Risk Factors Comparison 2025-01-10 to 2024-01-16 Form: 10-K

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

Based on currently available information as of January ~~16~~ **10** , ~~2024~~ **2025** , we believe that our existing cash, cash equivalents and short- term investments will be sufficient to fund our activities for at least the next ~~12~~ **twelve** months **. We have implemented a business model that conserves funds by collaborating with third parties to develop our technologies** . However, our projections of future cash needs and cash flows may differ from actual results. If current cash on hand, cash equivalents ~~and~~ **,** short- term investments **and cash that may be generated from our business operations** are insufficient to continue to operate our business, or if we elect to invest in or acquire a company or companies **or new technology or technologies** that are synergistic with or complementary to our technologies, we may be required to obtain more working capital. **During the year ended October 31, 2024, we raised approximately $ 2, 955, 000, net of expenses, through an at- the- market equity offering of 785, 290 shares of common stock. Under our at- the- market equity program, which is currently effective and may remain available for us to use in the future, as of October 31, 2024, we may sell up to $ 97 million of common stock.** We may seek to obtain working capital **during our fiscal year 2025 or thereafter** through sales of our equity securities ~~, including through our current at- the- market offering program,~~ or through bank credit facilities or public or private debt from various financial institutions where possible. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we do identify sources for additional funding, the sale of additional equity securities or convertible debt ~~could~~ **will** result in dilution to our stockholders ~~. Additionally, the sale of equity securities or issuance of debt securities may be subject to certain security holder approvals or may result in the downward adjustment of the exercise or conversion price of our outstanding securities~~ . We can give no assurance that we will generate sufficient cash flows in the future to satisfy our liquidity requirements or sustain future operations, or that other sources of funding, such as sales of equity or debt, would be available or would be approved by our security holders, if needed, on favorable terms or at all. If we fail to obtain additional working capital as and when needed, such failure could have a material adverse impact on our business, results of operations and financial condition. Furthermore, such lack of funds may inhibit our ability to respond to competitive pressures or unanticipated capital needs, or may force us to reduce operating expenses, which ~~would~~ **could** significantly harm the business and development of operations. We may have difficulty in raising capital and may consume resources faster than expected. We currently do not generate any revenue from our therapeutics or vaccines nor do we generate any other recurring revenues and as of October 31, ~~2023~~ **2024** , the Company had approximately $ ~~23~~ **19** , ~~844~~ **924** , 000 in cash, cash equivalents and short- term investments. Therefore, we have a limited source of cash to meet our future capital requirements, which may include the expensive process of obtaining FDA approvals for our CAR- T ovarian cancer therapeutic and our breast and ovarian cancer vaccines. We do not expect to generate significant revenues for the foreseeable future, which would leave us without resources to continue our operations and force us to resort to raising additional capital in the form of equity or debt financings, which may not be available to us. We may have difficulty raising needed capital in the near or longer term as a result of, among other factors, the very early stage of our therapeutics and vaccine businesses and our lack of revenues as well as the inherent business risks associated with an early stage, biotechnology company and present and future market conditions. Also, we may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated. Our inability to raise funds could lead to decreases in the price of our common stock and the failure of our therapeutics and vaccine businesses which would have a material adverse effect on the Company. ~~10~~ Failure to effectively manage our potential growth could place strains on our managerial, operational and financial resources and could adversely affect our business and operating results. Our business strategy and potential growth may place a strain on managerial, operational and financial resources and systems. Although we may not grow as we expect, if we fail to manage our growth effectively or to develop and expand our managerial, operational and financial resources and systems, our business and financial results will be materially harmed. We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success. Because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications 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 research and development programs for product candidates may not yield any commercially viable products. 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 strategic 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, or we may allocate internal resources to a product candidate which it would have been more advantageous to enter into a partnering arrangement. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. We have incurred net losses since our inception and we may never achieve or sustain profitability. Generally, losses incurred will carry forward until such losses expire (for losses generated prior to January 1, 2018) or are used to offset future taxable income, if any. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the " Internal Revenue Code "), if a corporation undergoes an " ownership change, " generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three- year period, the corporation' s ability to use its pre- change net operating loss, or NOL, carryforwards and other pre- change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We have not completed a study to assess whether an ownership change for purposes of

Section 382 or 383 has occurred, or whether there have been multiple ownership changes since our inception. We may have experienced ownership changes in the past and may experience ownership changes in the future as a result of shifts in our stock ownership (some of which shifts are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset such taxable income may be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. As a result, even if we attain profitability, we may be unable to use a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our future cash flows. ~~11~~ Risks Related to our Research & Development, Clinical and Commercialization Activities Our therapeutic and vaccine programs are pre- revenue, and subject to the risks of an early- stage biotechnology company. Since the Company' s primary focus for the foreseeable future will likely be our therapeutics and vaccine businesses, shareholders should understand that we are primarily an early- stage biotechnology company with no history of revenue- generating operations, and our only assets consist of our proprietary and licensed technologies and the know- how of our officers and employees. Therefore, we are subject to all the risks and uncertainties inherent in a new business, in particular new businesses engaged in CAR- T cancer therapeutics and cancer vaccines, as well as whether our current business plan is sound. Our CAR- T ovarian cancer therapeutic and our ~~breast and ovarian~~ cancer vaccines are in their early stages of development, and we still must establish and implement many important functions necessary to commercialize the technologies. Accordingly, you should consider the Company' s prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in their pre- revenue generating stages, particularly those in the biotechnology field. Shareholders should carefully consider the risks and uncertainties that a business with limited operating history will face. In particular, shareholders should consider that there is a significant risk that we will not be able to: ● successfully enroll sufficient numbers of qualified patients to participate in our clinical trials; ● obtain sufficient quantity and quality of materials manufactured for use in our clinical trials; ● successfully meet the primary endpoints in our clinical trials; ● implement or execute our current business plan; ● raise sufficient funds in the capital markets or otherwise to fully effectuate our business plan; ● maintain our management team; ● determine that the processes and technologies that we have developed or will develop are commercially viable; and / or ● attract, enter into or maintain contracts with potential commercial partners such as licensors of technology and suppliers or licensees of our technologies. Any of the foregoing risks may adversely affect the Company and result in the failure of our business. In addition, we expect to encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. Over the next several quarters, we will need to continue broadening our focus from a research and development company to a company capable of supporting clinical trials and commercial activities, or enter into collaborations with partners that may provide those capabilities. We may not be able to reach such achievements, which would have a material adverse effect on our Company. Our current business model relies on strategic collaborations with commercial partners to provide the resources and infrastructure to manufacture and ultimately market and / or sell our technologies. We may have difficulty in timing the establishment of these partnerships to achieve the greatest economic benefit for the Company, or in establishing these partnerships at all. We do not currently have the resources and infrastructure to manufacture, market or sell our products or technologies. While our technologies have generated interest from multiple potential strategic partners, due to the early stage of development of our technologies, we can give no assurance that we will be able to successfully establish any strategic partnerships. Further, even if we elect to engage with a potential strategic partner, development of these partnerships can take an extended period of time in which significant analysis is performed by the potential strategic partner on our technologies and our intellectual property, as well as on the market opportunities and how well our technologies may fit strategically with the partner' s existing business. Accordingly, it will be difficult for us to time the establishment of a strategic partnership to achieve the greatest economic benefit for the Company. ~~12~~ If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates. We will face an inherent risk of product liability as a result of the ongoing and upcoming human clinical testing and commercialization of our product candidates. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: ● decreased demand for our product candidates; ● injury to our reputation; ● withdrawal of clinical trial participants; ● initiation of investigations by regulators; ● costs to defend the related litigation; ● a diversion of management' s time and our resources; ● substantial monetary awards to clinical trial participants or patients; ● product recalls, withdrawals or labeling, marketing or promotional restrictions; ● loss of potential revenue; ● exhaustion of any available insurance and our capital resources; ● the inability to commercialize any product candidate; and ● a decline in our share price. While we carry product liability insurance, claims could be asserted that could result in damages in excess of such insurance coverage. If we do not maintain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims, the lack of sufficient coverage could prevent or inhibit the development and commercialization of any products we develop, alone or with corporate collaborators. If we cannot license rights to use technologies on reasonable terms, we may not be able to commercialize new products in the future. In the future, we may identify third- party technology we need, including to develop or commercialize new products or services. In return for the use of a third party' s technology, we may agree to pay the licensor royalties based on sales of our products or services. Royalties are a component of cost of products or services and affect the margins on our products or services. We may also need to negotiate licenses to patents or patent applications before or after introducing a commercial product. We may not be able to obtain necessary licenses to patents or patent applications, and our business may suffer if we are unable to enter into the necessary licenses on acceptable terms or at all, if any necessary licenses

are subsequently terminated, if the licensors fail to abide by the terms of the licenses or fail to prevent infringement by third parties, or if the licensed patents or other rights are found to be invalid or unenforceable. ~~13~~ Biotechnology and pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of uncertainty. We have never generated any revenue from biotechnology and pharmaceutical product sales and our biotechnology and pharmaceutical products may never be profitable. We are **in the early discovery stage of developing vaccines against high- incidence malignancies such as lung, colon and prostate cancers,** in the pre- clinical stage of developing our ovarian cancer vaccine technology and in the clinical stage with our CAR- T therapeutic technology and with our breast cancer vaccine technology. Our ability to generate revenue depends in large part on our ability, alone or with partners, to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize, product candidates. We do not anticipate generating revenues from sales of such products for the foreseeable future. Our ability to generate future revenues from product sales of our technologies depends heavily on our success in: ● progressing our discovery stage programs into pre- clinical testing; ● progressing our pre- clinical programs into human clinical trials; ● completing requisite clinical trials through all phases of clinical development of our product candidates; ● seeking and obtaining marketing approvals for our product candidates that successfully complete clinical trials, if any; ● launching and commercializing our product candidates for which we obtain marketing approval, if any, with a partner or, if launched independently, successfully establishing a manufacturing, sales force, marketing and distribution infrastructure; ● identifying and developing new product candidates; ● establishing and maintaining supply and manufacturing relationships with third parties; ● maintaining, protecting, expanding and enforcing our intellectual property; and ● attracting, hiring and retaining qualified personnel. Because of the numerous risks and uncertainties associated with biologic and pharmaceutical product development, we are unable to predict the likelihood or timing for when we may receive regulatory approval of our product candidates or when we will be able to achieve or maintain profitability, if ever. If we are unable to establish a development and or commercialization partnership, or do not receive regulatory approvals, our business, prospects, financial condition and results of operations will be adversely affected. Even if we or a partner obtain the regulatory approvals to market and sell one or more of our product candidates, we may never generate significant revenues from any commercial sales for several reasons, including because the market for our products may be smaller than we anticipate, or products may not be adopted by physicians and payors or because our products may not be as efficacious or safe as other treatment options. If we fail to successfully commercialize one or more products, by ourselves or through a partner, we may be unable to generate sufficient revenues to sustain and grow our business and our business, prospects, financial condition and results of operations will be adversely affected. Cancer vaccines are novel and present significant challenges. The development of preventive and therapeutic cancer vaccines is difficult, with very few cancer vaccines successfully reaching the market. The only vaccines shown to be effective in preventing cancer have been vaccines against cancer causing agents, not the cancer itself. Vaccines work by exposing a benign form of a disease agent to an individual' s immune system. The immune system identifies the agent and learns to attack and destroy it, retaining a memory of the agent so the immune system knows to react quickly if an individual is exposed to the disease agent months or years later. Most vaccines attack pathogens, such as viruses and bacteria. The immune system is better able to assail these agents because they come from outside the body. Cancer, however, is caused by aberrant cells that arise out of our resident cells, which can make it difficult for our immune system to find the diseased cells, especially as advancing age weakens our immune system. Once these aberrant cells gain critical mass, they become cancer. ~~14~~ CAR- T cell therapies are novel and present significant challenges. CAR- T product candidates represent a relatively new field of cellular immunotherapy. Advancing this novel and personalized therapy creates significant challenges for us, or a partner, including: ● obtaining regulatory approval, as the FDA and other regulatory authorities have limited experience with commercial development of T cell therapies for cancer; ● sourcing clinical and, if approved, commercial supplies for the materials used to manufacture and process our product candidates; ● developing a consistent and reliable process, while limiting contamination risks, for engineering and manufacturing T cells ex vivo and infusing the engineered T cells into the patient; ● educating medical personnel regarding the potential benefits, as well as the challenges, of incorporating our product candidates into their treatment regimens; ● establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of a novel therapy; and ● the availability of coverage and adequate reimbursement from third- party payors for our novel and personalized therapy. Our inability to successfully develop CAR- T cell therapies or develop processes related to the manufacture, sales and marketing of these therapies would adversely affect our business, results of operations and prospects. While CAR- T technology has shown positive results in B ~~-~~cell cancers by others, its safety and efficacy has not been seen in solid tumors and we cannot guarantee our CAR- T technology will be safe or effective in ovarian or other cancers. CAR- T therapies function through the binding of a genetically engineered killer T cell to a cancer cell. However, these engineered T cells destroy the cell they are bound to whether it is a cancer cell or a healthy cell. Therefore, the engineered T cells must be designed to only bind to either cancer cells or other target cells to minimize toxicity. Our CAR- T technology relies on the natural affinity of FSH to FSH- Receptor. Research by others has shown that in women the FSH- Receptor protein is found on ovary cells and generally in no other healthy tissue, and therefore, we engineer our T cells with FSH. However, as the research in this field is still new, we cannot guarantee that there is no FSH- Receptor on any other healthy tissue in the human body. While pre- clinical testing and the limited human clinical testing of our product candidates has been positive, we may experience unfavorable results once we collect statistically significant data from human clinical trials. We have limited human clinical data from our breast cancer vaccine and our CAR- T ovarian cancer therapeutic, and we have not initiated clinical trials for our ovarian cancer vaccine and we may not be able to commence clinical trials on the time frames we expect. **Further, our new vaccine research programs in high- incidence cancers of the lung, colon and prostate are in the early discovery stage, and have generated no data to date.** As our ~~discovery~~ **pre- clinical** stage product candidate has only been tested in animals and our clinical stage candidates currently have limited human data, we face significant uncertainty regarding how effective and safe they will be in human patients and the results from pre- clinical studies may not be indicative of the results of clinical trials. Pre-

clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre- clinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products. ~~15~~ Even if clinical trials are successfully completed, the FDA or foreign regulatory authorities may not interpret the results as we do, and more clinical trials could be required before we submit our product candidates for approval. To the extent that the results of our clinical trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional clinical trials in support of potential approval of our product candidates. We are dependent on third parties to conduct our pre- clinical studies and clinical trials. We depend and will continue to depend upon independent investigators and collaborators, such as universities, medical institutions, and strategic partners such as Moffitt for our CAR- T therapy and Cleveland Clinic for our ~~breast and ovarian~~ cancer vaccines to conduct our pre- clinical studies and clinical trials under agreements with us. Negotiations of budgets and contracts with study sites may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with current good clinical practices, or cGCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of these third parties fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities could require us to perform additional clinical trials before approving our marketing applications. It is possible that, upon inspection, such regulatory authorities could determine that any of our clinical trials fail to comply with the cGCP regulations. In addition, our clinical trials must be conducted with biologic product produced under current good manufacturing practices, or cGMPs, and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. Any third parties conducting our clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with these third parties, we cannot control whether they devote sufficient time and resources to our ongoing pre- clinical, clinical and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. ~~16~~ If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including: ● the patient eligibility criteria defined in the clinical trial protocol; ● the size of the patient population required for analysis of the trial' s primary endpoints; ● the proximity of patients to the study site; ● the design of the clinical trial; ● our ability to retain clinical trial investigators with the appropriate competencies and experience; ● our ability to obtain and maintain patient consents; ● the risk that patients enrolled in clinical trials will drop out of the clinical trials before completion; and ● competing clinical trials and approved therapies available for patients. In particular, our Phase 1 CAR- T ovarian cancer clinical trial is enrolling patients with late- stage ovarian cancer who have failed conventional treatment, and are willing and able to be treated at Moffitt. Our Phase 1a breast cancer vaccine clinical trial is enrolling patients who have undergone standard of care treatment for TNBC. Our Phase 1b breast cancer vaccine clinical trial is enrolling healthy women who, as a result of, among other things, testing positive for the BRCA1, BRCA2 or PALB2 gene mutations which are leading predictors of future incidence of breast cancer, have elected to have prophylactic mastectomies. Our Phase 1c breast cancer vaccine clinical trial is enrolling post- operative TNBC patients who have residual disease following neoadjuvant chemo-immunotherapy and are being treated with pembrolizumab (Keytruda ®). These potential trial participants must be willing and able to undergo treatment at the Cleveland Clinic. Our clinical trials will compete with other companies' clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our clinical trials may instead opt to enroll in a trial being conducted by one of our competitors. We expect to conduct our clinical trials at the same clinical trial sites that some of our competitors may use, which will reduce the number of patients who are available for our clinical trial in these clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use experimental therapies that use conventional technologies, such as chemotherapy and antibody therapy, rather than enroll patients in our clinical trials. Patients may also be

unwilling to participate in our clinical trials because of negative publicity from adverse events in the biotechnology or gene therapy industries. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our planned clinical trials, which could prevent completion of the clinical trials and adversely affect our ability to advance the development of our ovarian cancer CAR- T therapy and our breast cancer vaccine. ~~17~~ Any adverse developments that occur during any clinical trials conducted by academic investigators, our collaborators or other entities conducting clinical trials under independent IND applications may negatively affect the conduct of our clinical trials or our ability to obtain regulatory approvals or commercialize our product candidates. CAR- T, vaccines and other immuno- therapy technologies are being used by third parties in clinical trials for which we are collaborating or in clinical trials which are completely independent of our development programs. We have little to no control over the conduct of those clinical trials. If serious adverse events occur during these or any other clinical trials using technologies similar to ours, the FDA and other regulatory authorities may delay our clinical trial, or could delay, limit or deny approval of our product candidates or require us to conduct additional clinical trials as a condition to marketing approval, which would increase our costs. If we receive regulatory approval for any product candidate and a new and serious safety issue is identified in connection with clinical trials conducted by third parties, the applicable regulatory authorities may withdraw their approval of our products or otherwise restrict our ability to market and sell our products. In addition, treating physicians may be less willing to administer our products due to concerns over such adverse events, which would limit our ability to commercialize our products. Adverse side effects or other safety risks associated with our product candidates could cause us to suspend or discontinue clinical trials or delay or preclude approval. In third party clinical trials involving CAR- T cell therapies, the most prominent acute toxicities included symptoms thought to be associated with the release of cytokines, such as fever, low blood pressure and kidney dysfunction. Some patients also experienced toxicity of the central nervous system, such as confusion, cranial nerve dysfunction and speech impairment. Adverse side effects attributed to CAR- T therapies were severe and life- threatening in some patients. The life- threatening events were related to kidney dysfunction and toxicities of the central nervous system or other organ failure. Severe and life- threatening toxicities occurred primarily in the first two weeks after cell infusion and generally resolved within three weeks. In the past, several patients have also died in clinical trials by others involving CAR- T cell therapies. Side effects of our breast cancer vaccine may include mild effects such as injection site pain or irritation, or more severe side effects such as fever, inflammation, organ failure or other adverse effects. Undesirable side effects observed in our clinical trials, whether or not they are caused by our product candidates, could result in the delay, suspension or termination of clinical trials, by the FDA or other regulatory authorities or us for a number of reasons. In addition, because the patients who will be enrolled in our clinical trials may be suffering from a life-threatening disease and may often be suffering from multiple complicating conditions it may be difficult to accurately assess the relationship between our product candidate and adverse events experienced by very ill patients. If we elect or are required to delay, suspend or terminate any of our clinical trials, the commercial prospects of such therapy will be harmed and our ability to generate product revenues from such therapy will be delayed or eliminated. In addition, serious adverse events observed in clinical trials could hinder or prevent market acceptance of the product candidate at issue. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly. Clinical trials are expensive, time consuming and difficult to design and implement. Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Because our CAR- T ovarian cancer therapy is based on relatively new technology and engineered on a patient- by- patient basis, we expect that it will ~~require extensive research and development and~~ have substantial manufacturing and processing costs. In addition, costs to treat patients with relapsed / refractory cancer and to treat potential side effects that may result from therapies such as our current and future product candidates can be significant. Accordingly, our clinical trial costs are likely to be significantly higher than for more conventional therapeutic technologies or drug products. In addition, our proposed personalized product candidates involve several complex and costly manufacturing and processing steps, the costs of which will be borne by us. ~~18~~ In one of our breast cancer vaccine clinical trials, we will treat healthy women who, as a result of testing positive for certain gene mutations, have elected to have prophylactic mastectomies. Delivering an experimental treatment to a healthy individual is more complex and subject to more rigorous regulatory requirements and is more difficult to design and implement. In addition, in future clinical trials we will need to determine efficacy of the breast cancer vaccine as a cancer prevention which will be a considerably more complex clinical trial and will have significantly greater costs. The costs of our clinical trials may increase if the FDA does not agree with our clinical development plans or requires us to conduct additional clinical trials to demonstrate the safety and efficacy of our product candidates. We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively. The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well- established sales forces. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. Cell- based therapies rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all. Gene- modified cell therapy

manufacturing requires many specialty raw materials, some of which are manufactured by small companies with limited resources and experience to support a commercial product. Some suppliers typically support biomedical researchers or blood-based hospital businesses and may not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms. The suppliers may be ill- equipped to support our needs, especially in non- routine circumstances like FDA inspections or medical crises, such as widespread contamination. We also do not have commercial supply arrangements with many of these suppliers, and may not be able to contract with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key raw materials to support clinical or commercial manufacturing. In addition, some raw materials are currently available from a single supplier, or a small number of suppliers. We cannot be sure that these suppliers will remain in business, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. ~~19~~ We may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements. We may form or seek strategic alliances, create joint ventures or collaborations and enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non- recurring and other charges, increase our near and long- term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time- consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. It is possible that, following a strategic transaction or license, we may not achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations. The FDA regulatory approval process is lengthy and time- consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates. We have not previously submitted a Biologics License Application (“ BLA ”) or a New Drug Application (“ NDA ”) to the FDA, or similar approval filings to other foreign authorities. A BLA or NDA must include extensive pre- clinical and clinical data and supporting information to establish the product candidate’ s safety, purity and potency for each desired indication. It must also include significant information regarding the chemistry, manufacturing and controls for the product. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA has limited experience with commercial development of T cell therapies and vaccines for cancer. The regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained. We may also experience delays in completing planned clinical trials for a variety of reasons, including delays related to: ● the availability of financial resources to commence and complete our planned clinical trials; ● reaching agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites; ● recruiting suitable patients to participate in a clinical trial; ● having patients complete a clinical trial or return for post- treatment follow- up; ● clinical trial sites deviating from clinical trial protocol, failing to follow cGCPs, or dropping out of a clinical trial; ● adding new clinical trial sites; or ● manufacturing sufficient quantities of qualified materials under cGMPs and applying them on a subject- by- subject basis for use in clinical trials. ~~20~~ Also, before a clinical trial can begin at an NIH- funded institution, that institution’ s independent institutional review board, or IRB, and its Institutional Biosafety Committee must review the proposed clinical trial to assess the safety of the trial. In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of our product candidates. We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such clinical trials are being conducted, the Data Monitoring Committee for such clinical trial, or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates. Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers, third- party payors and others in the medical community. The use of engineered T cells as a potential cancer treatment and the use of therapeutic and prophylactic cancer vaccines are recently developed technologies and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers, third-party payors and others in the medical community. Many factors will influence whether our product candidates are accepted in the market, including: ● the clinical indications for which our product candidates are approved; ● physicians, hospitals, cancer

treatment centers and patients considering our product candidates as a safe and effective treatment; ● the potential and perceived advantages of our product candidates over alternative treatments; ● the prevalence and severity of any side effects; ● product labeling or product insert requirements of the FDA or other regulatory authorities; ● limitations or warnings contained in the labeling approved by the FDA or other regulatory authorities; ● the extent and quality of the clinical evidence supporting the efficacy and safety of our product candidates; ● the timing of market introduction of our product candidates as well as competitive products; ● the cost of treatment in relation to alternative treatments; ● the availability of adequate reimbursement and pricing by third- party payors and government authorities; ● the willingness and ability of patients to pay out- of- pocket in the absence of coverage by third- party payors, including government authorities; ● relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and ● the effectiveness of our or any of our strategic partners' sales and marketing efforts. If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete. ~~21~~ Risks Related to Our Intellectual Property If we are unable to obtain and maintain intellectual property protection, our competitive position will be harmed. Our ability to compete and to achieve sustained profitability will be impacted by our ability to protect our CAR- T cancer therapeutics technologies, our breast cancer vaccine technologies, our ovarian cancer vaccine technologies and other proprietary discoveries and technologies. We expect to rely on a combination of patent protection, copyrights, trademarks, trade secrets, know- how, and regulatory approvals to protect our technologies. Our intellectual property strategy is intended to help develop and maintain our competitive position. While we have been granted multiple patents related to our technologies, there is no assurance that we will be able to obtain further patent protection for our technologies or any other technologies, nor can we be certain that the steps we will have taken will prevent the misappropriation and unauthorized use of our technologies. If we are not able to obtain and maintain patent protection our competitive position may be harmed, including our ability to license any product if we choose to have other parties commercialize them. Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. Our commercial success depends upon our ability to develop, manufacture, market and sell our CAR- T therapeutics, our breast cancer vaccine, our ovarian cancer vaccine and other proprietary discoveries and technologies without infringing, misappropriating or otherwise violating the proprietary rights or intellectual property of third parties. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our CAR- T therapeutics, our breast cancer vaccine, our ovarian cancer vaccine and other proprietary discoveries and technologies. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party' s intellectual property rights, we could be required to obtain a license from such third party to continue developing our CAR- T therapeutics, our breast cancer vaccine, our ovarian cancer vaccine and other proprietary discoveries and technologies. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease developing the infringing technology or product. In addition, we could be found liable for monetary damages. Claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business. ~~22~~ We rely on licenses from Wistar for our CAR- T technology and Cleveland Clinic for our ~~breast and ovarian~~ cancer vaccine technologies, and if we lose any of these licenses we may be subjected to future litigation. We are party to royalty- bearing license agreements that grant us rights to use certain intellectual property, including patents and patent applications. We may need to obtain additional licenses from others to advance our research, development and commercialization activities. Our license agreements impose, and we expect that future license agreements if necessary will impose, various development, diligence, commercialization and other obligations on us. In spite of our efforts, our licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. If these in- licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties might have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization activities. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects. Moreover, disputes may arise with respect to any one of our licensing agreements, including: ● the scope of rights granted under the license agreement and other interpretation- related issues; ● the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; ● the sublicensing of patent and other rights under the licensing agreement and our collaborative development relationships; ● our diligence obligations under the license agreement and what activities satisfy those diligence obligations; ● the inventorship and ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and ● the priority of invention of patented technology. If we do not prevail in such disputes, we may lose any of such license agreements. In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we

may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects. Our failure to maintain such licenses could have a material adverse effect on our business, financial condition and results of operations. Any of these licenses could be terminated, such as if either party fails to abide by the terms of the license, or if the licensor fails to prevent infringement by third parties or if the licensed patents or other rights are found to be invalid or unenforceable. Absent the license agreements, we may infringe patents subject to those agreements, and if the license agreements are terminated, we may be subject to litigation by the licensor. Litigation could result in substantial costs and be a distraction to management. If we do not prevail, we may be required to pay damages, including treble damages, attorneys' fees, costs and expenses, royalties or, be enjoined from selling our products, which could adversely affect our ability to offer products, our ability to continue operations and our financial condition. ~~23~~ If our efforts to protect the proprietary nature of our technologies are not adequate, we may not be able to compete effectively in our market. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our markets. Certain intellectual property which is covered by our in- license agreements has been developed at academic institutions which have retained non- commercial rights to such intellectual property. There are several pending U. S. and foreign patent applications in our portfolio, and we anticipate additional patent applications will be filed both in the U. S. and in other countries, as appropriate. However, we cannot predict: ● if and when patents will issue; ● the degree and range of protection any issued patents will afford us against competitors including whether third parties will find ways to invalidate or otherwise circumvent our patents; ● whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or ● whether we will need to initiate litigation or administrative proceedings which may be costly whether we win or lose. Composition of matter patents for biological and pharmaceutical products are generally considered to be the strongest form of intellectual property. We cannot be certain that the claims in our pending patent applications directed to compositions of matter for our product candidates will be considered patentable by the U. S. Patent and Trademark Office (the " USPTO ") or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid by courts in the U. S. or foreign countries. Method of use patents have claims directed to the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products " off- label. " Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in- license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the U. S. or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the U. S. and most other countries are confidential for a period of time after filing, it is possible that patent applications in our portfolio may not be the first filed patent applications related to our product candidates. Furthermore, for U. S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third- party or instituted by the USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For U. S. applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law with the passage of the America Invents Act (2012) which brings into effect significant changes to the U. S. patent laws that are yet untried and untested, and which introduces new procedures for challenging pending patent applications and issued patents. A primary change under this reform is the creation of a " first to file " system in the U. S. This will require us to be cognizant going forward of the time from invention to filing of a patent application. ~~24~~ Obtaining and maintaining our patents depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent position could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. Such noncompliance events are outside of our direct control for **i** ~~(1~~) non- U. S. patents and patent applications owned by us, and **ii** ~~(2~~) patents and patent applications licensed to us by another entity. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business. Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO. If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and / or unenforceable. In patent litigation in the U. S.,

defendant counterclaims alleging invalidity and / or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the U. S. or abroad, even outside the context of litigation. Such mechanisms include re- examination, post grant review, and equivalent proceedings in foreign jurisdictions, for example, opposition proceedings. Any such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art and that prior art that was cited during prosecution, but not relied on by the patent examiner, will not be revisited. 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 patents directed to our product candidates. A loss of patent rights could have a material adverse impact on our business. ~~25~~ Changes in U. S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products. As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time- consuming and inherently uncertain. In addition, the U. S. has recently enacted and is currently implementing wide- ranging patent reform legislation. Recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the case, Assoc. for Molecular Pathology v. Myriad Genetics, Inc., the U. S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U. S. Congress or the USPTO may impact the value of our patents. We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world. We have limited intellectual property rights outside the U. S. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U. S. can be less extensive than those in the U. S. In addition, the laws of some foreign countries do not protect intellectual property to the same extent as federal and state laws in the U. S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U. S., or from selling or importing products made using our inventions in and into the U. S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patents to develop their own products and further, may export otherwise infringing products to territories where we have patents, but enforcement is not as strong as that in the U. S. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property in foreign jurisdictions. The legal systems of certain countries, particularly China and certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. To date, we have not sought to enforce any issued patents in these foreign jurisdictions. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. The requirements for patentability may differ in certain countries, particularly developing countries. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Certain countries in Europe and developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. 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. ~~26~~ Risks Related to Our Common Stock The issuance or sale of shares in the future to raise money or for strategic purposes could reduce the market price of our common stock. In the future, we may issue securities to raise cash for operations, to pay down then existing indebtedness, as consideration for the acquisition of assets, as consideration for receipt of goods or services, to pay for the development of our CAR- T cancer therapeutics, to pay for the development of our ~~breast~~ cancer ~~vaccine~~ **vaccines** ~~, to pay for the development of our ovarian cancer vaccine~~ and for acquisitions of companies. We have an at- the- market equity offering under which, as of January ~~16~~ **10** , ~~2024~~ **2025** we may issue up to approximately $ ~~98~~ **97** million of common stock, which is currently effective, and which may remain available to us in the future. We also have, and in the future may, issue securities convertible into our common stock. Any of these events may dilute stockholders' ownership interests in our company and have an adverse impact on the price of our common stock. In addition, sales of a substantial amount of our common stock in the public market, or the perception that these sales may occur, could reduce the market price of our common stock. This could also impair our ability to raise additional capital through the sale of our securities. Any actual or anticipated sales of shares by our stockholders may cause the trading price of our common stock to decline. The sale of a substantial number of shares of our common stock by our stockholders, or anticipation of such sales, could make it more difficult for us to sell equity or equity- related securities in the

future at a time and at a price that we might otherwise wish to effect sales. We may fail to meet market expectations because of fluctuations in quarterly operating results, which could cause the price of our common stock to decline. Our reported revenues and operating results have fluctuated in the past and may continue to fluctuate significantly from quarter to quarter in the future, specifically as we continue to devote our resources towards our CAR- T cancer therapeutics and our ~~breast and ovarian~~ cancer vaccines. It is possible that in future periods, we will have no revenue or, in any event, revenues could fall below or expenses could rise above the expectations of securities analysts or investors, which could cause the market price of our common stock to decline. The following are among the factors that could cause our operating results to fluctuate significantly from period to period: ● patient enrollment rates for our clinical trials; ● delays with respect to our clinical trials; ● clinical trial results relating to our CAR- T cancer therapeutics; ● clinical trial results relating to our breast cancer vaccine; ● results of pre- clinical studies relating to our ovarian cancer vaccine; ● **results of our new vaccine discovery efforts; ●** progress with regulatory authorities towards the certification / approval of our CAR- T cancer therapeutics, our breast cancer vaccine or our ovarian cancer vaccine; and ● costs related to acquisitions, alliances and licenses. ~~27~~ Biotechnology company stock prices are especially volatile, and this volatility may depress the price of our common stock. The stock market has experienced significant price and volume fluctuations, and the market prices of biotechnology companies have been highly volatile. We believe that various factors may cause the market price of our common stock to fluctuate, perhaps substantially, including, among others, the following: ● announcements of developments in the fields of CAR- T therapeutics or cancer vaccines; ● developments in relationships with third party vendors and laboratories; ● developments or disputes concerning our patents and other intellectual property; ● our or our competitors' technological innovations; ● variations in our quarterly operating results; ● our failure to meet or exceed securities analysts' expectations of our financial results; ● a change in financial estimates or securities analysts' recommendations; ● changes in management' s or securities analysts' estimates of our financial performance; ● announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies, or patents; and ● the timing of or our failure to complete significant transactions. In addition, we believe that fluctuations in our stock price during applicable periods can also be impacted by changes in governmental regulations in the drug development industry and / or court rulings and / or other developments in our remaining patent licensing and enforcement actions. In the past, companies that have experienced volatility in the market price of their stock have been the objects of securities class action litigation. If our common stock was the object of securities class action litigation due to volatility in the market price of our stock, it could result in substantial costs and a diversion of management' s attention and resources, which could materially harm our business and financial results. Our common stock is currently listed on NASDAQ Capital Market, however if our common stock is delisted for any reason, it will become subject to the SEC' s penny stock rules which may make our shares more difficult to sell. If our common stock is delisted from NASDAQ Capital Market, our common stock will then fit the definition of a penny stock and therefore would be subject to the rules adopted by the SEC regulating broker- dealer practices in connection with transactions in penny stocks. The SEC rules may have the effect of reducing trading activity in our common stock making it more difficult for investors to sell their shares. The SEC' s rules require a broker or dealer proposing to effect a transaction in a penny stock to deliver the customer a risk disclosure document that provides certain information prescribed by the SEC, including, but not limited to, the nature and level of risks in the penny stock market. The broker or dealer must also disclose the aggregate amount of any compensation received or receivable by him in connection with such transaction prior to consummating the transaction. In addition, the SEC' s rules also require a broker or dealer to make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser' s written agreement to the transaction before completion of the transaction. The existence of the SEC' s rules may result in a lower trading volume of our common stock and lower trading prices. ~~28~~ We have issued a significant number of securities pursuant to our incentive plans and may continue to do so in the future. The vesting and, if applicable, exercise of these securities and the sale of the shares of common stock issuable thereunder may dilute stockholders' percentage ownership interest and may also result in downward pressure on the price of our common stock. As of the date of this Report, we have issued and outstanding options to purchase ~~12~~ **13** , ~~735~~ **488** , ~~000~~ **062** shares of our common stock with a weighted average exercise price of $ 3. ~~68~~ **53** . Further, as of the date of this Report, our Board of Directors and Compensation Committee have the authority to issue awards totaling an additional ~~665~~ **645** , 000 shares of our common stock which is replenished on a yearly basis in accordance with the provisions of our plan. Additionally, we have registered for resale all of the shares of common stock issuable under our incentive plans. Because the market for our common stock is thinly traded, the sales and / or the perception that those sales may occur, could adversely affect the market price of our common stock. Furthermore, the mere existence of a significant number of shares of common stock issuable upon vesting and, if applicable, exercise of these securities may be perceived by the market as having a potential dilutive effect, which could lead to a decrease in the price of our common stock. We are a smaller reporting company and the reduced reporting requirements applicable to smaller reporting companies may make our common stock less attractive to investors. We are a smaller reporting company (" SRC ") and a non- accelerated filer, which allows us to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not SRCs or non- accelerated filers, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act of 2002, as amended, reduced disclosure obligations regarding executive compensation in our Annual Report and our periodic reports and proxy statements and providing only two years of audited financial statements in our Annual Report and our periodic reports. We will remain an SRC until (a) the aggregate market value of our outstanding common stock held by non- affiliates as of the last business day our most recently completed second fiscal quarter exceeds $ 250 million or (b) (1) we have over $ 100 million in annual revenues and (2) the aggregate market value of our outstanding common stock held by non- affiliates as of the last business day our most recently completed second fiscal quarter exceeds $ 700 million. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of 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 and may decline. We do not anticipate declaring any cash dividends on our common stock which may adversely impact the market price of our stock. We have never declared or paid cash dividends on our common stock and do not plan to pay any cash dividends in the near future. Our current policy is to retain all funds and any earnings for use in the operation and expansion of our business. If we do not pay dividends, our stock may be less valuable to you because a return on your investment will only occur if our stock price appreciates. Item 1B. Unresolved Staff Comments -