human Services, or~~ HHS. CMS decides whether and to what extent products will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Third- party payors determine which products and procedures they will cover and establish reimbursement levels. Even if a third- party payor covers a particular product or procedure, the resulting reimbursement payment rates may not be adequate. Patients who are treated in- office for a medical condition generally rely on third- party payors to reimburse all or part of the costs associated with the procedure, including costs associated with products used during the procedure, and may be unwilling to undergo such procedures in the absence of such coverage and adequate reimbursement. Physicians may be unlikely to offer procedures for such treatment if they are not covered by insurance and may be unlikely to purchase and use our product candidates, if approved, for our stated indications unless coverage is provided and reimbursement is adequate. In addition, for products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Reimbursement by a third- party payor may depend upon a number of factors, including the third- party payor' s determination that a procedure is safe, effective and medically necessary; appropriate for the specific patient; cost- effective; supported by peer- reviewed medical journals; included in clinical practice guidelines; and neither cosmetic, experimental, nor investigational. Further, increasing efforts by third- party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost- effectiveness of our products, in addition to the costs required to obtain FDA or comparable regulatory approvals. Additionally, we may also need to provide discounts to purchasers, private health plans or government healthcare programs. Our product candidates may nonetheless not be considered medically necessary or cost- effective. If third- party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. We expect to experience pricing pressures from third- party payors in connection with the potential sale of any of our product candidates. Decreases in third- party reimbursement for any product or a decision by a third- party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales. **Further, coverage policies and third- party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained for one or more of our product candidates, if approved, less favorable coverage policies and reimbursement rates may be implemented in the future.** Foreign governments also have their own healthcare reimbursement systems, which vary significantly by country and region, and we cannot be sure that coverage and adequate reimbursement will be made available with respect to the treatments in which our products are used under any foreign reimbursement system. There can be no assurance that ~~ITIL- 306, or~~ **our** ~~any other~~ product ~~candidate~~ **candidates** , if approved for sale in the United States or in other countries, will be considered medically reasonable and necessary, that it will be considered cost- effective by third- party payors, that coverage or an adequate level of reimbursement will be available or that reimbursement policies and practices in the United States and in foreign countries where our products are sold will not adversely affect our ability to sell our product candidates profitably, if they are approved for sale. Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop. We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or drugs caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • decreased demand for any product candidates or drugs that we may develop; • injury to our reputation and significant negative media attention; • withdrawal of clinical trial participants; • significant costs to defend the related litigation; • substantial monetary awards paid to trial participants or patients; • loss of revenue; • reduced resources of our management to pursue our business strategy; and • the inability to commercialize any products that we may develop. Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our business and operations would suffer in the event we, or the third parties ~~upon which~~ **with whom** we ~~rely~~ **work** , suffer computer system failures, cyberattacks or a deficiency in our or such third parties' cybersecurity. In the ordinary course of our business, we, and the third parties ~~upon which~~ **with whom** we ~~rely~~ **work** , ~~may~~ collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit and share (collectively, process) proprietary, confidential and sensitive data, including personal data (such as health- related data), data ~~we collect~~ about trial participants in connection with clinical trials, intellectual property ~~,~~ sensitive third- party data and trade secrets (collectively, sensitive information). Cyber- attacks,

malicious internet- based activity, online and offline fraud and other similar activities threaten the confidentiality, integrity and availability of our sensitive information and information technology systems and those of the third parties ~~upon which~~ **with whom** we ~~rely~~ **work** . Such threats are prevalent and continue to rise, are increasingly difficult to detect and come from a variety of sources, including traditional computer " hackers, " threat actors, " hacktivists, " organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states and nation- state- supported actors. Some actors now engage and are expected to continue to engage in cyber- attacks, including without limitation nation- state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, and the third parties ~~upon which~~ **with whom** we ~~rely~~ **work** , may be vulnerable to a heightened risk of these attacks, including retaliatory cyber- attacks, that could materially disrupt our systems and operations, supply chain and ability to produce, sell and distribute our goods and services. We and the third parties ~~upon which~~ **with whom** we **work are** ~~rely may be~~ subject to a variety of evolving threats, including but not limited to social- engineering attacks (including through deep fakes, which **are** ~~may be~~ increasingly difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial- of- service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply- chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program. We rely on third **parties** ~~- party service providers~~ and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, encryption and authentication technology, employee email and other functions. We also rely on third **parties** ~~- party service providers~~ to provide other products, services or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If ~~our~~ **these** third **parties** ~~- party service providers~~ experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if ~~our~~ **these** third **parties** ~~- party service providers~~ fail to satisfy their privacy or security- related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply- chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or **in the** ~~our third- party partners'~~ supply chains **of the third parties with whom we work** have not been or will not be compromised. ~~Any~~ **Certain** of the previously identified or similar threats ~~could~~ **have in the past and may in the future** cause a security incident or other interruption that **have in the past and** could **in the future** result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties ~~upon~~ **with** whom we ~~rely~~ **work. For example, we have been the target of unsuccessful phishing attempts and unsuccessful attempts to impersonate key personnel in email in the past, and expect such attempts will continue in the future** . A security incident or other interruption could disrupt our ability (and that of third parties ~~upon~~ **with** whom we ~~rely~~ **work**) to provide our services. We ~~may~~ expend ~~significant~~ resources or **may have to** modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations ~~may~~ require us to implement and maintain specific security measures or industry- standard or reasonable security measures to protect our information technology systems and sensitive information **. It may be difficult or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems** . While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps to detect **, mitigate** and remediate vulnerabilities **in our information systems (such as our hardware or software, including that of third parties with whom we work)** , but we ~~may~~ **have** not **in the past and may not in the future** be able to detect and remediate all vulnerabilities ~~because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore~~ , **including on** ~~such vulnerabilities could be exploited but may not be detected until after~~ a **timely basis** ~~security incident has occurred. These vulnerabilities pose material risks to our business~~ . Further, we **have (and** may **in the future)** ~~experience~~ **experienced** delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. **Vulnerabilities could be exploited and result in a security incident.** Applicable data privacy and security obligations may require us **, or we may voluntarily choose,** to notify relevant stakeholders **(including affected individuals, customers, regulators, and investors)** of security incidents **, or to take other actions, such as providing credit monitoring and identity theft protection services** . Such disclosures ~~are~~ **and related actions can be** costly, and the disclosure or the failure to comply with such **applicable** requirements could lead to adverse consequences. If we, or a third party ~~upon which~~ **with whom** we ~~rely~~ **work** , experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include government enforcement actions (for example, investigations, fines, penalties, audits and inspections), additional reporting requirements and / or oversight, restrictions on processing sensitive information (including personal data), litigation (including class claims), indemnification obligations,

negative publicity, reputational harm, monetary fund diversions, interruptions in our operations (including availability of data), financial loss and other similar harms. ~~Our~~ **Some of our** contracts ~~may~~ **do** not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all or that such coverage will pay future claims. In the ordinary course of business, we process personal data and other sensitive information. Our data processing activities ~~may~~ subject us to ~~numerous~~ data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations relating to data privacy and security. In the United States, federal, state and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act) and other similar laws (e. g., wiretapping laws). For example, **the federal Health Insurance Portability and Accountability Act of 1996, or** HIPAA, as amended by **the Health Information Technology for Economic and Clinical Health Act, or** HITECH, imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information. In addition, the California Consumer Privacy Act of 2018, or the CCPA, as amended ~~by the California Privacy Rights Act of 2020, or the CPRA~~, applies to personal data of consumers, business representatives and employees who are California residents and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for ~~administrative~~ fines ~~of up to $ 7, 500~~ per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. ~~Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data we may maintain about California residents. In addition, the CPRA expanded the CCPA' s requirements, including by adding a new right for individuals to correct their personal data and establishing a new regulatory agency to implement and enforce the law.~~ Other states ~~, such as Virginia and Colorado,~~ have also passed **or are considering** comprehensive privacy laws, and similar laws are being considered ~~in several other states, as well as~~ at the federal and local levels. These developments may further complicate compliance efforts and may increase legal risk and compliance costs for us and the third parties ~~upon which~~ **with whom** we ~~rely~~ **work**. Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the United Kingdom' s General Data Protection Regulation, or UK GDPR, imposes strict requirements for processing personal data. Under the UK GDPR, companies may face temporary or definitive bans on data processing and other corrective actions, fines of up to £ 17. 5 million or 4 % of annual global revenue, whichever is greater, or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. In **China, the PRC Data Security Law imposes data security and privacy obligations on entities and individuals carrying out data activities, and introduces a data classification and hierarchical protection system based on the importance of data in economic and social development, and** ~~the~~ **other** ~~ordinary course of business, we~~ **factors. The PRC Data Security Law also provides for a national security review procedure for data activities that** may ~~transfer~~ **affect national security and imposes export restrictions on certain data and information. In addition, the Personal Information Protection Law governs** personal ~~data from~~ **information processing,** the **rules** ~~United Kingdom to the United States. The United Kingdom has enacted laws requiring data to be localized or~~ **for** ~~limiting the transfer of personal data to other countries. In particular, the United Kingdom has significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and~~ cross-border **provision of** ~~data transfer laws. Although there are currently various mechanisms that may be used to transfer~~ personal **information** ~~data from the United Kingdom to the United States in compliance with law~~, ~~such as the United Kingdom' s international data transfer agreement, these~~ -- **the rights of individuals in** ~~mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer~~ personal **information** ~~data to the United States. If there is no lawful manner for us to transfer personal data from the United Kingdom to the United States, or if the requirements for a legally- compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data~~ processing activities ~~to~~ **,** ~~other~~ -- **the** ~~jurisdictions at significant expense~~ **obligations of personal information processors** , ~~increased exposure to regulatory actions, substantial fines~~ and ~~penalties, the inability to transfer data and work with partners, vendors and other~~ -- **the** ~~third parties and injunctions against our~~ **legal responsibilities for illegal collection,** processing ~~or transferring~~ **, and use** of personal **information** ~~data necessary to operate our business~~. **We** ~~Additionally, companies that transfer personal data out of the United Kingdom to other jurisdictions, particularly the United States,~~ are ~~subject to increased scrutiny from regulators, individual litigants and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the European Union' s General Data Protection Regulation' s, or EU GDPR, cross- border data transfer limitations. For example, in May 2023, the Irish Data Protection Commission determined that a major social media company' s use of the standard contractual clauses to transfer personal data from Europe to the United States was insufficient and levied a 1. 2 billion Euro fine against the company and prohibited the company from transferring personal data to the United States. Substantially similar legal considerations apply under the UK GDPR as those analyzed and applied in the context of the EU GDPR by the Irish Data Protection Commission in reaching the decision to levy this fine. In addition to data privacy and security laws, we may be contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We may~~ also ~~be~~ bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the UK GDPR and the CCPA, require our customers to impose specific contractual restrictions on their service providers. We

~~may~~ publish privacy policies, marketing materials and other statements regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive **, misleading** , unfair or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences. Obligations related to data privacy and security are quickly changing, becoming increasingly stringent and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources. These obligations may necessitate changes to our services, information technologies, systems and practices and to those of any third parties that process personal data on our behalf. We may at times fail, or be perceived to have failed, in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties ~~on which~~ **with whom** we ~~rely~~ **work** may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties ~~on which~~ **with whom** we ~~rely~~ **work** fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to government enforcement actions (e. g., investigations, fines, penalties, audits, inspections, and similar), litigation (including class- action claims) and mass arbitration demands, additional reporting requirements and / or oversight, bans on processing personal data, orders to destroy or not use personal data and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business or financial condition, including but not limited to loss of customers, interruptions or stoppages in our business operations including clinical trials, inability to process personal data or to operate in certain jurisdictions, limited ability to develop or commercialize our products, expenditure of time and resources to defend any claim or inquiry, adverse publicity or substantial changes to our business model or operations. In particular, plaintiffs have become increasingly more active in bringing privacy- related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could seriously harm our business. We and any contract manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third- party facilities. We also could incur significant costs associated with civil or criminal fines and penalties. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could seriously harm our business. Risks Related to Our Dependence on Third Parties We **intend to** rely on third parties to conduct **, supervise and monitor a significant portion of** our **research and preclinical testing and** clinical trials **for our product candidates** , and **if** those third parties ~~may~~ **do** not **successfully carry out their contractual duties, comply with regulatory requirements or otherwise** perform satisfactorily, ~~including failing~~ **we may not be able** to ~~meet established deadlines~~ **obtain regulatory approval** ~~for~~ **or** ~~the completion of~~ **commercialize product candidates, or** such **approval or commercialization may be delayed, and our business may be substantially harmed. We do not have a clinical operations team and intend to engage CROs and other third parties to conduct our planned preclinical studies or** clinical trials **and to monitor and manage data** . ~~Our reliance~~ **We expect to rely** on third parties ~~for~~ **, including** clinical ~~development activities reduces our control over~~ **data management organizations, medical institutions and clinical investigators, to conduct** ~~these~~ **those** ~~activities. However, if we sponsor~~ clinical trials **. If any** ~~, we are responsible for ensuring that each~~ of our **relationships** ~~clinical trials is conducted in accordance~~ with ~~the general investigational plan and protocols for the trials. Moreover, the FDA requires us to comply with requirements, commonly referred to as good clinical practices, for conducting, recording, and reporting the results of clinical trials to ensure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. Furthermore,~~ these third parties **terminate, we** may ~~also have~~ **not be able to timely enter into arrangements with alternative third parties or to do so on commercially reasonable terms, if at all. Switching or adding CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our** relationships with **our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial**

condition and prospects. Further, the performance of our CROs and other ~~entities, some of which~~ **third parties conducting our trials** may **also** be **interrupted by public health emergencies. In addition, any third parties conducting our clinical trials will not be our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether** ~~our~~ **or** ~~competitors~~ **not they devote sufficient time and resources to our clinical programs** . If these third parties do not successfully carry out their contractual duties or **obligations or** meet expected deadlines, ~~we may~~ **if they need to** be ~~delayed in~~ **replaced or if the quality or accuracy of the clinical data they** ~~obtaining~~ **obtain is compromised due to the failure to adhere to our clinical protocols,** regulatory ~~approvals~~ **requirements** ~~for~~ **or** ~~our product candidates and may be delayed in our efforts to successfully commercialize our product candidates for targeted diseases. In addition, investigator initiated trials, or~~ **for** ~~IITs~~ **other reasons** , ~~which are scientific research that is initiated, sponsored, and conducted by an independent investigator (s) and / or~~ **our** ~~institution (s) not affiliated with us, are being, and additional IITs, may be conducted involving potential product candidates, including the potential IITs in China. The investigator, sponsor, and / or investigator / sponsor remains responsible for conception, design, data analysis, publication, and compliance with applicable law. Investigator initiated trials can contribute towards enhancing the understanding of products (such as mechanism of action) and sparking new ideas for further research; however, IITs are generally not supported by pharmaceutical companies for the purposes of generating data that can lead to product labelling changes. Even if an IIT has positive results, additional studies, along with regulatory agency guidance and approval, would be required to advance a pharmaceutical product to the next stage of development and new potential labelling changes or indications. If we are unable to confirm or replicate the results from an IIT or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development. Further, if the data proves to be inadequate compared to the firsthand knowledge we might have gained had the IIT been sponsored and conducted by us, then our ability to design and conduct any future~~ clinical trials ~~ourselves~~ may be **extended, delayed** ~~adversely affected. Negative results in IITs could have a material adverse effect on our~~ **or** ~~efforts~~ **terminated and we may not be able** to obtain regulatory approval for ~~such~~ **or successfully commercialize our** product candidates ~~and the public perception~~ **. Consequently, our results** of ~~such~~ **operations and the commercial prospects for our** product candidates ~~. In addition~~ **would be harmed** , **our costs could increase substantially and our ability to generate revenue could be delayed significantly. We will rely on these parties for execution of our preclinical studies and clinical trials, and generally will not control their activities. Our reliance on these** third parties **for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring** that **each** ~~are investigating product candidates which have not been provided by us may seek and obtain regulatory approval~~ of ~~product candidates before we do, which may adversely affect~~ our ~~development strategy and eligibility for certain exclusivities for which we may otherwise be eligible. We intend to rely on third parties to conduct, supervise and monitor a significant portion of our research and preclinical testing and~~ clinical trials **is conducted in accordance with** ~~for our product candidates, and if those~~ **the general investigational plan and protocols for** ~~third parties do not successfully carry out their~~ **the** ~~contractual duties~~ **trial. Moreover** , **the FDA requires us to** comply with **standards** ~~regulatory requirements or otherwise perform satisfactorily~~ , **commonly referred** ~~we may not be able~~ to **as good** ~~obtain regulatory approval or commercialize product candidates, or such approval or commercialization may be delayed, and our business may be substantially harmed. We do not have a~~ clinical ~~operations team~~ **practices, or GCPs, for conducting, recording** and ~~intend~~ **reporting the results of clinical trials** to ~~engage~~ **assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. If we or any of our** CROs ~~and~~ **or** other third parties **, including trial sites, fail** to ~~conduct our planned~~ **comply with applicable GCPs, the** ~~preclinical~~ **clinical** ~~studies~~ **data generated in** ~~or~~ **our** clinical trials **may be deemed unreliable** and ~~to monitor and manage data. We expect to continue to rely on third parties, including clinical data management organizations, medical institutions and clinical investigators, to conduct those~~ **the FDA, MHRA, EMA or comparable foreign regulatory authorities may require us to perform additional** clinical trials **before approving our marketing applications** . ~~Any~~ **We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any** of **our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP conditions. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Furthermore,** these third parties may **also have** ~~terminate their engagements with us, some in the event of an uncured material breach and some at any time for convenience. If any of our~~ relationships with ~~these third parties terminate, we may not be able to timely enter into arrangements with alternative third parties or to do so on commercially reasonable terms, if at all. Switching or adding CROs involves substantial cost and requires management time and focus. In addition, there~~ **other entities** ~~is a natural transition period when a new CRO commences work. As a result~~ , **some of** ~~delays occur,~~ which **may** ~~can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can~~ be ~~no assurance that we will not encounter challenges or~~ **our competitors** ~~delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. Further, the performance of our CROs and other third parties conducting our trials may also be interrupted by public health emergencies. In addition, any third parties conducting our clinical trials will not be our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our clinical programs~~ . If these third parties do not successfully carry out their contractual duties or ~~obligations or~~ meet expected deadlines, **we may** ~~if they need to~~ be **delayed in** ~~replaced or if the quality or accuracy of the clinical data they obtain~~ **obtaining** ~~is compromised due to the failure to adhere to our clinical protocols,~~ regulatory ~~requirements~~ **approvals** ~~or~~ **for** ~~for other reasons,~~ our ~~clinical trials~~ **product candidates and** may be ~~extended,~~ delayed **in** ~~or~~ **our efforts** ~~terminated and we may not be able~~ to ~~obtain regulatory approval for or~~ successfully commercialize our product candidates ~~. Consequently, our results of operations and the commercial prospects for our product candidates would be~~

~~harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly. We rely on these parties for execution of our preclinical studies and clinical trials, and generally do not control their activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, or~~ **for targeted diseases** ~~GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. If we or any of our CROs or other third parties, including trial sites, fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, MHRA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP conditions. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process~ . We also are required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government- sponsored database, ClinicalTrials. gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval ~~for ITIL- 306 or~~ **our** ~~any other~~ product candidates. We also expect to rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential revenue. We **are currently party to a collaboration with ImmuneOnco and** may seek **additional** collaborations with third parties for the development or commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates. We **currently are party to a collaboration with ImmuneOnco related to our lead product candidate, AXN- 2510 / IMM2510, as well as AXN- 27M / IMM27M. We** may seek **additional** ~~third- party collaborators~~ **collaboration arrangements with pharmaceutical or biotechnology companies** for the development ~~and~~ **or** commercialization of our product candidates, including for the commercialization of any of our product candidates that are approved for marketing outside the United States. ~~Our likely~~ **We will face, to the extent that we decide to enter into additional collaboration agreements, significant competition in seeking appropriate** collaborators **. Moreover, collaboration arrangements are complex and time- consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish and implement collaborations** ~~for~~ **or** ~~any~~ **other arrangements should we so chose to enter into** such arrangements ~~include regional and national pharmaceutical companies and biotechnology companies~~ . **The terms of** ~~If we enter into~~ any ~~additional such~~ **collaborations or other** arrangements ~~with any third parties~~ **that we have or may establish may not be favorable to us** . **and** we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates would pose the following risks to us: • collaborators have significant discretion in determining the efforts and resources that they will apply to ~~these~~ collaborations; • collaborators may not perform their obligations as expected; • collaborators may not pursue development and commercialization of ~~any~~ **our** product candidates ~~that achieve regulatory approval~~ or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or **other** external factors, such as an acquisition, **or business combination,** that ~~divert~~ **diverts** resources or ~~create~~ **creates** competing priorities; • collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial ~~or~~ **,** abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing; • collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; • we could grant exclusive rights to our collaborators that would prevent us from collaborating with others; • our collaborators could be our competitors and product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or drugs, which may cause collaborators to cease to devote resources to the commercialization of our product candidates; • a collaborator with marketing **, manufacturing** and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products; • disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time- consuming and expensive; • collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way ~~as~~ **that gives rise** to ~~invite~~ **actual or threatened** litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential ~~litigation~~ **liability** ; • collaborators may infringe the intellectual property rights of third

parties, which may expose us to litigation and potential liability ~~not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities~~ ;• collaborators may **own** ~~not properly maintain~~ or ~~defend our~~ **co- own** intellectual property **covering our products that results from our collaborating with them,and in such cases,we would not have the exclusive** ~~rights~~ **right to develop** or **commercialize such** ~~may use our~~ intellectual property **;• a collaborator' s sales and marketing activities** or ~~proprietary information~~ **other operations may not be** in ~~a way that gives rise to actual~~ **compliance with applicable laws resulting in civil** or **criminal proceedings** ~~threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability~~ ;• disputes may arise between us and a collaborator that causes the delay or termination of the research,development or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources;• collaborations may be terminated,and,if terminated,may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products ~~;• collaborators~~ ; and • collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates. Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If any future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for any 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 the proposed collaborator' s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, MHRA, EMA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Collaborations are complex and time- consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate revenue. Risks Related to our Intellectual Property We **depend on our relationship with** ~~rely upon a combination of patents~~ , ~~trade secret protection~~ and **the comprehensiveness of** ~~confidentiality agreements to protect~~ the intellectual property **licensed from, ImmuneOnco, and termination of the IO Collaboration Agreement, or issues** related to **intellectual property could have a material adverse effect on our business. We depend on the know- how and other intellectual property licensed from ImmuneOnco through the IO Collaboration Agreement for the development and, if approved, commercialization of our lead product candidate, AXN- 2510 / IMM2510. If the agreement is terminated,** ~~our~~ **or found to be unenforceable, it could result in the loss of significant rights and could harm our ability to commercialize AXN- 2510 / IMM2510. The IO Collaboration Agreement imposes certain obligations on us, including obligations to use diligent efforts to meet development thresholds, funding requirements, payment obligations, and commercialization. If we are unable to meet our obligations, some or all of our rights under the IO Collaboration Agreement may be restricted or terminated. For example, the IO Collaboration Agreement is revocable in certain circumstances, including in the event we do not achieve certain payment deadlines. Without the patents under this agreement, we will not be able to continue to develop AXN- 2510 / IMM2510 or AXN-27M / IMM27M. The IO Collaboration Agreement may be terminated by ImmuneOnco in the event of a material breach by Axion Bio or if Axion Bio defaults in the performance of any of our material obligations under the agreement, and such default continues for 90 days, or with respect to any breach of any undisputed payment obligations, for 60 days. Additionally, our ability to realize the full potential of the IO Collaboration Agreement may be severely limited by factors involving intellectual property rights including: • whether and to what extent our technology and processes infringe on intellectual property rights of other third parties that are not subject to the IO Collaboration Agreement; • whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of intellectual property without their authorization; • our right to sublicense patent and other rights to third parties under collaborative development relationships; • our compliance with our obligations with respect to the use of the licensed technology in relation to our development and commercialization of** product candidates **; • ownership of specific intellectual property;** and **• the impact on payments and costs associated with commercialization if there is blocking intellectual property in or costs associated with prosecution, maintenance and enforcement under the IO Collaboration Agreement These issues, if they arise, could narrow what we believe to be the scope of our rights to the relevant intellectual property or** ~~technologies~~ **technology , increase what we believe to be our financial or other obligations under the relevant agreement, or increase our costs to develop, manufacture and commercialize products under the IO Collaboration Agreement** . Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our ~~proprietary technology and~~ product candidates

~~. As of the date of this Annual Report on Form 10- K, we do not currently in- license any intellectual property, but we may choose to do so in the future~~ . The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. We cannot offer any assurances about which of our patent applications will issue, the breadth of any resulting patent or whether any of the issued patents will be found invalid and unenforceable or will be threatened by third parties. We cannot offer any assurances that the breadth of our resulting or granted patents will be sufficient to stop a competitor from developing and commercializing a product, including a biosimilar product, that would be competitive with one or more of our product candidates. There is no assurance that all the potentially relevant prior art relating to our patent and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we or our future licensors were the first to file any patent application related to our product candidates and technologies. Additionally, a derivation proceeding before the United States Patent and Trademark Office can be initiated by a third party to contest inventorship of the subject matter claimed in our applications. Furthermore, any successful challenge to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any of our product candidates and technologies that we may develop. Even if they are unchallenged or such third- party challenges are unsuccessful, our patent and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates and technologies, or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent and patent applications we hold, obtain or pursue with respect to our product candidates and technologies is challenged, or if they fail to provide meaningful exclusivity for our product candidates and technologies, it could threaten our ability to commercialize our product candidates and technologies. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection, if approved, would be reduced. The patent prosecution process is expensive and time- consuming. We may not be able to prepare, file and prosecute all necessary or desirable patent applications at a commercially reasonable cost, in a timely manner, or in all jurisdictions. It is also possible that we may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection. Moreover, depending on the terms of any future in- licenses to which we may become a party, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology in- licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. In addition to the protection provided by our patent estate, we rely on trade secret protection and confidentiality agreements to protect proprietary scientific, business and technical information and know- how that is not or may not be patentable or that we elect not to patent. We seek to protect our proprietary information, data and processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and partners. Although these agreements are designed to protect our proprietary information, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Although we generally require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know- how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed with all third parties who may have helped to develop our intellectual property or who had access to our proprietary information, or that our agreements will not be breached. If any of the parties to these confidentiality agreements breaches or violates the terms of such agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time- consuming, and the outcome is unpredictable. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. We cannot guarantee that our employees, former employees or consultants will not file patent applications claiming our inventions. Because of the " first- to- file " laws in the United States and the uncertainties surrounding outcomes of derivation proceedings before the United States Patent and Trademark Office, such unauthorized patent application filings may defeat our attempts to obtain patents on our own inventions. Trade secrets and know- how can be difficult to protect as trade secrets and know- how will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Moreover, our competitors may independently develop knowledge, methods and know- how equivalent to our trade secrets. Competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets and proprietary know- how were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. While we have confidence in these individuals, organizations and systems, our agreements or security measures may be breached, and we may not have adequate remedies for any breach. Also, if the

steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. If we are unable to prevent material disclosure of the non- patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition. Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time, and if we do not obtain protection under the Hatch- Waxman Amendments and similar non- United States legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed. Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates may expire before or shortly after such candidates are commercialized. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U. S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Amendments, and similar legislation in the European Union. The Hatch- Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced and could have a material adverse effect on our business. If we fail to comply with our obligations imposed by any intellectual property licenses with third parties that we may need in the future, we could lose rights that are important to our business. **We** ~~Although we do not currently have any intellectual property licenses with third parties, we~~ may in the future require licenses to additional third- party technology and materials. Such licenses may not be available in the future or may not be available on commercially reasonable terms, or at all, which could have a material adverse effect on our business and financial condition. Even if we acquire the right to control the prosecution, maintenance and enforcement of the licensed and sublicensed intellectual property relating to our product candidates, we may require the cooperation of our licensors and any upstream licensor, which may not be forthcoming. Therefore, we cannot be certain that the prosecution, maintenance and enforcement of these patent rights will be in a manner consistent with the best interests of our business. If we or our licensor fail to maintain such patents, or if we or our licensor lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated and our right to develop and commercialize any of our product candidates that are the subject of such licensed rights could be adversely affected. In addition to the foregoing, the risks associated with patent rights that we license from third parties will also apply to patent rights we may own in the future. Further, if we fail to comply with our development obligations under our license agreements, we may lose our patent rights with respect to such agreement, which would affect our patent rights worldwide. Termination of any future license agreements would reduce or eliminate our rights under these agreements and may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. Any of the foregoing could prevent us from commercializing our other product candidates, which could have a material adverse effect on our operating results and overall financial condition. In addition, intellectual property rights that we in- license in the future may be sublicenses under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop and commercialize our product candidates may be materially harmed. Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future patents. Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States. Furthermore, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific, and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. For example, on September 16, 2011, the Leahy- Smith America Invents Act, or the Leahy- Smith Act, was signed into law. The Leahy- Smith Act included a number of significant changes to U. S. patent law. These included provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO has developed new and untested regulations and procedures to govern the full implementation of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act, and in particular, the first to file provisions, became effective in March 2013. The Leahy- Smith Act has also introduced procedures making it easier for third parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy- Smith Act contained new statutory provisions that require the USPTO to issue new regulations

for their implementation, and it may take the courts years to interpret the provisions of the new statute. It is too early to tell what, if any, impact the Leahy- Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future patents. Further, the United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening 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 actions by the United States 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 patents that we have owned or licensed or that we might obtain in the future. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition. Similarly, changes in patent laws and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we may obtain in the future. As an example, some European patent applications will have the option, upon grant of a patent, of becoming a Unitary Patent, which will be subject to the jurisdiction of the Unitary Patent Court, or UPC. The option of a Unitary Patent is a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation in the UPC. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance in a given country of a patent covering an invention is not followed by the issuance in other countries of patents covering the same invention, or if any judicial interpretation of the validity, enforceability or scope of the claims or the written description or enablement, in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection. We may be involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful. Competitors may infringe our issued patents or any patents issued as a result of our pending or future patent applications. 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 a patent of ours is not valid or is unenforceable, or may refuse to stop the other party in such infringement proceeding 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 any of our patent applications at risk of not yielding an issued patent. If we 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 or product candidate is invalid and / or unenforceable. In patent litigation in the United States, counterclaims alleging invalidity and / or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the PTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re- examination, post grant review, inter partes review and equivalent proceedings in foreign jurisdictions (for example, opposition proceedings, nullity proceedings or litigation or invalidation trials or invalidation proceedings). Such proceedings could result in revocation of 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 of our patents, 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 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. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could have a material adverse impact on our business. Derivation proceedings initiated by third parties or us may be necessary to determine the inventorship (and possibly also ownership) of inventions with respect to our patent applications or resulting patents, or patent applications or resulting patents of third parties. An unfavorable outcome could require us to cease using the related technology or force us to take a license under the patent rights of the prevailing party, if available. Furthermore, our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. We may not identify relevant third party patents or may incorrectly interpret the relevance, scope or expiration of a third party patent which might adversely affect our ability to develop and market our products. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents,

the scope and validity of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent' s prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third party patent or may incorrectly predict whether a third party' s pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products. We may be unsuccessful in licensing or acquiring intellectual property from third parties that may be required to develop and commercialize our product candidates. A third party may hold intellectual property, including patent rights that are important or necessary to the development and commercialization of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to acquire or obtain a license to such intellectual property from these third parties, and we may be unable to do so on commercially reasonable terms or at all. The licensing or acquisition of third- party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third- party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third- party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third- party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business. Our commercial success depends in part on our ability to develop, manufacture, market and sell our drug candidates and use our proprietary technologies without infringing or otherwise violating the patents and proprietary rights of third parties. As our current and future product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation proceedings, post grant reviews, inter partes reviews, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates, and there may be third- party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates and technologies. Third parties, including our competitors may initiate legal proceedings against us alleging that we are infringing or otherwise violating their patent or other intellectual property rights. We cannot provide any assurance that our current and future product candidates do not infringe other parties' patents or other proprietary rights, and competitors or other parties may assert that we infringe their proprietary rights in any event. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and future product candidates, including interference or derivation proceedings before the USPTO. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third- party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize ~~ITIL- 306 or~~ **our** ~~any future~~ product candidates. In order to successfully challenge the validity of any such U. S. patent in federal court, we would need to overcome a presumption of validity. As this burden is high and requires us to present clear and convincing evidence as to the invalidity of any such U. S. patent claim, there is no assurance that a court of competent jurisdiction would agree with us and invalidate the claims of any such U. S. patent. Moreover, given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. While we may decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in the United States and abroad could uphold the validity of any such patent. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates. Regardless of when filed, we may fail to identify relevant third- party patents or patent applications, or we may incorrectly conclude that a third- party patent is invalid or not infringed by our product candidates or activities. If a patent holder believes that one of our product candidates infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. In addition, third parties may obtain patents in the future and claim that our product candidates or technologies infringe upon these patents. Moreover, we may face patent infringement claims from non- practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the drug or product candidate that is the subject of the actual or threatened suit. If we are found to infringe a third party' s valid intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if a license can be obtained on acceptable terms, the rights may be non- exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our

operations. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Under certain circumstances, we could be forced, including by court orders, to cease commercializing our product candidates. In addition, in any such proceeding or litigation, we could be found liable for substantial monetary damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed the patent at issue. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business. The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management' s attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations. We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties. We employ individuals who were previously employed at other biotechnology or biopharmaceutical companies. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know- how of others in their work for us, 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 our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our future patents. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. We may be subject to claims challenging the inventorship or ownership of our future patents and other intellectual property. We may also be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patent applications, our future patents issued as a result of our pending or future applications, or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Although it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self- executing or the assignment agreements may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. If we rely on third parties to manufacture or commercialize our product candidates, or if we collaborate with additional third parties for the development of such product candidates, we must, at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third- party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know- how and trade secrets, a competitor' s discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations. In addition, these agreements typically restrict the ability of our advisors, employees, third- party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, we may not be able to prevent the unauthorized disclosure or use of our technical know- how or other trade secrets by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time- consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. We may enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world. Filing and prosecuting patent applications and defending patents covering our product candidates in

all countries throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as that in the United States or Europe. These products may compete with our product candidates, and our future patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. In addition, we may decide to abandon national and regional patent applications before they are granted. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology. While we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions. The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and Europe and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property rights, especially those relating to life sciences, which could make it difficult for us to stop the infringement of our future patents or marketing of competing products in violation of our proprietary rights generally. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our future patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing as patents, 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. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. 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 from third parties. Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and / or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents and / or applications and any patent rights we may obtain in the future. Furthermore, the USPTO and various non- U. S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals and rely on such third parties to help us comply with these requirements and effect payment of these fees with respect to the patent and patent applications that we own, and if we in- license intellectual property, we may have to rely upon our licensors to comply with these requirements and effect payment of these fees with respect to any patents and patent applications that we license. In many cases, an inadvertent lapse of a patent or patent application can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non- compliance can result in abandonment or lapse of the patents or patent applications, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market, which could have a material adverse effect on our business. Any trademarks we have obtained or may obtain may be infringed or otherwise violated, or successfully challenged, resulting in harm to our business. We expect to rely on trademarks as one means to distinguish our product candidates, if approved for marketing, from the drugs of our competitors. Once we select new trademarks and apply to register them, our trademark applications may not be approved. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our drugs, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe or otherwise violate our trademarks and we may not have adequate resources to enforce our trademarks. Any of the foregoing events may have a material adverse effect on our business. Moreover, any name we propose to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional

resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Any collaboration arrangements that we may enter..... resulting in civil or criminal proceedings. Intellectual property rights do not necessarily address all potential threats to our competitive advantage. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative: • others may be able to make products that are similar to or otherwise competitive with our product candidates but that are not covered by the claims of our current or future patents; • an in- license necessary for the manufacture, use, sale, offer for sale or importation of one or more of our product candidates may be terminated by the licensor; • we **, our collaborators,** or future collaborators might not have been the first to make the inventions covered by our **licensed- in,** issued or future issued patents or our pending patent applications; • we **, our collaborators,** or future collaborators might not have been the first to file patent applications covering certain of our inventions **or the inventions we have licensed- in** ; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; • it is possible that our pending patent applications will not lead to issued patents; • issued patents that we own or in- license may be held invalid or unenforceable as a result of legal challenges by our competitors; • issued patents that we own or in- license may not provide coverage for all aspects of our product candidates in all countries; • our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we may not develop additional proprietary technologies that are patentable; and • the patents of others may have an adverse effect on our business. Should any of these events occur, they could significantly harm our business, results of operations and prospects. Risks Related to Legal and Regulatory Compliance Matters Our relationships with customers, healthcare providers, including physicians, and third- party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. Healthcare providers, including physicians, and third- party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third- party payors subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti- Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations promulgated under such laws. These laws will impact, among other things, our clinical research, proposed sales, marketing and educational programs, and other interactions with healthcare professionals. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations include, but are not limited to: • the federal Anti- Kickback Statute, which prohibits, among other things, individuals or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind in return for, or to induce, either the referral of an individual, or the purchase, lease, order or arrangement for or recommendation of the purchase, lease, order or arrangement for any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term " remuneration " has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation; • the federal civil and criminal false claims laws, including, without limitation, the federal False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from the federal government, including Medicare, Medicaid and other government payors, that are false or fraudulent or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes " any request or demand " for money or property presented to the U. S. federal government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non- reimbursable, uses. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act; • HIPAA, which created additional federal criminal statutes which prohibit, among other things, a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third- party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • HIPAA, as amended by HITECH, and its implementing regulations, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without the appropriate authorization by entities subject to the law, such as health plans, healthcare clearinghouses and healthcare providers and their respective business associates and their covered subcontractors; • the federal transparency laws, including the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, medical devices, biologicals and

medical supplies for which payment is available under Medicare, Medicaid or the State Children' s Health Insurance Program, with specific exceptions, to report annually to ~~the Centers for Medicare & Medicaid Services, or~~ CMS, information related to: (i) payments or other " transfers of value " made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and (ii) ownership and investment interests held by physicians and their immediate family members; **and** • analogous state and foreign laws and regulations; state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or that otherwise restrict payments that may be made to healthcare providers; and state and local laws that require the registration of pharmaceutical sales representatives ~~; and • laws, regulations, and industry standards governing data privacy and security, including laws requiring data to be localized or limiting the transfer of personal data to other countries, data breach notification laws, and personal data privacy laws, such as the UK GDPR, which imposes strict requirements on the processing of personal data, the CCPA, which requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights, and comprehensive privacy laws of other states such as Virginia and Colorado~~ . Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in federal and state funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, contractual damages, diminished profits and future earnings, reputational harm and the curtailment or restructuring of our operations, any of which could harm our business. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. 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. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and / or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements. Our collaboration ~~in China~~ **with ImmuneOnco** ~~subject~~ **subjects** us to risks and uncertainties relating to challenged and changing relations between the United States and China. ~~Trade and political~~ **Political** relations between the United States and China are strained. Each country has been enacting sanctions and threatening additional sanctions against the other. The United States Congress has been pursuing potential legislation targeting certain China- based biopharmaceutical companies, ~~among~~ **and** other China- based companies. Additionally, the biopharmaceutical industry in China is strictly regulated by the Chinese government. Changes to Chinese regulations affecting biopharmaceutical companies, and U. S. laws and regulations affecting biopharmaceutical companies based in or operating in China are also unpredictable. Any regulatory changes and changes in United States and China relations may have a material adverse effect on our collaboration **with ImmuneOnco** , which could harm our business and financial condition. Even if we obtain regulatory approval for any product candidates, they will remain subject to ongoing regulatory oversight, which may result in significant additional expense. Even if we obtain any regulatory approval for any product candidates, such product candidates, they will be subject to ongoing regulatory requirements applicable to manufacturing, labeling, packaging, storage, advertising, promoting, sampling, record- keeping and submission of safety and other post- market information, among other things. Any regulatory approvals that we receive for any product candidates may also be subject to a risk evaluation and mitigation strategy, limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or requirements that we conduct potentially costly post- marketing testing and surveillance studies, including Phase 4 trials and surveillance to monitor the quality, safety and efficacy of the drug. An unsuccessful post- marketing study or failure to complete such a study could result in the withdrawal of marketing approval. We will further be required to immediately report any serious and unexpected adverse events and certain quality or production problems with our products to regulatory authorities along with other periodic reports. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. We will also have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drug products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product' s approved label. As such, we will not be allowed to promote our products for indications or uses for which they do not have approval, commonly known as off- label promotion. The holder of an approved BLA must submit new or supplemental applications and obtain prior approval for certain changes to the approved product, product labeling, or manufacturing process. A company that is found to have improperly promoted off- label uses of their products may be subject to significant civil, criminal and administrative penalties. In addition, drug manufacturers are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the BLA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a drug, such as adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that drug, a regulatory

authority may impose restrictions relative to that drug, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the drug from the market or suspension of manufacturing. If we fail to comply with applicable regulatory requirements following approval of any product candidates, a regulatory authority may: • issue a deficiency letter, untitled letter or warning letter asserting that we are in violation of the law; • seek an injunction or impose administrative, civil or criminal penalties or monetary fines; • suspend or withdraw regulatory approval; • suspend any ongoing clinical trials; • refuse to approve a pending marketing application or supplement to an approved application or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners; • restrict the marketing or manufacturing of the drug; • seize or detain the drug or otherwise require the withdrawal of the drug from the market; • refuse to permit the import or export of products or product candidates; or • refuse to allow us to enter into supply contracts, including government contracts. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any product candidates and harm our business, financial condition, results of operations and prospects. Even if we obtain FDA, MHRA or EMA approval any of our product candidates in the United States or European Union, we may never obtain approval for or commercialize any of them in any other jurisdiction, which would limit our ability to realize their full market potential. In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country- by- country basis regarding safety and efficacy. Approval by the FDA in the United States or the EMA in the European Union does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in foreign markets, and we do not have experience in obtaining regulatory approval in any jurisdiction, including in foreign markets. If we fail to comply with regulatory requirements in foreign markets or to obtain and maintain required approvals, or if regulatory approvals in foreign markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized. Healthcare legislative or regulatory reform measures may have a negative impact on our business and results of operations. In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post- approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy makers and payors in the United States and elsewhere, there ~~is~~ **has been** significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and / or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U. S. pharmaceutical industry. The ACA, among other things: (i) established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs; (ii) expanded the entities eligible for discounts under the 340B drug pricing program; (iii) increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23. 1 % and 13 % of the average manufacturer price for most branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100 % of the Average Manufacturer Price, or AMP; (iv) expanded the eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new eligibility categories for individuals with income at or below 133 % (as calculated, it constitutes 138 %) of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; (v) addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics that are inhaled, infused, instilled, implanted or injected; (vi) introduced a new Medicare Part D coverage gap discount program in which manufacturers must now agree to offer 70 % point- of- sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer' s outpatient drugs to be covered under Medicare Part D (increased from 50 %, effective January 1, 2019, pursuant to the Bipartisan Budget Act of 2018); (vii) created a new Patient- Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and (viii) established the Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug. There have been **amendments to and** executive, judicial and congressional challenges to certain aspects of the ACA. For example ~~, on June 17, 2021, the U. S. Supreme Court dismissed the most recent judicial challenge the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Further~~ , on August 16, 2022, ~~President Biden signed~~ the Inflation Reduction Act of 2022, or the IRA, **was signed** into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the " donut hole " under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost and through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or congressional challenges in the future. It is unclear how such challenges and any additional healthcare reform measures of the ~~Biden~~ **current** administration will impact the ACA or our business. Other

legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2 % per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, will remain in effect until 2032 unless additional congressional action is taken. ~~The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.~~ Additionally, on March 11, 2021, ~~President Biden signed~~ the American Rescue Plan Act of 2021 **was signed** into law, which eliminates the statutory Medicaid drug rebate cap, ~~currently~~ **previously** set at 100 % of a drug' s average manufacturer price, for single source and innovator multiple source drugs, ~~beginning~~ **effective** January 1, 2024. These laws may result in additional reductions in Medicare, Medicaid and other healthcare funding, which could have an adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations. Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, ~~in July 2021, the Biden administration released an executive order, " Promoting Competition in the American Economy, " with multiple provisions aimed at prescription drugs. In response to Biden' s executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. Additionally,~~ the IRA, among other things, directs HHS to negotiate the price of certain high- expenditure, single- source ~~drugs and~~ biologics **that have been on the market for at least 11 years** covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated " maximum fair price " under the law **, or the Medicare Drug Price Negotiation Program** , and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. These provisions ~~took~~ **began to take** effect progressively starting in fiscal year 2023 **. On August 15, 2024, HHS announced the agreed- upon prices of the first ten drugs that were subject to price negotiations** , although the Medicare ~~drug~~ **Drug** ~~price~~ **Price** ~~negotiation~~ **Negotiation** ~~program~~ **Program** is currently subject to legal challenges. ~~It~~ **On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. Further, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march in rights under the Bayh- Dole Act was announced. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March- In- Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march- in- rights. While march- in- rights have not previously been exercised, it** is **uncertain if that** ~~currently unclear how the IRA~~ will **continue under** ~~be effectuated but is likely to have a significant impact on the pharmaceutical industry. Further, in response to the Biden administration' s October 2022 executive order, on February 14, 2023, HHS released a report outlining three~~ -- **the** new **framework** ~~models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Similar reform measures have been considered and adopted at the state level as well~~ . We expect that these and 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 receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The ~~implementation~~ **current administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office** of ~~cost containment~~ **Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions may, for example, include directives to reduce agency workforce, rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation, or CMMI, to consider new payment and healthcare models to limit drug spending and eliminating the Biden administration' s executive order that directed HHS to establishing an AI task force and developing a strategic plan. Additionally, in its June 2024 decision in Loper Bright Enterprises v. Raimondo, or Loper Bright, the U. S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA. We cannot predict which additional** measures ~~or other healthcare reforms~~ may **be adopted** ~~prevent us from being able to generate revenue, attain profitability, or commercialize our~~ - **or** ~~drugs~~ **the impact of current and additional measures on the marketing, pricing and demand for our product candidates, if approved, which could have a material adverse effect on our business, financial condition and results of operations** . In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for ~~ITIL- 306 or our~~ ~~any future~~ product candidates. We cannot determine how changes in regulations, statutes, policies, or interpretations when and if issued, enacted or adopted, may

affect our business in the future. Such changes could, among other things, require: • additional clinical trials to be conducted prior to obtaining approval; • changes to manufacturing methods; • recalls, replacements, or discontinuance of one or more of our products; and • additional recordkeeping **. Further, the standards that the FDA and comparable foreign regulatory authorities use require judgment and can change, which makes it difficult to predict with certainty their application. We may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or the impact of such changes, if any. For example, the Oncology Center of Excellence within the FDA has recently advanced Project Optimus, an initiative to reform the dose optimization and dose selection paradigm in oncology drug development to emphasize selection of an optimal dose, which is a dose or doses that maximizes not only the efficacy of a drug but the safety and tolerability as well. This shift from the prior approach, which generally determined the maximum tolerated dose, may require sponsors to spend additional time and resources to further explore a product candidate' s dose- response relationship to facilitate optimum dose selection in a target population. Other recent Oncology Center of Excellence initiatives have included Project FrontRunner, a new initiative with a goal of developing a framework for identifying candidate drugs for initial clinical development in the earlier advanced setting rather than for treatment of patients who have received numerous prior lines of therapies or have exhausted available treatment options, and Project Equity, an initiative to ensure that the data submitted to the FDA for approval of oncology medical products adequately reflect the demographic representation of patients for whom the medical products are intended** . Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of ~~ITIL- 306 or~~ **our** ~~other~~ product candidates, and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any products would harm our business, financial condition, and results of operations **. U. S.- China trade relations may adversely impact our supply chain operations and business. The U. S. and Chinese governments have taken certain actions that change trade policies, including tariffs that affect certain products which are manufactured in China and mutual exchange of certain types of data. Due to our collaboration with ImmuneOnco, we are reliant on collaborating with a company with significant operations in China. It is unknown whether and to what extent new tariffs, laws or regulations will be adopted that increase the cost or feasibility of importing and / or exporting products, components and information from China to the United States and vice versa. Further, the effect of any such new tariffs or actions on our industry and customers is unknown and difficult to predict. As additional new tariffs, legislation and / or regulations are implemented, or if existing trade agreements are renegotiated or if China or other affected countries take retaliatory trade actions, such changes could have a material adverse effect on our clinical development plans, business, financial condition, results of operations or cash flows** . Risks Related to Employee Matters and Managing our Growth Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel. We are highly dependent on the management, development, clinical, financial and business development expertise of our executive officers. Each of our executive officers may currently terminate their employment with us at any time. We do not maintain " key person " insurance for any of our executives or employees. Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of our product pipeline toward scaling up for commercialization, manufacturing and sales and marketing personnel, will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited. Our resources may not be sufficient to manage our future growth; failure to properly manage our potential growth could disrupt our operations and adversely affect our business, financial condition, results of operations and prospects. Even if we obtain funding for operations, we may fail to adequately manage our future growth. As and to the extent our development progresses, we expect to experience significant growth and change in the scope of our operations, particularly in the areas of clinical product development, regulatory affairs, manufacturing and, if any of our product candidates receives marketing approval, sales, marketing and distribution. Any change in our operations may place a significant strain in our administrative, financial and operational resources, and increase demands on our management, as well as our operational and administrative systems, controls and other resources. There can be no assurances that our existing personnel, systems, procedures or controls will be adequate to support our operations in the future; or that we will be able to successfully implement appropriate measures consistent with our growth strategy. To strategically manage our future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit, train and retain additional personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such potential future growth, we may not be able to effectively manage the strategic expansion of our operations, manage our employee base or recruit, train and retain additional personnel. Our failure to properly manage our

potential growth may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. Our employees, independent contractors, consultants, collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements. We are exposed to the risk that our employees, independent contractors, consultants, collaborators, principal investigators, CROs, suppliers and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended 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, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, and the curtailment or restructuring of our operations. Risks Related to Ownership of our Common Stock and our Status as a Public Company An active trading market for our common stock may not continue to be developed or sustained. Prior to our initial public offering, there was no public market for our common stock. Although our common stock is listed on The Nasdaq Stock Market LLC, if an active trading market for our shares does not continue to be developed or sustained, it may be difficult for you to sell shares of our common stock at an attractive price or at all. The trading price of the shares of our common stock may be volatile, and purchasers of our common stock could incur substantial losses. Our stock price has been ~~,~~ and may continue to be **very** volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including: • the results of our collaboration **with ImmuneOnco** , the commencement, enrollment or results of our clinical trials of any future clinical trials we may conduct, or changes in the development status of our product candidates; • our ability to license- in or otherwise acquire any new product candidates; • any delay in our regulatory filings for any product candidate we may develop, and any adverse development or perceived adverse development with respect to the applicable regulatory authority' s review of such filings, including without limitation the FDA' s issuance of a " refusal to file " letter or a request for additional information; • delays in or termination of clinical trials ~~, such as the recent cessation of our ITIL- 306 clinical trials and discontinuation of our ITIL- 168 clinical program~~ ; • adverse regulatory decisions, including failure to receive regulatory approval of our product candidates; • unanticipated serious safety concerns related to the use of any product candidate; • changes in financial estimates by us or by any equity research analysts who might cover our stock; • conditions or trends in our industry; • changes in the market valuations of similar companies; • announcements by our competitors ~~of~~ **with respect to competing product candidates or** new product candidates or technologies, or the results of clinical trials or regulatory decisions; • stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry; • publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts; • announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures, such as ~~the~~ **our** recent **strategic reprioritizations** ~~reduction in our U. S. workforce to a team of approximately 15; • to lead global business operations~~ and **restructurings** ~~potential reductions in our UK workforce to re- align our operating model~~ ; • our relationships with our collaborators; • announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us; • investors' general perception of our company and our business; • recruitment or departure of key personnel; • overall performance of the equity markets; • trading volume of our common stock; • disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; • significant lawsuits, including patent or stockholder litigation; • changes in the structure of healthcare payment systems; • general political and economic conditions **, including fluctuations in interest rates** ; and • other events or factors, many of which are beyond our control. The stock market in general, and the Nasdaq Stock Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including the ongoing armed conflicts in Ukraine and the Middle East, supply chain disruptions, heightened inflation and **fluctuations in** interest ~~rate~~ **rates** ~~increases~~ , recent and potential future **international trade** disruptions ~~in access to bank deposits or lending, commitments due to bank failures~~ and potentially worsening global economic conditions, may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this section, could have a significant and material adverse impact on the market price of our common stock. In

addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. This risk is especially relevant for us because pharmaceutical and biotechnology companies have experienced significant stock volatility in recent years. Recently, multiple plaintiffs' law firms publicly issued announcements stating that they are investigating potential securities law claims on behalf of our investors. Such litigation, if instituted against us, could cause us to incur substantial costs, subject us to damages or settlement awards and divert management' s attention and resources from our business, which could materially harm our reputation, business, financial condition, results of operations and prospects. If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline. The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us and our business. We have only limited research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline. A significant portion of our total outstanding shares are available for immediate resale. This could cause the market price of our common stock to drop significantly, even if our business is doing well. Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly. ~~As of March 19, 2024, we had 6, 503, 913 shares of common stock outstanding.~~ In addition, we have filed ~~a~~ registration ~~statement~~ **statements** on Form S- 8 under the Securities Act of 1933, as amended, or the Securities Act, registering the issuance of approximately ~~1~~ **2** . ~~6~~ **0** million shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements on Form S- 8 will be available for sale in the public market subject to vesting arrangements and exercise of options ~~, the lock- up agreements described above and the restrictions of Rule 144 in the case of our affiliates~~ . Additionally, as of December 31, ~~2023~~ **2024** the holders of approximately ~~2~~ **1** . ~~9~~ **6** million shares of our common stock, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. 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 and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other stockholders. For example, our Board of Directors has the authority to issue up to 10, 000, 000 shares of preferred stock. The Board of Directors can 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 of 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. Our charter documents also contain other provisions that could have an anti- takeover effect, including: • only one of our three classes of directors will be elected each year; • stockholders will not be entitled to remove directors other than by a 66 2 / 3 % vote and only for cause; • stockholders will not be permitted to take actions by written consent; • stockholders cannot call a special meeting of stockholders; and • stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings. 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 of 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. Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions. Our executive officers, directors and current beneficial owners of 5 % or more of our common stock and their respective affiliates beneficially own a ~~majority~~ **significant portion** of our outstanding common stock. As a result, these persons, acting together, would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions. Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the current market price of our common stock and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders. We are an " emerging growth company " and a " smaller reporting company " and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies and smaller reporting companies, our common stock may be less attractive to investors. We are an " emerging growth company " as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including: • being permitted

to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced " Management' s Discussion and Analysis of Financial Condition and Results of Operations " disclosure; • not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting; • not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor' s report providing additional information about the audit and the financial statements; • reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and • not being required to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (i) December 31, 2026, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $ 1. 235 billion, (iii) the last day of the fiscal year in which we are deemed to be a ~~"~~ " large accelerated filer ~~"~~ " as defined in Rule 12b- 2 under the Exchange Act, which would occur if the market value of our common stock held by non- affiliates exceeded $ 700. 0 million as of the last business day of the second fiscal quarter of such year or (iv) the date on which we have issued more than $ 1. 0 billion in non- convertible debt securities during the prior three- year period. Even after we no longer qualify as an emerging growth company, we may, under certain circumstances, still qualify as a " smaller reporting company, " which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We will have broad discretion in the use of our cash and cash equivalents ~~, including the net proceeds from our initial public offering~~ . We have broad discretion over the use of our cash and cash equivalents. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. Our failure to apply our cash and cash equivalents 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 these net proceeds. You will not have the opportunity to influence our decisions on how to use our cash and cash equivalents. Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment. You should not rely on an investment in our common stock to provide dividend income. We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common stock. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and 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 amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: • any derivative action or proceeding brought on our behalf; • any action asserting a breach of fiduciary duty; • any action asserting a claim against us arising under the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws; and • any action asserting a claim against us that is governed by the internal- affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. These exclusive forum provisions 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 lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive- forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business. General Risk Factors We have incurred and will continue to incur increased costs and demands upon management as a result of being a public company. As a public company listed in the United States, we incur significant additional legal, accounting and other costs ~~, which we anticipate to be approximately $ 3 million annually~~ . These additional costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and the Nasdaq Stock Market, may increase legal and financial compliance costs and make some activities more time- consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management' s time and attention from revenue- generating activities to

compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed. Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, on committees of our Board of Directors or as members of senior management. If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired. We are subject to the reporting requirements of the Securities Exchange Act of 1934, the Sarbanes- Oxley Act of 2002, or the Sarbanes- Oxley Act, and the rules and regulations of the stock market on which our common stock is listed. The Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in our Annual Report on Form 10- K each year, as required by Section 404 of the Sarbanes- Oxley Act. This requires that we incur substantial professional fees and internal costs on accounting and finance functions and that we expend significant management efforts. Prior to our fiscal year ended December 31, 2022, we had never been required to test our internal control within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner. We may identify weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system' s objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. If we are not able to comply with the requirements of Section 404 of the Sarbanes- Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the Securities and Exchange Commission or other regulatory authorities. Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts. We are subject to taxation in more than one tax jurisdiction. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including passage of newly enacted tax legislation or regulations, changes in the mix of our profitability from jurisdiction to jurisdiction, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities and changes in accounting for income taxes. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements. We might not be able to utilize a significant portion of our net operating loss carryforwards. We have generated and expect to continue to generate in the future significant federal and state net operating loss, or NOL, carryforwards. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Act, as modified by the CARES Act, federal NOLs incurred in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs is limited. ~~It is uncertain how various states will respond to the Tax Act and CARES Act.~~ In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an " ownership change, " which is generally defined as a greater than 50 % change, by value, in its equity ownership over a three- year period, the corporation' s ability to use its pre- change NOL carryforwards and other pre- change tax attributes to offset its post- change income or taxes may be limited. Our initial public offering, together with private placements and other transactions that have occurred since our inception, may have triggered such an ownership change pursuant to Section 382. We have not yet completed a Section 382 analysis. We may experience ownership changes as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our NOL carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. We have a full valuation allowance for deferred tax assets including NOLs. Our business activities will be subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti- bribery and anti- corruption laws. As we expand our business activities outside of the United States, including our clinical trial efforts **with collaborators in China** , we will be subject to the FCPA and similar anti- bribery or anti- corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non- United States government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non- United States governments. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers will be subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our

employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition. Disruptions at the FDA ~~, the SEC~~ and other government agencies caused by funding shortages **, layoff, shifting priorities under the new administration** or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, **layoffs** and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result ~~. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable~~ . Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or biologics to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. ~~For example~~ **In addition, the current administration has discussed several changes to the reach and oversight of the FDA, which could affect its relationship with the pharmaceutical industry, transparency in decision making and ultimately the cost and availability of prescription drugs. Additionally** , over the last several years ~~, including most recently from December 22, 2018 to January 25, 2019~~ , the U. S. government has shut down ~~several~~ **multiple** times and certain regulatory agencies, such as the FDA ~~and the SEC~~ , have had to furlough critical FDA ~~, SEC~~ and other government employees and stop critical activities. If **funding for the FDA is reduced, FDA priorities change, or** a prolonged government shutdown occurs ~~, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Separately, in response to the COVID- 19 pandemic, the FDA periodically had to postpone inspections of foreign and domestic manufacturing facilities and products. While such inspections have resumed, the FDA may use remote interactive evaluations where in- person inspections are not feasible or may defer action due to factors including travel restrictions. Regulatory authorities outside the United States adopted similar restrictions or other policy measures creating a risk of delays in their regulatory activities. If a prolonged government shutdown occurs, or if a global health concern prevents the FDA or other regulatory authorities from conducting business as usual or conducting inspections, reviews or other regulatory activities~~ , it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Unfavorable global economic and political conditions could adversely affect our business, financial condition or results of operations. Our results of operations could be adversely affected by general conditions in the global economy, the global financial markets and global political conditions. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the ongoing conflicts in Ukraine and the Middle East, terrorism or other geopolitical events **, and political tensions between the U. S. and China** . Sanctions imposed by the United States and other countries in response to such conflicts **and political tensions** ~~, including the one in Ukraine,~~ may also adversely impact our business, the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. **We are funding and expect to fund additional clinical trials in China related to AXN- 2510 / IMM2510 and AXN- 27M / IMM27M, and** ~~Portions~~ **portions** of our future clinical trials may be conducted outside of the United States **,** and **unfavorable political tensions between the U. S. and China could pose risks to our collaboration with ImmuneOnco. Furthermore,** unfavorable economic conditions resulting in the weakening of the U. S. dollar would make those clinical trials more costly to operate. Furthermore, a severe or prolonged economic downturn, including a recession or depression resulting from a disease outbreak, epidemic or pandemic, or political disruption could result in a variety of risks to our business, including weakened demand for our product candidates or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption, including any international trade disputes, could also strain our **collaborators, who are also our** manufacturers **, as well as** ~~or~~ **our other** suppliers, possibly resulting in ~~supply disruption~~ **disruptions** ~~,~~ **to clinical trials** ~~or~~ **for** ~~cause~~ our ~~customers to delay making payments for our potential products~~ **product candidates and obtaining data therefrom** . Any of the foregoing could seriously harm our business, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could seriously harm our business.