Risk Factors Comparison 2025-04-15 to 2024-04-02 Form: 10-K

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

Risks Related to our Business and Industry We have incurred significant losses in every year since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability. We are a ~~preclinical~~ **clinical** stage biopharmaceutical company with a limited operating history, and we have incurred significant net losses since our inception in 2016. We incurred net losses of approximately $ **8. 3 million and $** 7. **3** ~~5 million and $ 11. 8~~ 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 **approximately** $ ~~42~~ **70** . ~~2~~ **9** million. We have funded our operations to date primarily with proceeds from the sale of our equity securities in private financing transactions. We have no products approved for commercial sale and we are devoting, and expect to continue devoting, substantially all of our financial resources and efforts to R & D of our only programmed CER- T cell product candidate, CER- 1236, as well as to building out our manufacturing infrastructure, CDMO relationships and CER- T cell programming technologies. Investment in biopharmaceutical product development, especially preclinical products, is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will not successfully undergo or complete necessary clinical trials, fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We expect that it could take several years until any of our product candidates, which at present is solely CER- 1236, receive regulatory and marketing approval and are commercialized, and we may never be successful in obtaining regulatory and marketing approval and commercializing product candidates. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. These net losses will adversely impact our stockholders' equity and net assets and may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we: ● continue our ongoing and planned R & D activities for our CER- T cell therapies and product candidates; ● pursue preclinical studies and initiate clinical trials for our CER- T cell therapies and other product candidates; ● seek to discover and develop additional product candidates and further expand our product pipeline; ● seek regulatory and marketing approvals for any product candidates that successfully complete clinical trials; ● establish sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain regulatory approval; ● develop and refine the manufacturing process for our product candidates; ● change or add additional manufacturers or suppliers of biological materials or product candidates; ● establish or supplement relationships with CDMOs, CROs and other third **-** party collaborators; ● develop, maintain, expand and protect our intellectual property portfolio; ● acquire or in- license other product candidates and technologies; ● hire clinical, quality control and manufacturing personnel; ● add clinical, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and ● incur additional legal, accounting and other expenses associated with operating as a public company. To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials for our product candidates, preparing a satisfactory filing package for regulatory authorities, obtaining regulatory approval, manufacturing, marketing and selling any products for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with the development, manufacturing, delivery and commercialization of complex autologous cell therapies, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase and profitability could be further delayed. 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 securities and could impair our ability to raise capital, expand our business, maintain our R & D efforts or continue our operations. A decline in the value of our securities could also cause you to lose all or part of your investment. **There is** ~~Our independent registered public accountants have expressed~~ substantial doubt as to our ability to continue as a going concern **. As of December 31, 2024, the Company reported $ 3. 3 million of cash and cash equivalents, with an accumulated deficit of $ 70. 9 million. Additional funds are necessary to maintain current operations and to continue R & D activities. However, there can be no assurance that sufficient funding will be available to allow the Company to successfully continue its R & D activities and planned regulatory filings with the FDA. If the Company is unable to obtain the necessary funds, significant reductions in spending and the delay or cancellation of planned activities may be necessary. These actions would have a material adverse effect on the Company' s business, results of operations, and prospects. These conditions raise substantial doubt about the Company' s ability to continue as a going concern within one year from the date these accompanying financial statements are issued** . In its report on our financial statements for the year ended December 31, ~~2023~~ **2024**, our independent registered public accounting firm included an explanatory paragraph that expressed substantial doubt about our ability to continue as a going concern. Our current cash level raises substantial doubt about our ability to continue as a going concern. In addition, our future financial statements may include similar qualifications about our ability to continue as a going concern. Our financial statements were prepared assuming that we will continue as a going concern and do not include any adjustments that may result from the outcome of this uncertainty. If we are unable to meet our current operating costs, we will need to seek additional financing or modify or cease our operational

plans. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all. Our limited operating history makes it difficult to evaluate our business and assess our future viability and prospects. We are a ~~preclinical~~ --- **clinical** stage company with a limited operating history. We commenced operations in 2016, and our operations to date have been limited to organizing and planning our development efforts, raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates, undertaking preclinical studies, and establishing arrangements with third parties for the manufacture of initial quantities of CER- 1236 and component materials. We have not yet demonstrated our ability to successfully complete any clinical trials, obtain regulatory approvals, manufacture a commercial- scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product 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. In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a R & D focus to a company capable of supporting commercial activities. We may not be successful in such a transition. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance. Our business is highly dependent on the success of our lead product candidate. If we are unable to advance clinical development, obtain approval of and successfully commercialize our lead product candidate for the treatment of patients in approved indications, our business would be significantly harmed. Our business and future success depends on our ability to advance clinical development, obtain regulatory approval of, and then successfully commercialize, CER- 1236, our lead product candidate. Because our CER- 1236 product candidate will be among the first autologous T cell product candidates engineered with cytotoxic and phagocytic potency to be evaluated in clinical trials, the failure of such product candidate, or the failure of other autologous T cell therapies, including for reasons due to safety, efficacy or durability, may impede our ability to develop our product candidates, and significantly influence physicians' and regulators' opinions with regard to the viability of our entire pipeline of autologous T cell therapies. All of our product candidates, including our lead product candidate, will require additional preclinical, clinical and non- clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. In addition, because our other product candidates are based on similar technology as our lead product candidate, if the lead product candidate encounters additional safety issues, efficacy problems, manufacturing problems, developmental delays, regulatory issues or other problems, our development plans and business would be significantly harmed. We have not generated any revenue and may never be profitable. Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue. We do not expect to generate significant revenue unless or until we successfully complete clinical development and obtain regulatory approval of, and then successfully commercialize, our product candidates. We do not know when, or if, we will generate any revenue. ~~All~~ **We received clearance** of our **IND for our first** product ~~candidates~~ **candidate** , ~~including~~ CER- 1236, **and the rest of our product candidates** are in the preclinical stages of development ~~and~~ **. Our product candidates** will require additional preclinical studies, clinical development regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to: ● successfully complete preclinical studies and clinical trials for our CER- T cell product candidates; ● timely file and receive acceptance of INDs, and amendments thereto, as applicable, in order to commence our planned and future clinical trials; ● successfully enroll subjects in, and complete, clinical trials for our CER- T cell product candidates; ● hire additional staff, including clinical, scientific and management personnel; ● timely file BLAs and receive regulatory approvals for our product candidates from the FDA and other regulatory authorities; ● initiate and successfully complete clinical trials and safety studies required to obtain U. S. and applicable foreign marketing approval for our product candidates; ● establish commercial manufacturing capabilities through third- party manufacturers and CDMOs for clinical supply and commercial manufacturing of our product candidates; ● obtain and maintain patent and trade secret protection or regulatory exclusivity for our product candidates; ● launch commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others; ● maintain a continued acceptable safety profile of the product candidates following approval; ● obtain and maintain acceptance of the product candidates, if and when approved, by patients, the medical community and third- party payors; ● position our products to effectively compete with other therapies; ● obtain and maintain favorable coverage and adequate reimbursement by third- party payors for our product candidates; and ● enforce and defend intellectual property rights and claims with respect to our product candidates. Many of the factors listed above are beyond our control and could cause us to experience significant delays or prevent us from obtaining regulatory approvals or commercialize our product candidates. Even if we are able to commercialize our product candidates, we may not achieve profitability soon after generating product sales, if ever. If we are unable to generate sufficient revenue through the sale of our product candidates or any future product candidates, we ~~may~~ **will** be unable to continue operations without continued funding. Our engineered CER- T cells represent a novel approach to cancer treatment that creates significant challenges for us. We are developing autologous T- cell product candidates that are engineered from healthy donor T- cells to express chimeric engulfment receptors (" CERs ") and are intended for use in patients with certain cancers. Advancing these novel product candidates creates significant challenges for us, including: ● manufacturing our product candidates to our ~~or~~ regulatory specifications and in a timely manner to support our clinical trials, and, if approved, commercialization; ● sourcing clinical and, if approved, commercial supplies for the raw materials used to manufacture our product candidates; ● understanding and addressing variability in the quality of a donor' s T cells, which could

ultimately affect our ability to produce product in a reliable and consistent manner and treat certain patients; ● educating medical personnel regarding the potential side effect profile of our product candidates, if approved, such as the potential adverse side effects related to CRS, neurotoxicity, prolonged cytopenia, coagulation abnormalities, thrombosis, hypotension, aplastic anemia and neutropenic sepsis; ● using medicines to preempt or manage adverse side effects of our product candidates and such medicines may be difficult to source or costly or may not adequately control the side effects or may have other safety risks or a detrimental impact on the efficacy of the treatment; ● conditioning patients with cyclophosphamide, fludarabine, or bendamustine in advance of administering our product candidates, which may be difficult to source, costly or increase the risk of infections and other adverse side effects; ● obtaining regulatory approval, as the FDA and other regulatory authorities have limited experience with development of CER T cell therapies for cancer; ● establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of a novel therapy; and ● obtaining acceptance and approval by physicians, patients, hospitals, cancer treatment centers and others in the medical community. Our **current product candidates are in early clinical or** preclinical ~~programs~~ **development and have never been tested in humans. One or all of our current product candidates** may ~~experience~~ **fail in clinical development or suffer** delays **that materially and** ~~or may never advance to clinical trials, which would~~ adversely affect ~~our~~ **their commercial** ~~ability~~ **viability** ~~to obtain regulatory approvals or to commercialize these programs on a timely basis or at all, which would have an adverse effect on our business~~. Our **current** product candidates **are in early clinical and preclinical development and we are subject to the risks of failure inherent in the development of product candidates based on novel approaches** , ~~including~~ **targets and mechanisms of action. Although we received IND clearance for** CER- 1236 **from** ~~, are in~~ the **FDA in November 2024 and for additional indications in March 2025, and** ~~preclinical development stage. The risk of failure of preclinical programs is high. Before~~ we ~~can commence~~ **anticipate beginning** clinical trials **in the first half** ~~for a product candidate, we are nearing completion~~ of ~~extensive preclinical testing and studies~~ **2025, there is no guarantee that we will be able** to **proceed with** ~~obtain regulatory clearance to initiate human~~ clinical ~~trials with~~ **development of** CER- 1236 **or any of our** ~~, and have engaged in a pre- IND meeting with the~~ **other product candidates or** ~~FDA. We expect~~ that ~~our~~ **any product candidate will demonstrate a** clinical **benefit once we advance** ~~trials will be conducted on populations based in the~~ **these candidates to** ~~United States and Europe. We cannot be certain of the timely completion or outcome of our preclinical~~ testing **in patients. Accordingly** ~~and studies and cannot predict if the FDA~~ , ~~the EMA~~ **you should consider** ~~or~~ **our prospects in light of** ~~other~~ -- **the** ~~regulatory authorities will accept our proposed~~ **costs, uncertainties, delays and difficulties frequently encountered by early** clinical **stage biotechnology companies such as** ~~programs or if the outcome of our~~ **ours** ~~preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our clinical programs on the timelines we expect, if at all~~ . Success in preclinical studies or clinical trials may not be indicative of results in future clinical trials. Results from preclinical studies are not necessarily predictive of future clinical trial results, and interim results of a clinical trial are not necessarily indicative of final results. Our product candidates may ultimately fail to show the desired safety and efficacy in clinical settings despite positive results in preclinical studies or having successfully advanced through initial clinical trials. This failure to establish sufficient efficacy and safety could cause us to abandon clinical development of our product candidates. Manufacturing genetically engineered products is complex and we, or our third- party manufacturers, may encounter difficulties in production. If we or any of our third- party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented. Manufacturing genetically engineered products is complex and may require the use of innovative technologies to handle living cells. Manufacturing these products requires facilities specifically designed for and validated for this purpose and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at manufacturing facilities, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination. In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale- up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency and timely availability of raw materials. Even if we obtain marketing approval for any of our product candidates, there is no assurance that we or our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA, the EMA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. If we or our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects. Genetic engineering of T cells to create CER- T cells is a relatively new technology, and if we are unable to use this technology in our intended product candidates, our revenue opportunities will be materially limited. Our technology involves a relatively new approach to T cell gene therapy. This technology may also not be shown to be effective in clinical studies that we may conduct ~~,~~ or may be associated with safety issues that may negatively affect the development of our product candidates. For instance, lentiviral gene transduction may create unintended changes to the DNA such as a non- target site gene insertion, a large deletion, or a DNA translocation, any of which could lead to oncogenesis. We may not be successful in our efforts to identify or discover additional product candidates. The success of our business depends primarily upon our ability to identify, develop and commercialize products based on our CER- T cell technology. Our research programs may fail to

identify other potential product candidates outside of CER- 1236 for clinical development for a number of reasons. We may be unsuccessful in identifying potential product candidates or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. If any of these events occur, we may be forced to abandon our research, development or commercialization efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations. Even if we obtain regulatory approval of a product candidate, the product may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community. The use of engineered T cells as a potential cancer treatment is nascent and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community. We expect physicians with expertise in immunotherapy to be particularly important to the market acceptance of our products and we may not be able to educate them on the benefits of using our product candidates for many reasons. For example, certain of the product candidates that we will be developing may result in unacceptable and unanticipated side effects, including death. Additional 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 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 coverage and adequate reimbursement by third- party payors and government authorities; ● the willingness of patients to pay out- of- pocket in the absence of coverage and adequate reimbursement by third- party payors and government authorities; ● relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and ● the effectiveness of our sales and marketing efforts. If 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. Data from our preclinical studies is limited and may change as patient data become available or may not be validated in any future or advanced clinical trial. Data from preclinical studies and any clinical trials that we may complete is subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available. For example, preclinical and Phase 1 results are preliminary in nature and should not be viewed as predictive of ultimate success. It is possible that such results will not continue or may not be repeated in any clinical trial of our product candidates. For instance, our preclinical studies provide limited data and any clinical trials may not validate such results. Additionally, manufacturing can impact clinical outcomes and we have not yet completed manufacturing runs with a CDMO. We may also fail to develop and transfer to a CDMO any optimized manufacturing processes for any of our programs. Ultimately, if we cannot manufacture our product candidates with consistent and reproducible product characteristics, our ability to develop and commercialize any product candidate would be significantly impacted. Preliminary data also remains 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, initial, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. We may not be able to file INDs or IND amendments to commence clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed. **The** ~~We may not be able to file INDs, including the~~ IND for CER- 1236 ~~,~~ **was filed** on **June 28, 2024 and on November 15, 2024, the FDA cleared us to begin clinical trials for the treatment of AML and we submitted a second IND application for the investigation of CER- T cell therapy in NSCLC and ovarian cancer, which was accepted by the FDA on March 27, 2025, but there are no assurances regarding the acceptance of any amendments or future INDs, which may impact** the timelines we expect. For example, we may experience manufacturing delays or other delays with **future** IND- enabling studies. Moreover, ~~we cannot~~ **there can** be ~~sure~~ **no assurances** that **once** ~~submission of an IND will result in the FDA allowing clinical~~ trials ~~to~~ begin ~~, or that, once begun~~ , issues will not arise that suspend or terminate **such** clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs. Clinical trials are difficult to design and implement, involve uncertain outcomes and may not be successful. Human clinical trials are difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial that will be successful to achieve regulatory approval. There is a high failure rate for biological products proceeding through clinical trials, which may be higher for our product candidates because they are based on new technology and engineered on a patient- by- patient basis. 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. We will depend on enrollment of

patients in our clinical trials for our product candidates. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected. Identifying and qualifying patients to participate in clinical trials of our product candidates will be critical to our success. 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 protocol; ● the number of patients with the disease or condition being studied; ● the perceived risks and benefits of the product candidate in the trial; ● clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating or drugs that may be used off- label for these indications; ● the size and nature of the patient population required for analysis of the trial' s primary and secondary endpoints; ● the proximity of patients to study sites; ● the design of the clinical trial; ● our ability to recruit clinical trial investigators with the appropriate competencies and experience; ● competing clinical trials for similar therapies or other new therapeutics not involving T cell- based immunotherapy; ● 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 of their treatment; and ● other public health factors, including the coronavirus pandemic or outbreaks of other infections. In particular, some of our clinical trials will look to enroll patients with characteristics which are found in a very small population. For example, our clinical trial for CER- 1236 will seek to enroll patients with hematologic malignancies, including AML, MCL, CLL, and other B cell and myeloid neoplasms. Other companies are conducting clinical trials with their engineered T cell therapies in hematologic malignancies and seek to enroll patients in their studies that may otherwise be eligible for our clinical trials, which could lead to slow recruitment and delays in our clinical trials. In addition, since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which could further reduce the number of patients who are available for our clinical trials in these clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential study participants and their doctors may be inclined to use conventional therapies, such as chemotherapy and antibody therapy, rather than participate in our clinical trials. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these clinical trials and adversely affect our ability to advance the development of our product candidates. In addition, many of the factors that may 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. If the market opportunities for any of our product candidates are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer. We are focused initially on the development of treatments for cancers such as AML, MCL and CLL, and plan to eventually extend our treatments to other forms of cancer. Our internal projections of addressable patient populations that have the potential to benefit from treatment with our product candidates are based on estimates. If any of our estimates are inaccurate, the market opportunities for any of our product candidates could be significantly diminished and have an adverse material impact on our business. We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if licensed, we may not be able to generate product revenue. We currently have no sales, marketing or distribution capabilities and have no experience in marketing products. We intend to develop an in- house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our product candidates following their approval. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates. There can be no assurance that we will be able to develop in- house sales and distribution capabilities or establish or maintain relationships with third- party collaborators to commercialize any product in the United States or overseas. We face competition from companies that have developed or may develop product candidates for the treatment of the diseases that we may target, including companies developing novel therapies and platform technologies. If these companies develop platform technologies or product candidates more rapidly than we do, if their platform technologies or product candidates are more effective or have fewer side effects, our ability to develop and successfully commercialize product candidates may be adversely affected. The development and commercialization of cell and gene therapies is highly competitive. We compete with a variety of large pharmaceutical companies, multinational biopharmaceutical companies, other biopharmaceutical companies and specialized biotechnology companies, as well as technology and / or therapeutics being developed at universities and other research institutions. Our competitors are often larger and better funded than we are. Our competitors have developed, are developing or will develop product candidates and processes competitive with ours. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments that are currently in development or that enter the market. We believe that a significant number of product candidates are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may try to develop product candidates. There is intense and rapidly evolving competition in the biotechnology and biopharmaceutical fields. We believe that while our T- cell based platform, its associated intellectual property portfolio, the characteristics of our current and potential future product candidates and our scientific and technical

know- how together give us a competitive advantage in this space, competition from many sources remains. Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our product candidates, the ease with which our product candidates can be administered, the timing and scope of regulatory approvals for these product candidates, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products and product candidates could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products and product candidates may make any product we develop obsolete or noncompetitive before we recover the expense of developing and commercializing such product. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive or better reimbursed than any products that we may commercialize. Our competitors also may obtain FDA, EMA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position for either the product or a specific indication before we are able to enter the market. We are highly dependent on our key personnel, including individuals with expertise in cell therapy development and manufacturing, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on the expertise of our management, scientific and medical personnel, including our chief executive officer (" Chief Executive Officer "), **Chris Ehrlich** ~~Brian G. Atwood~~ , our chief ~~technical~~ **development** officer **(" Chief Development Officer ")** , ~~Daniel Corey~~ **Kristen Pierce** , **our chief financial officer (" Chief Financial Officer "), Andrew " Al " Kucharchuk** and the head of our scientific advisory board ~~(the " Scientific Advisory Board ")~~ , Lawrence Corey. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business. We conduct substantially all of our operations at our facilities in the South San Francisco area. The San Francisco Bay Area region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. Attrition may lead to higher costs for hiring and retention, diversion of management time to address retention matters and disrupt the business. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity- based compensation for retention purposes. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements **or consulting agreements** with our key employees, these ~~employment~~ agreements provide for at- will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain " key person " insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid- level and senior managers as well as junior, mid- level and senior scientific and medical personnel. We will need to continue to grow the size of our organization, and we may experience difficulties in managing this growth. As our development, manufacturing and commercialization plans and strategies develop, we expect to add managerial, operational, sales, R & D, marketing, financial and other personnel. Current and future growth imposes and will impose significant added responsibilities on members of management, including: ● identifying, recruiting, integrating, maintaining and motivating additional employees; ● managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and ● improving our operational, financial and management controls, reporting systems and procedures. Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage our growth, and our management may also have to divert a disproportionate amount of its attention away from day- to- day activities in order to devote a substantial amount of time to managing these growth activities. We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. We may also be subject to penalties or other liabilities if we mis- classify employees as consultants. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring and retaining employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop, manufacture and commercialize our product candidates and, accordingly, may not achieve our research, development, manufacturing and commercialization goals. Conversely, if we expand ahead of our business progress, we may take on unnecessary costs. We may form or seek strategic alliances or enter into 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 or enter into 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. Any delays in entering into 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. If we license products or new technologies or acquire 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. For instance, certain of our agreements may require significant R & D that may not result in the development and commercialization of product candidates. We cannot be certain that, following a strategic transaction or license, we will achieve the results, revenue or specific net income that justifies such transaction. We will need substantial additional financing to develop our product candidates and implement our operating plans, which financing we may be unable to obtain, or unable to obtain on acceptable terms. If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our product candidates. We expect to spend a substantial amount of capital in the development and manufacturing of our product candidates, and we will need substantial additional financing to do so. In particular, we will require substantial additional financing to enable commercial production of our product candidates and initiate and complete registrational trials for multiple products in multiple regions. Further, if approved, we will require significant additional capital in order to launch and commercialize our product candidates. As of ~~March 20~~ **December 31** , 2024, we had **approximately** $ ~~4~~ **3** . ~~7~~ **3** million in cash and cash equivalents. Changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may also need to raise additional capital sooner than we currently anticipate if we choose to expand more rapidly than we presently plan. In any event, we will require additional capital for the further development and commercialization of our product candidates, including funding our internal manufacturing capabilities. We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other R & D initiatives. We could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our Common Stock to decline. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our product candidates. Until such time, if ever, as we can generate substantial revenue from the sale of our product candidates, we will need substantial additional financing to develop our product candidates and implement our operating plans. 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 could 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. 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 research programs or product candidates or grant licenses on terms that may not be favorable to us or that may be at less than the full potential value of such rights. If we are unable to raise additional funds through equity or debt financings or other arrangements with third parties when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves **. The issuance of shares of our Common Stock upon conversion or exercise of our outstanding Preferred Shares and Common Warrants and other securities that we may issue in future financing transactions may result in substantial dilution to our stockholders. As of April 11, 2025, the Company currently has outstanding (i) 1, 429 shares of Series A Preferred Stock with a conversion value of approximately $ 1. 4 million, convertible into shares of Common Stock at a conversion rate of the stated value thereof divided by a current effective conversion price of $ 1. 96; (ii) 198 shares of Series B Preferred Stock with a conversion value of approximately $ 0. 2 million, convertible into shares of Common Stock at a conversion rate of the stated value thereof divided by a floating conversion price of 80 % of the lowest volume weighted average price during the five trading days immediately prior to conversion; (iii) 2, 537 shares of Series C Preferred Stock with a stated value of approximately $ 2. 5 million, convertible into shares of Common Stock at a conversion rate of the stated value thereof divided by a conversion price of $ 1. 96 (iv) Series A Warrants to purchase 6, 127 shares of Common Stock at an exercise price of $ 139. 00 per share; (v) Series C Warrants to purchase 81, 753 shares of Common Stock at an exercise price of $ 0. 04; (vi) December 2024 and January 2025 Common Warrants to purchase an aggregate of 247, 914 shares of Common Stock at an exercise price ranging from $ 5. 61 to $ 5. 82, (vii) February 2025 Common Warrants to purchase an aggregate of 2, 551, 020 shares of Common Stock at an exercise price of $ 1. 96, (viii) Pre- Funded Warrants to purchase an aggregate of 215, 740 shares of Common Stock at an exercise price of $ 0. 0001, and (ix) Public Warrants**

and Private Placement Warrants to purchase an aggregate of 91, 925 shares of Common Stock at an exercise price of $ 1, 150. 00 per share. Although each of the conversion price of the Preferred Shares and the exercise prices of the December 2024 Common Warrants, January 2025 Common Warrants, and Series A Warrants are at or above the trading price of our Common Stock as of the date of this Annual Report, if such trading price increases, such conversion prices and exercise prices will not change as a result thereof and could be below the trading price of our Common Stock as of the date of any future conversion or exercise thereof, resulting in dilution to our stockholders. In addition, the terms of the Series A Preferred Stock, the Series B Preferred Stock and the Series C Preferred Stock contain certain penalties and adjustments to the amount included in determination of the conversion rate following certain breaches of the Company' s obligations thereunder, including, among other things, as a result of a failure to file or cause the SEC to declare one or more registration statements relating to the resale of the shares of Common Stock issuable upon conversion thereof by specified deadlines, certain defaults under indebtedness of the Company or judgments against the Company and failure to deliver shares of Common Stock upon conversion in a timely manner. For example, the penalties and adjustments include a 25 % premium added to the stated value for determining the conversion rate in connection with breaches other than the breach of the requirement to redeem the shares of Series A Preferred Stock and Series B Preferred Stock by August 14, 2025, which results in a 50 % premium, and the addition to the stated value of an amount equal to the value of the shares of Common Stock into which the Series A Preferred Stock or Series B Preferred Stock would have been convertible if the conversion price were equal to 80 % of the lowest volume weighted average price during the five trading days immediately prior to conversion. Such penalties and adjustments, which applied during the period when substantially all of the conversions since the Business Combination described in the preceding paragraph occurred as a result of a failure to file and cause the SEC to declare a registration statement with respect to the resale of the underlying shares in a timely manner, have resulted and may in the future result in the issuance of shares of Common Stock at an effective conversion price below the trading price of our Common Stock at the time of such conversion. We cannot assure you that we will remain in compliance with all of the terms of the Series A Preferred Stock, Series B Preferred Stock or Series C Preferred Stock and that such penalties and adjustments will not apply in the future. In addition, we cannot assure you that we will not issue additional convertible or other derivative securities with highly dilutive penalty or adjustment provisions. As described elsewhere in this Annual Report, the Company needs to obtain financing to fund its research and development activities and clinical trials, as well as other operations. Under challenging conditions in the equity capital markets, particularly for pre- commercialization biotech companies, we may have no viable alternatives to agreeing to inclusion of such provisions in the terms of future financings . If our security measures, or those of our CROs, CDMOs, collaborators, contractors, consultants or other third parties upon whom we rely, are compromised or the security, confidentiality, integrity or availability of our information technology, software, services, networks, communications or data is compromised, limited or fails, we could experience a material adverse impact. In the ordinary course of our business, we may collect, process, receive, store, use, generate, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively processing) proprietary, confidential and sensitive information, including personal data (including health information), intellectual property, trade secrets, and proprietary business information owned or controlled by ourselves or other parties. We may also share or receive sensitive information with our partners, CROs, CDMOs, or other third parties. 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 we (or a third party upon whom we rely) experience a security incident or **compromise, or** are perceived to have experienced a security incident **or compromise** , we may also experience adverse consequences. Our internal computer systems and those of our CROs, CDMOs, collaborators, contractors, consultants or other third parties are vulnerable to damage from computer viruses, unauthorized access, cybersecurity threats, and telecommunication and electrical failures. In addition, as many of our personnel work from home at least part of the time and utilize network connections outside our premises, this poses increased risks to our information technology systems and data. Cyberattacks, malicious internet- based activity, and online and offline fraud are prevalent and are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. These threats come from a variety of sources, including traditional computer " hackers, " " hacktivists, " organized criminal threat actors, threat actors, personnel (such as through theft or misuse), sophisticated nation- states, and nation- state- supported actors. Some actors now engage and are expected to continue to engage in cyber- attacks, including without limitation nation- state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, and the third parties upon which we rely, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber- attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce and distribute our product candidates. We and the third parties upon which we rely are subject to a variety of evolving threats, including social- engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial- of- service (such as credential stuffing), credential harvesting, social engineering attacks (including through phishing attacks), viruses, ransomware, supply chain attacks, personnel misconduct or error and other similar threats. We may also be the subject of software bugs, server malfunction, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures or other similar issues. In particular, ransomware attacks are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, disruptions to our clinical trials, loss of data (including data related to clinical trials), significant expense to restore data or systems, reputational loss and the 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. Similarly, supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain have not been compromised or that they do not contain exploitable defects or bugs

that could result in a breach to our information technology systems or the third- party information technology systems that support us and our services. 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. Any of the previously identified or similar threats could cause a security incident **, compromise,** or other interruption. A security incident **, compromise,** or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to manufacture or deliver our product candidates. We may expend significant resources, or modify our business activities and operations, including our clinical trial activities, in an effort to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures or use industry- standard or reasonable security measures to protect our information technology systems and sensitive information. Although we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We **, and the third parties on whom we rely,** have experienced **, and expect to continue to experience, threats to and** attempts to compromise **the security of** our information technology systems or otherwise cause a security incident **.** ~~, but, to our knowledge, such~~ **Such** ~~attempts have been unsuccessful. In addition, from time to time, our vendors inform us of~~ security incidents ~~. To date, our~~ **or compromises** ~~review of such incidents as reported to us did not reveal material information being lost~~ , **if experienced** ~~CERo- specific security vulnerabilities or provide any useful information or insight into our systems or environment. However~~ , ~~we may not have all information related to such incidents and future incidents~~ could have an adverse impact on our business. We may be unable to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Despite our efforts to identify and remediate exploitable critical vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Any failure to prevent or mitigate security incidents or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state, federal, and international law and may cause a material adverse impact to our reputation, affect our ability to conduct our clinical trials and potentially disrupt our business. Applicable data protection laws, privacy policies and data protection obligations may require us to notify relevant stakeholders of security incidents **or compromises** . Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may also 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 contracts may not contain limitations of liability, and even where they do, there can be no assurance that the 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 adequately mitigate liabilities arising out of our privacy and security practices, or that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. Disruptions at the FDA, the SEC and other government agencies caused by **reduction in staffing,** funding shortages 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 **staffing levels,** government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, 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 R & D activities is subject to the political process, which is inherently fluid and unpredictable. **The Trump Administration has issued executive orders seeking to greatly reduce the size of the federal workforce, including through layoffs and severance packages offered to employees of federal agencies within the executive branch and independent agencies, including the SEC and the FDA. Any such reduction in personnel may result in longer review times by the FDA or SEC.** Disruptions **and personnel turnover, as a result of leadership changes, staff reductions or otherwise,** at the FDA and other **government** agencies may also slow the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. ~~For example~~ **In addition to the potential reduction in staffing** , **a government shutdown could adversely affect the FDA review process.** ~~over~~ **Over** the last several years the U. S. government has shut down several 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 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. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Since March 2020, when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume pre- pandemic levels of inspection activities, including routine surveillance, bioresearch monitoring and pre- approval inspections. Should the

FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel or otherwise, and the FDA does not determine a remote interactive evaluation to be adequate, the FDA has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. Business disruptions, including financial institution distress, could seriously harm our future revenue and financial condition and increase our costs and expenses. Our operations, and those of our CROs, CDMOs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical pandemics or epidemics and other natural or man- made disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man- made or natural disaster or other business interruption. Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and / or negligent conduct that fails to comply with the regulations of the FDA and other similar foreign regulatory authorities, provide true, complete and accurate information to the FDA and other similar foreign regulatory authorities, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws and regulations will increase significantly, and our costs associated with compliance with such laws and regulations are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission (s), certain customer incentive programs and other business arrangements generally. For more information, see the section entitled ‘‘ Business — Healthcare Laws and Regulations. ” The distribution of biotechnology and biopharmaceutical products is subject to additional requirements and regulations, including extensive record- keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of biotechnology and biopharmaceutical products. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource- consuming and can divert a company’ s attention from other aspects of its business. It is not always possible to identify and deter employee misconduct, and our code of ethics and the other precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and 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 criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, diminished profits and future earnings, individual imprisonment, and exclusion from participation in government 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, reputational harm, and we may be required to curtail or restructure our operations, any of which could adversely affect our ability to operate our business and our results of operations. 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. 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 provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to induce or reward improper performance generally is typically governed by the national anti- bribery laws of European Union Member States, and in respect of the U. K. (which is longer a member of the European Union), the U. K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment. European Union Directive 2001 / 83 / EC, which is the European Union Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the UK despite its departure from the European Union. Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician’ s employer, his or her competent professional organization and / or

the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the European Union General Data Protection Regulation (“ GDPR ”), which became effective on May 25, 2018, as well as the United Kingdom’ s General Data Protection Regulations (the “ UK GDPR ”), which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The GDPR is wide- ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third- party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to € 20 million or 4 % of annual global revenues, whichever is greater; UK GDPR mirrors such fines under the GDPR. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR will be a rigorous and time- intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with European activities. This and other future developments regarding the flow of data across borders could increase the cost and complexity of delivering our product candidates, if approved, in some markets and may lead to governmental enforcement actions, litigation, fines and penalties or adverse publicity, which could have an adverse effect on our reputation and business. Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences. Future undesirable or unacceptable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Approved autologous T cell therapies and those under development by other companies have shown frequent rates of CRS, neurotoxicity, serious infections, prolonged cytopenia and hypogammaglobulinemia, and adverse events have resulted in the death of patients. Similar adverse events may occur for our T cell product candidates. In addition, we utilize a lymphodepletion regimen, which generally includes fludarabine, cyclophosphamide or bendamustine, that may cause serious adverse events. For instance, because the regimen will cause a transient and sometimes prolonged immune suppression, patients will have an increased risk of infection, such as to COVID- 19, that may be unable to be cleared by the patient and ultimately lead to other serious adverse events or death. Our lymphodepletion regimen has caused and may also cause prolonged cytopenia and aplastic anemia. We may also combine the use of our product candidates with other investigational or approved therapies that may cause separate adverse events or events related to the combination or potentiate side effects of approved drugs. If unacceptable toxicities arise in the development of our product candidates, we could suspend or terminate our trials or the FDA, the EMA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Any data safety monitoring board may also suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk, including risks inferred from other unrelated immunotherapy trials. Treatment- related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from T cell therapy are not normally encountered in the general patient population and by medical personnel. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient deaths. Any of these occurrences may harm our business, financial condition and prospects significantly. Our product candidates may target healthy cells expressing target antigens, leading to potentially fatal adverse effects. Our product candidates target specific antigens that are also expressed on healthy cells. For example, cell surface phosphatidylserine, the target of CER- 1236, has been observed on activated immune cells, including platelets, and in rapidly dividing cells across various organs including the gastrointestinal system, hepatic system, cardiovascular system, renal system, pulmonary system, and the central nervous system and related peripheral nervous system. Our product candidates may target healthy cells, leading to serious and potentially fatal adverse effects. Even though we intend to closely monitor the side effects of our product candidates in both preclinical studies and clinical trials, we cannot guarantee that products will not target and kill healthy cells. Our product candidates may have serious and potentially fatal cross- reactivity to lipids, peptides or protein sequences within the body. Our product candidates may recognize and bind to a peptide unrelated to the target antigen to which it is designed to bind. If this peptide is expressed within normal tissues, our product candidates may target and kill the normal tissue in a patient, leading to serious and potentially fatal adverse effects. Additionally, our product candidates may bind with non- targeted lipids, leading to off- target reactivity. Detection of any on- target off- tumor or non- specific- reactivity may halt or delay any ongoing clinical trials for any CER- T cell based product candidate and prevent or delay regulatory approval. Unknown binding- reactivity of the CER- T cell binding domain to related proteins could also occur. Any non- specific binding interactions that impacts patient safety could materially impact our ability to advance our product candidates into clinical trials or to proceed to marketing approval and commercialization. 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 face an inherent risk of product liability as a result of the planned clinical testing of our product candidates and

will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, packaging, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: ● decreased demand for our product candidates or products that we may develop; ● 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 trial participants or patients; ● product recalls, withdrawals or labeling, marketing or promotional restrictions; ● loss of revenue; ● exhaustion of any available insurance and our capital resources; ● the inability to commercialize any product candidate; and ● a decline in our stock price. Failure to obtain or retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Although we plan on purchasing clinical trial insurance, such insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise. Public opinion and scrutiny of cell- based ~~immuno~~ **immune** - oncology therapies for treating cancer, or negative clinical trial results from our cell- based therapy competitors, or auto- immune cell therapy candidates, may impact public perception of our company and product candidates, or impair our ability to conduct our business. Our autologous cell therapy platforms utilizes a relatively novel technology involving the genetic modification of cells, and no CER- T cell- based immunotherapy has been approved to date. Public perception may be influenced by claims, such as claims that cell- based immunotherapy is unsafe, unethical, or immoral and, consequently, our approach may not gain the acceptance of the public or the medical community. Negative public reaction to cell- based immunotherapy in general, or negative clinical trial results from our cell- based therapy competitors, or auto- immune cell therapy candidates, could result in greater government regulation and stricter labeling requirements of cell-based immunotherapy products, including any of our product candidates, and could cause a decrease in the demand for any products we may develop. Adverse public attitudes may adversely impact our ability to enroll patients in clinical trials. More restrictive government regulations or negative public opinion could have an adverse 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 we may develop. For example, in November 2023, the FDA announced that it would be conducting an investigation into reports of T-cell malignancies following BCMA- directed or CD19- directed autologous CAR- T cell immunotherapies following reports of T cell lymphoma in patients receiving these therapies. In January 2024, the FDA determined that new safety information related to T cell malignancies should be included in the labeling with boxed warning language on these malignancies for all BCMA- and CD- 19- directed genetically modified autologous T cell immunotherapies. While CER- 1236 and our engineered CER- T cells are designed to utilize a different mechanism of action, FDA' s investigation into CAR- T therapies and other similar actions could result in increased government regulation, unfavorable public perception and publicity, potential impacts on enrollment in our clinical trials, 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. Our product candidates for which we intend to seek approval as biological products may face competition sooner than anticipated, including from other therapeutic modalities. The Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the 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. 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. We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk 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 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 any approved products are subject to biosimilar competition sooner than we expect, we will face significant pricing pressure and our commercial opportunity will be limited. The insurance coverage and reimbursement status of newly- approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new products could limit our product revenues. Our ability to commercialize any of our product candidates successfully will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. In the United States, the principal decisions about reimbursement for new therapies are typically made by CMS, an agency within the United States Department of Health and

Human Services. CMS decides whether and to what extent a new therapy will be covered and reimbursed under Medicare, and private payors tend to follow CMS determinations to a substantial degree. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments, such as cellular immunotherapy. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products by government and third- party payors. In particular, there is no body of established practices and precedents for reimbursement of cellular immunotherapies, and it is difficult to predict what the regulatory authority or private payor will decide with respect to reimbursement levels for novel products such as ours. Our product candidates may not qualify for coverage or direct reimbursement, or may be subject to limited reimbursement. If reimbursement or insurance coverage is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates, if approved. Even if coverage is provided, the approved reimbursement amount may not be sufficient to allow us to establish or maintain pricing to generate income. In addition, reimbursement agencies in foreign jurisdictions may be more conservative than those in the United States. Accordingly, in markets outside the United States, the reimbursement for our product candidates, if approved, may be reduced as compared with the United States and may be insufficient to generate commercially reasonable revenues and profits. Moreover, increasing efforts by governmental and third- party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved, and as a result, they may not cover or provide adequate payment for our product candidates. Failure to obtain or maintain adequate reimbursement for any products for which we receive marketing approval will adversely affect our ability to achieve commercial success, and could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition. Even if we obtain regulatory and marketing approval for a product candidate, our product candidates will remain subject to regulatory oversight. Even if we receive marketing and regulatory approval for CER- 1236 or any other product candidates, regulatory authorities may still impose significant restrictions on the indicated uses or marketing or impose ongoing requirements for potentially costly post- approval studies. CER- 1236 and other product candidates will also be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record- keeping, and submission of safety and other post- market information. The FDA has significant post- market authority, including, for example, the authority to require labeling changes based on new safety information and to require post- market studies or clinical trials to evaluate serious safety risks related to the use of a biologic. Any regulatory approvals that we receive for CER- 1236 or other product candidates may also be subject to a REMS, limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing testing, including post- approval clinical trials, and surveillance to monitor the quality, safety, and efficacy of the product, all of which could lead to lower sales volume and revenue. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA also must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. In addition, product manufacturers and their facilities 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 (s) previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or disagrees with the promotion, marketing or labeling of that product, a regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we or our contractors fail to comply with applicable regulatory requirements following approval of CER- 1236 or our other product candidates, a regulatory authority may: ● issue a warning letter, untitled letter, or Form 483, asserting that we are in violation of the law; ● request voluntary product recalls; ● 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 BLA or comparable foreign marketing application (or any supplements thereto); ● restrict the marketing or manufacturing of the product; ● seize or detain the product or otherwise require the withdrawal of the product from the market; ● refuse to permit the import or export of 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 CER- 1236 or other product candidates and adversely affect our business, financial condition, results of operations, and prospects. Prior treatments can alter the cancer or target of CER- T cell therapy and negatively impact chances for achieving clinical activity with our programmed T cells. Patients with hematological cancers receive highly toxic lympho- depleting chemotherapy as their initial treatment. These therapies can impact the viability of the T cells collected from the patient and can contribute to highly variable responses to programmed T cell therapies. Patients could also have received prior therapies that target the same target antigen on the cancer cells as our intended programmed T cell product candidate and thereby lead to a selection of cancer cells with low or no expression of the target. Cancers also naturally evolve and select clones with low or no expression of the target. As a result, our programmed T cell product candidates may not recognize the cancer cell and may fail to achieve clinical activity. If any of our product candidates do not achieve a sufficient level of clinical activity, we may discontinue the development of that product candidate, which could adversely affect our business, financial condition, results of operations, and prospects. Risks Related to Reliance on Third- Parties We will rely on third parties to conduct our clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates. We expect to utilize and depend upon independent investigators and collaborators, such

as medical institutions, CROs, CDMOs and strategic partners to conduct our preclinical studies under agreements with us and in connection with our clinical trials. We expect to have to negotiate budgets and contracts with CROs, trial sites and CDMOs which 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. As a result, we have less direct control over the conduct, timing and completion of these clinical trials and the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal and regulatory requirements 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 GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biological product produced under cGMP regulations, including current good tissue practice (“ cGTP ”) regulations, and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal 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 such third parties, we cannot control whether or not they devote sufficient time and resources to our product candidates. 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, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. Additionally, 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. We rely on third parties to manufacture and store our clinical product supplies, and we may have to rely on third parties to produce and process our product candidates, if approved. There can be no assurance that we will be able to establish or maintain relationships with such third parties. We may in the future establish our own manufacturing facility and infrastructure in addition to or in lieu of relying on third parties for the manufacture of our product candidates, which would be costly, time- consuming and which may not be successful. Our product candidates are manufactured in the United States by third parties, and we manage all other aspects of the supply, including planning, oversight, disposition and distribution logistics. There can be no assurance that we will not experience supply or manufacturing issues in the future. We have a long- term agreement in place with a CDMO for the manufacture of CER- 1236. However, we have not yet caused our product candidates to be manufactured or processed on a commercial scale and may not be able to achieve manufacturing and processing and may be unable to create an inventory of mass- produced product to satisfy demands for any of our product candidates. Our clinical supply will also be limited to small quantities and any latent defects discovered in our supply could significantly delay our development timelines. In addition, our actual and potential future reliance on a limited number of third- party manufacturers exposes us to the following risks: ● We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA may have questions regarding any replacement contractor. This may require new testing and regulatory interactions. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA questions, if any. ● Our third- party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any. ● Contract manufacturers may not be able to execute our manufacturing procedures appropriately. ● Manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third- party manufacturers’ compliance with these regulations and standards. ● We may not own, or may have to share, the intellectual property rights to any improvements made by our third- party manufacturers in the manufacturing process for our products. ● Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products. ● Our third- party manufacturers could breach or terminate their agreement with us. Our contract manufacturers would also be subject to the same risks we face in developing our own manufacturing capabilities, as described above. Our current and potential future CDMOs may also be required to shut down in response to the spread of health epidemics or pandemics, or they may prioritize manufacturing for therapies or vaccines for other diseases. In addition, our CDMOs have certain responsibilities for storage of

raw materials and in the past have lost or failed to adequately store our raw materials. We will also rely on third parties to store our released product candidates, and any failure to adequately store our product candidates could result in significant delay to our development timelines. Any additional or future damage or loss of raw materials or product candidates could materially impact our ability to manufacture and supply our product candidates. Each of these risks could delay our clinical trials ~~,~~ **or** the approval **of** ~~, if~~ any of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue. In addition, we will rely on third parties to perform release tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm. We maintain single supply relationships for certain key components, and our business and operating results could be harmed if supply is restricted or ends or the price of raw materials used in our suppliers' manufacturing process increases. We are dependent on sole suppliers or a limited number of suppliers for certain components that are integral to our product candidates, including CER- 1236. If these or other suppliers encounter financial, operating or other difficulties or if our relationship with them changes, we may be unable to quickly establish or qualify replacement sources of supply and could face production interruptions, delays and inefficiencies. In addition, technology changes by our vendors could disrupt access to required manufacturing capacity or require expensive, time- consuming development efforts to adapt and integrate new equipment or processes. Our growth may exceed the capacity of one or more of these suppliers to produce the needed equipment and materials in sufficient quantities to support our growth. Any one of these factors could harm our business and growth prospects. Our product candidates rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all. Our product candidates, including CER- 1236, require many specialty raw materials, some of which are manufactured by small companies with limited resources and experience to support a commercial product. In addition, those suppliers normally support blood- based hospital businesses and generally do 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 an FDA inspection or medical crisis, such as widespread contamination. We also do not have contracts 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 of our raw materials are currently available from a single supplier, or a small number of suppliers. For example, the type of cell culture media and cryopreservation buffer that we currently use in our manufacturing process for the CER- T cells are available from multiple suppliers, but each version may perform differently, requiring us to characterize them and modify our protocols if we change suppliers. Disruption of our cell manufacturing process may affect product health, fitness, and potentially anti- tumor activity and clinical responses. In addition, the cell processing equipment and tubing that we use in our current manufacturing process is only available from a single supplier. We also use certain biologic materials, including certain activating antibodies, that are available from multiple suppliers, but each version may perform differently, requiring us to characterize them and potentially modify some of our protocols if we change 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. If we are required to change suppliers, the materials may only be available from another supplier on terms that are less favorable to us than the terms under which we currently obtain the materials. Accordingly, if we no longer have access to these suppliers, we may experience delays in our clinical or commercial manufacturing which could harm our business or results of operations. If we or our third- party suppliers use hazardous, non-hazardous, biological or other materials in a manner that causes injury or violates applicable law, we may be liable for damages. Our R & D activities involve the controlled use of potentially hazardous substances, including chemical and biological materials. We and our suppliers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that we and our suppliers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we and our suppliers cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. In addition, any violation in the use, manufacture, storage, handling and disposal under foreign law may subject us to additional liability. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations. Risks Related to Government and Regulation Clinical development and the regulatory approval process involve a lengthy and expensive process with an uncertain outcome and results of earlier studies and preclinical data, and trials may not be predictive of future clinical trial results. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate. The research, testing, manufacturing, labeling, licensure, sale, marketing and distribution of biological products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, and such regulations differ from country to country. We are not permitted to market our product candidates in the United States or in any foreign countries until they receive the requisite licensure from the applicable regulatory authorities of such jurisdictions. We have not previously submitted a BLA to the FDA or similar licensure applications to comparable foreign regulatory authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish the product candidate' s safety, purity and potency for each desired indication. The BLA must also include significant information regarding the manufacturing controls for the product. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy,

and licensure may not be obtained. We cannot be certain that our preclinical studies and clinical trial results will be sufficient to support regulatory approval of our product candidates. Clinical testing is expensive and can take many years to complete and its outcome is inherently uncertain. Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Failure or delay can occur at any time during the clinical trial process. We may experience delays in obtaining the FDA' s authorization to initiate clinical trials under future INDs and completing ongoing clinical studies of our product candidates due to a variety of factors. Additionally, we cannot be certain that preclinical studies or clinical trials for our product candidates will begin on time, not require redesign, enroll an adequate number of subjects on time, or be completed on schedule, if at all. Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to: ● the availability of financial resources to commence and complete the planned trials ; ● the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials; ● delays in obtaining regulatory approval to commence a clinical trial; ● our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory authority that any of our product candidates are safe, potent and pure; ● the FDA' s or the applicable foreign regulatory agency' s disagreement with our trial protocol or the interpretation of data from preclinical studies or clinical trials; ● our inability to demonstrate that the clinical and other benefits of any of our product candidates outweigh any safety or other perceived risks; ● the FDA' s or the applicable foreign regulatory agency' s requirement for additional preclinical studies or clinical trials; ● the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for licensure; ● the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain licensure of our product candidates in the United States or elsewhere; ● reaching agreement on acceptable terms with prospective CDMOs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CDMOs and clinical trial sites; ● obtaining IRB or ethics committee approval at each clinical trial site; ● recruiting an adequate number of suitable patients to participate in a clinical trial; ● having subjects complete a clinical trial or return for post- treatment follow- up; ● clinical trial sites deviating from clinical trial protocol or dropping out of a clinical trial; ● addressing subject safety concerns that arise during the course of a clinical trial; ● adding a sufficient number of clinical trial sites; ● obtaining sufficient product supply of product candidate for use in preclinical studies or clinical trials from third- party suppliers; ● the FDA' s or the applicable foreign regulatory agency' s findings of deficiencies or failure to approve the manufacturing processes or facilities of third- party manufacturers upon which we rely; or ● the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. We may experience numerous adverse or unforeseen events during, or as a result of, preclinical studies and clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including: ● we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials; ● we may obtain a result from preclinical studies such as a binder specificity study or a safety toxicology study that require us to modify the design of our clinical trials, abandon our research efforts for product candidates, or result in delays; ● 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 our research efforts for our other product candidates; ● 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 our clinical trials at a higher rate than we anticipate; ● our third- party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls or be unable to provide us with sufficient product supply to conduct and complete preclinical studies or clinical trials of our product candidates in a timely manner, or at all; ● we or our investigators 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; ● the quality of our product candidates or other materials necessary to conduct preclinical studies or 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 ● future collaborators 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 moderately positive or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs. In addition, costs to treat patients with relapsed or refractory cancer and to treat potential side effects that may result from our product candidates can be significant. Accordingly, our clinical trial costs are likely to be significantly higher than those for more conventional therapeutic technologies or drug product candidates. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such clinical trials are being conducted, by the Data Safety Monitoring Board for such clinical trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial 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 the product candidates, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. **For example, in July 2024, we announced a clinical hold as a result of insufficient data provided with regard to two issues within pharmacology and toxicology of CER- 1236. In November 2024, we announced that the clinical hold was resolved and that the FDA had cleared our IND for Phase 1 clinical trials.** Any delay in obtaining, or inability to obtain,

applicable regulatory approval would delay or prevent commercialization of our product candidates and would materially adversely impact our business and prospects and our ability to generate revenues from any of these product candidates will be delayed or not realized at all. 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. If one or more of our product candidates generally prove to be ineffective, unsafe or commercially unviable, our CER- T cell platform would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects. Any of these factors, many of which are beyond our control, may result in our failing to obtain regulatory approval to market any of our product candidates, or a delay in such approval, which would significantly harm our business, results of operations, and prospects. Of the large number of biological products in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized. Even if we eventually complete clinical testing and receive licensure from the FDA or applicable foreign regulatory authorities for any of our product candidates, the FDA or the applicable foreign regulatory may license our product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA, or applicable foreign regulatory agency, may not license our product candidates with the labeling that we believe is necessary or desirable for the successful commercialization of such product candidates. Our manufacturing process needs to comply with FDA regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of our clinical programs and suspension or withdrawal of any regulatory approvals. In order to commercially produce our products at a third party' s facility, we will need to comply with the FDA' s cGMP regulations and guidelines, including cGTPs. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP, cGTP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill- finish, packaging, or storage of our CER- T cells as a result of a failure of the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our CER- T cell programs, including leading to significant delays in the availability of our CER- T cells for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our CER- T cell product candidates. Significant non- compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our CER- T cell product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business. Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products. If the FDA, EMA or any other comparable regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration requirements, applicable product tracking and tracing requirements and continued compliance with cGMPs, including cGTPs, and GCP, for any clinical trials that we conduct post- approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with any future potential manufacturing facilities we may own, third- party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things: ● restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary product recalls; ● fines, untitled or warning letters or holds on clinical trials; ● refusal by the FDA, the EMA or any other comparable regulatory authority to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product approvals; ● product seizure or detention, or refusal to permit the import or export of products; and ● injunctions or the imposition of civil or criminal penalties. Moreover, if any of our product candidates are approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about biopharmaceutical products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product' s approved labeling. 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 or our collaborators' ability to commercialize our product candidates, and harm our business, financial condition and results of operations. In addition, the policies of the FDA, the EMA and other comparable regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements, or if we are unable to maintain regulatory compliance, marketing approval that has been obtained may be lost and we may not achieve or sustain profitability. Regulatory requirements in the United States and abroad governing cell therapy products have changed frequently and may continue to change in the future, which could negatively impact our ability to complete clinical trials and commercialize our product candidates in a timely manner, if at all. Regulatory requirements in the United States and abroad

governing cell therapy products have changed frequently and may continue to change in the future. In 2016, the FDA established the Office of Tissues and Advanced Therapies (“ OTAT ”) within its Center for Biologics Evaluation and Research to consolidate the review of gene therapy and related products, and has established the Cellular, Tissue and Gene Therapies Advisory Committee, among others, to advise this review. In September 2022, the FDA announced retitling of OTAT to the Office of Therapeutic Products (“ OTP ”) and elevation of OTP to a “ Super Office ” to meet its growing cell and gene therapy workload. In addition, under guidelines issued by the National Institute of Health (the “ NIH ”), gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee (“ IBC ”), a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. Before a clinical trial can begin at any institution, that institution’ s institutional review board, or IRB, and its IBC assesses the safety of the research and identifies any potential risk to public health or the environment. While the NIH guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH guidelines voluntarily follow them. Moreover, serious adverse events or developments in clinical trials of gene therapy product candidates conducted by others may cause the FDA or other regulatory bodies to initiate a clinical hold on our clinical trials or otherwise change the requirements for approval of any of our product candidates. Although the FDA decides whether individual cell and gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation. We may seek fast track and breakthrough therapy designations or priority review for one or more of our product candidates, but we might not receive such designation or priority review, and even if we do, such designation or priority review may not lead to a faster development or regulatory review or approval process, and does not assure FDA approval of our product candidates. Even if a product qualifies for such designation or priority review, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may seek fast track, breakthrough therapy, and / or regenerative medicine advanced therapy designations or priority review for one or more of our product candidates. The FDA may issue a fast track designation to a product candidate if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life- threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new biologic may request that the FDA designate the biologic as a fast track product at any time during the clinical development of the product. For fast track products, sponsors may have greater interactions with the FDA during product development. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA. However, the FDA’ s goal for reviewing a BLA fast track application under the PDUFA does not begin until the last section of the application is submitted. Fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process. 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. Fast track designation, priority review, and breakthrough therapy designation are within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for any such designation, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of such designation may expedite the development or approval process, but do not change the standards for approval. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may seek approval of our product candidates, where applicable, under the FDA’ s accelerated approval pathway. This pathway may not lead to a faster development, regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval. A product may be eligible for accelerated approval if it is designed to treat a serious or life- threatening disease or condition and generally provides a meaningful advantage over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, (“ IMM ”) that is reasonably likely to predict an effect on IMM or other clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as IMM. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor’ s agreement to conduct, in a diligent manner, additional post- approval confirmatory studies to verity and describe the drug’ s clinical benefit.

Under the FDORA, the FDA is permitted to require, as appropriate, that a post- approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of accelerated approval was granted. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post- approval studies fail to verify the drug' s predicted clinical benefit. Under FDORA, the FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post- approval confirmatory study or submit timely reports to the agency on their progress. In addition, the FDA currently requires, unless otherwise informed by the agency, pre- approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product. Thus, even if we seek to utilize the accelerated approval pathway, we may not be able to obtain accelerated approval and, even if we do, we may not experience a faster development, regulatory review or approval process for that product. There can be no assurance that the FDA would allow any of the product candidates we may develop to proceed on an accelerated approval pathway, and even if the FDA did allow such pathway, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. Moreover, even if we received accelerated approval, any post- approval studies required to confirm and verify clinical benefit may not show such benefit, which could lead to withdrawal of any approvals we have obtained. Receiving accelerated approval does not assure that the product' s accelerated approval will eventually be converted to a traditional approval. We may not be able to obtain orphan drug exclusivity for one or more of our product candidates, and even if we do, that exclusivity may not prevent the FDA from approving other competing products. Regulatory authorities may designate drugs for relatively small patient populations as " orphan " drugs. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of market exclusivity, which, subject to certain exceptions, precludes the FDA from approving another marketing application for the same drug for the same indication for that time period. The applicable market exclusivity period is seven years in the United States. Obtaining orphan drug exclusivity for our product candidates may be important to our commercial strategy. If a competitor obtains orphan drug exclusivity for and approval of a product with the same indication as our product candidates before we do, and if the competitor' s product is the same drug or a similar medicinal product as ours, we could be excluded from the market. Even if we obtain orphan drug exclusivity after FDA approval, we may not be able to maintain it. For example, if a competitive product that is the same drug or a similar medicinal product as our product candidate is shown to be clinically superior to our product candidate, any orphan drug exclusivity we have obtained will not block the approval of such competitive product. In addition, orphan drug exclusivity will not prevent the approval of a product that is the same drug as our product candidates if the FDA finds that we cannot assure the availability of sufficient quantities of the drug to meet the needs of the persons with the disease or condition for which the drug was designated. If one or more of these events occur, it could have a material adverse effect on our company. We are subject to stringent and changing privacy laws, regulations and standards as well as policies, contracts and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to enforcement or litigation (that could result in fines or penalties), a disruption of clinical trials or commercialization of products, reputational harm, or other adverse business effects. In the ordinary course of business, we will collect, receive, store, process, use, generate, transfer, disclose, make accessible, protect, secure, dispose of, transmit and share (collectively, processing) personal data and other sensitive information, including, but not limited to, proprietary and confidential business information, trade secrets, intellectual property, and information we collect about patients in connection with clinical trials. Accordingly, we are, or may become, subject to numerous federal, state, local and international data privacy and data security laws, regulations, guidance, and industry standards as well as external and internal privacy and data security policies, contracts and other obligations that apply to our processing of personal data and the processing of personal data on our behalf. 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 and other similar laws (e. g., unfair or deceptive acts or practices pursuant to Section 5 (a) of the Federal Trade Commission Act). For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (" HITECH "), and their respective implementing regulations, imposes requirements relating to the privacy, security and transmission of protected health information. Among other things, HITECH, through its implementing regulations, makes certain of HIPAA' s privacy and security standards directly applicable to business associates, defined as a person or organization, other than a member of a covered entity' s workforce, that creates, receives, maintains or transmits protected health information for or on behalf of a covered entity for a function or activity regulated by HIPAA as well as their covered subcontractors. In addition, the California Consumer Privacy Act (" CCPA ") **, as amended by the California Privacy Rights Act,** applies to personal information of consumers, business representatives, and employees, and creates individual privacy rights and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide disclosures to California consumers, affords California residents certain rights related to their personal data, including the right to opt- out of certain sales of personal data, and allow for a ~~new~~ **private** cause of action for certain data breaches **. The CCPA also created a new state regulatory agency to implement and enforce the law** . Although there are limited exemptions for clinical trial data under the CCPA, as our business progresses, the CCPA may become applicable and significantly impact our business activities and exemplifies the vulnerability of our business to evolving regulatory environment related to personal data and protected health information. ~~Furthermore, the California Privacy Rights Act of 2020, effective January 1, 2023, expands the CCPA' s requirements, including by applying to personal information of business representatives and employees and establishing a new regulatory agency to implement and enforce the law.~~ In addition, **several** other states ~~, such as Virginia and Colorado,~~ have also passed

comprehensive privacy laws, and similar laws are being considered in **additional** ~~several other~~ states, as well as at the federal and local levels. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. Moreover, **some** ~~data privacy and security laws have been proposed at the federal, state~~ **states** , **such as Washington, Nevada** and ~~local levels in recent years~~ **Connecticut, adopted legislation protecting consumer health information specifically. Washington' s My Health My Data Act** , which ~~could further complicate~~ **is now in effect, features a private right of action, heightening** ~~compliance~~ **noncompliance** ~~efforts~~ **risks** . Outside the United States, there are an increasing number of laws, regulations and industry standards concerning privacy, data protection, information security and cross- border personal data transfers. For example, GDPR, UK GDPR, and China' s Personal Information Protection Law impose strict requirements for processing personal data. Failure to comply with the requirements of the GDPR and the applicable national data protection laws of the European Union Member States may result in fines of up to € 20, 000, 000 or up to 4 % of the total worldwide annual turnover of the preceding financial year, whichever is higher, other administrative penalties, and 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. If we cannot implement a valid compliance mechanism for cross- border data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or other foreign jurisdictions. The inability to import personal data to the United States could significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere; limiting our ability to collaborate with parties that are subject to such cross- border data transfer or localization laws; or requiring us to increase our personal data processing capabilities and infrastructure in foreign jurisdictions at significant expenses. European regulators have also ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR' s cross- border data transfer limitations. In addition, privacy advocates and industry groups have proposed, and may propose, standards with which we are legally or contractually bound to comply. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. If any of our privacy policies or related materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences. Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. As a result, preparing for and complying with these obligations requires significant resources and may necessitate changes to our information technologies, systems and practices, as well as those of any third- party collaborators, service providers, contractors, consultants or other third parties that process personal data on our behalf. Although we endeavor to comply with all applicable privacy and security obligations, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees, third- party collaborators, service providers, contractors or consultants fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third- party service provider to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to or interruption in our ability to operate our business and proceedings against us by governmental entities or others. If we fail, or are perceived to have failed, to address or comply with obligations related to data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e. g., investigations, fines, penalties, audits and inspections, and similar); litigation (including class- related claims); additional reporting requirements and / or oversight; temporary or permanent bans on all or some processing of 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. **Regulators and legislators in the U. S. are increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, Executive Order 14117 of February 28, 2024, Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government- Related Data by Countries of Concern, as implemented by U. S. Department of Justice, prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Actual or alleged violations of these regulations may be punishable by criminal and / or civil sanctions, and may result in exclusion from participation in federal and state programs. Like many companies, we may use artificial intelligence and machine learning (AI) technologies, including generative AI, to efficiently grow and manage our business. These technologies have increasingly been the focus of attention for lawmakers and regulators around the globe. The use of new and evolving technologies, such as artificial intelligence (AI), in our offerings may result in spending material resources and presents risks and challenges that can impact our business including by posing security and other risks to our confidential information, proprietary information and personal information, and as a result we may be exposed to reputational harm and liability. We may continue to build and integrate AI into our offerings, and this innovation presents risks and challenges that could affect its adoption, and therefore our business. The use of certain artificial intelligence technology can give rise to intellectual property risks, including compromises to proprietary intellectual property and intellectual property infringement. Additionally, we expect to see increasing government and supranational regulation related to artificial intelligence use and ethics, which may also significantly increase the burden and cost of research, development and compliance in this area. For example, the European Union' s Artificial Intelligence Act (" AI Act ") has now entered into force. This sweeping legislation, with broad extraterritorial**

reach, imposes significant obligations on providers and deployers of high risk artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. If we develop or deploy AI systems that are governed by the AI Act, we may be required to adopt higher standards of data quality, transparency, and human oversight, and adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. Likewise, in the U. S., several states, including Colorado and California, passed laws that will take effect in 2026, to regulate various uses of artificial intelligence, including to make consequential decisions. In addition, various federal regulators have issued guidance and focused enforcement efforts on the use of AI in regulated sectors. The U. S. Food and Drug Administration, for example, issued guidance on the use of artificial intelligence in medical devices, requiring detailed risk management and review processes to obtain approvals. If we develop or use AI systems governed by these laws or regulations, we will need to meet higher standards of data quality, transparency, monitoring and human oversight, and we would need to adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements, with the potential for significant enforcement or litigation in the event of any perceived non- compliance. The rapid evolution of AI will require the application of significant resources to design, develop, test and maintain our products and services to help ensure that AI is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. Our vendors may in turn incorporate AI tools into their own offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business. The impact of recent healthcare reform legislation and other changes in the healthcare industry and in healthcare spending on us is currently unknown, and may adversely affect our business model. Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition. There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. For more information, see the section of this report titled " Business – Healthcare Laws and Regulations – Healthcare Reform. " The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and / or impose price controls may adversely affect: ● the demand for our product candidates, if we obtain regulatory approval; ● our ability to set a price that we believe is fair for our products; ● our ability to obtain coverage and reimbursement approval for a product; ● our ability to generate revenue and achieve or maintain profitability; ● the level of taxes that we are required to pay; and ● the availability of capital. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. Our business could be negatively impacted by environmental, social and corporate governance matters or our reporting of such matters. Investors have increased their emphasis on the environmental, social and governance (" ESG ") practices of companies across all industries, including the environmental impact of operations and human capital management. Expectations regarding voluntary ESG initiatives and disclosures may result in increased costs (including but not limited to increased costs related to compliance, stakeholder engagement, contracting and insurance), enhanced compliance or disclosure obligations, or other adverse impacts to our business, financial condition, or results of operations. While we have internal efforts directed at ESG matters and preparations for any increased required future disclosures, such initiatives may be costly and may not have the desired effect. We may be perceived to be not acting responsibly in connection with these matters, which could negatively impact us. Moreover, we may not be able to successfully complete such initiatives due to factors that are within or outside of our control. Even if this is not the case, our actions may subsequently be determined to be insufficient by various stakeholders, and we may be subject to investor or regulator engagement on our ESG efforts, even if such initiatives are currently voluntary **. In addition, investor or regulatory expectations for ESG practices may change materially as a result of the change in presidential administration and executive orders issued thereby restricting the implementation of diversity, equity and inclusion programs and we may be unable to adapt to such changes in a timely manner and / or without substantial cost** . Certain market participants, including major institutional investors and capital providers, use third- party benchmarks and scores to assess companies' ESG profiles in making investment or voting decisions. A failure to comply with investor expectations and standards, which are evolving and vary considerably, or the perception that we have not responded appropriately to the growing concern for ESG issues, could result in reputational harm to our business and could have an adverse effect on us. To the extent ESG matters negatively impact our reputation, it may also negatively impact our share price as well as our access to and cost of capital and impede our ability to compete as effectively to attract and retain employees, which may adversely impact our operations. Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited. Under current law, federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited to 80 % of taxable income. It is uncertain if and to what extent various states will conform to federal tax laws. Under Sections 382 and 383 of the Code, and corresponding provisions of state law, if a corporation undergoes an " ownership change " (generally defined as a greater than 50 percentage point change (by value) in the equity ownership of certain stockholders over a rolling three- year period), the corporation' s ability to use its pre- change net operating loss carryforwards and other pre- change tax attributes to offset its post- change

income or taxes may be limited. We have not yet completed a Section 382 or Section 383 analysis, and therefore, there can be no assurances that any previously experienced ownership changes have not materially limited our utilization of affected net operating loss carryforwards or other tax attributes. We may experience ownership changes in the future ~~, including in connection with the proposed Business Combination~~ as a result of shifts in our stock ownership. We anticipate incurring significant additional net losses for the foreseeable future, and our ability to utilize net operating loss carryforwards associated with any such losses to offset future taxable income may be limited to the extent we incur future ownership changes. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could adversely affect our future cash flows. Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations. New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the ~~Biden~~ **Trump** administration **has** ~~and Congress have~~ proposed various U. S. federal tax law changes, which if enacted could have a material impact on our business, cash flows, financial condition or results of operations. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one- time charges, and could increase our future U. S. tax expense. Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential. In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would 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. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed. Our business operations and current and future relationships with healthcare professionals, principal investigators, consultants, customers and third- party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti- kickback, fraud and abuse, false claims, physician payment transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to substantial penalties. Healthcare providers, 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 may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation, the U. S. federal Anti- Kickback Statute and the U. S. federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to physician payment transparency laws and patient privacy and security regulation by the U. S. federal government and by the states and foreign jurisdictions in which we conduct our business. For more information, see the section of this report titled " Business – Healthcare Laws and Regulations. " Because of the breadth of these laws and the narrowness of their exceptions and safe harbors, it is possible that our business activities can be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have continued their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of significant investigations, prosecutions, convictions and settlements in the healthcare industry. Efforts to ensure that our internal operations and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, monetary fines, imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with the law and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including future collaborators, are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also affect our business. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials

and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. We may be affected by regulatory responses to climate- related issues. The Biden administration ~~has~~ made climate change and the limitation of greenhouse gas (" GHG ") emissions one of its primary objectives. **Although the Trump administration is expected to reverse such priorities,** ~~Several~~ **several** states and other geographic regions in the United States have also adopted legislation and regulations to reduce emissions of GHGs. On March 6, 2024, the SEC finalized new rules for public companies that ~~will~~ **would** require extensive climate- related disclosures and significant analysis of the impact of climate- related issues on our business strategy, results of operations, and financial condition (the " SEC Climate Disclosure Rules "). **Following** ~~The new rules will require us to disclose our~~ **court** ~~material climate- related risks~~ **challenges initiated during the Biden administration** and **while the SEC was led by former Chairman Gensler that** ~~opportunities, GHG emissions inventory, climate- related targets and goals, and financial impacts of physical and transition risks. As a result~~ **resulted in the indefinite delay in implementation** of the SEC Climate Disclosure Rules, **on March 27, 2025, the SEC announced that it had voted to end its defense of such rules in court. Nevertheless, if the SEC or state regulatory authorities were to seek to impose such rules in the future,** our legal, accounting ~~,~~ and other compliance expenses ~~may~~ **would** increase significantly **.** ~~, and compliance efforts may divert management time and attention~~ . We may also be exposed to legal or regulatory action or claims as a result of ~~these~~ **any such** new regulations. All of these risks could have a material adverse effect on our business, financial position, and / or stock price. Risks Related to Intellectual Property Our intellectual property rights are valuable, and any inability to protect them could reduce the value of our products, services and brand. The loss of any procured intellectual property rights in our products could permit our competitors to manufacture their own version of our products. We have attempted to protect our intellectual property rights in our products through a combination of patents, confidentiality agreements, non- compete agreements and other contractual protection mechanisms, and we will continue to do so. While we intend to defend against threats to our intellectual property, our patents or various contractual protections may not adequately protect our intellectual property. In addition, we could be required to expend significant resources to defend our rights to proprietary information, and may not be successful in such defense. As such, we may not be successful in preventing third parties from infringing, copying or misappropriating our intellectual property. There can also be no assurance that pending patent applications owned by us will result in patents being issued to us, that patents issued to or licensed by us in the past or in the future will not be challenged or circumvented by competitors or that such patents will be found to be valid or sufficiently broad to protect our products or to provide us with any competitive advantage. Third parties could also obtain patents that may require us to negotiate to obtain licenses to conduct our business, and any required licenses may not be available on reasonable terms or at all. We also rely on confidentiality and non-compete agreements with certain employees, independent distributors, consultants and other parties to protect, in part, trade secrets and other proprietary rights. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop substantially equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets or proprietary knowledge. It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. We cannot assure investors that any of the currently pending or future patent applications will result in granted patents, nor can we predict how long it will take for such patents to be granted. Our commercial success will depend in part on us obtaining and maintaining patent protection and trade secret protection of our current and future product candidates, as well as successfully defending these patents against third- party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities and the right under our licensed patents to contest alleged infringement. The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States or in many jurisdictions outside of the United States. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our owned or licensed intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the patents that may be issued from the applications we currently or may in the future own or license from third parties. Further, if any patents we obtain or license are deemed invalid or unenforceable, our ability to commercialize or license our technology could be adversely affected. Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in- licensed by us, or that we will not be involved in interference, opposition or invalidity proceedings before U. S. or non- U. S. patent offices. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example: ● others may be able to make product candidates or develop a platform similar to, or better than, ours in a way that is not covered by the claims of our licensed or owned patents; ● others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of patents we own or that are licensed to us; ● we or our prospective licensors or future collaborators might not have been the first

to make the inventions covered by any pending patent applications issued patents that we own or license; ● we or our prospective licensors or future collaborators might not have been (or may not be in the future) the first to file patent applications for certain of our inventions; ● others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; ● our pending patent applications may not lead to issued patents; ● issued patents that we own or license may be held invalid or unenforceable as a result of legal challenges by our competitors or others; ● our competitors might conduct R & D 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; ● any patents that we obtain, or are licensed to us, may not provide us with any competitive advantages or protection against competitors, or may be challenged by third parties; ● we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or may in- license in the future will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries; ● if we attempt to enforce our patents, a court may hold that our patents are not invalid, unenforceable or not infringed; ● we may not develop additional proprietary technologies that are patentable; ● we may need to initiate litigation or administrative proceedings to enforce and / or defend our patent rights which will be costly whether we win or lose; ● we may choose not to file a patent in order to maintain certain trade secrets or know- how, and a third party may subsequently file a patent covering such intellectual property; ● we may be required to change, redesign or stop using trademarks, service marks, domain names, logos, trade names and other identifiers that we own or use to avoid infringing the rights of third parties; ● we may fail to adequately protect and police our trade secrets; or ● the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications. Should any of these events occur, they could significantly harm our business, results of operations and prospects. Without patent protection on the composition of matter of our product candidates, our ability to assert our patents to stop others from using or selling our product candidates in a non- pharmaceutically acceptable formulation may be limited. Due to the patent laws of a country, or the decisions of a patent examiner in a country, or our own filing strategies, we may not obtain patent coverage for all of our product candidates or methods involving these candidates in parent patent applications. We may have to pursue divisional patent applications or continuation patent applications in the United States and other countries to obtain claim coverage for inventions which were disclosed but not claimed in parent patent applications. Moreover, it is possible that our pending patent applications will not result in granted patents, and even if such pending patent applications are granted as patents, they may not provide a basis for intellectual property protection of commercially viable products nor provide us with any competitive advantages. Further, it is possible that, for any of the patents that may be granted in the future, others will design around the patent rights or identify cancer treatment methods that do not concern the rights covered by our patent rights or licenses. Further, we cannot assure investors that other parties will not challenge any patents granted to us or that courts or regulatory agencies will hold our patents to be valid or enforceable. We also cannot guarantee that we will be successful in defending challenges made against our patents. Any successful third- party challenge to our patents could result in the unenforceability or invalidity of such patents, or to such patents being interpreted narrowly or otherwise in a manner adverse to our interests. Our ability to establish or maintain a technological or competitive advantage over our competitors may be diminished because of these uncertainties. We may also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or feasible. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors or other third parties. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets may be expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know- how. If we are unable to obtain and maintain patent protection for any products we develop and for our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop and our technology may be adversely affected. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment and development that are important to our business. If we do not adequately protect our intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our product candidates that are important to our business; we may in the future also license or purchase patent applications filed by others. If we are unable to secure or maintain patent protection with respect to our technology and any proprietary products and technology we develop, our business, financial condition, results of operations and prospects could be materially harmed. We cannot provide any assurances that any of our current or future patents have or will include claims with a scope sufficient to protect our current and future product candidates or otherwise provide any competitive advantage. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its earliest U. S. non- provisional filing date. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our patents and patent applications are, and may in the future be, owned by or co- owned with third parties. Any of the foregoing could have a material adverse effect on our competitive position, business,

financial conditions, results of operations and prospects. The patent prosecution process is complex, expensive, time-consuming and inconsistent across jurisdictions. We may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent rights at a commercially reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is possible that we will fail to identify important patentable aspects of our R & D efforts in time to obtain any patent protection. While we enter into non- disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our R & D efforts, including for example, our employees, former employees, corporate collaborators, external academic scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby endangering our ability to seek patent protection. In addition, publications of discoveries in the scientific and scholarly literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Consequently, we cannot be certain that we were the first to file for patent protection on the inventions claimed in our patents or pending patent applications. The issuance or grant of a patent is not irrefutable as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. We may in the future, become subject to a third- party pre- issuance submission of prior art or opposition, derivation, revocation, re- examination, post- grant or inter partes review, or interference proceedings or other similar proceedings challenging our patent rights or the patent rights of others in the USPTO or other foreign patent office. An unfavorable determination in any such submission, proceeding or litigation could reduce the scope of or invalidate our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or extinguish our ability to manufacture or commercialize products without infringing third- party patent rights. Third- party claims of intellectual property infringement may prevent or delay our product discovery and development efforts, and could increase our costs. Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, reexamination, and post grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and / or proprietary technologies infringe their intellectual property rights. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties allege they have patent rights encompassing our product candidates, technologies or methods. Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting preclinical and clinical trials and other development activities in the United States is not considered an act of infringement. If CER- 1236 or another product candidate is cleared / approved by the FDA, a third party may then seek to enforce its patent by filing a patent infringement lawsuit against us. While we do not believe that any patent claims that could have a materially adverse effect on the commercialization of our product candidates are valid and enforceable, we may be incorrect in this belief, or we may not be able to prove it in litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is " clear and convincing, " a heightened standard of proof. There may be issued third- party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Patent applications can take many years to issue. There may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third- party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we were to obtain a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we were to obtain a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third- party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be

a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly. We could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent of a third party. A finding of infringement could prevent us from commercializing our product candidates or any future product candidates or force us to cease some of our business operations, which could materially harm our business. Although we have reviewed certain third- party patents and patent filings that we believe may be relevant to our therapeutic candidates or products, we have not conducted a freedom- to- operate search or analysis for any of our therapeutic candidates or products, and we may not be aware of patents or pending or future patent applications that, if issued, would block us from commercializing our therapeutic candidates or products. Thus, we cannot guarantee that our therapeutic candidates or products, or our commercialization thereof, do not and will not infringe any third party' s intellectual property. We may not be successful in obtaining or maintaining necessary rights to product components and processes for our manufacturing and development pipeline through acquisitions and in- licenses. Presently, we have rights to certain intellectual property, under issued patents that we own, including U. S. Patent No. 11, ~~655~~ **708** , ~~282~~ **423** and EP Patent No. 3, 519, 441, which relate to CER- 1236, as well as additional patents which relate to certain other product candidates. U. S. Patent Application Number ~~17~~ **16** / ~~400~~ **646** , ~~082~~ **530** was allowed and later issued on ~~May 23~~ **July 25** , 2023 as U. S. Patent Number 11, ~~655~~ **708** , ~~282~~ **423** . This patent provides coverage over our CER- 1236 product candidate and includes claims directed to a CER comprising, at least in part, **a** Tim- 4 ~~, a~~ phosphatidylserine binding domain ~~, its sequence,~~ and **a TLR signaling domain** ~~various Tim- 4 proteins~~ . Because additional product candidates may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in- license or use these proprietary rights. In addition, while we have patent rights directed to certain T cell constructs, we may not be able to obtain intellectual property rights to broader T cell or engineered T cell constructs. Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. Similarly, efficient production or delivery of our product candidates may also require specific compositions or methods, and the rights to these may be owned by third parties. We may be unable to acquire or in- license any compositions, methods of use, processes or other third- party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third- party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Moreover, the specific antibodies that will be used with our product candidates may be covered by the intellectual property rights of others. Additionally, we may collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions may provide us with an option to negotiate a license to any of the institution' s rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third- party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer. The licensing and acquisition of third- party intellectual property rights is a competitive area, and companies which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third- party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. We may be involved in lawsuits to protect or enforce our patents which could be expensive, time- consuming and unsuccessful. Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. In addition, in a legal proceeding, a court may decide that one or more of our patents is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put one or more of our pending patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Interference or derivation proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority or provenance of inventions with respect to our patents or patent applications or those of our prospective licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the

prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference or derivation proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, 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. In addition, there could 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 substantial adverse effect on the price of our Common Stock. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and patent agencies outside the United States 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, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent include failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents covering our product candidates, our competitors might be able to enter the market, which would harm our business. In addition, to the extent that we have responsibility for taking any action related to the prosecution or maintenance of patents or patent application in- licensed from a third party, any failure on our part to maintain the in- licensed rights could jeopardize our rights under the relevant license and may expose us to liability. We may be subject to claims challenging the inventorship of our patents and other intellectual property. We may in the future be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co- inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. 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. We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms. A third party may hold intellectual property rights, including patent rights, that are important or necessary to the development or manufacture 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 obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, and we could be forced to accept unfavorable contractual terms. If we are unable to obtain such licenses on commercially reasonable terms, our business could be harmed. Issued patents covering our product candidates could be found unpatentable, invalid or unenforceable if challenged in court or the USPTO. 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 candidate, as applicable, is invalid and / or unenforceable. In patent litigation in the United States, 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 United States or abroad, even outside the context of litigation. Such mechanisms include inter partes review, ex parte re- examination and post grant review in the United States, and equivalent proceedings in foreign jurisdictions (e. g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our product candidates. The outcome following legal assertions of unpatentability, invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of unpatentability, invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business. Changes to patent law in the United States and in foreign jurisdictions 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 United States continues to adapt to wide- ranging patent reform legislation, including legislation that became effective starting in 2012. Moreover, 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 by us will be found invalid based on this decision, we cannot

predict how future decisions by the courts, Congress or the USPTO may impact the value of our patents. Similarly, any adverse changes in the patent laws of other jurisdictions could have a material adverse effect on our business and financial condition. Changes in the laws and regulations governing patents in other jurisdictions could similarly have an adverse effect on our ability to obtain and effectively enforce our patent rights. We may not be able to protect our intellectual property rights throughout the world. We may not be able to protect our intellectual property rights outside the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries which we could expand to, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties. We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking patent protection for our product candidates, we also rely on trade secrets, including unpatented know- how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, our competitors may independently develop knowledge, methods and know- how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. 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 were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. Our 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. Because we will rely on third parties to research and develop and to manufacture our product candidates, we must share trade secrets with them. 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 and 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 independent discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business. 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, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with will likely expect to be granted rights to publish data arising out of such collaboration and any joint R & D programs may require us to share trade secrets under the terms of our R & D or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements

with third parties, independent development or publication of information by any of our third- party collaborators. A competitor' s discovery of our trade secrets would impair our competitive position and have an adverse impact on our business. We may not have sufficient patent lifespan to effectively protect our products and business. All of our patents are in early stages. Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its earliest U. S. non- provisional filing date. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after the resulting products are commercialized. As a result, our patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We expect to seek extensions of patent terms for our issued patents, where available. This includes in the United States under the Hatch- Waxman Act, which permits a patent term extension of up to five years beyond the original expiration date of the patent as compensation for regulatory delays. However, such a patent term extension cannot lengthen the remaining term of a patent beyond a total of 14 years from the product' s approval date. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. During the period of patent term extension, the claims of a patent are not enforceable for their full scope but are instead limited to the scope of the approved product. In addition, the applicable authorities, including the FDA in the United States, and any comparable foreign regulatory authorities, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. In addition, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to the expiration of relevant patents or otherwise failing to satisfy applicable requirements. The terms of our patents may also be affected by the filing of terminal disclaimers during prosecution before the USPTO and foreign authorities recognizing similar disclaimer mechanisms. A patent subject to a terminal disclaimer may have its term limited so that its lifespan does not extend beyond the term of a related patent having a shorter term. If any of the foregoing occurs, any period during which we have the right to exclusively market our product will be shorter than we would otherwise have expected, and our competitors may obtain approval of and launch products earlier than might otherwise have been the case. The life of patent protection is limited, and third parties could develop and commercialize products and technologies similar or identical to ours and compete directly with us after a patent licensed to us expires, which could materially and adversely affect our ability to commercialize our products and technologies. The life of a patent and the protection it affords is limited. For example, in the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U. S. non- provisional filing date. In Europe, the expiration of an invention patent is 20 years from its filing date. Even if we successfully obtain patent protection for an approved product candidate, it may face competition from biosimilar medications. Manufacturers of other drugs may challenge the scope, validity or enforceability of the patents underlying our technology in court or before a patent office, and the patent holder may not be successful in enforcing or defending those intellectual property rights and, as a result, we may not be able to develop or market the relevant product candidate exclusively, which would materially adversely affect any potential sales of that product. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, the patents or pending applications licensed to us may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Even if we believe that the patents involved are eligible for certain (and time- limited) patent term extensions, there can be no assurance that the applicable authorities, including the FDA and the USPTO, and any equivalent regulatory authority in other countries, will agree with our assessment of whether such extensions are available, and such authorities may refuse to grant extensions to such patents, or may grant more limited extensions than requested. Moreover, the applicable time period or the scope of patent protection afforded could be less than requested. If we are unable to obtain patent term extension or term of any such extension is less than requested, our competitors may obtain approval of competing products following our patent expiration, and our business could be harmed. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The patent pending applications for our product candidates are expected to expire on various dates. Upon the expiration, we will not be able to assert such licensed patent rights against potential competitors, which would materially adversely affect our business, financial condition, results of operations and prospects. Risks Related to Ownership of our Securities **Sales of a substantial number of our securities in the public market by our existing securityholders could cause the price of our Common Stock and Warrants to fall. Sales of a substantial number of shares of our Common Stock in the public market could occur at any time (after the expiration of any applicable lock- up period, assuming the satisfaction of any applicable vesting conditions and subject to the beneficial ownership and stock exchange limitations described herein). These sales, or the perception in the market that the holders of a large number of shares of our Common Stock intend to sell shares, could increase the volatility of the market price of our Common Stock or result in a significant decline in the public trading price of our Common Stock. The resale, or expected or potential resale, of a substantial number of shares of our Common Stock in the public market could adversely affect the market price for our Common Stock and make it more difficult for you to sell your holdings at times and prices that you determine are appropriate. Accordingly, the adverse market and price pressures resulting from an offering may continue for an extended period of time. Sales of substantial number of such shares in the public market could adversely affect the market price of our Common Stock. We have filed (in each case, the share numbers set forth below have been adjusted for the Reverse Stock Split): ● a registration statement with the SEC for purposes of registering the resale from time to time of up to 2, 100, 000 Shares of Common Stock, which consists of (i) 2, 086, 357 shares of Common Stock under the New Keystone Purchase Agreement and (ii) 13, 643 shares of Common Stock under the Old Keystone Purchase Agreement; ● a registration statement with the SEC for purposes of registering the resale from time to time of up to 266, 191 Shares of Common Stock, which consists of (i) 250, 000 Keystone Purchase Shares, (ii) 6, 191 Keystone**

Commitment Shares, and (iii) 10, 000 Arena Commitment Shares; ● a registration statement with the SEC for purposes of registering (1) the resale from time to time of up to 357, 737 shares of Common Stock, which consists of (i) 20, 557 shares of Common Stock issued to certain selling securityholders for their portion of the merger consideration in connection with the consummation of the Business Combination in exchange for shares of common stock of Legacy CERo; (ii) 200, 800 shares of Common Stock issuable upon the conversion of shares of our Series A Preferred Stock, purchased by certain investors pursuant to the First Securities Purchase Agreement; (iii) 12, 520 shares of Common Stock issuable upon the conversion of shares of our Series B Preferred Stock, purchased by certain investors pursuant to the Second Securities Purchase Agreement; (iv) 31, 712 shares of Common Stock initially issued to the Sponsor and distributed to its members in a distribution- in- kind immediately prior to the Business Combination; (v) 10, 000 shares of Common Stock issued to the Sponsor, which are subject to forfeiture upon the vesting of the Tertiary Earnout Shares; (vi) 1, 850 shares of Common Stock issued to investors other than the Sponsor in a private placement concurrently with the Initial Public Offering; (vii) 16, 495 shares of our Common Stock issued to certain third- party vendors and service providers; (viii) 3, 250 shares of Common Stock issuable upon the exercise of warrants to purchase shares of our Common Stock that were converted from Legacy CERo warrants in connection with the Business Combination; (ix) 6, 127 shares of Common Stock issuable upon the exercise of warrants to purchase shares of our Common Stock sold to certain investors pursuant to the First Securities Purchase Agreement; (x) 50, 000 shares of Common Stock issuable upon the exercise of warrants to purchase shares of our Series A Preferred Stock sold to certain investors pursuant to the First and Second Securities Purchase Agreement and conversion of the underlying shares of Series A Preferred Stock into Common Stock and (xi) 4, 425 shares of Common Stock issuable upon the exercise of Private Placement Warrants to purchase shares of our Common Stock, at an exercise price of $ 1, 150. 00 per share, that were originally sold in a private placement concurrently with the Initial Public Offering; and (2) the issuance by us of up to 87, 500 shares of Common Stock issuable upon the exercise of public warrants to purchase shares of our Common Stock, at an exercise price of $ 1, 150. 00 per share, that were originally issued in the Initial Public Offering; ● a registration statement with the SEC for purposes of registering of the resale from time to time of up to 6, 385, 638 shares of Common Stock, which consists of (i) 576, 710 shares of Common Stock issuable upon the conversion of shares of our Series A Preferred Stock purchased by certain investors pursuant to the First Securities Purchase Agreement; (ii) 91, 829 shares of Common Stock issuable upon the conversion of shares of our Series B Preferred Stock purchased by certain investors pursuant to the Second Securities Purchase Agreement; (iii) 707, 394 shares of Common Stock issued upon the conversion of shares of our Series A Preferred Stock and Series B Preferred Stock; (iv) 4, 366, 837 shares of Common Stock issuable upon the conversion of 300 % of the number of outstanding shares of our Series C Preferred Stock purchased by certain investors pursuant to the Third Securities Purchase Agreement; (v) 2, 500 shares of Common Stock issued to a stockholder in a reallocation of shares in connection with the consummation of the Business Combination; (vi) 81, 752 shares of Common Stock issuable upon the exercise of warrants to purchase shares of our Common Stock, at an exercise price of $ 9. 80 per share, which warrants were sold to certain investors pursuant to the Third Securities Purchase Agreement (the " Series C Warrants "); and (ii) 558, 617 shares of Common Stock issuable upon the conversion of shares of Series A Preferred Stock resulting from the exercise of outstanding Preferred Warrants; and ● a registration statement with the SEC for the purposes of registering the primary issuance by the Company of (i) 300, 000 shares of Common Stock (ii) 2, 551, 020 new common warrants to purchase up to an aggregate of 2, 551, 020 shares of our Common Stock and an aggregate of 2, 551, 020 shares of our Common Stock issuable upon exercise of the common warrants and (ii) Pre- Funded Warrants to purchase up to 2, 251, 020 shares of Common Stock, in lieu of shares of Common Stock. In addition to any resales pursuant to such registration statements, subject to applicable transfer restrictions and the conditions to the availability of Rule 144 for former shell companies under Rule 144 (i), shares of Common Stock held by these stockholders will be eligible for resale, potentially subject to, in the case of stockholders who are our affiliates, volume, manner of sale, and other limitations under Rule 144 promulgated under the Securities Act. In addition, shares of our Common Stock issuable upon exercise or vesting of incentive awards under our incentive plans are, once issued, eligible for sale in the public market, subject to any lock- up agreements and, in some cases, limitations on volume and manner of sale applicable to affiliates under Rule 144. Furthermore, shares of our Common Stock reserved for future issuance under our incentive plan may become available for sale in future. The market price of shares of our Common Stock could drop significantly if the holders of the shares of Common Stock described above sell them or are perceived by the market as intending to sell them. These factors could also make it more difficult for us to raise additional funds through future offerings of shares of our Common Stock or other securities. Most of our outstanding Common Warrants are " out- of- the- money. " If the trading price of our Common Stock does not increase, the holders thereof will be unlikely to exercise such Common Warrants and we will not receive the proceeds of such exercises. Holders of our Warrants will be less likely to exercise their Warrants if the exercise prices of their Warrants exceed the market price of our Common Stock. There is no guarantee that our Warrants will continue to be in the money prior to their expiration, and as such, the Warrants may expire worthless. As such, any cash proceeds that we may receive in relation to the exercise of the Warrants overlying shares of Common Stock being offered for sale in this Annual Report will be dependent on the trading price of our Common Stock. There is no assurance that the holders of the Warrants will elect to exercise any or all of such Warrants. As of the date of this Annual Report, (i) all of the Private Placement Warrants and Public Warrants, which have an exercise price of $ 1, 150. 00 per share, (ii) December 2024 Common Warrants, which have an exercise price of $ 5. 61 per share, (iii) January 2025 Common Warrants, which have an exercise price of $ 5. 82 per share, (iv) February 2025 Common Warrants to purchase shares of Common Stock, at a current exercise price of $ 1. 96 per share issued by the Company in a public offering on

February 7, 2025. and (v) all of the Series A Warrants, which have a current exercise price of $ 139. 00 per share, are " out of the money, " meaning the exercise price is higher than the market price of our Common Stock. Holders of such " out of the money " Warrants are not likely to exercise such Warrants. There can be no assurance that such Warrants will be in the money prior to their respective expiration dates, and therefore, we may not receive any cash proceeds from the exercise of such Warrants. An active trading market for our Common Stock may not be available on a consistent basis to provide stockholders with adequate liquidity. The price of our Common Stock may be extremely volatile, and stockholders could lose all or part of their investment. The trading price of our Common Stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this " Risk Factors " section and elsewhere in this Annual Report, these factors include: ● the commencement, enrollment or results of any planned and future preclinical studies and clinical trials of our product candidates or changes in the development status of our product candidates; ● any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority' s review of such filings; ● adverse results from or delays in preclinical studies and clinical trials of our product candidates, including as a result of clinical holds, safety events, enrollment difficulties, or study protocol amendments; ● ~~Our~~ **our** decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial; ● adverse regulatory decisions, including failure to receive regulatory approval of our drug to market for our product candidates; ● adverse developments concerning our manufacturers; ● ~~Our~~ **our** inability to obtain adequate product supply for any approved drug or inability to do so at acceptable prices; ● ~~Our~~ **our** inability to establish collaborations, if needed; ● ~~Our~~ **our** failure to commercialize our product candidates; ● additions or departures of key scientific or management personnel; ● unanticipated serious safety concerns related to the use of our product candidates; ● introduction of new drugs by our competitors; ● announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors; ● any significant change in our management; ● ~~Our~~ **our** ability to effectively manage our growth; ● the size and growth of our initial target markets; ● actual or anticipated variations in quarterly operating results; ● ~~Our~~ **our** cash position; ● ~~Our~~ **our** failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public; ● the public' s response to press releases or other public announcements by us or third parties, including our filings with the SEC; ● publication of research reports about us or our industry, or microbiome therapies in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts; ● guidance, if any, that we provide to the public, any changes in this guidance or our failure to meet this guidance; ● changes in the market valuations of similar companies; ● overall performance of the equity markets; ● sales of our Common Stock by us or our stockholders, in the future; ● ~~sales of our Common Stock by certain stockholders pursuant to, and following the termination or expiry of the applicable lock- up period pursuant to the Investor Rights Agreement, the Existing Lock- Ups, or any similar agreement restricting our securityholders' ability to sell our Common Stock; ●~~ trading volume of our Common Stock; ● investor perceptions of the investment opportunity associated with our Common Stock relative to other investment alternatives; ● actions by institutional or activist stockholders; ● change in accounting standards, policies, guidelines, interpretations or principles; ● ineffectiveness of our internal controls; ● 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 payments systems; ● issuance of additional shares of our Common Stock to comply with the full ratchet antidilution rights contained in our outstanding Warrants; ● failure to raise additional funds on acceptable terms, or at all; ● changes in business or regulatory conditions, including new laws or regulations or new interpretations of existing laws or regulations applicable to our business; ● general political, economic, industry and market conditions, including rising interest rates and inflation; and ● other events or factors, many of which are beyond our control. In addition, the stock market in general, and the markets for special purpose acquisition company ~~(" SPAC ")~~ post- business combination businesses and healthcare companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our Common Stock, regardless of our actual operating performance. In addition, price volatility may be greater if the public float and trading volume of our Common Stock is low. If the market price of our Common Stock falls, you may not realize any return on your investment and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company' s securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management' s attention and resources, which would harm our business, operating results or financial condition. Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates, higher interest rates and uncertainty about economic stability. For example, the Russia- Ukraine war and the Israel- Hamas war created volatility in the global capital markets and may have further global economic consequences, including disruptions of the global supply chain and energy markets. **The imposition of tariffs by the United States on imports from Canada, China and Mexico and retaliatory tariffs or other actions by the governments of such countries have also created economic uncertainty and disruptions in the capital markets.** There have also been disruptions to the U. S. banking system due to bank failures in the past several years, including with respect to Silicon Valley Bank, Signature Bank and First Republic Bank. Any such volatility and disruptions may have adverse consequences on us or the third parties on whom ~~it relies~~ **we rely** . If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Increased inflation rates can adversely affect us by increasing its costs, including labor and employee benefit costs. In addition, higher inflation

could also increase customers' operating costs, which could result in reduced budgets for customers and potentially less demand for our products, if and when approved. Any significant increases in inflation and related increase in interest rates could have a material adverse effect on our business, results of operations and financial condition. We do not intend to pay dividends on our Common Stock, so any returns will be limited to the value of ~~its~~ **our** stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, future debt or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our Common Stock. Any return to stockholders will therefore be limited in the foreseeable future to the appreciation of the market price (if any) of our stock. We are an " emerging growth company " and a " smaller reporting company ", and the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our Common Stock less attractive to investors. We are an " emerging growth company " within the meaning of the Securities Act, as modified by the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of certain exemptions from various public company 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 have its internal control over financial reporting audited by our independent registered public accounting firm under Section 404 of the Sarbanes- Oxley Act (" Section 404 "), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We may take advantage of these exemptions until the last day of the fiscal year ending after the fifth anniversary of the consummation of our ~~IPO~~ **Initial Public Offering** or until we are no longer an emerging growth company, whichever is earlier. We will cease to be an emerging growth company prior to the end of such five- year period if certain earlier events occur, including if we become a " large accelerated filer " as defined in Rule 12b- 2 under the Exchange Act, our annual gross revenues equal or exceed $ 1. 235 billion or we issue more than $ 1. 0 billion of non- convertible debt in any three- year period prior to such time. In particular, in this Annual Report ~~on~~, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if it were not an emerging growth company, and it may elect to take advantage of other reduced reporting requirements in future filings. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have elected to take advantage of the extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available to emerging growth companies. As a result of the accounting standards election, we will not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies, which may make comparison of its financials to those of other public companies more difficult. As a result of these elections, the information that we provide in this Annual Report may be different than the information you may receive from other public companies in which you hold equity interests. In addition, it is possible that some investors will find our Common Stock less attractive as a result of these elections, which may result in a less active trading market for our Common Stock and higher volatility in its share price. We are also a " smaller reporting company " as defined in the Exchange Act. We may continue to be a smaller reporting company even after we is no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our Common Stock held by non- affiliates is less than $ 250. 0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $ 100. 0 million during the most recently completed fiscal year and our Common Stock held by non- affiliates is less than $ 700. 0 million measured on the last business day of our second fiscal quarter. Our operating results may fluctuate significantly, which makes future operating results difficult to predict and could cause operating results to fall below expectations or guidance. Our operations to date have been primarily limited to researching and developing our product candidates. We have not yet obtained regulatory approvals for any of its product candidates. 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 approved products on the market. Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict future operating results. From time to time, we may enter into license or collaboration agreements with other companies that include development funding and significant upfront and milestone payments and / or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under current and any potential future license and collaboration agreements and sales of our drugs, if approved. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in operating results from one period to the next. In addition, our ~~measures~~ **measurement of** compensation cost for stock- based awards made to employees, directors and non- employee consultants **is** based on the fair value of the award on the grant date and we recognize the cost as an expense over the requisite service period **or upon the completion of performance- based vesting terms** , as applicable. Because the variables that we ~~uses~~ **use** as a basis for valuing stock- based awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly. Furthermore, operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following: ● delays in the commencement, enrollment and the timing of clinical testing for our product candidates; ● the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among

our competitors or partners; ● any delays in regulatory review and approval of product candidates in clinical development; ● the timing and cost of, and level of investment in, R & D activities relating to our product candidates, which may change from time to time; ● the cost of manufacturing our product candidates, which may vary depending on FDA guidelines and requirements, and the quantity of production; ● our ability to obtain additional funding to develop product candidates; ● expenditures that our will or may incur to acquire or develop additional product candidates and technologies; ● the level of demand for our product candidates, should they receive approval, which may vary significantly; ● potential side effects of our product candidates that could delay or prevent commercialization or cause an approved drug to be taken off the market; ● the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our product candidates, if approved; ● ~~Our~~ **our** dependency on third- party manufacturers to supply or manufacture our product candidates; ● our ability to establish an effective sales, marketing and distribution infrastructure in a timely manner; ● market acceptance of our product candidates, if approved, and our ability to forecast demand for those product candidates; ● our ability to receive approval and commercialize product candidates outside of the United States; ● ~~Our~~ **our** ability to establish and maintain collaborations, licensing or other arrangements; ● ~~Our~~ **our** ability and third parties' abilities to protect intellectual property rights; ● costs related to and outcomes of potential litigation or other disputes; ● ~~Our~~ **our** ability to adequately support future growth; ● ~~Our~~ **our** ability to attract and retain key personnel to manage our business effectively; ● potential liabilities associated with hazardous materials; ● ~~Our~~ **our** ability to maintain adequate insurance policies; and ● future accounting pronouncements or changes in our accounting policies. The cumulative effect of such factors could result in large fluctuations and unpredictability in quarterly and annual operating results. As a result, comparing operating results on a period- to- period basis may not be meaningful. Investors should not rely on past results as an indication of future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our Common Stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue and / or earnings guidance we may provide. Anti- takeover provisions under our organizational documents and Delaware law could delay or prevent a change of control which could limit the market price of our Common Stock and may prevent or frustrate attempts by our stockholders to replace or remove our then- current management. Our ~~second amended and restated certificate of incorporation (" Charter ");~~ and ~~second amended and restated bylaws (" Bylaws ")~~, contain provisions that could delay or prevent a change of control of our board of directors that our stockholders might consider favorable. Some of these provisions include: ● a board of directors divided into three classes serving staggered three- year terms, such that not all members of the board of directors will be elected at one time; ● a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders; ● a requirement that special meetings of stockholders be called only by the chairperson of our board of directors, our Chief Executive Officer or by a majority of the total number of authorized directors; ● a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law and subject to the rights of the holders of any series of preferred stock to elect additional directors under specified circumstances, upon the approval of not less than two- thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors; ● a requirement of approval of not less than two- thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our Charter; and ● the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of Common Stock. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the ~~Delaware General Corporation Law (" DGCL ")~~, which may prohibit certain business combinations with stockholders owning 15 % or more of our outstanding voting stock. These anti- takeover provisions and other provisions in our Charter or Bylaws could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by the then- current board of directors and could also delay or impede a merger, tender offer, or proxy contest. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our Common Stock to decline. If we engage in future acquisitions or strategic partnerships, this may increase capital requirements, dilute stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks. We intend to evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary drugs, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including: ● increased operating expenses and cash requirements; ● the assumption of additional indebtedness or contingent liabilities; ● the issuance of our equity securities; ● assimilation of operations, intellectual property and drugs of an acquired company, including difficulties associated with integrating new personnel; ● the diversion of our management' s attention from our existing drug programs and initiatives in pursuing such a strategic partnership, merger or acquisition; ● retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships; ● risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and ● ~~Our~~ **our** inability to generate revenue from acquired technology and / or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one- time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. Our Bylaws provide that the Court of Chancery of the State of Delaware and, to the extent

enforceable, 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. The Charter provides that, unless we consent to the selection of an alternative forum, 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 or any of our current or former directors, officers or other employees arising under the DGCL, the Charter, or the Bylaws; ● any action seeking to interpret, apply, enforce or determine the validity of this Charter or our Bylaws; ● any action as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; 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, the Charter further provides that, unless we consent to the selection of an alternative forum, 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, including all causes of action asserted against any defendant named in such complaint. While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and 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 the Charter. 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. If a court were to find either exclusive forum provision in the Charter to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could seriously harm our business, financial condition, results of operations, and prospects. 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, or could result in increased costs for a stockholder to bring a claim, particularly if they do not reside in or near Delaware, both of which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive forum provision in the Charter 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. We will incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which could adversely affect our business, results of operations, and financial condition. As a public company, we are subject to the reporting requirements of the Exchange Act, the listing standards of Nasdaq, and other applicable securities rules and regulations. We expect that the requirements of these rules and regulations will continue to increase our legal, accounting and financial compliance costs, make some activities more difficult, time- consuming and costly, and place significant strain on our personnel, systems and resources. For example, the Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and results of operations. As a result of the complexity involved in complying with the rules and regulations applicable to public companies, our management' s attention may be diverted from other business concerns, which could harm our business, results of operations and financial condition. Although we have already hired additional employees to assist us in complying with these requirements, we may need to hire more employees in the future or engage outside consultants, which will increase our operating expenses. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs, and making some activities more time- consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest substantial 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 business operations to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. We also expect that being a public company and these new rules and regulations will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee (the " Audit Committee ") and compensation committee ~~(the " Compensation Committee ")~~, and qualified executive officers. As a result of disclosure of information in the filings required of a public company, our business and financial condition will become more visible, which may result in an increased risk of threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and results of operations could be harmed, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and harm our business, results of operations, and financial condition. ~~As~~ **We have identified** a ~~result~~ **material weakness in our internal control over financial reporting. If our remediation** of ~~becoming a public~~ **such material weaknesses is not effective, or if we identify additional material weaknesses in the future or otherwise fail to develop and maintain effective internal control over**

financial reporting, our ability to produce timely and accurate financial statements or ~~company~~ **comply** ~~, we~~ **with applicable laws and regulations could be impaired. We** are ~~obligated~~ **required, pursuant** to ~~develop and maintain proper and~~ **Section 404, to furnish a report by management on, among other things, the** ~~effective~~ **effectiveness of our** internal controls over financial reporting ~~and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common stock. We are required, pursuant to Section 404, to furnish a report by management on, among other things, the effectiveness of our internal controls over financial reporting~~ . In 2026, five years after our ~~IPO~~ **Initial Public Offering** , we ~~will~~ **may** be required to comply with auditor attestation requirements, as required by Section 404. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. **In preparing** ~~We may identify weaknesses in~~ our **accompanying** ~~system of internal financial and accounting controls and procedures that could result in a material misstatement of our~~ consolidated financial statements **, we identified a material weakness in our system of internal financial and accounting controls and procedures, as defined in the SEC guidelines for public companies. The material weakness identified relates to our conclusion that due to a lack of sufficient and qualified resources, we lack effective processes and controls to ensure the accuracy and completeness of our financial statements. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis. Effective internal controls are necessary for us to provide reliable financial reports and prevent fraud. We continue to evaluate steps to remediate the material weakness. These remediation measures may be time consuming and costly and there is no assurance that these initiatives will ultimately have the intended effects** . Our 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 **. We cannot assure you that the measures we have taken to date, or any measures we may take in the future, will be sufficient to avoid potential future material weaknesses** . Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If our financial statements are not accurate, investors may not have a complete understanding of our operations. If we do not file financial statements on a timely basis as required by the SEC, we could face severe consequences. If we are unable to conclude that its internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our Common Stock could decline, and we could be subject to sanctions or investigations by the Nasdaq, the SEC or other regulatory authorities. Moreover, responding to such investigations ~~,~~ are likely to consume a significant amount of our management resources and cause us to incur significant legal and accounting expenses. Failure to remedy any material weakness in internal control over financial reporting, or to maintain effective control systems, could also restrict our future access to the capital markets. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. As a public reporting company, we are subject to filing deadlines for reports that we file pursuant to the Exchange Act, and our failure to timely file such reports may have material adverse consequences on our business. Following the consummation of the Business Combination, we failed to timely file our Form 8- K with Form 10 information prior to the " staleness " date (as determined in accordance with the applicable rules and regulations of the SEC) applicable to the financial statements that were required by the applicable accounting requirements and other rules and regulations of the SEC to be included in such filing (including pro forma financial information); thus, we have not remained current in our reporting requirements with the SEC since we became an SEC reporting company on February 14, 2024. Although we have since regained status as a current filer by filing a Form 8- K / A with current financial statements on April 1, 2024, we will not be eligible to use a registration statement on Form S- 3 that would allow us to continuously incorporate by reference our SEC reports into the registration statement, or to use " shelf " registration statements to conduct offerings, until approximately one year from the date we regained (and maintain) status as a current filer. Until such time, if we determine to pursue an offering, we would be required to conduct the offering on an exempt basis, such as in accordance with Rule 144A, or file a registration statement on Form S- 1. Using a Form S- 1 registration statement for a public offering would likely take significantly longer than using a registration statement on Form S- 3 and increase our transaction costs, and could, to the extent we are not able to conduct offerings using alternative methods, adversely impact our liquidity, ability to raise capital or complete acquisitions in a timely manner. The use of Form S- 1 would also prevent us from conducting offerings on a " shelf basis, " limiting our flexibility as to the terms, timing or manner of any such offering. We cannot guarantee that in the future our reporting will always be timely. If we are unable to satisfy SEC filing deadlines or otherwise provide disclosures of material information on a timely basis, stockholders and potential investors in our Common Stock may have incomplete information about our business and results of operations, which may impact their ability to make an informed investment decision, result in a reduction in the trading price, trading volume or analyst coverage of our Common Stock or expose us to potential liability. We could be subject to securities class action litigation. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management' s attention and resources, which could harm our business. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time- consuming, and could divert management' s attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of ~~the~~ our

Common Stock. Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of **our securities. On July 19, 2024, we received a letter (the " Bid Price Requirement Letter ") from the staff at Nasdaq notifying us that, for the 30 consecutive trading days prior to the date of the Bid Price Requirement Letter, the closing bid price for the Common Stock has been below the minimum $ 1. 00 per share required for continued listing on Nasdaq set forth in Nasdaq Listing Rule 450 (a) (1), which is required for continued listing of the Common Stock on Nasdaq (the " Bid Price Requirement "). On October 23, 2024, the trading price for our Common Stock closed under $ 0. 10 and was the tenth consecutive trading day to do so. On October 24, 2024, we received a letter from the staff at Nasdaq notifying us that, because our Common Stock had a closing bid price of $ 0. 10 or less for ten consecutive trading days, it was no longer eligible to rely upon the 180- day cure period set forth in the Bid Price Requirement Letter. In addition, on October 30, 2024, the Company received a letter from the staff at Nasdaq notifying the Company that it had not regained compliance with the continued listing requirement to maintain a minimum market value of $ 50, 000, 000 (the " MVLS Requirement ") for** its **listed** securities **within the 180- day compliance period granted by Nasdaq in May 2024** . ~~If~~ **On July 19, 2024,** we ~~fail~~ **also received a letter (the " MVPHS Letter ") from Nasdaq notifying the Company that the Market Value of Publicly Held Shares (the " MVPHS ") of the Common Stock had been below the minimum of $ 15, 000, 000 for the last 30 consecutive business days prior to the date of the MVPHS Letter, which is required for continued listing of the Common Stock on Nasdaq (the " MVPHS Requirement "). Each of the Bid Price Requirement and MVLS Requirement (as defined below) deficiencies results in the commencement of delisting proceedings. However, we attended a hearing before a Nasdaq panel (the " Nasdaq Panel ") on December 17, 2024, at which we submitted a plan to regain compliance with the listing requirements. On January 17, 2025, the Nasdaq Panel granted the Company' s request for an extension of the deadline for regaining compliance with Nasdaq listing requirements to April 22, 2025, subject to certain conditions (the " Nasdaq Conditions "). Pursuant to the Nasdaq Conditions, the Company shall demonstrate compliance with the Bid Price Requirement and apply to transfer its listing to the Nasdaq Capital Market on or prior to January 22, 2025. The Company is also required** to satisfy the **$ 2. 5 million stockholders' equity requirement of the Nasdaq Capital Market on or prior to April 22, 2025, submit certain plans to Nasdaq and make certain disclosures. On February 12, 2025, we received a letter from the Nasdaq confirming that we have regained compliance with the Bid Price Requirement and we have been moved to the Nasdaq Capital Market, as required by the Nasdaq Panel. Regaining compliance with the Bid Price Requirement is one of the conditions set forth by the Nasdaq Panel in its previously disclosed decision granting our request for an extension to regain compliance with certain Nasdaq** continued listing requirements **until April 22, 2025. We continue to make progress towards satisfaction** of **the other conditions. Nevertheless, as of the date of this Annual Report, the trading price of our Common Stock is below the Bid Price Requirement and we have not satisfied the $ 2. 5 million stockholder' s equity requirement. We cannot assure you that we will obtain compliance with these requirements in a timely manner, or at all. Nevertheless, if the Company is unable to satisfy the** Nasdaq **Conditions** , ~~such as~~ **it is likely that** the **Company' s** ~~corporate governance requirements or the minimum share price requirement, Nasdaq may take steps to delist our~~ securities **would be delisted. In addition, if we fail to comply with the Bid Price Requirement at any time prior to the first anniversary of the Reverse Stock Split, we will be ineligible for a 180- day compliance period during which we would otherwise be able to seek to regain compliance by soliciting stockholder approval for another reverse stock split** . Such a delisting would likely have a negative effect on the price of the securities and would impair your ability to sell or purchase the securities when you wish to do so. In the event of a delisting, any action taken by us to restore compliance with listing requirements may not allow our securities to become listed again, stabilize the market price or improve the liquidity of our securities, prevent our securities from dropping below the Nasdaq minimum share price requirement or prevent future non- compliance with Nasdaq' s listing requirements. Additionally, if our securities are not listed on, or become delisted from Nasdaq for any reason, and are quoted on the over- the- counter bulletin board, an inter- dealer automated quotation system for equity securities that is not a national securities exchange, the liquidity and price of our securities may be more limited than if we were quoted or listed on Nasdaq or another national securities exchange. If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our Common Stock share price and trading volume could decline. The trading market for our Common Stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. If few or no securities or industry analysts cover us, the trading price for our Common Stock would likely be negatively impacted. If one or more of the analysts who cover us downgrade our Common Stock or publish inaccurate or unfavorable research about our business, our share price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our share price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our Common Stock could decrease, which might cause our share price and trading volume to decline. Future sales of our Common Stock, or the perception that future sales may occur, may cause the market price of our Common Stock to decline, regardless of our operating performance. ~~Due to the significant number of redemptions of Class A common stock, par value $ 0. 0001 per share (the " Class A common stock "), of PBAX in connection with the Business Combination, there was a significantly lower number of shares of Class A common stock that converted into shares of our Common Stock in connection with the Business Combination. As a result, the shares of our Common Stock being registered for resale (a portion of which may not be resold until the expiration of the applicable lock- up period) are anticipated to constitute a considerable percentage of our public float. Additionally, a significant portion of the shares of our Common Stock being registered for resale were purchased by selling securityholders pursuant to investments in Legacy CERo that date from February 2017 onwards at prices considerably below the current market price of our Common Stock. This discrepancy in purchase prices may have an impact on the market perception of our Common Stock' s value and could increase the volatility of the market price of our Common Stock or result in a significant decline in the public trading price of our Common Stock. The registration of these shares for resale creates the possibility of a~~

~~significant increase in the supply of our Common Stock in the market. The increased supply, coupled with the potential disparity in purchase prices, may lead to heightened selling pressure, which could negatively affect the public trading price of our Common Stock. We will not receive the proceeds from the resale of the shares of Common Stock by the selling securityholders. In connection with the Business Combination, 8, 457, 653 million shares of Common Stock were issued to the stockholders of Legacy CERo and, of such shares, only 1, 755, 554 are subject to contractual lock- up restrictions and / or held by affiliates whose ability to sell is dependent upon the effectiveness of a resale registration statement. All shares of Common Stock that are not subject to such restrictions may be sold at any time.~~ Sales of a substantial number of our shares of Common Stock and / or Public Warrants in the public market by our existing securityholders, or the perception that those sales might occur, could depress the market price of our shares of Common Stock and Public Warrants and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our shares of Common Stock and Public Warrants **. Furthermore, the sale of a substantial number of shares of Common Stock pursuant to the registration statements we have filed with the SEC, or the perception that such sale may occur, may materially and adversely affect the prevailing market price of our Common Stock and thus restrict the amount we are able to raise in an equity offering, or require us to issue and sell more Common Stock to generate the same amount of gross proceeds than we would otherwise have had to, which would result in greater dilution to our existing stockholders. We expect that because there is a large number of shares registered pursuant to such registration statements, the holders thereunder will continue to offer the securities covered thereby for a significant period of time, the precise duration of which cannot be predicted. Accordingly, the adverse market and price pressures and constraint on our ability to raise additional capital resulting from the shares registered hereunder may continue for an extended period of time** . Our Warrants are exercisable for Common Stock, the exercise of which would increase the number of shares eligible for future resale in the public market and result in dilution to our ~~shareholders~~ **stockholders** . As of April ~~1~~ **11** , ~~2024~~ **2025** , there were (i) **Series A** ~~8, 750, 000 Public~~ Warrants ~~with~~ **to purchase 6, 127 shares of Common Stock at** an exercise price of $ ~~11~~ **139** . ~~50~~ **00** per ~~warrant~~ **share** ; (ii) **Series C** ~~442, 500 private placement warrants (the " Private Placement~~ Warrants ~~") with~~ **to purchase 81, 753 shares of Common Stock at** an exercise price of $ ~~11~~ **0** . ~~50~~ **04** per ~~warrant~~ **share** ; (iii) **December 2024 and January 2025 Common** ~~warrants~~ **Warrants** to purchase an aggregate of ~~325~~ **247** , ~~536~~ **914** shares of Common Stock ~~(" Rollover Warrants "),~~ at an exercise price ~~of~~ **ranging from** $ ~~10~~ **5** . **61 to $ 5. 82,** ~~00 per warrant that were converted from Legacy CERo warrants;~~ (iv) **February 2025 Common** ~~warrants~~ **Warrants** to purchase ~~612~~ **an aggregate of 2** , ~~746~~ **551, 020** shares of Common Stock **at** ~~(the " Common Warrants ") with~~ an exercise price of $ ~~9~~ **1** . **96,** ~~20 per warrant; and warrants (the " Preferred~~ **v) Pre- Funded** Warrants ~~"~~ **to purchase** ~~and~~ **an aggregate of 215** , ~~together with the~~ **740 shares of Common Stock at an exercise price of $ 0. 0001, and (vi)** Public Warrants ~~,~~ **and** Private Placement Warrants **to purchase** ~~, Rollover Warrants, and~~ **an aggregate of 91, 925 shares of** Common ~~Warrants, the " Warrants ") to purchase 2, 500 shares of Series A convertible preferred stock, par value $ 0. 0001 per share (the " Series A Preferred~~ Stock **at** ~~"), with~~ an exercise price of $ 1, ~~000~~ **150** . 00 per ~~warrant, which shares~~ **share** ~~of Series A Preferred Stock are convertible into 2, 500, 000 shares of Common Stock, assuming conversion at $ 1. 00~~ . To the extent such warrants are exercised, additional shares of our Common Stock will be issued, which will result in dilution to the holders of our Common Stock and increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market could adversely affect the market price of our Common Stock, the impact of which increases as the value of our stock price increases ~~. Our Warrants may not be exercised at all and we may not receive any cash proceeds from the exercise of the Warrants. Holders of our Warrants will be less likely to exercise their Warrants if the exercise prices of their Warrants exceed the market price of our Common Stock. There is no guarantee that our Warrants will continue to be in the money prior to their expiration, and as such, the Warrants may expire worthless. As such, any cash proceeds that we may receive in relation to the exercise of the Warrants overlying shares of Common Stock will be dependent on the trading price of our Common Stock. There is no assurance that the holders of the Warrants will elect to exercise any or all of such Warrants. As of the date of this Annual Report, (i) all of the Private Placement Warrants and Public Warrants, which have an exercise price of $ 11. 50 per warrant, (ii) all of the Rollover Warrants, which have an exercise price of $ 10. 00 per warrant, and (iii) all of the Common Warrants, which have an exercise price of $ 9. 20 per warrant, are " out of the money, " meaning the exercise price is higher than the market price of our Common Stock. Holders of such " out of the money " Warrants are not likely to exercise such Warrants. There can be no assurance that such Warrants will be in the money prior to their respective expiration dates, and therefore, we may not receive any cash proceeds from the exercise of such Warrants. Certain of our Warrants are accounted for as liabilities and the changes in value of such Warrants could have a material effect on, or cause volatility in, our financial results. In connection with the Business Combination, we assumed 8, 750, 000 Public Warrants, 442, 500 Private Placement Warrants and 74, 977 Rollover Warrants. In addition, in connection with a private placement, we issued 612, 746 Common Warrants and 2, 500 Preferred Warrants. We preliminarily evaluated the accounting treatment of such Warrants and concluded that certain of such Warrants are required to be classified as liabilities measured at fair value. The fair value of such Warrants is remeasured on a quarterly basis with changes in the estimated fair value recorded in Other (expense) income on the condensed consolidated statement of operations and comprehensive loss. Due to the recurring fair value measurement, we expect that we will recognize non- cash gains or losses on such Warrants each reporting period and that the amount of such gains or losses could materially impact or cause volatility in our financial results~~ . Our Earnout Shares are accounted for as liabilities and the changes in value of such shares could have a material effect on, or cause volatility in, our financial results. We evaluated the accounting treatment of our Earnout Shares ~~(as defined below)~~ subject to forfeiture if the applicable conditions to transferability thereof are not satisfied and determined to classify such shares as liabilities measured at fair value. The fair value of such shares is remeasured on a quarterly basis over the earn- out period with changes in the estimated fair value recorded in Other **income** (expense) ~~income~~ on the ~~condensed~~ consolidated statement of operations ~~and comprehensive loss~~ . Due to the recurring fair value measurement, we expect that we

will recognize non- cash gains or losses on our Earnout Shares each reporting period and that the amount of such gains or losses could materially impact or cause volatility in our financial results. ~~85~~