Risk Factors Comparison 2025-03-19 to 2024-03-19 Form: 10-K

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

Risks Related to Our Financial Position and Capital Needs • ~~There is substantial doubt about our ability to continue as a going concern. •~~ We ~~have a history of net losses, we may not achieve or maintain profitability, and we~~ will need substantial additional capital in the future in order to fund our business **and have identified conditions that raise substantial doubt about our ability to continue as a going concern** . • We **have a limited number of shares of common stock available for future issuance which could adversely affect our ability to raise capital or consummate strategic transactions. • We have a history of net losses, and we** may ~~incur substantially~~ **not achieve or maintain profitability. • Our strategic prioritization and streamlining of resources undertaken to extend our cash runway and focus** more ~~debt of or our take~~ **capital resources on PRGN- 2012 might not achieve our intended outcome. Zopapogene imadenovec is** ~~other~~ -- **the nonproprietary name for** ~~actions that would intensify~~ the ~~risks discussed above~~ **investigational therapeutic known as PRGN- 2012. Zopapogene imadenovec has not been approved by any health authority in any country for any indication. • We expect our future capital requirements will be substantial and will depend on many factors** . Risks Related to the Discovery and Development of Our Product Candidates • Our business is dependent on our ability to advance our current and future product candidates through clinical trials, obtain marketing approval, and ultimately commercialize them. • The market opportunities for our product candidates may be smaller than we estimate. • The regulatory process of the United States Food and Drug Administration, or FDA, and comparable foreign authorities are lengthy, time- consuming, and inherently unpredictable, and we may be unable to obtain FDA approval of our product candidates. The denial or delay of any such approval would prevent or delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business, and our results of operations. • Clinical development involves a lengthy and expensive process with uncertain outcomes. We may incur additional costs and experience delays in developing and commercializing or be unable to develop or commercialize our current and future product candidates. • As an organization, we have limited experience designing and implementing clinical trials and failure to adequately design a trial, conduct a trial in accordance with regulatory requirements, or enroll patients in clinical trials, could result in adverse effects, including but not limited to increased or unexpected costs and delayed timelines. • Cell and gene therapies are novel, complex, and difficult to manufacture. • Interim and preliminary results from our clinical trials that we announce or publish from time to time may change, which could result in material changes in the final data. • We have chosen to prioritize certain of our product candidates and, as a result, may expend our limited resources on product candidates that do not yield a successful product, or fail to capitalize on opportunities that may be more profitable. Risks Related to the Commercialization of Product Candidates and Other Legal Compliance Matters • Even if a product candidate receives marketing approval, it may fail to achieve the degree of market acceptance necessary for commercial success. • Delays in obtaining regulatory approval of manufacturing processes and facilities or disruptions in manufacturing processes may delay or disrupt our commercialization efforts. • Even if we receive marketing approval of a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. • As a company, we have never commercialized a product, we currently have no active sales force and we may lack the necessary expertise, personnel and resources to successfully commercialize our product candidates. • The successful commercialization of our product candidates will depend in part on the extent to which third- party payers provide coverage and adequate reimbursement levels. • We are subject to certain United States and foreign anti- corruption, anti- money laundering, export control, sanctions and other trade laws and regulations. • Failure to comply with current or future federal, state and foreign laws and regulations and industry standards relating to privacy and data protection laws could lead to governmental enforcement actions (which could include civil or criminal penalties), private litigation, and / or adverse publicity. Risks Related to Our Business Operations and Strategy • We may rely on third parties to develop and commercialize some of our product candidates **, and we may fail to successfully manage, or disputes may arise from, any such collaborations** . • If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. • We may be sued for product liability. • Our insurance policies are expensive and protect only from some business risks, which leaves us exposed to significant uninsured liabilities. • Competitors and potential competitors may develop products and technologies that make ours obsolete or garner greater market share than ours. • If we lose key personnel, including key management personnel, or are unable to attract and retain additional personnel, it could delay our product development programs, harm our research and development efforts, and we may be unable to continue to commercialize our product candidates. • If we experience a significant breach of data security or disruption in our information systems, our business could be adversely affected ~~. • The effects of the COVID- 19 pandemic have disrupted, and will likely continue to disrupt, our business operations, which could have a material adverse effect on our results of operations, cash flows, and financial position~~ . • We may pursue strategic acquisitions and investments that could have an adverse impact on our business. Risks Related to Our Intellectual Property • Our ability to compete may decline if we do not adequately protect our proprietary technologies or intellectual property rights. • Litigation or other proceedings or third- party claims of intellectual property infringement, misappropriation or other violation could require us to spend significant time and money and could prevent us from commercializing our technologies or impact our stock price. Risks Related to Our Common Stock • **We have failed in the past and may fail in the future to meet all applicable continued listing requirements of the Nasdaq Global Select Market, which could result in a delisting of our common stock. •** Our quarterly and annual operating results may fluctuate in the future. As a result, we may fail to meet or exceed the expectations of research analysts or investors, which could cause our stock

price to decline. • Our stock price is volatile, and purchasers of our common stock could incur substantial losses. • We do not anticipate paying cash dividends, and accordingly, shareholders will have to rely on any stock appreciation for return on their investment. • As of February 15, ~~2024~~ **2025** , Randal J. Kirk controlled approximately ~~39~~ **40** percent of our common stock and may be able to control or significantly influence shareholder votes and other corporate actions. • Sales of a substantial number of shares of our common stock in the public market could occur at any time. This could cause the market price of our common stock to drop significantly, even if our business is doing well. • Our articles of incorporation authorize us to issue preferred stock with terms that are preferential to those of our common stock. • We are subject to anti- takeover provisions in our articles of incorporation and bylaws and under Virginia law that could delay or prevent an acquisition of our Company, even if the acquisition would be beneficial to our shareholders. PART I Item 1. Business Overview We are a dedicated discovery and clinical- stage biopharmaceutical company advancing the next generation of gene and cell therapies with the overall goal of improving outcomes for patients with significant unmet medical needs. We are leveraging our proprietary technology platforms to develop product candidates designed to target urgent and intractable diseases in our core therapeutic areas of immuno-oncology, autoimmune disorders, and infectious diseases. We have developed an extensive pipeline of therapies across multiple indications. We believe that our array of technology platforms uniquely positions us among other biotechnology companies to advance precision medicine. Precision medicine is the practice of therapeutic product development that takes into account specific genetic variations within populations impacted by a disease to design targeted therapies to improve outcomes for a disease or patient population. Our proprietary and complementary technology platforms provide a strong foundation to realize the core promise of precision medicine by supporting our efforts to construct powerful gene programs to drive efficacy, deliver these programs through viral, non- viral, and microbe- based approaches to drive lower costs, and control gene expression to drive safety. Our therapeutic platforms, including UltraCAR- T, AdenoVerse immunotherapy, and ActoBiotics, are designed to allow us to precisely control the level and physiological location of gene expression and modify biological molecules to control the function and output of living cells to treat underlying disease conditions. We ~~are actively advancing our lead clinical programs, including: PRGN- 3005, PRGN- 3006, and PRGN- 3007, which are built on our UltraCAR- T platform; PRGN- 2009 and PRGN- 2012, which are based on our AdenoVerse immunotherapy platform. In addition, we have completed a Phase 1b / 2a study of AG019, which is built on our ActoBiotics platform. We also have a robust pipeline of preclinical programs that we are pursuing in order to drive long- term value creation. We~~ have developed a proprietary electroporation device, UltraPorator, designed to further streamline and ensure the rapid and cost- effective manufacturing of UltraCAR- T therapies. UltraPorator has received FDA clearance for manufacturing UltraCAR- T cells in clinical trials, and we have been dosing patients with UltraCAR- T cells manufactured with UltraPorator in our clinical trials **. Our clinical pipeline includes PRGN- 2012 and PRGN- 2009, which are based on our AdenoVerse immunotherapy platform; and PRGN- 3005, PRGN- 3006 and PRGN- 3007, which are built on our UltraCAR- T platform. We have completed enrollment in the Phase 1b clinical trial of PRGN- 3006. As part of the strategic prioritization of our pipeline, we have paused enrollment in the PRGN- 3005 and PRGN- 3007 clinical trials. In addition, we have completed a Phase 1b / 2a study of AG019, which is built on our ActoBiotics platform, which we have completed the shut- down of, as discussed below under our Biopharmaceuticals segment (Precigen ActoBio, Inc.). We have reduced our focus on preclinical programs, while continuing select projects that we believe could provide further near- term validation of our technology platforms. In August 2024, we announced strategic prioritization of our pipeline to focus on development of our lead program, PRGN- 2012. We plan to minimize UltraCAR- T spending and focus on strategic partnerships to further advance UltraCAR- T programs. As part of this restructuring, we have paused enrollment in PRGN- 3005 and PRGN- 3007 UltraCAR- T clinical trials. In addition, we plan to continue PRGN- 2009 Phase 2 clinical trials under a cooperative research and development agreement (" CRADA") with the National Cancer Institute (" NCI") in recurrent / metastatic cervical cancer and in newly diagnosed HPV- associated oropharyngeal cancer. We have reduced our focus on preclinical programs, while continuing select projects that we believe could provide further near- term validation of our technology platforms. We have completed the shutdown of our ActoBio subsidiary operations, including the elimination of all ActoBio personnel. In conjunction with this shutdown, ActoBio' s portfolio of intellectual property is available for prospective transactions. These strategic changes are designed to enable us to focus on the pre- commercialization efforts on PRGN- 2012, including supporting regulatory approval, conducting the confirmatory clinical trial, and manufacturing of commercial products. Additionally, we will continue acceleration of commercial readiness efforts for a potential launch. We have completed submission of a Biologics License Application (" BLA") for PRGN- 2012 for the treatment of adults with Recurrent Respiratory Papillomatosis (" RRP") and the FDA has granted priority review with a Prescription Drug User Fee Act (" PDUFA") target action date set for August 27, 2025** . We exercise discipline in our portfolio management by systematically evaluating data from our preclinical programs in order to make rapid" go" and" no go" decisions. Through this process, we believe we can more effectively allocate resources to programs that we believe show the most promise and advance such programs to clinical trials. To guide our decision- making and operations, we have adopted the following tenets, which form the core of our operating ideology: • Financial Discipline. Responsibly allocate capital in an effort to ensure maximum value creation. • Active Portfolio Management. Continuously evaluate our portfolio and strictly adhere to data- driven" go" and" no go" decisions to advance programs with the highest probability of success. • Rapid Execution. Advance priority programs quickly to value inflection points. • Strategic Partnerships. Seek strategic partnerships to maximize value generation. Our Strategy Our strategy is to use our discovery and clinical development infrastructure to continue advancement of our clinical programs with the goal of improving outcomes for patients with significant unmet medical needs. The key elements of our strategy include: • Advancing our lead clinical stage programs and seeking opportunities to maximize their value. We are actively advancing our lead programs that we believe have significant potential value. We intend to efficiently pursue these programs toward clinical proof- of- concept and commercialization, whether independently or with collaborators. • Strategically

pursuing our preclinical programs. We ~~have a robust pipeline of~~ **are strategically focusing on selecting** preclinical programs ~~that we are pursuing in order~~ to ~~drive~~ **create** long- term value ~~creation~~. We exercise discipline in our portfolio management by systematically evaluating data from our preclinical programs in order to make rapid" go" and" no go" decisions. Through this process, we believe we can more effectively allocate resources to programs that we believe show the most promise and advance such programs to clinical trials. • Leveraging our technology and therapeutic platforms across indications. Through the application of our suite of proprietary and complementary synthetic biology technologies, we believe we can create optimized biological processes and overcome the limitations of traditional techniques, leading to precision medicines that are manufactured more efficiently and cost- effectively with superior performance. We continually assess the application of these technologies across therapeutic areas to determine where we can develop and provide unique solutions to challenges facing existing therapies. We have strategically focused our efforts on developing an innovative pipeline of therapies based on our transformative UltraCAR- T ~~,~~and AdenoVerse immunotherapy therapeutic platforms. A core focus of our research and development programs has been an effort to address the drawbacks associated with conventional cell and gene therapy manufacturing approaches. To this end, we are developing therapeutic candidates that reduce manufacturing risk by eliminating the need for centralized cell therapy manufacturing and have invested in internal manufacturing capabilities to de- risk our clinical and, in certain cases, commercial production. Our Clinical Pipeline Our Healthcare Business Our Biopharmaceuticals reportable segment is primarily comprised of the Company' s legal entities of Precigen and ActoBio, as well as royalty interests in therapeutics and therapeutic platforms from companies not controlled by us. Our Exemplar reportable segment is comprised of Exemplar Genetics LLC, doing business as Precigen Exemplar, or Exemplar, our wholly owned subsidiary focused on developing research models and services for healthcare research applications. Precigen is a dedicated discovery and clinical stage biopharmaceutical company advancing the next generation of gene and cell therapies using precision technology to target urgent and intractable diseases in immuno- oncology, autoimmune disorders and infectious diseases. Precigen' s Technology Platforms We leverage a diverse portfolio of proprietary technology platforms to accelerate research and development efforts to deliver the promise of precision medicine. Precigen' s innovative technology platforms enable us to construct powerful, multigenic programs that we believe will drive efficacy, deliver multigenic constructs using viral and non- viral approaches that we believe will drive lower costs, and control expression of genes and performance of therapeutics in vivo for precise targeting of complex malignancies. The following discussion describes the technology platforms that we use for our approach to precision medicine. We believe that the development of innovative biological products requires a deep understanding of the complexity of cellular processes and the construction of improved gene programs developed in conditions reflective of the natural environment. We accomplish the design of optimized gene programs for our therapeutic approaches via our UltraVector platform that incorporates advanced DNA construction technologies and computational models to design and assemble genetic components into complex gene expression programs. UltraVector- enabled matrices facilitate rapid identification of components that yield desired gene expression. Our library of characterized genetic components and associated functional characterization data ~~enable~~ **enables** construction of gene programs for optimized expression of multiple effector genes. Expression of our membrane- bound interleukin- 15, or mbIL15, gene improves functional characteristics of certain immune cells, including T- cells, by enhancing their potential for expansion and persistence. We deliver gene programs via viral, non- viral, and microbe- based approaches, including Sleeping Beauty, AttSite recombinases, and gorilla adenoviral vectors, from our AdenoVerse library. Sleeping Beauty is a non- viral transposon / transposase system licensed from the University of Texas MD Anderson Cancer Center that stably reprograms immune cells by inserting specific DNA sequences into their genome. The Sleeping Beauty system has been shown to promote random integration in the genome without insertion bias, which contrasts with the predilection of other viral and non- viral methods such as lentiviral vectors and the PiggyBac transposon system for integration at transcriptionally active sites. We believe that our non- viral system may confer benefits including a reduction of the risk of genotoxicity. Precigen has made significant improvements to the Sleeping Beauty system by optimizing gene elements, genetic payload capacity, and efficiency of delivery, which provides a system tailored to our multigenic UltraCAR- T platform. Our AttSite recombinases, which break and rejoin DNA at specific sequences in ~~a~~ unidirectional, irreversible fashion to direct integration of a transgene into the host cell genome, allow for stable, site- specific gene integration. The UltraPorator system includes proprietary hardware and software solutions and potentially represents major advancements over current electroporation devices by significantly reducing the processing time and contamination risk. UltraPorator is designed for rapid and cost- effective manufacturing of UltraCAR- T therapies and has the potential to enable rapid manufacturing of a range of gene and cell therapies beyond UltraCAR- T. Genetically engineered adenoviruses (a common group of viruses) called adenovectors that are designed to insert genes into cells are an important part of our technology platforms. Our AdenoVerse technology platform is composed of a library of engineered adenovector serotypes that yield greater tissue specificity and target selection as compared to known human Ad5 adenovectors. This includes our gorilla adenovectors, which provide a potential competitive advantage with their large payload capacity, ability for repeat administrations and generation of robust antigen- specific immune responses. The final component of our approach to precision medicine is our ability to control gene expression and regulation using the RheoSwitch, kill switches, and tissue- specific promoters. The RheoSwitch Therapeutic System, our inducible gene switch system, provides quantitative dose- proportionate regulation of the amount and timing of target protein expression in response to an orally available activator ligand. We have developed kill switches, which allow us to selectively eliminate cell therapies in vivo after their administration, to improve their safety profile. We are developing tissue- specific promoters to only induce gene expression locally in cells or tissues of therapeutic interest. We have leveraged our proprietary and complementary technology platforms discussed above and our expertise in immunology to develop key therapeutic platforms, including UltraCAR- T and AdenoVerse, to address multiple pathways of complex disorders with significant unmet medical needs and to realize our core promise of precision medicine. Precigen' s Therapeutic Platforms ~~" Off- the- shelf" AdenoVerse Immunotherapy~~ Our AdenoVerse ~~immunotherapy~~ platform utilizes a library of proprietary adenovectors for the

efficient gene delivery of therapeutic effectors, immunomodulators, and vaccine antigens. We have established proprietary manufacturing cell lines and production methodologies from our AdenoVerse ~~immunotherapy~~ platform, which we believe are scalable for commercial supply. We believe that our proprietary gorilla adenovectors, part of the AdenoVerse technology, have superior performance characteristics as compared to current competition, including standard human adenovirus serotype 5, or Ad5, rare human adenovirus types and other non- human primate adenovirus types. The key advantages of AdenoVerse ~~immunotherapy~~ platform include: Large genetic payload capacity Our gorilla adenovectors have a larger genetic payload capacity than other viral vectors that currently dominate the gene therapy field, allowing us to engineer multigenic therapeutic candidates to treat complex diseases. Currently, we are able to engineer up to a 12kb genetic payload using our gorilla adenovectors, providing us with an advantage to express multiple genes in a controlled manner. Repeat administration Unlike most competing approaches, our gorilla adenovectors are suitable for repeat administration, which can lead to boosted antibody and T- cell responses. This suitability for repeat administration stems from the very low to non- existent seroprevalence of and limited immunity to gorilla adenoviruses in the human population. For example, our gorilla adenovector variant GC46 has been shown to have a seroprevalence of less than 6 percent in the United States, with low seropositive titers. In comparison, the seroprevalence of Ad5 in the United States is estimated to be 58 percent, with most of seropositive individuals having high titers. This high Ad5 seroprevalence limits the effectiveness of Ad5- based adenovectors in clinical studies. The rare and weak pre- existing immunity against gorilla adenovectors may therefore provide an advantage in clinical applications as compared to existing competition. Replication incompetence Our gorilla adenovectors are engineered and manufactured using a process that ensures the production of replication incompetent adenoviral therapeutic candidates with no cytopathic or cytotoxic effect in normal human cells. This has been achieved by engineering deletions of two regions essential for replication of the adenoviral genome. The use of a proprietary complementing cell line provides the necessary genetic elements for manufacture of AdenoVerse immunotherapy candidates. We believe our AdenoVerse immunotherapy candidates have reduced regulatory and commercialization risk due to their design, which renders them incapable of replicating and therefore less susceptible to manufacturing failures. Furthermore, our gorilla adenovector manufacturing process has yielded therapeutic candidates at a very high titer and has reduced the complexity of manufacturing. Durable antigen- specific immune response Gorilla adenovectors have been shown in preclinical studies to generate high- level and durable antigen- specific neutralizing antibodies and effector T- cell immune responses, as well as an ability to boost these antibody and T- cell responses via repeat administration. cGMP Manufacturing Facility We have built internal cGMP manufacturing capabilities for our Adenoverse- based therapeutics in Germantown, Maryland, with the aim to reduce the risks associated with technology transfer and timing when outsourcing to contract manufacturing organizations. We are able to execute drug substance manufacturing at this facility in an expedited manner at reduced cost compared to contract manufacturing organizations. We ~~are expanding~~ **have expanded** our drug substance cGMP manufacturing capabilities at this facility with an aim to support the possible commercial launch of our PRGN- 2012 asset. We will continue to evaluate internal and external strategies to support cGMP manufacturing needs of our AdenoVerse- based therapeutics. Precigen' s most advanced programs based on the AdenoVerse immunotherapy platform include: (i) PRGN- 2012, a first- in- class, investigational" off- the- shelf" AdenoVerse ~~immunotherapy~~ **gene therapy** designed to elicit immune responses directed against cells infected with HPV type 6, or HPV6, or HPV type 11, or HPV11, **for** which **BLA** is **submitted to the FDA for adults** ~~in a Phase 1 / 2 trial in patients~~ with recurrent respiratory papillomatosis, or RRP; and (ii) PRGN- 2009, a first- in- class, investigational" off- the- shelf" ~~immunotherapy~~ **treatment** utilizing the AdenoVerse platform, is designed to activate the immune system to recognize and target human papillomavirus- positive, or HPV , solid tumors, which is in two Phase 2 clinical trials for patients with HPV- associated cancers. PRGN- 2012 is **an** ~~a first- in- class,~~ investigational" off- the- shelf" AdenoVerse ~~immunotherapy~~ **gene therapy** for the treatment of RRP. PRGN- 2012 is **engineered with** an ~~innovative therapeutic vaccine with~~ optimized antigen design ~~that~~ **and** uses our gorilla adenovector technology, part of our proprietary AdenoVerse platform, to elicit immune responses directed against cells infected with HPV6 and HPV11. Gorilla adenovectors have numerous advantages, including the ability for repeat administration, the inability to replicate in vivo, which may improve safety, and the ability to deliver large payload capacity. RRP is a rare, difficult- to- treat and sometimes fatal neoplastic disease of the upper and lower respiratory tracts that is caused by infection with HPV6 or HPV11. RRP is classified based on age of onset as juvenile or adult. RRP prevalence is estimated to be approximately ~~15~~ **27** , 000 **adult** ~~to 20, 000~~ patients in the U. S and more than 125, 000 patients outside the U. S., based on our commissioned research. There is no approved therapeutic treatment for RRP and the current standard- of- care is repeated endoscopic debulking with ablation or excision of papillomatous lesions. Surgeries are not curative and recurrence of papilloma after surgical removal is very common and repeated procedures are required to debulk and monitor the disease, which exposes patients to anesthetic and surgical risks, and emotional distress. Patients with aggressive RRP can undergo hundreds of lifetime surgeries to control their disease. RRP morbidity and mortality results from the effects of papilloma mass on the vocal cords, trachea, and lungs, which may cause voice changes, stridor, airway occlusion, loss of lung volume, and / or post- obstructive pneumonia. Although rare, RRP has the potential for malignant transformation in three to seven percent of adult patients. In addition, more than 90 percent of genital warts are related to HPV6 and HPV11 infection. In preclinical models, PRGN- 2012 has demonstrated strong HPV6 and HPV11- specific T- cell response in RRP patient samples in vitro. **We have completed Phase 1 / 2 pivotal clinical trial of** PRGN- 2012 ~~is currently under evaluation~~ in ~~a~~ **adults with RRP. Phase 1 / 2 pivotal study met the primary safety and efficacy endpoints. The** Phase 1 / 2 clinical trial **(** ~~. The~~ clinical trial **identifier: NCT04724980)** ~~evaluates PRGN- 2012 as an immunotherapy following standard- of- care surgery in adult patients with RRP. We have completed Phase 1 dose escalation and dose expansion portion of the PRGN- 2012 Phase 1 / 2 trial. The Phase 1 clinical trial~~ evaluated safety and efficacy of PRGN- 2012 ~~as an immunotherapy following standard- of- care RRP surgery~~ . ~~Trial~~ **The study** design included ~~a~~ **an initial** 3 3 dose escalation cohort ~~followed by a dose expansion cohort~~ to **identify** ~~enroll additional patients at~~ the recommended Phase 2 dose (RP2D). Adult **RRP** patients **who had three** ~~with severe, aggressive RRP, defined as greater~~

~~than~~ or **more** ~~equal to 3~~ surgeries in the prior 12 months ~~,~~ were eligible for the **study** ~~clinical trial~~. The Phase 1 **/ 2** study enrolled a total of ~~15~~ **38** patients **. Of these, 3 patients received four administrations of PRGN- 2012** at **1x** ~~one of the following dose levels with patients receiving four PRGN- 2012 administrations (on days 1, 15, 43 and 85) via subcutaneous injection at one of the two dose levels: (i) Dose Level 1: 1 x~~ 1011 particle units (PU) / dose ~~; N = 3; or~~ **and 35 patients received four administrations of PRGN- 2012 at RP2D** (~~ii) Dose Level 2:~~ 5 x 1011 PU / dose ~~; N =~~ **) over a** 12 **- week treatment period via subcutaneous injection. Primary endpoints included safety and Complete Response rate defined as the percentage of patients who require no RRP surgeries in the 12- month period after PRGN- 2012 treatment completion. Key secondary endpoints included HPV- specific immune responses, extent of papilloma growth as measured by Derkay scoring, and quality of life measurement as measured by Vocal Handicap Index- 10 (VHI- 10)**. Baseline patient characteristics **of the 35 adult patients** included a median age of ~~51~~ **49** years (range: ~~30 to 73~~ **20- 88**) ~~. Ten~~ **; 20 of the** patients were male and ~~five~~ **15** were female. Patients had ~~an average~~ **a median** of **4** ~~6. 2~~ surgeries (range: 3 ~~to~~ - 10) in the ~~prior~~ 12 **-** months before ~~enrolling in the trial~~ **PRGN- 2012 treatment initiation**. ~~The Phase~~ **Average years since RRP diagnosis was 20 (range:** 1 ~~data demonstrated that the repeated administrations of~~ **- 65) with 12 and 23 patients with juvenile and adult onset RRP, respectively.** PRGN- 2012 ~~were~~ **treatment was** well- tolerated with no ~~DLTs. There were~~ **dose- limiting toxicities and** no **treatment- related adverse events, or** TRAEs **,** greater than Grade 2. All patients received four administrations of PRGN- 2012 at the intended dose ~~level~~ **levels**. TRAEs were ~~all~~ **mostly** mild **with no** ~~and reduced in frequency over the~~ treatment ~~interval~~ **- related serious adverse events reported**. The most common TRAE was injection site reaction ~~, which occurred in all of the patients~~. ~~Most other~~ **Other common** TRAEs occurring in more than one subject were ~~similar to seasonal vaccines and the most common were~~ fatigue, **chills, and** fever ~~, and chills~~. There was ~~a low~~ **no meaningful anti** - **drug** ~~level increase in neutralizing antibodies against gorilla adenovector after first administration and lack of significant neutralizing~~ antibody response ~~to gorilla adenovector over time~~ with ~~subsequent vaccinations highlights the ability to deliver repeated~~ -- **repeat** administrations of PRGN- 2012. **Primary** ~~The Phase 1~~ efficacy **endpoint analysis demonstrated** ~~data for Dose Level 1 showed~~ that **51** ~~PRGN- 2012 treatment reduced the need for surgeries for 100~~ % (~~3~~ **18** out of ~~3~~ **35**) ~~severe, aggressive RRP~~ **(95 % CI: 34- 69)** patients **treated at RP2D achieved Complete** ~~. Patients in Dose Level 1 had a 33 % (1 out of 3) Overall~~ Response ~~Rate (ORR), defined as greater than or equal to 50 % reduction in the surgeries in 12- months post PRGN- 2012 treatment completion compared to 12- months pre- treatment. Additionally, PRGN- 2012 treatment at Dose Level 1 resulted in improvement in average time to recurrence (TTR), which is defined as time from start of treatment to first RRP surgery, post treatment~~. The **Complete Response rate was** ~~Phase 1 efficacy data for Dose Level 2 showed PRGN- 2012 treatment significantly reduced the need for surgeries for severe, aggressive RRP patients. At Dose Level 2,~~ 50 % (6 out of 12) ~~patients had a~~ **and 52 % (12 out of 23) in the Phase 1 and Phase 2 portions of the study, respectively.** Complete ~~Response~~ **Responses were durable with median durability of response yet to be reached.** ~~, which is defined as no surgeries needed during the 12- month period following~~ PRGN- 2012 treatment ~~completion~~ **significantly (p < 0** . **0001) reduced the need for surgeries in RRP** ~~Patients~~ **patients compared to pre- treatment history. PRGN- 2012 treatment reduced the need for RRP surgeries** in **86** ~~Dose Level 2 had a 58~~ % (~~7~~ **30** out of ~~12~~ **35**) ~~ORR. 83 % (10 out of 12)~~ of patients **compared to their pre-** ~~treated~~ **treatment history.** ~~at Dose Level 2 had reduced~~ RRP surgeries **were** ~~in 12- months post PRGN- 2012 treatment compared to pre- treatment. The number of RRP surgeries in the patients (N = 12) in Dose Level 2~~ reduced from a median of **4** ~~5 surgeries~~ (range: 3- 10) in the 12 ~~-~~ months pre- treatment to 0 ~~. 5 surgeries~~ (range: 0- ~~6~~ **7**) in **the** 12 ~~-~~ months post PRGN- 2012 treatment completion. ~~In addition, there was a significant improvement in TTR for patients treated with PRGN- 2012 at Dose Level 2. We announced in January 2024 that all Complete Responses from Phase 1 trial remain durable ongoing at more than 2 years after~~ PRGN- 2012 treatment ~~. Additionally, PRGN- 2012 treatment at Dose Level 2~~ showed **a** significant **(p < 0. 0001)** improvement in anatomical Derkay scores, a tool used for research purposes to quantify RRP severity based on involvement of laryngeal structures, ~~and voice~~ **with mean Derkay scores reducing from 9 (range: 5- 19) at baseline to 1 (range: 0- 5) at 24 weeks post- treatment in patients with Complete Response.** ~~quality~~ **Quality of life** , **as** evaluated using the validated **VHI** ~~Vocal Handicap Index~~ - 10 **, significantly** (~~VHI- 10~~ **p < 0. 0001**) ~~,~~ **improved from a mean of 25 (range: 12- 38) at baseline to 7 (range: 0- 30)** at 24 **-** weeks post PRGN- 2012 treatment ~~completion compared to baseline~~ **in patients with Complete Response** . ~~The Phase 1 data showed that~~ PRGN- 2012 treatment **induced** ~~resulted in an increase in~~ HPV 6 / 11- specific T ~~-~~ cell ~~response~~ **responses** in ~~the peripheral blood of~~ RRP patients ~~. A~~ **with a** significantly greater expansion of **peripheral** HPV- specific T ~~cell~~ **cells** ~~responses after PRGN- 2012 treatment were~~ observed in responders compared ~~to~~ **with** non- ~~complete~~ responders ~~. We have completed enrollment and dosing in the Phase 2 study of PRGN- 2012 with 23 patients enrolled. The Phase 2 trial is anticipated to be completed in the second quarter of 2024. We have announced that the FDA has confirmed that the ongoing Phase 1 / 2 single- arm study will serve as pivotal and that no additional randomized, placebo- controlled trial will be required to support submission of a BLA under an accelerated approval pathway. The FDA has confirmed that the current primary endpoint for the ongoing Phase 1 / 2 study, which is Complete Response rate (percentage of patients with no surgical interventions during the 12 months following treatment with PRGN- 2012), along with an immunological surrogate marker demonstrating an induction of HPV- specific T cell responses following PRGN- 2012 treatment, is acceptable for the accelerated approval request. Based on the FDA guidance, we plan to initiate a confirmatory study prior to submission of the BLA~~. PRGN- 2012 has been granted Breakthrough Therapy Designation and Orphan Drug designation for the treatment of RRP by the FDA. PRGN- 2012 has received Orphan Drug Designation for the Treatment of RRP from the European Commission as well. **We have completed the submission of, and received priority review for Precigen' s BLA for** PRGN- 2012 ~~Phase 2 pivotal trial~~ **, which is intended for treating adults with RRP. The PDUFA target action** ~~data~~ **date is set for August 27,** ~~are anticipated in the second quarter of 2024~~ **2025** . **PRGN- 2009,** ~~We plan to submit a BLA under~~ an ~~accelerated approval pathway in the second half of 2024. We are preparing for commercial readiness for a potential launch, if approved, of PRGN- 2012 in 2025. PRGN- 2009, a first- in- class,~~ " off- the- shelf" investigational ~~immunotherapy~~ **AdenoVerse gene therapy** , is designed to activate the immune system

to recognize and target HPV solid tumors. PRGN- 2009 leverages our UltraVector and AdenoVerse platforms to optimize HPV type 16, or HPV16, and HPV type 18, or HPV18, antigen design for delivery via a proprietary gorilla adenovector with a large genetic payload capacity and the ability for repeat administrations. Guided by our bioinformatics analysis and in silico protein engineering, PRGN- 2009 encodes for a novel, multi- epitope antigen design to target HPV16 and HPV18 infected cells and potentially differentiates from the competition. PRGN- 2009 has been engineered using our AdenoVerse platform to be replication deficient in vivo. HPV infections account for 5 percent of all cancers globally, and 690, 000 new cancer cases are attributable to HPV infections per year. HPV infects the squamous cell carcinoma. Some cervical cancers come from HPV infection of gland cells in the cervix and are referred to as adenocarcinomas. HPV- related cancers include cervical, oropharyngeal, anal, penile, vaginal, and vulvar. Nearly 44, 000 HPV- associated cancers occur in the United States each year. Of these, approximately 25, 000 occur in women and 19, 000 occur in men. HPV is considered responsible for more than 90 percent of anal and cervical cancers, about 70 percent of vaginal and vulvar cancers, and more than 60 percent of penile cancers. Recent studies indicate that about 70 percent of cancers of the oropharynx also may be related to HPV. **We have completed a Phase 1 clinical trial of PRGN- 2009 as a monotherapy or in combination with bintrafusp alfa, or M7824, an investigational bifunctional fusion protein, for patients with HPV- associated cancers in collaboration with the National Cancer Institute, or NCI, pursuant to a cooperative research and development arrangement, or CRADA.** PRGN- 2009 is **being evaluated** in ~~a~~ **two** Phase ~~1 /~~2 clinical ~~trial~~ **trials in combination with anti- PD1 monoclonal antibody, pembrolizumab,** for patients with HPV- associated cancers in collaboration with NCI pursuant to a ~~Cooperative Research and Development Agreement (~~ CRADA ~~). We have completed the Phase 1 portion of the trial~~ . The **first** ~~Phase 2 portion of the study is designed to evaluate PRGN- 2009 as a monotherapy in patients with newly- diagnosed stage II / III HPV16- positive oropharyngeal cancer and patients with newly diagnosed operable stage II / III / IVA / IVB HPV sinonasal squamous cell cancer. We have completed enrollment in the Phase 2 monotherapy arm with twenty evaluable patients. In June 2023, the Principal Investigator of the PRGN- 2009 clinical study presented Phase 1 data at the 2023 American Society of Clinical Oncology, or ASCO, Annual Meeting. Phase 1 study enrolled a total of seventeen adult patients (N = 6 Arm 1A, N = 11 Arm 1B). In the monotherapy arm, patients (N = 6) were enrolled in two sequential dose level cohorts with PRGN- 2009 delivered via subcutaneous injection. PRGN- 2009 at 5x1011 particle units (PU) per dose was selected as the recommended phase 2 dose (RP2D). In the combination arm, PRGN- 2009 was administered at the RP2D in combination with bintrafusp alfa. Patients received up to 20 doses of PRGN- 2009 for a duration of 1. 8 to 17. 9 months in the monotherapy arm and 0. 5 to 23. 0 months in the combination arm. The median age in both arms was 61. The median number of prior lines of therapies in the metastatic setting was 2. 5 for the monotherapy arm and 2 for the combination arm. All patients in the monotherapy arm (N = 6) and 10 of 11 patients in the combination arm received prior immune checkpoint blockade (ICB) therapy. PRGN- 2009 treatment in both monotherapy and combination arms was well- tolerated. In both study arms, there was a low incidence of PRGN- 2009 treatment- related adverse events (TRAEs) with only Grade 1 or 2 TRAEs in the monotherapy arm. TRAEs reported in the combination arm were in line with the safety profile reported for bintrafusp alfa and TRAEs attributable to PRGN- 2009 in the combination arm were Grade 1 or 2. Tumor responses were observed in patients after treatment with PRGN- 2009 in combination with bintrafusp alfa (Arm 1B), including in ICB- resistant patients. The majority (6 / 6 Arm 1A, 8 / 10 Arm 1B) of patients developed HPV- 16 and / or HPV- 18 specific immune responses after treatment with PRGN- 2009 in both monotherapy and combination arms. There was a lack of significant neutralizing antibody response to gorilla adenovector over time with subsequent vaccinations. PRGN- 2009 combined with bintrafusp alfa resulted in a 30 % objective response rate (ORR) in patients with pretreated recurrent or metastatic (R / M) HPV- associated cancers that were naïve or resistant to checkpoint blockade. A~~ Phase 2 clinical trial **is** designed to evaluate PRGN- 2009 in combination with anti- PD1 antibody, pembrolizumab, in adult patients with newly- diagnosed HPV- associated oropharyngeal cancer is ongoing in collaboration with NCI pursuant to a CRADA. The primary objective of the study is to determine if there is an increase in CD3 tumor infiltrating T cells post treatment compared with pre- treatment. Secondary objectives include safety and overall survival (OS). **The second** ~~In addition, we have received FDA clearance of an Investigational New Drug Application, or IND, to initiate a~~ Phase 2 **clinical trial is** randomized, open- label clinical trial of PRGN- 2009 in combination with pembrolizumab to treat patients with **recurrent or metastatic, or** R / M **,** cervical cancer. Patients in the Phase 2 trial will be randomized 1: 1 to the combination of PRGN- 2009 and pembrolizumab (cohort 1) or pembrolizumab monotherapy (cohort 2). Patients randomized to the PRGN- 2009 plus pembrolizumab cohort will receive PRGN- 2009 via subcutaneous (SC) injection (5 x 1011 PU every 3 weeks for three administrations followed by administration each 6 weeks thereafter). Patients in the PRGN- 2009 plus pembrolizumab cohort and pembrolizumab monotherapy cohort will receive pembrolizumab via intravenous (IV) infusion (400 mg every 6 weeks). Patients randomized to the pembrolizumab monotherapy cohort will be offered the option to crossover to the PRGN- 2009 plus pembrolizumab cohort if certain conditions are met. The primary objective of the Phase 2 trial in R / M cervical cancer is to assess the objective response rate (ORR) per RECIST v1. 1 following treatment with PRGN- 2009 in combination with pembrolizumab or pembrolizumab monotherapy. Secondary objectives include the evaluation of safety and tolerability, progression- free survival (PFS), overall survival (OS), best overall responses (BOR), Disease Control Rate (DCR), time to response and duration of response. The Phase 2 trial in R / M cervical cancer is enrolling patients. **As part of the strategic prioritization of our pipeline announced in August 2024, we plan to enroll patients in the PRGN- 2009 clinical trials only at NCI under a CRADA.** Recent technological advances have revolutionized the field of immunotherapy for the treatment of cancer. Of the many immunotherapy approaches, chimeric antigen receptor T, or CAR- T, cell therapies in particular have shown remarkable responses in cancer patients with hematological malignancies. These therapies rely on the genetic modification of T- cells to express chimeric antigen receptors and enable these modified T- cells to bind to specific antigens on the patient' s tumor cells and kill the tumor cells. Concerns remain, however, regarding complex and lengthy manufacturing processes and the safety profile of CAR- T cell therapies. Furthermore, current autologous and allogeneic CAR- T cell therapies

face challenges in the treatment of solid tumors due to rapid exhaustion and limited in vivo persistence of CAR- T cells. Current approaches to CAR- T manufacturing require extensive ex vivo expansion following viral vector transduction to achieve clinically relevant cell numbers. We believe such an ex vivo expansion process can result in the exhaustion of CAR- T cells prior to their administration, limiting their potential for persistence in patients after administration. Furthermore, **the** lengthy and complex manufacturing of current CAR- T approaches results in high manufacturing costs and long delays in providing the CAR- T treatment to cancer patients. Time is of the essence for advanced cancer patients and even modest delays in treatment can adversely affect outcomes. Our UltraCAR- T platform is differentiated from the competition, and we believe it has the potential to address the shortcomings of current technologies and disrupt the CAR- T treatment landscape by increasing patient access through shortening manufacturing time from weeks to days, decreasing manufacturing- related costs, and improving outcomes. We advanced the UltraCAR- T platform to address the inhibitory tumor microenvironment by incorporating intrinsic checkpoint blockade without the need for complex and expensive gene editing techniques. The next generation of UltraCAR- T utilizes a single multicistronic transposon DNA and our overnight, decentralized manufacturing process of UltraCAR- T. We have introduced our vision for a new UltraCAR- T library approach, which is intended to transform the personalized cell therapy landscape for cancer patients. Our goal is to develop and validate a library of non- viral plasmids to target tumor- associated antigens. Enabled by what we believe to be design and manufacturing advantages of UltraCAR- T, coupled with the capabilities of the UltraPorator system, we are working to empower cancer centers to deliver personalized, autologous UltraCAR- T treatment with overnight manufacturing to any cancer patient. If our goal is realized, one or more non- viral plasmids could be selected based on the patient' s cancer indication and biomarker profile from the library to build a personalized UltraCAR- T treatment. After initial treatment, this approach has the potential to allow for redosing of UltraCAR- T targeting the same or new tumor- associated antigens based on the treatment response and the changes in antigen expression of the patient' s tumor. The key advantages of UltraCAR- T versus the traditional CAR- T approaches include: Advanced non- viral multigenic delivery system We have optimized and advanced the Sleeping Beauty system using our UltraVector DNA construction platform to produce multigenic UltraCAR- T cells. As a result of this optimization, our UltraCAR- T cells are precision- engineered to produce a homogeneous cell product that simultaneously co- expresses antigen- specific CAR, kill switch, and mbIL15 genes in any genetically modified UltraCAR- T cell. We recently introduced the next generation UltraCAR- T platform that addresses the inhibitory tumor microenvironment by incorporating a novel mechanism for intrinsic downregulation of one or more checkpoint inhibitor, or CPI, genes. This design achieves intrinsic CPI blockade without gene editing and is aimed at avoiding systemic toxicity and the high cost of combining CPI antibodies. The next generation UltraCAR- T cells simultaneously express CAR, mbIL15, and a kill switch, and ~~incorporates~~ **incorporate** intrinsic CPI blockade using a single multicistronic non- viral transposon. This design differentiates our UltraCAR- T platform from the approaches used by our competitors and, we believe, reduces the developmental risk as compared to those approaches because product homogeneity is a critical consideration for later stages of clinical development and subsequent commercialization. We utilize our protein engineering and immunology expertise to optimize antigen binding, hinge, and signaling domains of each CAR based on the target antigen expression profile and cancer indication. We have also included our proprietary kill switch technology in our UltraCAR- T cells to improve the safety profile. Enhanced persistence and elimination of ex vivo expansion step due to expression of mbIL15 A key driver of improved UltraCAR- T cell performance is mbIL15. The expression of mbIL15 has been shown to enhance in vivo expansion of UltraCAR- T cells in the presence of tumor antigens and prevent T- cell exhaustion to maintain a less differentiated, stem- cell like memory phenotype leading to longer persistence of UltraCAR- T cells. This yields an enduring anti- tumor response that has been shown to outlast conventional CAR- T cells in preclinical studies, which we believe is essential to successfully targeting solid tumors. This design allows us to eliminate the need for ex vivo expansion prior to administration, a requirement that is a major limitation of current CAR- T treatments. Scalable, rapid, decentralized manufacturing process Another key differentiator of the UltraCAR- T therapeutic platform is our rapid and decentralized proprietary manufacturing process, which allows us to manufacture UltraCAR- T cells overnight at a medical center' s current good manufacturing practices, or cGMP, facility and reinfuse the patient the following day after gene transfer. This process improves upon current approaches to CAR- T manufacturing, which require extensive ex vivo expansion following viral vector transduction that we believe can result in the exhaustion of CAR- T cells prior to their administration, limiting their potential for persistence in patients. The decentralized nature of the manufacturing process allows us to scale beyond the confines of a dedicated facility. We believe we are the first company to validate non- viral, rapid, decentralized manufacturing of CAR- T cells in the clinic by infusing patients one day after gene transfer at two different sites in our ongoing clinical trials. We believe UltraCAR- T is the only autologous CAR- T platform with manufacturing, quality control release and infusion back to the patient, occurring in one day. We have developed a proprietary electroporation device, UltraPorator, designed to further streamline and ensure the rapid and cost- effective manufacturing of UltraCAR- T therapies. The UltraPorator system, intended to be a viable scale- up and commercialization solution for decentralized UltraCAR- T manufacturing, includes proprietary hardware and software solutions and potentially represents major advancements over current electroporation devices by significantly reducing ~~the~~ processing time and contamination risk. The FDA has cleared UltraPorator as a manufacturing device for clinical trials of our UltraCAR- T investigational therapies. We believe our UltraCAR- T manufacturing process will provide a significant potential competitive advantage in the timeline and cost required to manufacture and deliver CAR- T therapies to patients as compared to current treatment approaches that require large, centralized facilities to support manufacturing of a relatively small number of treatments. We believe development of rapid and successful overnight manufacturing of UltraCAR- T therapies at medical centers signifies a paradigm shift in CAR- T therapy by eliminating manufacturing and timing risks associated with conventional CAR- T therapies, and our intent is for it to take place directly in numerous treatment centers, which can improve the accessibility of our therapies for patients. Precigen' s most advanced programs based on the UltraCAR- T platform include PRGN- ~~3005~~ **3006** , which ~~is~~ **has completed enrollment** in a Phase 1b clinical trial for patients with **relapsed**

or refractory acute myeloid leukemia, or AML, and high- risk myelodysplastic syndromes, or MDS; PRGN- 3005, which is in a Phase 1b clinical trial for patients with advanced ovarian, fallopian tube, or primary peritoneal cancer; ~~PRGN- 3006, which is in a Phase 1b clinical trial for patients with relapsed or refractory acute myeloid leukemia, or AML, and high- risk myelodysplastic syndromes, or MDS;~~ and PRGN- 3007, based on the next generation UltraCAR- T, which **is in** ~~has received FDA clearance to initiate~~ a Phase 1 / 1b clinical trial for patients with advanced receptor tyrosine kinase- like orphan receptor 1- positive, or ROR1 , hematological and solid tumors. PRGN- 3005 is **an** ~~a first- in- class,~~ investigational autologous CAR- T therapy that utilizes our UltraCAR- T platform to simultaneously express a CAR targeting the unshed portion of the Mucin 16 antigen, or MUC16, mbIL15, and kill switch genes. MUC16 is an extremely large, type I transmembrane cell surface glycoprotein that plays a key role in the pathogenesis of ovarian cancer by promoting an increase in cell proliferation, metastasis, resistance to chemotherapy and immune system evasion by cancer cells. MUC16 is overexpressed on more than 80 percent of ovarian tumors but has limited expression in healthy tissues, making it an attractive CAR- T target for ovarian cancer. Other cancers with known overexpression of MUC16 include pancreatic, breast, endometrial, lung, and bladder cancers. MUC16 undergoes proteolytic cleavage in the extracellular domain resulting in shedding of a large portion of extracellular domain, termed CA125, from the cell surface and leaving only a short, unshed extracellular domain tethered to the cell surface. Therapies that target the region of MUC16 that is shed from the cell surface may have limited effectiveness due to their binding to CA125 in circulation which is not associated with tumor cells. In order to eliminate binding to circulating CA125, we have designed our MUC16 CAR using an antigen binding domain that specifically binds the unshed portion of MUC16 and optimized its affinity to preferentially target PRGN- 3005 to tumor cells. ~~PRGN- 3005 is being evaluated for the treatment of advanced ovarian, fallopian tube, and primary peritoneal cancers.~~ Advanced ovarian cancer is often fatal, with Stage IV survival rates as low as 20 percent, and has limited treatment options. Patients with ovarian cancer represent a large population, with approximately 300, 000 patients diagnosed worldwide annually, including 22, 000 in the United States alone. In preclinical in vitro studies, PRGN- 3005 UltraCAR- T **has** ~~cells have~~ shown robust MUC16- specific cytotoxicity of ovarian cancer cell lines, a stem- cell like memory phenotype and significant improvement in their longevity even in the absence of exogenous cytokines as compared to conventional CAR- T cells. PRGN- 3005 UltraCAR- T cells have shown significantly superior anti- tumor response in mouse models of ovarian cancer compared to mice treated with a saline solution or conventional MUC16 CAR- T cells lacking mbIL15 expression. ~~Specifically, a single administration of PRGN- 3005 one day after non- viral gene transfer showed significantly superior expansion and preferred memory phenotype of UltraCAR- T in vivo and significantly superior efficacy compared to traditional CAR- T resulting in all PRGN- 3005 treated mice becoming tumor- free. Furthermore, rechallenging these tumor- free mice three months later with ovarian tumors for a second time (to simulate tumor relapse) led to the elimination of tumor burden without additional PRGN- 3005 UltraCAR- T treatment.~~ These data demonstrated the potential of UltraCAR- T cells to persist long- term in vivo, prevent CAR- T cell exhaustion, and mount a durable anti- tumor response with the ability to continue to respond upon tumor rechallenge. ~~The Phase~~ **PRGN- 3005 is in a** 1 / 1b clinical **trial** ~~study of PRGN- 3005 is~~ designed to enroll in two phases, an initial dose escalation phase (Phase 1) followed by a dose expansion phase (Phase 1b). We have completed the Phase 1 dose escalation portion of the PRGN- 3005 Phase 1 / 1b study. The Phase 1 portion of the study is a dual- arm, non- randomized, open- label clinical trial in patients with advanced, recurrent platinum- resistant ovarian, fallopian tube or primary peritoneal cancer. Patients in the Phase 1 dose escalation trial ~~receive~~ **received** either intraperitoneal, or IP (Arm 1), or intravenous, or IV (Arm 2), administration of PRGN- 3005 without prior lymphodepletion. **After receiving** ~~Previously we had announced~~ FDA clearance ~~to~~ **, we also** ~~incorporate~~ **incorporated** a cohort with lymphodepletion at Dose Level 3 of the IV arm in the Phase 1 study. The primary objectives of the Phase 1 trial **included** ~~are to assess~~ **assessment** ~~the~~ **of** safety and maximum tolerated dose, or MTD, of PRGN- 3005 ~~. In June 2023, the Principal Investigator of the PRGN- 3005 clinical study presented Phase 1 data at the 2023 American Society of Clinical Oncology, or ASCO, Annual Meeting. The presentation included the complete data set for the Phase 1 dose escalation portion of the study~~ . The Phase 1 study enrolled a total of 27 patients (N = 12 IP; N = 6 IV; and N = 9 IV with lymphodepletion). ~~The mean age of patients in the study was 57. 4 in the IP arm without lymphodepletion, 67. 3 in the IV arm without lymphodepletion and 62. 7 in the IV arm with lymphodepletion.~~ Patients were heavily pretreated with a median of greater than or equal to 8 prior lines of therapy across all arms. Patients had significantly advanced stage disease with a high baseline tumor burden with most patients having distant metastases, including liver, spleen, bladder and lung. ~~Patients treated in the non- lymphodepletion cohort and lymphodepletion cohort received a single administration of 1. 8 to 50 x 106 and 4. 4 to 83 x 106 UltraCAR- T cells via IV infusion, respectively.~~ PRGN- 3005 **treatment** was well- tolerated with low incidence of treatment related adverse events (TRAEs), no dose limiting toxicities (DLTs), and no neurotoxicity. The most common side effects for the IV and IP arms without lymphodepletion were abdominal pain, fever and decreased absolute lymphocyte count (ALC). Serious Adverse Events included five incidences of Cytokine Release Syndrome (CRS), with no incidence of CRS greater than Grade 2. One patient with CRS required specific intervention which **was** resolved following standard CRS management after 24 hours. There was no use of tocilizumab or dexamethasone or kill switch. PRGN- 3005 administered via either IP or IV infusion resulted in a dose- dependent expansion and encouraging persistence in peripheral blood. Best responses in patients treated without lymphodepletion were stable disease with complete responses observed in certain individual target lesions. Incorporating lymphodepletion prior to IV infusion led to an encouraging anti- tumor activity with a decrease in tumor burden in 67 % (6 / 9) of patients and stable or partial response in 90 % of the individual target lesions in these patients. Subsequently, we ~~have~~ initiated the Phase 1b dose expansion study of PRGN- 3005 UltraCAR- T at Dose Level 3 with lymphodepletion prior to IV infusion. **As part of the strategic** ~~We previously communicated, based on portfolio reprioritization~~ -- **prioritization** ~~efforts~~ **of our pipeline announced in August 2024** , ~~that~~ we **have paused enrollment in** ~~will not add an extensive number of new clinical sites for~~ the Phase 1b ~~study. Instead, we anticipate to activate a new site under the CRADA with the National Cancer Institute (NCI) to continue the advancement of the Phase 1b dose expansion study without incurring major~~ clinical **trial of PRGN- 3005** ~~/ contract research organization (CRO) costs~~ . PRGN-

3006 is **an** ~~a first- in- class,~~ investigational autologous CAR- T therapy that utilizes our UltraCAR- T platform to express a CAR to target CD33, mbIL15 and a kill switch for better precision and control. CD33, also known as Siglec- 3, is a single pass transmembrane glycoprotein and a member of the sialic acid- binding immunoglobulin- like lectin super- family. CD33 is an attractive target for immunotherapy because it is over- expressed on AML blasts and leukemic stem cells, or LSCs, but is not expressed on normal blood stem cells, also known as hematopoietic stem cells. Approximately 85- 90 percent of AML patients express CD33 on their tumor cells. In addition to broad expression on AML blasts, CD33 is expressed on LSCs underlying AML. LSCs are thought to be more resistant to chemotherapy treatment and to be capable of reinitiating the disease resulting in high relapse rates for AML. In healthy subjects, CD33 is primarily expressed on normal myeloid precursors, colony- forming cells, monocytes, and maturing granulocytes. Because CD33 is not expressed outside the hematopoietic system or on normal hematopoietic stem cells, it is an attractive target for treatment of AML. AML is among the most common types of leukemia in adults with approximately 20, 000 AML patients diagnosed in the United States annually. AML is a heterogeneous disease with 50- 70 percent relapse rates and rapid progression. The prognosis for patients with AML is poor, with an average five- year survival rate of approximately 25 percent overall, and less than a 5 percent five - year survival rate for patients older than 65. More than 10, 000 cases of higher- risk MDS are diagnosed annually in the United States. Due to the aggressive nature of AML progression, rapid availability of treatment is of even greater importance in this patient population, and our non- viral UltraCAR- T manufacturing process would represent a significant potential advantage over current approaches that require long lead times for manufacturing. In preclinical studies, PRGN- 3006 demonstrated robust expansion in the presence of CD33 antigen, lack of autonomous expansion in the absence of CD33 and prolonged persistence in the absence of exogenous cytokines. PRGN- 3006 exhibited target- specific killing of CD33 tumor cells as well as a significant release of inflammatory cytokines such as IFNγ, upon co- culture with AML tumor cells. PRGN- 3006 cells were specifically eliminated by kill switch activator treatment, displaying functionality of the kill switch, which is intended to improve the safety profile of PRGN- 3006. In vivo, a single administration of PRGN- 3006 UltraCAR- T cells only one day after gene transfer effectively eliminated the tumor burden and significantly improved overall survival of tumor bearing mice compared to CAR- T cells lacking mbIL15 expression (conventional CAR- T) in an aggressive xenograft model of AML. PRGN- 3006 demonstrated engraftment and significantly higher expansion and persistence in mice compared to conventional CAR- T cells, which lack mbIL15 expression. ~~The~~ **PRGN- 3006 is in a** Phase 1 / 1b clinical **trial** ~~study of PRGN- 3006 is~~ designed to enroll in two phases, an initial dose escalation phase (Phase 1) followed by a dose expansion phase (Phase 1b). We have completed Phase 1 dose escalation portion **and completed enrollment in** ~~of the PRGN- 3006~~ Phase ~~1 /~~ 1b ~~study~~ **portion of the trial** . The Phase 1 portion of this study is a dual- arm, non- randomized, dose- escalation clinical trial where PRGN- 3006 is delivered via intravenous infusion. The patient population ~~includes~~ **included patients with** relapsed or refractory AML, or r / r AML, higher- risk MDS, and CMML. In the Phase 1 3 3 dose escalation portion, patients are treated in one of the two arms: patients in Cohort 1, or No Lymphodepletion arm, receive UltraCAR- T cell infusion without prior lymphodepletion, and patients in Cohort 2, or Lymphodepletion arm, receive lymphodepleting chemotherapy prior to UltraCAR- T infusion. The primary objective **included** ~~of this trial is to assess~~ **assessment** ~~the~~ **of** safety of PRGN- 3006 and ~~determine~~ **determination of** the MTD. The ~~Principal Investigator of the PRGN- 3006 clinical study presented complete~~ Phase 1 ~~data at the 64th American Society of Hematology (ASH) Annual Meeting and Exposition. The presentation included the complete data set for the Phase 1 dose escalation portion of the study. The~~ study enrolled a total of 26 patients (N = 10 non- lymphodepletion; N = 16 with lymphodepletion) and included 21 patients with r / r AML, 2 patients with chronic myelomonocytic leukemia (CMML), and 3 patients with MDS. The median age was 60. 5 years (range: 32- 77). Patients were heavily pre- treated with a median of 3. 5 prior regimens (range: 1- 9) and 58 % of patients (N = 15) had prior allogeneic hematopoietic stem cell transplantation (allo- HSCT). Patients treated in the non- lymphodepletion cohort and lymphodepletion cohort received a single administration of 1. 8 to 50 x 106 and 4. 4 to 83 x 106 UltraCAR- T cells via IV infusion, respectively. In both the non- lymphodepletion (Cohort 1) and the lymphodepletion (Cohort 2) cohorts, PRGN- 3006 was well- tolerated with no dose- limiting toxicities (DLTs) reported. The majority of treatment emergent adverse events (TEAEs) were either Grade 1 or 2. There was only one transient Grade 3 CRS reported in each cohort with the Cohort 2 event subsequently downgraded to Grade 1 by the investigator. Incidence of immune effector cell- associated neurotoxicity syndrome (ICANS) was rare with one Grade 1 event and one Grade 2 event in Cohort 1 and Cohort 2, respectively ~~. No patients experienced a significant increase in serum IL- 15, demonstrating that mbIL15 remains tethered to the UltraCAR- T cells as designed and is not released~~ . Excellent dose- dependent expansion and persistence of PRGN- 3006 in peripheral blood and bone marrow was observed following a single infusion in both the non- lymphodepletion and lymphodepletion cohorts highlighting the ability of UltraCAR- T cells to engraft and survive even in the absence of lymphodepletion. Higher peak expansion (> 10 fold) in peripheral blood was observed in the lymphodepletion cohort compared to non- lymphodepletion cohort at the same dose level. In the lymphodepletion cohort (Cohort 2), an objective response rate (ORR) of 27 % (3 out of 11) was reported for heavily pre- treated r / r AML patients with poor prognosis (median prior treatments: 4; range: 1- 9). ~~Responders received a single PRGN- 3006 dose ranging between 4. 4 to 28 x 106 cells following lymphodepletion.~~ A disease control rate (DCR) of 45 % (5 out of 11) **was reported** at day 28 for r / r AML patients and 100 % of MDS patients, respectively ~~. One patient with CRi was bridged to allo- HSCT at three months post treatment and remains in a measurable residual disease- negative CR 18 months post- transplant~~ . Additionally, of the 15 evaluable patients in the lymphodepletion cohort (Cohort 2), 60 % (9 out of 15) heavily pre- treated patients had a reduction in bone marrow blasts following a single PRGN- 3006 infusion, with 4 patients experiencing a substantial decrease to ≤ 5 %. Analysis of peripheral blood samples post PRGN- 3006 infusion showed gene expression changes consistent with improvement in the immune compartment function for anti- tumor effect in responders. There was an increase in cytotoxicity, costimulatory signaling, and lymphoid compartment and decreased apoptosis pathway scores in the lymphodepletion cohort on Days 14 and 28 post PRGN- 3006 treatment compared to baseline. **Based on the results of correlative studies of the patient samples from the Phase 1 / 1b study, we have identified clinical biomarkers**

that correlate to objective responses after PRGN- 3006 treatment in r / r AML patients. This advancement may further enable patient stratification and positively impact efficacy. We have ~~initiated a~~ **completed enrollment in the** Phase 1b dose expansion study ~~where PRGN- 3006 is being evaluated following lymphodepletion~~ . ~~The~~ **We are preparing for an end of** Phase 1b ~~dose expansion study of~~ **meeting with the FDA to discuss the results and next steps. We plan to focus on strategic partnership opportunities to advance** PRGN- 3006 UltraCAR- T **program** ~~was expanded to Mayo Clinic~~ in **AML** ~~Rochester, Minnesota, joining the existing Moffitt Cancer Center, Tampa, Florida site enhancing the decentralized manufacturing model~~ . PRGN- 3006 has been granted Orphan Drug designation in patients with AML and Fast Track Designation in patients with r / r AML by the FDA. PRGN- 3007 is **an** ~~a first- in- class,~~ investigational autologous CAR- T therapy that utilizes the next generation UltraCAR- T platform to express a CAR to target ROR1, mbIL15, kill switch, and a novel mechanism for the intrinsic blockade of the programmed death 1, or PD- 1, gene expression. ROR1 is a type I orphan- receptor that is expressed during embryogenesis and by certain hematological and solid tumors but is undetectable on normal adult tissues. ROR1 in malignancies is aberrantly expressed in B- cell malignancies such as B- cell acute lymphoblastic leukemia, or B- ALL, diffuse large cell B- cell lymphoma, or DLBCL, chronic lymphocytic leukemia, or CLL, and mantle cell lymphoma, or MCL. Furthermore, upregulated expression has been detected in various solid tumors, including ovarian cancer, breast adenocarcinomas encompassing triple negative breast cancer, or TNBC, pancreatic cancer, Ewing' s sarcoma and lung adenocarcinoma. The increased expression of ROR1 in hematological and solid tumor malignancies has been associated with tumor proliferation, metastasis and poor clinical outcomes. The PD- 1 / programmed death ligand 1, or PD- L1, pathway plays a vital role in how tumor cells evade immune response. While the blockade of the PD- 1 / PD- L1 pathway has demonstrated considerable benefit for treating various cancers, the use of systemic CPI can lead to side effects associated with autoimmune response. The innovative design of PRGN- 3007, where the blockade of PD- 1 expression is intrinsic and localized to UltraCAR- T cells, is aimed at avoiding systemic toxicity and the high cost of CPI by eliminating the need for combination treatment. In preclinical in vitro studies, PRGN- 3007 showed significant reduction in PD- 1 expression on UltraCAR- T cells compared to control ROR1 CAR- T cells lacking PD- 1 blockade. The downregulation of PD- 1 expression on PRGN- 3007 resulted in enhanced ROR1- specific cytotoxicity and release of inflammatory cytokines upon co- culture with various ROR1- positive, or ROR1 , PD- L1 hematological and solid tumor cells compared to Control ROR1 CAR- T, especially at low effector to target cell ratios. Single- cell cytokine proteomics showed that the downregulation of PD- 1 expression on PRGN- 3007 resulted in a significantly higher number of polyfunctional CAR- T cells compared to Control ROR1 CAR- T. ~~Expression of mbIL15 on~~ PRGN- 3007 **showed** ~~UltraCAR- T, with or without downregulation of PD- 1 expression, resulted in~~ robust expansion in presence of ROR1 antigen, lack of autonomous expansion in absence of ROR1, and durable persistence even in absence of exogenous cytokines in vitro. PRGN- 3007 was selectively and effectively eliminated by the kill switch activator treatment demonstrating functionality of the kill switch, which is intended to improve the safety profile of PRGN- 3007. In preclinical in vivo testing, a single administration of PRGN- 3007, only one day after gene transfer, effectively reduced tumor burden and significantly improved overall survival of tumor bearing mice compared to Control ROR1 CAR- T in an aggressive xenograft model of mantle cell lymphoma. Blood analyses demonstrated sustained downregulation of PD- 1 expression, rapid expansion, long- term persistence, and a predominant central memory phenotype of PRGN- 3007 in tumor bearing mice. The Phase 1 / 1b clinical trial is **designed as** an open- label study designed to evaluate the safety and efficacy of PRGN- 3007 in patients with advanced ROR1 hematological (Arm 1) and solid (Arm 2) tumors. The target patient population for Arm 1 includes relapsed or refractory CLL, relapsed or refractory MCL, relapsed or refractory B- ALL, and relapsed or refractory DLBCL. The target patient population for Arm 2 includes locally advanced unresectable or metastatic histologically confirmed TNBC. The study will enroll in two parts: an initial 3 3 dose escalation in each arm followed by a dose expansion at the maximum tolerated dose. ~~Arm 1 and Arm 2 will~~ **As part of the strategic prioritization of our pipeline announced in August 2024, we have paused** ~~enroll~~ **enrollment** in **the** ~~parallel. The~~ Phase 1 **clinical** trial **of** ~~is being conducted in collaboration with Moffitt Cancer Center, a pioneer in CAR- T clinical development.~~ PRGN- 3007 ~~manufacturing technology transfer to Moffit Cancer Center was completed for initiation of the Phase 1 study. We have initiated dosing in the Phase 1 dose escalation portion of the Phase 1 / 1b study~~ . Preclinical Programs We have a robust pipeline of preclinical programs in order to drive long- term value creation. Our pipeline includes product candidates based on UltraCAR- T and" off- the- shelf" AdenoVerse immunotherapy therapeutic platforms. We expect to continue development of a number of potential product candidates in our preclinical pipeline and, consistent with our commitment to actively manage our portfolio programs, we exercise discipline in our portfolio management by systematically evaluating data from our preclinical programs in order to make rapid" go" and" no go" decisions. Through this process, we believe we can more effectively allocate resources to programs that we believe show the most promise and advance such programs to clinical trials. Precigen ActoBio (ActoBio) ActoBio ~~is pioneering~~ **has developed** a proprietary class of microbe- based biopharmaceuticals that enable expression and local delivery of disease- modifying therapeutics. We refer to these microbe- based biopharmaceuticals as ActoBiotics. ~~Precigen~~ ActoBio ~~'~~**'** s **lead asset** ~~Therapeutic Platforms Our ActoBiotics platform~~ is ~~a unique delivery platform precisely tailored for specific disease modification with the potential for superior efficacy and safety. ActoBiotics combine the advantages of highly selective protein- based therapeutic agents with local delivery by the well- characterized and food- grade bacterium Lactococcus lactis, or L. lactis. ActoBiotics can be delivered orally in a capsule, through an oral rinse or in a topical solution. We believe ActoBiotics have the potential to provide superior safety and efficacy via the sustained release of appropriate quantities of select therapeutic agents as compared to injectable biologics, while reducing the side effects commonly attributed to systemic delivery and corresponding peaks in concentration. ActoBiotics work via genetically modified bacteria that deliver proteins and peptides at mucosal sites, rather than the insertion of one or more genes into a human cell by means of a virus or other delivery mechanism. By foregoing this insertion, ActoBiotics allow" gene therapy" without the need for cell transformation. The key advantages of ActoBiotics include: Food- grade bacterium with easy genetic manipulation ActoBiotics combine the advantages of highly~~

~~selective protein- based therapeutic agents with local delivery by the well- characterized and food- grade bacterium with L. lactis, which has a long history of safe use. ActoBiotics are generated by genetically modifying L. lactis via chromosomal integration through targeted double homologous recombination to express and release a variety of highly versatile biological moieties. Multiple therapeutic agents, such as proteins, peptides, and antibodies, can be incorporated into a single ActoBiotics therapeutic, enabling the simultaneous targeting of multiple pathways in one disease. The L. lactis host is also engineered for environmental containment, thus preventing the spread of bacteria outside the human body. Cost- effective and scalable manufacturing We have established an efficient and reliable cGMP manufacturing process for the production of ActoBiotics that we believe is easily scalable for commercial supply. The manufacturing process involves fermentation of genetically modified L. lactis to generate significant quantities of the therapeutic agent, followed by concentration and freeze- drying. The process does not require the costly purification required to produce conventional biologics. Convenient delivery method ActoBiotics can be delivered to the oral cavity through a mouthwash, intestinally via a capsule, or through a topical formula. Physiological dosing is low, and our ActoBiotics product candidates have been well- tolerated in preclinical and clinical studies. As compared to conventional biologics, we believe ActoBiotics have the potential to provide superior safety and efficacy via the sustained release of appropriate quantities of select therapeutic agents while reducing the side- effects commonly attributed to systemic delivery and corresponding peaks in concentration of conventional biologics. ActoBio' s most advanced internal pipeline candidate,~~ AG019, ~~is~~ a ~~first- in- class~~ disease modifying antigen- specific, investigational immunotherapy for the prevention, delay, or reversal of type 1 diabetes mellitus, or T1D ~~. AG019 is an easy- to- take capsule formulation of ActoBiotics engineered to deliver the autoantigen human proinsulin, or hPINS, and the tolerance- enhancing cytokine human interleukin- 10 to the mucosal lining of gastro- intestinal tissues in patients with T1D. We believe this design can reduce T1D pathology by reestablishing immunological tolerance to islet antigens via the production of regulatory T, or Treg, cells. T1D represents a highly unmet medical need, with approximately 132, 000 patients, most commonly children and young adults, diagnosed each year. In T1D, the immune system destroys insulin- producing beta cells in the pancreas, creating a blood glucose imbalance and numerous symptoms, including polyuria, polydipsia, polyphagia, weight loss, lassitude, nausea and blurred vision. The current treatment standard for T1D consists of exogenous insulin along with diet and lifestyle modification, but no disease- modifying treatment is available. We believe that AG019 has the potential to address the unmet medical need for disease modifying treatment in T1D. Preclinical studies in mice have shown that AG019, in association with a short- term treatment with a low- dose anti- CD3 monoclonal antibody, induced stable reversion to normal blood sugar levels and reversed the disease in diabetic mice treated at an early stage. Furthermore, AG019 treatment induced accumulation and proliferation of PINS- specific FoxP3 Treg cells in the pancreas and peripheral lymph nodes~~ . We have completed a Phase 1b / 2a clinical trial of AG019 for the treatment of early- onset T1D. **As part** ~~The Phase 1b open- label portion~~ of ~~the study evaluated the safety and tolerability of AG019 monotherapy administered as a single dose and repeated daily doses in adult and adolescent patients. The Phase 2a double- blind portion of the study investigated the safety and tolerability of AG019 in combination with teplizumab, or~~ **our strategic prioritization, we have completed** ~~TZIELD. The primary endpoint of both~~ the **shutdown of** ~~Phase 1b AG019 monotherapy and the Phase 2a AG019 combination therapy was met. AG019 was well- tolerated when administered to adults and adolescents either as monotherapy or~~ **our ActoBio subsidiary operations, including** ~~in combination with teplizumab. A single 8- week treatment cycle of oral AG019 as a monotherapy and in combination with teplizumab showed stabilization or increase of C- peptide levels during~~ the **elimination of all ActoBio personnel** ~~first 6 months post treatment initiation in recent- onset T1D~~ . In ~~an independent analysis performed in a subset of adult and adolescent patients by the Immune Tolerance Network (ITN), a leading independent research group sponsored by the United States National Institutes of Health, AG019 monotherapy and combination therapy induced antigen- specific tolerance in~~ conjunction with ~~the reduction of disease- specific T- cell responses. The extent of these antigen- specific immune modulatory effects in the combination therapy patients was similar to what was seen in AG019 monotherapy patients indicating that~~ this **shutdown, ActoBio' s portfolio** ~~effect may be attributed to the single 8- week treatment cycle~~ of ~~oral AG019~~ **intellectual property is available for prospective transactions** . Exemplar is committed to enabling the study of life- threatening human diseases through the development of MiniSwine Yucatan miniature pig research models and services. Historically, researchers have lacked animal models that faithfully represent human diseases. As a result, a sizeable barrier has blocked progress in the discovery of human disease mechanisms; novel diagnostics, procedures, devices, prevention strategies and therapeutics; and the ability to predict in humans the efficacy of those next- generation procedures, devices, and therapeutics. Exemplar' s MiniSwine models are genetically engineered to exhibit a wide variety of human disease states, which provides a more accurate platform to test the efficacy of new medications and devices. As of December 31, ~~2023~~ **2024** , Exemplar had 25 employees. Exemplar' s primary domestic production facilities are located in Sioux County and Johnson County, Iowa, and include approximately 57, 960 square feet of production, lab, and office facilities. Competition: Healthcare Business While we believe that our novel approach to developing the next generation of gene and cell therapies utilizing our **AdenoVerse and** UltraCAR- T ~~, AdenoVerse immunotherapy or ActoBiotics platform~~ **platforms** to target the most urgent and intractable challenges in immuno- oncology, autoimmune disorders, and infectious diseases provides us with competitive advantages, our industry is highly competitive and subject to rapid and significant technological change. Many of our competitors have significantly greater financial, technical, and human resource capabilities than we do, and certain of our competitors may also benefit from local government subsidies and other incentives that are not available to us. In addition, mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. As a result of the resources available to our competitors, our competitors may be able to develop competing and / or superior technologies and processes, and compete more aggressively and sustain that competition over a longer period of time than we can. Product candidates that we successfully develop and commercialize will compete with a range of therapies that are currently approved and any new therapies that may become available in the future. Our ability to compete successfully will depend on our ability to develop proprietary

technologies that can be used to produce products that reach the market in a timely manner and are technologically superior to and / or are less expensive than other products on the market. The availability of reimbursement from government and other third- party payers will also significantly affect the pricing and competitiveness of our products. Our competitors may also obtain FDA 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 before we are able to enter the market. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products, as well as the availability of intellectual property protection. **AdenoVerse Immunotherapy** For our product candidate PRGN- 2012 for the treatment of RRP,while we believe our approach for PRGN- 2012 is novel based on the design of antigen targeting HPV6 and HPV11 and use of our gorilla adenovector,we face competition in the treatment of RRP.We believe our main competitor in the field is INOVIO Pharmaceuticals with their investigational DNA vaccine INO- 3107 targeting HPV6 and HPV11 antigens.For our PRGN- 2009 candidate in HPV- associated cancers,we believe that INOVIO Pharmaceuticals,BioNTech SE,PDS Biotechnology,Hookipa Pharma ~~and ,~~ Transgene S.A. **and Nykode Therapeutics** are developing immunotherapies that are in clinical testing.TG4001 is an investigational therapeutic cancer vaccine candidate using an attenuated and modified poxvirus,or MVA,as a vector expressing the HPV16 E6 and E7 proteins and interleukin- 2.We believe TG4001 is in a clinical trial in combination with anti- PD- L1 antibody avelumab for anogenital HPV cancers.INOVIO' s lead investigational candidate VGX- 3100 is a plasmid DNA based vaccine designed to increase T cell immune responses against the E6 and E7 antigens of HPV16 and HPV18.VGX- 3100 is in clinical trials for precancerous cervical dysplasia,vulvar dysplasia,and anal dysplasia. ~~Inovio~~ **INOVIO** is also developing INO- 3112,a DNA medicine candidate targeting HPV 16 / 18,combined with a DNA plasmid for IL- 12 in combination with an anti- PD1 monoclonal antibody for locoregionally advanced,high- risk,HPV16 / 18 positive oropharyngeal squamous cell carcinoma.We believe BioNTech is developing BNT113,an investigational HPV16 E6 / 7 mRNA vaccine.We believe BNT113 in combination with an anti- PD1 monoclonal antibody is in a clinical trial for HPV16 PD1 Head and Neck squamous cell carcinoma.We believe PDS Biotechnology is developing ~~PDS- 0101~~ **Versamune ® HPV (previously PDS0101)** ,an investigational HPV16 peptide vaccine for various HPV- associated cancers.We believe ~~PDS0101~~ **Versamune HPV** is in clinical trials as monotherapy and combination therapy for recurrent / metastatic HPV16 head and neck cancer,pre- metastatic HPV- associated oropharyngeal cancer,and HPV anal,cervical,head and neck,penile,vaginal,vulvar cancers.We believe Hookipa is developing **Eseba- vec (** HB- 200 **)** ,based on two single- vector compounds with arenaviral backbones based on lymphocytic choriomeningitis virus and pichinde virus expressing the same transgene encoding an HPV16 E7E6 fusion protein,which is in a clinical trial for HPV16 head and neck cancers.Cellid is developing BVAC- C,which is based on CeliVax technology that uses patient- derived B cells and monocytes transfected with E6 / E7 recombination gene of HPV16 and HPV18 and loaded with an adjuvant for HPV- associated cancers. **Nykode Therapeutics is developing VB10.16,a DNA- based therapeutic vaccine targeting malignancies caused by HPV16,which is being evaluated in multiple clinical trials.** In addition to our direct competitors developing vaccines for treatment of HPV- associated cancers,various development- stage companies are involved in different vaccine and immunotherapy technologies,including ~~Advaxis Immunotherapies,and~~ Bavarian Nordic.We also face competition from non- vaccine based approaches being developed by companies such as Kite,Iovance,Bristol- Myers Squibb,and Merck. ~~Actobio We are using our suite of proprietary and complementary synthetic biology technologies for the preclinical and clinical development of product candidates for the treatment of autoimmune disorders,including T1D.While we believe AG019 is the first disease~~ Our lead product candidates include PRGN- 3005, PRGN- 3006, and PRGN- 3007, each of which are built on our UltraCAR- T platform. While we are employing a novel approach, there are a number of competitors pursuing CAR- T cell therapies for the treatment of cancer. We believe that, among others, Bristol- Myers Squibb, and Anixa Biosciences are developing CAR- T based treatments for ovarian cancer and Adaptimmune is developing TCR- T based treatment for ovarian cancer. We believe that Kite, Amgen, Cellectis S. A., Autolus and Allogene Therapeutics are also using CAR- T technology to develop product candidates for the treatment of AML. We believe that Lyell Immunopharma, and Oncternal Therapeutics are developing ROR1 CAR- T cells for treatment of ROR1- positive ~~cancers. We believe that INOVIO Pharmaceuticals, AstraZeneca, Transgene SA, PDS Biotech, and Advaxis Immunotherapies are developing immunotherapies against HPV- associated~~ cancers. Anixa Biosciences is developing an autologous CAR- T treatment targeting follicle stimulating hormone receptor (FSHR) for ovarian cancer, which we believe is in a clinical trial. Arsenal Biosciences is developing AB- 1015 CAR- T, which we believe is in a clinical trial for platinum resistant ovarian cancer. Adaptimmune is developing ADP- A2M4CD8 TCR T- cell therapy that coepxresses CD8α co- receptor alongside the engineered TCR targeting MAGE- A4 which we believe is in a clinical trial. Regeneron and 2seventy bio are developing bbT4015, an engineered CAR T- cell therapy targeting MUC16, which we believe is in preclinical development. For the treatment of AML using cell therapies, we believe that Kite, 2seventy bio and Nkarta have product candidates in the most advanced clinical trials. ~~Kite is developing KITE- 222, an investigational autologous T- cell therapy engineered with a CAR that specifically targets CLL- 1 for treatment of AML. We believe that 2seventy bio is developing DARIC33, a pharmacologically controlled CD33- targeted CAR- T therapy which is in a clinical trial for pediatric AML.~~ Nkarta is developing NKX101, an investigational allogeneic NK cell therapy expressing a CAR target NKG2D ligands and mbIL- 15. We believe NKX101 is in a clinical trial for AML and MDS. ~~Amgen is developing AMG 553, an FMS- like tyrosine kinase 3, or FLT3, CAR- T cell therapy utilizing autologous T- cells genetically modified ex vivo to express a transmembrane CAR to target FLT3 protein on the surface of AML cells irrespective of FLT3 mutational status. Celleetis S. A. is also developing UCART123, an allogeneic anti- CD123 CAR- T cell therapy, which utilizes lentivector transduction followed by TALEN- mediated gene editing to eliminate expression of TCRαβ from donor T- cells.~~ Vor Biopharma is developing **Trem- cel (** VOR33 **)** , an investigational hematopoietic stem cell (HSC) therapy with elimination of CD33 expression via gene- editing, in combination with MylotargTM, an anti- CD33 antibody drug conjugate (ADC). Vor Biopharma is also developing VCAR33, an autologous anti- CD33 CAR- T as a monotherapy and in combination with ~~VOR33~~ **Trem- cel** . We believe

Autolus is developing AUTO09, an autologous CAR- T targeting CD33, CD123 and CLL- 1, is in preclinical development. ~~Finally~~ **We believe Arcellx is developing ACLX- 002** , **CAR- T targeting CD123 based on ARC- SparX platform. We believe** Allogene Therapeutics' allogeneic CAR- T ~~therapies~~ **therapy** ALLO ~~- 316 and ALLO- 819~~ , targeting ~~FLT3 and~~ CD70 **is** ~~, respectively, which we believe are in preclinical and discovery stage of development respectively, are~~ manufactured using healthy donor T- cells that are engineered using lentiviral transduction to express CAR followed by gene editing to eliminate expression of TCR to reduce the potential of rejection of therapy by a patient' s immune system. ~~Lyell Immunopharma is developing LYL797, a ROR1- targeted CAR T- cell product, which we believe recently received FDA clearance to initiate Phase 1 clinical trial for patients with relapsed / refractory ROR1 TNBC or non- small cell lung cancer, or NSCLC, and other solid tumors. We believe that Lyell is also developing another ROR1 CAR- T candidate, LYL119, which is in preclinical development for ROR1 solid tumors.~~ Oncternal Therapeutics is developing ONCT- 808, a ROR1 targeted autologous CAR- T cell therapy, which we believe is ~~currently~~ in a **clinical trial** ~~Phase 1 / 2 study~~ in patients with relapsed / refractory aggressive B cell malignancies. In addition to our direct competitors that are using CAR- T therapies specifically for the treatment of ovarian cancer and AML, the CAR- T technology space has significant other competition including from multiple companies and their collaborators, such as Novartis and University of Pennsylvania, Kite and Gilead, Bristol- Myers Squibb, Janssen and Legend Biotech, Adaptimmune, Autolus Therapeutics, **Roche and** Poseida Therapeutics, **and** Gracell and AstraZeneca ~~, and Bellicum Pharmaceuticals~~ . We also face competition from non- cell based cancer treatments offered by other companies such as Amgen, AstraZeneca, Incyte, Merck, Abbvie, and Roche. See" Precigen' s Therapeutic Platforms" for a discussion of the features that we believe differentiate our UltraCAR- T treatments from our competitors. For our product candidate PRGN- 2012....., Midatech Pharma, and MerciaPharma. Precigen Exemplar **provides** ~~is providing~~ porcine research models and services that aid scientists in the understanding of human disease mechanisms and development of new therapeutics. We use precise genome modification to recapitulate numerous human diseases in our Yucatan MiniSwine platform, which are utilized by our industry and academic clientele for the development of new small ~~molecule~~ **molecules** , gene, and cell therapies. We believe that the primary competitors of Exemplar are smaller privately owned entities. We apply a multilayered approach for protecting intellectual property relating to the inventions we have developed internally, as well as those we have acquired from third parties, such as by assignment or by in- license. As we advance technologies, we evaluate and determine under the circumstances what type or types of intellectual property is appropriate for the technology, including patents, trademarks, know-how and trade secret protections. We seek patent protection in the United States and in other countries for our inventions, and we develop and protect our know- how and trade secrets relating to our platform technologies, as well as to our pipeline products including those of our subsidiaries and collaborators. For instance, we pursue protection to switch technologies, gene delivery technologies, and genetic componentry related to our pipeline products. In addition, we seek patents covering specific collaborator' s products. We focus our intellectual property on aspects of our platforms and technologies that provide for the design and creation of cells, vectors and components for our pipeline and the pipelines of our collaborators, as well as technologies directed to improve delivery and expression of our pipeline products. Our success depends, in part, upon our ability to obtain patents and maintain adequate protection for our intellectual property relating to our technologies and product pipeline. We have adopted a strategy of seeking patent protection in the United States and in other jurisdictions globally as we deem appropriate under the circumstances, with respect to certain of the technologies used in or relating to our technologies and product pipeline. For instance, where we believe appropriate, we have counterpart patents and patent applications in other jurisdictions, such as Australia, Canada, China, Europe, Hong Kong, India, Israel, Japan, Korea, and South Africa. In the future, we may file in these or additional jurisdictions as deemed appropriate for the protection of our technologies. As of December 31, ~~2023~~ **2024** , we owned or in- licensed patents in the United States and have pending United States patent applications relating to various aspects of our platforms and technologies, and we have pursued counterpart patents and patent applications in other jurisdictions around the world, as we have deemed appropriate. We continue to actively develop our portfolio through the filing of new patent applications, provisional and continuations or divisionals relating to our advancing technologies, methods and products as we and our collaborators deem appropriate. We work to maintain protection for our key technologies including: our various switch technologies, with a last to expire patent currently in ~~2038~~ **2039** ; our portfolio around various gene delivery technologies and their use, with a last to expire patent in ~~2040~~ **2046** ; and our portfolio around various genetic componentry such as specialized vectors containing these genetic componentry and their use, with a last to expire patent in 2044. Although we have no certainty that these patents will not be subject to challenge in the future, as of this filing, there are currently no material contested proceedings and / or third- party claims with respect to any of these patent portfolios. Additionally, we complement our intellectual property portfolio with exclusive and non- exclusive patent licenses and options for licenses to third- party technologies. We further solidify our intellectual property protection through a combination of trade secrets, know- how, confidentiality, nondisclosure and other contractual provisions, and security measures to protect our confidential and proprietary information related to each platform and collaborator program. We regularly assess and review the risks and benefits of protecting our developments through various aspects of intellectual property available to us. Because we rely on trade secrets, know- how, and continuing technological advances to protect various aspects of our technology, we require our employees, consultants and scientific collaborators to execute confidentiality and invention assignment agreements with us to maintain the confidentiality of our trade secrets and proprietary information. Our confidentiality agreements generally provide that the employee, consultant or scientific collaborator will not disclose our confidential information to third parties. These agreements also provide that inventions conceived by the employee, consultant or scientific collaborator in the course of working for us will be our exclusive property. Additionally, our employees agree to take certain steps to facilitate our assertion of ownership over such intellectual property. These measures may not adequately protect our trade secrets or other proprietary information. If they do not adequately protect our rights, third parties could use our technologies, and we could lose any competitive advantage we may have. In addition, others may independently develop similar proprietary information or techniques or otherwise gain access

to our trade secrets, which could impair any competitive advantage we may have. Regulatory Environment With our diverse portfolio of proprietary technologies and novel therapeutic candidates, we are subject to significant and diverse regulations governing, among other things, research, operations and product approval. Regulatory compliance is critical to our ability to operate, our management of potential liabilities, and ultimately, our freedom to sell our products. Moreover, the products we are pursuing or are produced by us are subject to extensive regulation. Moreover, to the extent we utilize, now and in the future, third party service providers or license our programs to collaborators, we will need to rely on such third parties' compliance with laws and regulations applicable to the products or services they provide. We may not be able to independently monitor whether such third parties comply with applicable laws and regulations. Please see the risk factor entitled" We may rely on third parties, including through collaborations, to develop and commercialize some of our product candidates. Markets in which our collaborators develop product candidates using our technologies are subject to extensive regulation, and we will rely on our collaborators to comply with all applicable laws and regulations." Environmental regulations affecting our business We are subject to various federal, state and local environmental laws, rules and regulations, including those relating to the discharge of materials into the air, water and ground; the generation, storage, handling, use, transportation and disposal of hazardous materials; and the health and safety of employees with respect to laboratory activities required for the development of products and technologies. These laws and regulations require us to obtain environmental permits and comply with numerous environmental restrictions. These laws and regulations also may require expensive pollution control equipment or operational changes to limit actual or potential impacts to the environment. Our laboratory activities inherently involve the use of potentially hazardous materials, which are subject to health, safety and environmental regulations. We design our infrastructure, procedures, and equipment to meet our obligations under these regulations. We perform recurring internal and third- party audits and provide employees ongoing training and support, as required. All of our employees must comply with safety instructions and procedures, which are codified in our employment policies. Federal and state laws and regulations impose requirements on the production, importation, use, and disposal of chemicals and genetically- modified material which impact us. Our processes may contain genetically engineered organisms which, when used in industrial processes, are considered new chemicals under the Toxic Substances Control Act program of the United States Environmental Protection Agency, or EPA. These laws and regulations would require us to obtain and comply with the EPA' s Microbial Commercial Activity Notice process to operate. In the European Union, we may be subject to a chemical regulatory program known as REACH (Registration, Evaluation, Authorization and Restriction of Chemical Substances). Under REACH, companies are required to register their products with the European Commission, and the registration process could result in significant costs or delay the manufacture or sale of products in the European Union. Healthcare regulations affecting our business Human therapeutics regulation Governmental authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, including any manufacturing changes, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, sale, marketing, import and export of therapeutic products such as those being developed by us. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes, regulations, and requirements imposed by regulatory agencies, require the expenditure of substantial time and financial resources. In the United States, pharmaceuticals and biological products must receive approval from the FDA before being marketed. The FDA approves drug products other than biological products through its authority under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations. The FDA licenses biological products, or biologics, through its authority under the Public Health Service Act, or PHSA, and implementing regulations. The development processes for obtaining FDA approval for a non- biological drug product under the FDCA and for biologic licensure under the PHSA are generally similar but have product- related differences reflected in regulations and in FDA guidance documents. United States pharmaceutical development process The process required by the FDA before a pharmaceutical product candidate may be marketed generally involves the following: • completion of preclinical laboratory tests and in vivo studies in accordance with applicable regulatory requirements, which may include the FDA' s current Good Laboratory Practice regulations and the Animal Welfare Act; • submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials commence; • performance of adequate and well- controlled human clinical trials according to the FDA' s Good Clinical Practices, or GCP, regulations, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed product candidate for each intended use; • preparation and submission to the FDA of an application for marketing approval that includes substantial evidence of safety, purity and potency for a biologic, or of safety and efficacy for a non- biologic drug, including from results of nonclinical testing and clinical trials; • satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product candidate is produced to assess compliance with cGMP and that the methods and controls are adequate to assure the product candidate' s identity, safety, strength, quality, potency and purity; • potential FDA inspection of the nonclinical and clinical trial sites that generated the data in support of the application; and • FDA review and approval of the application. Preclinical testing Before testing any product candidate in humans in the United States, a company must develop preclinical data, generally including laboratory evaluation of the product candidate' s chemistry and formulation, as well as toxicological and pharmacological studies in animal species to assess safety and quality. Certain types of animal studies must be conducted in compliance with the FDA' s Good Laboratory Practice regulations and the Animal Welfare Act, which is enforced by the Department of Agriculture. IND application A person or entity sponsoring clinical trials in the United States to evaluate a product candidate' s safety and effectiveness must submit to the FDA, prior to commencing such trials, an IND application, which contains preclinical testing results and other data and information that allow the FDA to evaluate whether there is an adequate basis for testing the drug in humans. If the FDA does not object to the IND application within 30 days of submission, the clinical testing proposed in the IND may begin. Even after the IND has gone into effect and clinical testing has begun, the FDA may put clinical trials on" clinical hold," suspending or, in some cases, ending them because

of safety concerns or for other reasons. Human clinical trials under an IND Clinical trials involve administering the product candidate to healthy volunteers or patients under the supervision of qualified investigators. Clinical trials must be conducted and monitored in accordance with the FDA' s regulations, such as GCP requirements. Each clinical trial must also be conducted under a protocol that details, among other things, the study objectives, parameters for monitoring safety, and the efficacy criteria, if any, to be evaluated. The protocol is submitted to the FDA as part of the IND and reviewed by the agency. Further, each clinical trial must be reviewed and approved by an Institutional Review Board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers, among other things, whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The sponsor of a clinical trial, the investigators, and IRBs each must comply with requirements and restrictions that govern, among other things, obtaining informed consent from each study subject, complying with the protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting adverse events. Clinical trials involving recombinant or synthetic nucleic acid molecules, such as DNA, conducted at institutions that receive any funding from the National Institutes of Health also must be reviewed by an institutional biosafety committee, an institutional committee that reviews and oversees basic and clinical research that utilizes recombinant DNA at that institution. The sponsor of a clinical trial or the sponsor' s designated responsible party may be required to register certain information about the trial and disclose certain results on government or independent registry websites, such as clinicaltrials. gov. Human clinical trials typically are conducted in three sequential phases that may overlap or be combined: • Phase 1. The product candidate is introduced into a small number of healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain early understanding of its effectiveness. For some product candidates for severe or life- threatening diseases, especially when the product candidate may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients with the targeted disease. • Phase 2. The product candidate is administered and evaluated in a limited patient population to identify possible adverse effects and safety risks, to evaluate preliminary efficacy evidence for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule. • Phase 3. The product candidate is administered to an expanded patient population with the target disease or disorder, often at geographically dispersed clinical trial sites, in adequate and well- controlled clinical trials to generate sufficient data to evaluate the safety and efficacy of the non- biologic drug, or the safety, purity, and potency of the biologic. These clinical trials are intended to establish the overall risk / benefit profile of the product candidate and provide an adequate basis for product labeling. Post- approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted, or may be required to be conducted, after initial approval to further assess the risk / benefit profile of the product and to gain additional experience from treatment of patients in the intended indication, including for long- term safety follow- up. Additional regulation for gene therapy clinical trials Additional standards apply to clinical trials involving gene therapy. The FDA has issued guidance documents regarding gene therapies, which relate to, among other things: preclinical assessments; chemistry, manufacturing and controls, or CMC, information that should be included in an IND application; the proper design of tests to measure product potency in support of an application; and long- term follow- up measures to observe delayed adverse effects in subjects exposed to investigational gene therapies when the risk of such effects is not low or when the gene therapy utilizes genome- editing technology, shows signs of persistence, has the potential for latency and reactivation, or genetically alters the human genome. United States review and approval processes The results of the preclinical tests and clinical trials, together with detailed information relating to the product' s CMC and proposed labeling, among other things, are submitted to the FDA as part of an application requesting approval to market the product for one or more uses, or indications. When an application is submitted, the FDA makes an initial determination as to whether the application is sufficiently complete to be accepted for review. If the application is not, the FDA may refuse to accept the application for filing and request additional information. A refusal to file, which requires resubmission of the application with the requested additional information, delays review of the application. For gene therapies, selecting patients with applicable genetic defects is often a necessary condition to effective treatment and may require diagnostic devices that the FDA has cleared or approved prior to or contemporaneously with approval of the gene therapy. Under the Pediatric Research Equity Act, or PREA, certain marketing applications generally must contain data to assess the safety and effectiveness of the product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product candidate is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any product candidate for an indication for which orphan designation has been granted. On the basis of the marketing application and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information for the FDA to reconsider the application. If those deficiencies have been addressed to the FDA' s satisfaction in a resubmission of the application, the FDA may issue an approval letter. If a product candidate receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a Risk Evaluation and Mitigation Strategy, or REMS, or otherwise limit the scope of any approval. In addition, the FDA may require postmarketing clinical trials designed to further assess the risk / benefit profile of the product and to gain additional experience from treatment of patients in the intended indication, including for long- term safety follow- up. Compliance with cGMP requirements Drug and biologics manufacturers must comply with applicable cGMP regulations. Manufacturers and others involved in the manufacture and distribution of such products also must register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must

register and provide additional information to the FDA upon their initial participation in the manufacturing of drugs. Establishments may be subject to periodic, unannounced inspections by the FDA and other government authorities to ensure compliance with cGMP requirements and other laws. Discovery of problems may result in a government entity placing restrictions on a product, manufacturer or holder of an approved product application and may extend to requiring withdrawal of the product from the market. Orphan Drug Designation in the United States Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs and biological products intended to treat a" rare disease or condition," which generally is a disease or condition that affects fewer than 200, 000 individuals in the United States. Orphan drug designation must be requested before submitting a marketing application or supplement seeking approval for the orphan indication. After the FDA grants orphan drug designation, the common identity of the therapeutic agent and its potential orphan use are publicly disclosed by the FDA. Orphan drug designation does not — by itself — convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product that has an orphan drug designation subsequently receives the first FDA approval for that drug or biologic for the indication for which it has been designated, the product is entitled to an orphan exclusivity period in which the FDA may not approve any other applications to market the same drug or biologic for the same indication for seven years. Exceptions to the seven- year exclusivity period may apply in limited circumstances, such as where the sponsor of a different version of the product is able to demonstrate that its product is clinically superior to the approved orphan drug product. This exclusivity does not prevent a competitor from obtaining approval to market a different product that treats the same disease or condition, or the same product to treat a different disease or condition. The FDA can revoke a product' s orphan drug exclusivity under certain circumstances, including when the holder of the approved orphan drug application is unable to assure the availability of sufficient quantities of the drug to meet patient needs. Orphan exclusivity operates independently from other regulatory exclusivities and other protections against generic or biosimilar competition. A sponsor of a product application that has received an orphan drug designation is also granted tax incentives for clinical research undertaken to support the application. In addition, the FDA may coordinate with the sponsor on research study design for an orphan drug and may exercise its discretion to grant marketing approval on the basis of more limited product safety and efficacy data than would ordinarily be required, based on the limited size of the applicable patient population. Orphan drug designation does not, however, change the legal standard required for a product candidate to obtain FDA approval. The FDA has a number of expedited review programs for drugs that are intended for the treatment of a serious or life- threatening condition. As one example, under the agency' s Fast Track program, the sponsor of a new drug candidate may request the FDA to designate the product for a specific indication as a Fast Track product concurrent with or after the filing of the IND for the product candidate, if nonclinical and clinical data demonstrate the product' s potential to address unmet medical needs and the product is intended to treat a serious condition. The FDA must determine if the product candidate qualifies for Fast Track designation within 60 days after receipt of the sponsor' s request. In addition to other benefits, such as the ability to have more frequent interactions with the FDA, the agency may initiate review of sections of a Fast Track product' s marketing application before the application is complete. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA' s review period for a Fast Track application does not begin until the last section of the marketing application is submitted. In addition, the Fast Track designation may be withdrawn by the FDA if the agency believes that the designation is no longer supported by data emerging in the clinical trial process. Regenerative Medicine Advanced Therapy Designation The FDA may grant regenerative medicine advanced therapy, or RMAT, designation to regenerative medicine therapies, which may include cell therapies, human gene therapies, therapeutic tissue engineering products, and human cell and tissue products, if certain criteria are met. In particular, a drug may be eligible for RMAT designation if the drug is a regenerative medicine therapy as defined in Section 506 (g) (8) of the FDCA; the drug is intended to treat, modify, reverse, or cure a serious or life- threatening disease or condition; and preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease and condition. The FDA must determine if the product candidate qualifies for RMAT designation within 60 days after receipt of the sponsor' s request. A grant of RMAT designation includes all of the benefits of Fast Track designation, intensive guidance on efficient drug development beginning as early as Phase 1, and organizational commitment involving senior managers. The RMAT designation may be withdrawn by the FDA if the agency believes that the designation is no longer supported by data emerging in the clinical trial process. A Breakthrough Therapy designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint (s). The FDA may expedite the development and review of the application for approval of drugs that are intended to treat a serious or life- threatening disease or condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Under the Breakthrough Therapy program, the sponsor of a new product candidate may request that the FDA designate the product candidate for a specific indication as a breakthrough therapy concurrent with, or after, the filing of the IND for the product candidate. A Breakthrough Therapy designation provides all Fast Track designation features, offers intensive guidance on an efficient drug development program and ensures organizational commitment involving senior management at FDA. The FDA must determine if the product candidate qualifies for Breakthrough Therapy designation within 60 days of receipt of the sponsor’ s request. Post- approval requirements Rigorous and extensive FDA regulation of drugs and biologics continues after approval, including requirements relating to recordkeeping, periodic reporting, product sampling and distribution, adverse experiences with the product, cGMP, and advertising and promotion. Changes to the product, manufacturing process, or facility often require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval. Additionally, the FDA may require postmarketing studies or clinical trials, changes to a product' s approved labeling, including the addition of new warnings and contraindications, or the implementation

of other risk management measures, including distribution restrictions, if new safety information emerges. Failure to comply with the applicable requirements may result in administrative, judicial, civil or criminal actions and adverse publicity. These actions may include FDA' s refusal to approve or delay in approving pending applications or supplemental applications, withdrawal of approval, clinical hold, suspension or termination of clinical trial, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines or other monetary penalties, refusals of government contracts, mandated corrective advertising or communications with healthcare providers, debarment, restitution, disgorgement of profits or other civil or criminal penalties. Regulatory Exclusivity and Biosimilar Competition in the United States In 2010, the federal Biologics Price Competition and Innovation Act, or BPCIA, was enacted, creating a statutory pathway for licensure, or approval, of biological products that are biosimilar to, and possibly interchangeable with, reference biological products licensed under the Public Health Service Act. Under the BPCIA, innovator manufacturers of original biological products are granted twelve years of marketing exclusivity after first licensure before biosimilar versions of such products can be licensed for marketing in the United States. This means that the FDA may not approve an application for a biosimilar product that references data in an innovator' s Biologics License Application, or BLA, until 12 years after the date of approval of the reference biological product, with a potential six- month extension of exclusivity if certain pediatric studies are conducted and the results are reported to the FDA. A biosimilar application may be submitted four years after the date of licensure of the reference biological product, but the FDA cannot approve the application until the full exclusivity period has expired. This 12- year exclusivity period operates independently from other protections that may apply to biosimilar competitors, including patents that are held for those products. Additionally, the BPCIA establishes procedures by which the biosimilar applicant must provide information about its application and product to the reference product sponsor and by which information about potentially relevant patents may be shared and litigation over patents may proceed in advance of approval. The BPCIA also provides a period of exclusivity for the first biosimilar to be determined by the FDA to be interchangeable with the reference product. Under the Best Pharmaceuticals for Children Act, which was subsequently made applicable to biological products by the BPCIA, the FDA may also issue a Written Request asking a sponsor to conduct pediatric studies related to a particular active moiety; if the sponsor agrees and meets certain requirements, the sponsor may be eligible to receive an additional six months of marketing exclusivity for its drug product containing such active moiety. Other regulatory exclusivity may be granted to drugs, including, but not limited to, three- year and five- year exclusivity granted to non- biologic drugs under the Drug Price Competition and Patent Term Restoration Act of 1984, also referred to as the Hatch- Waxman Amendments. Depending upon the timing, duration, and specifics of FDA approval of a product candidate, some of a sponsor' s United States patents may be eligible for limited patent term extension under the Hatch- Waxman Amendments. The Hatch- Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product' s approval date. The United States Patent and Trademark Office, or USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. Only one patent applicable to an approved drug product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. Foreign regulation of human therapeutics In addition to regulations in the United States, Precigen and ActoBio, and any third party service providers or collaborators will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of the products enabled by our technologies outside of the United States. Whether or not the developer obtains FDA approval for a product, they must obtain approval by the comparable regulatory authorities of foreign countries or economic areas, such as the European Union, before they may commence clinical trials or market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval. Under Regulation (EC) No 141 / 2000, PRGN- 2012 Orphan drug designation in the European Union (EU) was granted by the European Commission in January 2024 based on a positive opinion issued by the European Medicines Agency (EMA) adopted by the Committee for Orphan Medicinal Products (COMP). Anti- Kickback, False Claims, and Other Marketing and Fraud and Abuse Laws Healthcare providers, physicians and others will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with healthcare providers, patients and third- party payers will expose us to broadly applicable United States fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and any collaborative partners through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations are discussed in the" Risk Factors" section below. Privacy Laws In the United States, we may be subject to data privacy and security laws and regulations by both the federal government and the states in which we conduct our business. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. Numerous federal and state laws and regulations, including state data breach notification laws, state health information and / or genetic privacy laws and federal and state consumer protection laws (e. g., Section 5 of the Federal Trade Commission, or FTC, Act and the California Consumer Privacy Act, as amended by the California Privacy Rights Act, or CCPA), govern the collection, use, disclosure, protection and other processing of health- related and other personal information. Many of these laws differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Compliance with these laws is difficult, constantly evolving, and time consuming. Federal regulators, state attorneys general, and plaintiffs' attorneys, including class action attorneys, have been and will likely continue to be active in this space. The Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. We may obtain health information from third parties, such as research institutions, that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA other than

with respect to providing certain employee benefits, we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. In addition, the CCPA establishes certain requirements for data use and sharing transparency, and provides California residents certain rights concerning the use, disclosure, and retention of their personal data. The CCPA and its implementing regulations have already been amended multiple times since their enactment. Similarly, **numerous other states have enacted, or are considering enacting, comprehensive data privacy laws that share similarities with the CCPA, and** there are a number of legislative proposals in the United States ~~,~~ at ~~both~~ the federal ~~and state~~ level ~~that~~ **, in each case which** could impose new obligations or limitations in areas affecting our business. These laws and regulations are evolving and subject to interpretation, and may impose limitations on our activities or otherwise adversely affect our business. The CCPA and evolving legislation may require us, among other things, to update our notices and develop new processes internally and with our partners. Internationally, laws and regulations in many jurisdictions also apply broadly to the collection, use, storage, disclosure, protection and other processing of data that identifies or may be used to identify or locate an individual. Please see the risk factor entitled " Failure to comply with current or future federal, state and foreign laws and regulations and industry standards relating to privacy and data protection laws could lead to governmental enforcement actions (which could include civil or criminal penalties), private litigation, and / or adverse publicity and could negatively affect our operating results and business. " Healthcare Reform In the United States and some foreign jurisdictions, there have been, and continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities, and affect our ability, or the ability of any collaborators, to profitably sell any products for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved products. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, has substantially changed the way healthcare is financed by both governmental and commercial payers and significantly impacts the pharmaceutical industry. Certain provisions of the Affordable Care Act have been subject to judicial challenges, as well as efforts to repeal, replace, or otherwise modify them or to alter their interpretation or implementation. For example, the Tax Cuts and Jobs Act, or Tax Act, enacted in December ~~,~~ 2017 eliminated the tax- based payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, as amended, commonly referred to as the" individual mandate," effective January 1, 2019. Additional legislative changes, regulatory changes, and judicial challenges related to the Affordable Care Act remain possible. It is unclear how the Affordable Care Act and its implementation, as well as efforts to repeal, replace, or otherwise modify, or invalidate, the Affordable Care Act, or portions thereof, will affect our business. In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, as amended, among other things led to aggregate reductions in Medicare payments for all items and services, including prescription drugs and biologics, to service providers of, on average, 2 percent per fiscal year beginning April 1, 2013, and, due to subsequent legislation, continuing until 2030 (with the exception of a temporary suspension from May 1, 2020, through March 31, 2021) unless Congress takes additional action. It is possible that the Affordable Care Act, as currently enacted or may be amended in the future, as well as other healthcare reform measures that may be adopted in the future, and their implementation may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, and new payment methodologies and in additional downward pressure on coverage and payment and the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from commercial payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Reportable Segments As of December 31, ~~2023~~ **2024** , our reportable segments were (i) Biopharmaceuticals and (ii) Exemplar. These identified reportable segments met the quantitative thresholds to be reported separately for the year ended December 31, ~~2023~~ **2024** . See" Notes to the Consolidated Financial Statements- Note 16" appearing elsewhere in this Annual Report for a discussion of our reportable segments and Segment Adjusted EBITDA. **Research and Development** As of December 31, ~~2023~~ **2024** , we had ~~134~~ **99** employees supporting our research and development functions of our healthcare operations, including operational and facility activities. We incurred expenses of $ **53. 1 million, $** 48. 6 million ~~,~~ **and** $ 47. 2 million ~~and $ 47. 9 million~~ in **2024,** 2023, **and** 2022 ~~, and 2021~~ , respectively, on research and development activities for continuing operations. We anticipate that our research and development expenditures could increase as we advance our healthcare programs and platforms. As of December 31, ~~2023~~ **2024** , our primary domestic research and development operations were located in laboratory facilities in Germantown, Maryland, and our primary international research and development operations were located in a laboratory facility in Ghent, Belgium. Financial Information Collaboration revenues, product revenues, service revenues and other revenues and operating loss for each of the last three fiscal years, along with assets as of December 31, **2024, and** 2023 ~~and 2022~~ , are set forth in the consolidated financial statements, which are included in Item 8 of this Annual Report. Financial information about geographic areas is set forth in" Notes to the Consolidated Financial Statements- Note 16" appearing elsewhere in this Annual Report. Human Capital Management As of December 31, ~~2023~~ **2024** , out of ~~202~~ **143** employees, ~~177~~ **123** support our healthcare operations, of which ~~134~~ **99** support our research and development functions including operational and facility activities. Of these research and development employees, ~~72~~ **40** have advanced degrees, of which ~~35~~ **24** are PhDs. Our corporate employees provide support to all of our operating subsidiaries and are responsible for the execution of all corporate functions, including executive, operational, finance, human resources, information technology, legal, and corporate communications. None of our employees are represented by a collective bargaining agreement. We structure our compensation packages to compete for the best talent. Our compensation packages include a competitive base salary and bonus, the issuance of equity incentives, a 401 (k) plan, and health and wellness benefits,

including a health insurance plan with a Platinum actuarial value. ~~We pride ourselves on a diverse workforce as evidenced by our international subsidiaries and 76 % of our domestic employees identifying as ethnic, racial, and / or gender minorities. Worldwide 49 % of our research and development employees are female.~~ Our ~~2023~~ **2024** employee development initiatives included employee training targeting specific areas of interest, executive and manager coaching, and performance management, which encompass performance goals and competency evaluations. Additional Information Our website is www. precigen. com. The information on, or that can be accessed through, our website does not constitute part of ~~,~~ and is not deemed to be incorporated by reference into, this Annual Report. We post regulatory filings on this website as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. These filings include annual reports on Form 10- K; quarterly reports on Form 10- Q; current reports on Form 8- K; Section 16 reports on Forms 3, 4, and 5; and any amendments to those reports filed with or furnished to the SEC. We also post our press releases on our website. Access to these filings or any of our press releases on our website is available free of charge. Copies are also available, without charge, from Precigen Investor Relations, 20374 Seneca Meadows Parkway, Germantown, Maryland 20876. Reports filed with the SEC may be viewed at www. sec. gov. In addition, our Corporate Governance Guidelines, Code of Business Conduct and Ethics, and charters for the Audit Committee, the Compensation and Human Capital Management Committee and the Nominating and Governance Committee are available free of charge to shareholders and the public through the" Corporate Governance" section of our website. Printed copies of the foregoing are available to any shareholder upon written request to our Communications Department at the address set forth on the cover of this Annual Report or may be requested through our website, www. precigen. com. Item 1A. Risk Factors Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with the other information contained in this Annual Report, including our consolidated financial statements and the related notes appearing at the end of this Annual Report, before making your decision to invest in shares of our common stock. We cannot assure you that any of the events discussed in the risk factors below will not occur. These risks could have a material and adverse impact on our business, results of operations, financial condition, or prospects. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment. This Annual Report also contains forward- looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward- looking statements as a result of certain factors, including the risks faced by us described below and elsewhere in this Annual Report. See" Special Note Regarding Forward- Looking Statements" for information relating to these forward- looking statements. We ~~will need substantial additional capital in the future in order to fund our business and~~ have identified conditions that raise substantial doubt about our ability to continue as a going concern **and we may need substantial additional capital in the future in order to fund our business** . Our consolidated financial statements as of and for the year ended December 31, ~~2023~~ **2024** have been prepared on the basis that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. We have incurred significant losses since our inception and we expect that we will continue to incur losses **in the near term** as we aim to successfully execute our business plan **, which includes the commercialization of PRGN- 2012** . Based on our balance of cash, cash equivalents and short- term investments of $ ~~62~~ **97** . 9 million at December 31, ~~2023~~ **2024** and forecasted negative cash flows from operating activities and purchases of property, plant and equipment ~~for the foreseeable future~~ , there is substantial doubt about our ability to continue as a going concern within one year after the date that these financial statements are issued. **The forecasted negative cash flows used in our going concern analysis do not include the potential revenue from PRGN- 2012 for the treatment of adults with RRP, which is considered outside of our direct control, as the BLA (which was accepted by the FDA in February 2025 under a priority review with a PDUFA target action date set for August 27, 2025) has not yet been approved.** Our ability to fund our operations is dependent upon **the FDA' s approval of our BLA and the successful commercialization of PRGN- 2012 with revenues sufficient to support our cost structure. In addition, we may decide,** ~~our~~ **or** ~~ability~~ **be required** to raise additional capital ~~in the near term~~ . This additional capital could be raised through a combination of non- dilutive financings (including debt financings, collaborations, strategic alliances, monetization of ~~non- core~~ assets, marketing, distribution or licensing arrangements), **and / or** dilutive financings (including equity and / or debt financings with an equity component) ~~and, in the longer term, from revenue related to product sales, to the extent our product candidates receive marketing approval and can be commercialized by us directly or through a collaboration~~ . There can be no assurance that new financings or other transactions will be available to us on commercially acceptable terms, or at all, and such financings may adversely affect the holdings or rights of our stockholders and may cause significant dilution to existing stockholders. Further, the doubt regarding our potential ability to continue as a going concern may adversely affect our ability to obtain new financing on reasonable terms or at all. Also, any collaborations, strategic alliances, monetization of non- core assets or marketing, distribution or licensing arrangement may require us to give up some or all of our rights to a product or technology, which in some cases may be at less than the full potential value of such rights. If we are unable to **successfully commercialize PRGN- 2012 or** obtain additional capital, we will assess our capital resources and may be required to delay, reduce the scope of, or eliminate some or all of our operations, which may include research and development, clinical trials and preparing for commercial readiness **, or seeking bankruptcy protection** . This may have a material adverse effect on our business, financial condition, results of operations and ability to operate as a going concern. The accompanying audited financial statements do not include any adjustments that might be necessary if we are not able to continue as a going concern. Additionally, if we are unable to continue as a going concern, our stockholders may lose some or all of their investment in us. See also " Notes to Condensed Consolidated Financial ~~Statement~~ **Statements** - Note 1 appearing elsewhere in this Annual Report for additional discussion of our liquidity and ability to continue as a going concern. We **are currently authorized to issue 400, 000, 000 shares of common stock under our amended and restated certificate of incorporation. As of February 15, 2025, we** have **issued 294** ~~a history of net losses~~ , **042, 973 shares of common stock, approximately 28, 463, 388 shares of common stock were committed for issuance giving effect to the assumed exercise of all outstanding**

options and **vesting of restricted stock units and performance stock units and approximately 70, 222, 215 shares of common stock initially underlying the Series A Preferred Stock and 52, 666, 669 shares of common stock initially underlying the Warrants. The exercisability of the Series A Preferred Stock and the Warrants is contingent upon us obtaining stockholder approval to increase the number of authorized shares of common stock. Due to the limited number of authorized shares common stock available for future issuance,** we may not ~~achieve~~ **be able to raise additional equity capital, complete a merger or other business combination, unless we increase the number of shares we are authorized to issue. We would need to seek stockholder approval to increase the number of** ~~or~~ **our** ~~maintain profitability~~ **authorized shares of common stock, and we can provide no assurance that we would succeed in amending our amended and restated certificate of incorporation to increase the number of shares of common stock we are authorized to issue which could negatively impact our business, prospects and results of operations. On August 6, 2024, we publicly announced a strategic prioritization of our clinical portfolio and streamlining of resources, including a reduction of over 20 % of our work force, to focus on potential commercialization of PRGN- 2012 for the treatment of RRP. In connection with the implementation of our strategic prioritization and streamlining of resources, we recorded non- cash impairment charges to goodwill and other assets of approximately $ 32. 9 million, net of tax, in the second quarter of 2024 and we also recorded a charge related to employee severance and termination benefits of $ 2. 1 million, which were paid in the third quarter of 2024. We may continue to incur additional expenses not currently contemplated due to events associated with strategic prioritization and streamlining of resources; for example, the reduction in force may have a future impact on other areas of our liabilities and obligations, which could result in losses in future periods. The reduction in force may result in unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond the intended number of employees, and decreased morale among our remaining employees. In addition, while positions have been eliminated, certain functions necessary to our operations remain, and we might not successfully distribute the duties and obligations of our terminated employees among our remaining employees. The reduction in workforce could also make it difficult for us to pursue, or prevent us from pursuing, new opportunities and initiatives due to insufficient personnel, or require us to incur additional and unanticipated costs to hire new personnel to pursue such opportunities or initiatives. Moreover, we may not realize, in full or in part, the anticipated benefits and savings from this strategic prioritization and streamlining of resources due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the anticipated benefits from the strategic prioritization and streamlining of resources, or if we experience significant adverse consequences from such actions, our business, financial condition and results of operations may be materially adversely affected. In addition, we may need to undertake additional workforce reductions or restructuring activities in the future** . We have incurred net losses since our inception, with the exception of 2022 where we had $ 28. 3 million in net income due to the sale of TransOva, which generated a gain on divestiture of $ 94. 7 million. As of December 31, ~~2023~~ **2024** , we had an accumulated deficit of $ 2. ~~0~~ **1** billion. We expect to incur losses and negative cash flows from operating activities for the foreseeable future. We anticipate that our expenses will increase substantially as we continue to advance the preclinical and clinical development of our existing product candidates and our research programs as well **as** prepare commercial capabilities for our lead product candidate, and there is a significant risk that our product candidates will fail to demonstrate adequate efficacy or an acceptable safety profile, obtain regulatory approval, or become commercially viable. A significant period of time could pass before commercialization of our various product candidates or before the execution of contractual relationships providing for up- front payments, milestones or royalties sufficient to achieve profitability. As a result, our expenses may exceed revenues for the foreseeable future, and we may not achieve profitability. If we fail to achieve profitability, or if the time required to achieve profitability is longer than we anticipate, we may not be able to continue our business. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. ~~We expect our future capital requirements will be substantial and will depend on many factors.~~ Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts to continue the preclinical and clinical development of our current and future programs and commercialization. We expect our future capital requirements will be substantial and will depend on many factors, including: • progress in our research and development programs, as well as the magnitude of these programs; • capital expenditures related to building out our manufacturing capabilities and preparing for commercial readiness; • the timing of potential regulatory approval of products; • the timing, receipt, and amount of any payments received in connection with strategic transactions; • the timing, receipt, and amount of sales and royalties, if any, from our product candidates; • the timing and capital requirements to scale up our various product candidates and service offerings and customer acceptance thereof; • our ability to maintain and establish collaborative arrangements and / or new strategic initiatives; • the resources, time, and cost required for the preparation, filing, prosecution, maintenance, and enforcement of our intellectual property portfolio; • strategic mergers and acquisitions, if any, including both the upfront acquisition cost as well as the cost to integrate, maintain, and expand the strategic target; and • the costs associated with legal activities, including litigation, arising in the course of our business activities and our ability to prevail in any such legal disputes. We raised approximately $ ~~72~~ **30** . ~~8~~ **9** million in net proceeds in an offering of equity securities in ~~January~~ **August** ~~2023~~ **2024 and approximately $ 78. 5 million in net proceeds in an offering of equity securities in December 2024** . If future financings involve the issuance of equity securities, our existing shareholders would suffer further dilution. If we raise debt financing, we may be subject to restrictive covenants that limit our ability to conduct our business. We may not be able to raise sufficient additional funds on terms that are favorable to us, if at all. If we fail to raise sufficient funds and continue to incur losses, our ability to fund our operations, take advantage of strategic opportunities, develop product candidates or technologies, commercialize or otherwise respond to competitive pressures could be significantly limited. If this happens, we may be forced to delay or terminate research or development programs or the commercialization of product candidates resulting from our technologies, curtail or cease operations or obtain funds through strategic transactions or other collaborative and

licensing arrangements that may require us to relinquish commercial rights, or grant licenses on terms that are not favorable to us. In addition, raising funds in the current ~~economic~~ **macroeconomic and geopolitical** environment may present additional challenges. For example, ~~any sustained disruption in the capital markets from~~ adverse macroeconomic **or geopolitical** conditions, such as the disruption and uncertainty caused by ~~rising~~ **heightened** inflation **and** ~~, increasing~~ interest rates and slower economic growth or recession, **uncertainty caused by tariffs and trade policies, and geopolitical conflicts such as the war between Russia and Ukraine and the conflict in the Middle East, could result in a sustained disruption in the capital markets. We cannot predict the extent or duration of such macro- economic and geopolitical disruptions, and if they deepen or persist, this** could negatively impact our ability to raise capital **on favorable terms,** ~~and we cannot predict the extent~~ or **at all** ~~duration of such macro- economic disruptions~~ . If adequate funds are not available, we will not be able to successfully execute our business plan or continue our business. Failure of the U. S. federal government to manage its fiscal matters or to raise or further suspend the debt ceiling may expose us to increased financial and operational risk. Congressional disagreement over the federal budget and the maximum amount of debt the federal government is permitted to have outstanding (commonly referred to as the " debt ceiling ") has previously caused the U. S. federal government to shut down for periods of time. Generally, if effective legislation to fund government operations and manage the level of federal debt is not enacted, the federal government may suspend its investments for certain government accounts, among other available options, in order to prioritize payments on its obligations. A failure by the U. S. Congress to pass spending bills or address the debt ceiling at any point in the future would increase the risk of default by the U. S. on its obligations, the risk of a lowering of the U. S. federal government' s credit rating, and the risk of other economic dislocations. Such a failure, or the perceived risk of such a failure, could consequently have a material adverse effect on the financial markets and economic conditions in the U. S. and globally. Twice in the past decade, by the appropriations legislation deadline Congress failed to pass a new appropriations bill or continuing resolution to temporarily extend funding, resulting in U. S. government shutdowns that caused federal agencies to halt non- essential operations and may have negative consequences for us: • devaluation in any U. S. government bond investments held by the Company; • inability to access capital markets, or increased difficulty in doing so; or • government shutdown, or reduced operation, of agencies such as the FDA, which could impede our ability to progress our planned clinical development of product candidates. We are early in our development efforts. We initiated our first clinical trial for our lead programs in October 2018 ~~,~~ and currently have a pipeline of clinical and preclinical programs. Our ability to generate product revenues, which we do not expect will occur until a product candidate is approved by FDA, if ever, will depend heavily on the successful development and eventual commercialization of some or all of these product candidates, and any future product candidates we develop, which may never occur. Our current and future product candidates will require additional preclinical or clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other jurisdictions, coverage from pricing and reimbursement authorities, sufficient cGMP manufacturing supply for both preclinical and clinical development and commercial production, building of a commercial organization and substantial investment, and significant marketing efforts before we generate any revenues from product sales. The clinical and commercial success of our current and future product candidates will depend on several factors, including the following: • sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials; • timely and successful completion of preclinical studies and clinical trials; • acceptance of INDs for future product candidates; • successful enrollment in and completion of clinical trials; • data from our clinical programs that supports an acceptable risk- benefit profile of our product candidates in the intended patient populations; • our ability to consistently manufacture our product candidates on a timely basis or to establish agreements with third- party manufacturers that can do so; • whether we are required by the FDA or comparable foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned or anticipated to support approval of our product candidates; • acceptance of our proposed indications and the primary endpoint assessments evaluated in the clinical trials of our product candidates by the FDA and comparable foreign regulatory authorities; • receipt and maintenance of timely marketing approvals from applicable regulatory authorities; • the build up of a commercialization organization and successful launch of commercial sales of our product candidates, if approved; • the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates, if approved; • entry into collaborations to further the development of our product candidates; • our ability to obtain and maintain patent and other intellectual property protection or regulatory exclusivity for our product candidates; • acceptance of the benefits and uses of our product candidates, if approved, by patients, the medical community, and third- party payers; • maintenance of a continued acceptable safety, tolerability and efficacy profile of the product candidates following approval; • our compliance with any post- approval requirements imposed on our products, such as postmarketing studies, a REMS, or additional requirements that might limit the promotion, advertising, distribution or sales of our products or make the products cost prohibitive; • our ability to compete effectively with other therapies; and • our ability to obtain and maintain healthcare coverage and adequate reimbursement from third- party payers. These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize our current or future product candidates, and could otherwise materially harm our business. Successful completion of preclinical studies and clinical trials does not mean that any of our current or future product candidates will receive regulatory approval. Even if regulatory approvals are obtained, we could experience significant delays or an inability to successfully commercialize our current and any future product candidates, which would materially harm our business. If we are not able to generate sufficient revenue through the sale of any current or future product candidate, we may not be able to continue our business operations or achieve profitability. Our projections of both the number of people who have the diseases we are targeting, as well as the subset of people with these diseases who are in a position to receive our product candidates, and who have the potential to benefit from treatment with our product candidates, are based on our own estimates. These estimates may be inaccurate or based on imprecise data. We do not have verifiable internal marketing data regarding the potential size of the commercial market for any of our product candidates, nor have we obtained current independent marketing

surveys to verify the potential size of the commercial markets for our current product candidates or any future product candidates. Since our current product candidates and any future product candidates will represent novel approaches to treating various conditions, it may be difficult, in any event, to accurately estimate the potential revenues from these product candidates. For example, our estimates of the number of people who have recurrent respiratory papillomatosis, or RRP, the target indication for PRGN- 2012, is based on our own internal estimates including, commissioned research which reviewed a variety of sources, including scientific literature, surveys of treating physicians, analogous products based on disease severity, prevalent population and efficacy of therapy and other forms of market research. These estimates may be inaccurate or based on imprecise data. As RRP is a rare disease and there are currently no approved therapeutics for RRP, limited research is available regarding its prevalence and severity and the market opportunity for a therapeutic. In addition, the addressable market opportunity for PRGN- 2012 will depend on, among other things, the final labeling for PRGN- 2012 as agreed with the U. S. Food and Drug Administration or comparable regulatory authorities in other jurisdictions, acceptance by the medical community and patient access and drug pricing and reimbursement. **In addition, the prevalence of RRP could be reduced as a result of the increased use of vaccines like Gardasil.** The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidate or new patients may become increasingly difficult to identify or gain access to, all of which could materially adversely affect our business, financial condition, results of operations and prospects. The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time- consuming, and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be materially harmed. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. There can be no assurance that we will not experience problems or delays in developing new product candidates and that such problems or delays will not cause unanticipated costs, or that any such development problems can be solved. We also may experience unanticipated problems or delays in expanding our manufacturing capacity, which may delay or prevent the completion of clinical trials and the ~~commercializing~~ **commercialization** of product candidates on a timely or profitable basis, if at all. For example, we, a collaborator, or another group may uncover a previously unknown risk with any of our product candidates, which may prolong the period of observation required for obtaining regulatory approval, may necessitate additional clinical testing, or may otherwise result in a change in the requirements for approval of any of our product candidates. In addition, the clinical trial requirements of the FDA, European Medicines Agency, or EMA, and other regulatory authorities and the criteria these regulators use when evaluating product candidates vary substantially according to the type, complexity, novelty, and intended use and market of such product candidates. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known, or more extensively studied product candidates. Even if we are successful in developing product candidates, it is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals in either the United States or jurisdictions outside the United States or how long it will take to commercialize these product candidates. Regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future. For example, the FDA has established the Office of Tissues and Advanced Therapies and the Division of Cellular and Gene Therapies within the Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products and has established the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER in its marketing application review process. We may be unable to obtain FDA approval of our product candidates under applicable regulatory requirements. The denial or delay of any such approval would prevent or delay commercialization of our product candidates and adversely impact **on** our potential to generate revenue, our business, and our results of operations. To gain approval to market our product candidates in the United States, we must provide the FDA with clinical data that adequately demonstrate the safety, purity, and potency, including efficacy, of the product candidate for the proposed indication or indications in a BLA submission. Product development is a long, expensive, and uncertain process, and delay or failure can occur at any stage of any of our clinical development programs. The field of gene therapy is still early in development. The FDA first approved a gene therapy for use in humans in 2017, and to date has only approved a limited number. Clinical trials with gene therapies have encountered a multitude of significant technical problems in the past, including unintended integration with host DNA leading to serious adverse events, poor levels of protein expression, transient protein expression, viral overload, immune reactions to either viral capsids utilized to deliver DNA, DNA itself, proteins expressed or cells transfected with DNA. There can be no assurance that our development efforts will be timely or successful, that we or our collaborators will receive the regulatory approvals necessary to initiate clinical trials, where applicable, or that we will ever be able to successfully commercialize a product candidate enabled by our technologies. To the extent that we utilize viral constructs or other systems to deliver gene therapies and the same or similar delivery systems demonstrate unanticipated and / or unacceptable side effects in preclinical or clinical trials conducted by ourselves or others, we may be forced to, or elect to, discontinue development of such product candidates. Additionally, we are pursuing the development and commercialization of adoptive cell therapies based on CAR T- cell therapies targeting a variety of cancer malignancies. Because this is a newer approach to cancer immunotherapy and cancer treatment generally, developing and commercializing such product candidates subjects us to a number of challenges, including: • developing and deploying consistent and reliable processes for engineering a patient' s T- cells ex vivo and infusing the engineered T- cells back into the patient; • possibly conditioning patients with chemotherapy in conjunction with delivering each of the potential product candidates, which may increase the risk of adverse side effects of the potential products; • educating medical personnel regarding the potential side effect profile of each of the potential products, such as the potential adverse side effects related to cytokine release; • developing processes for the safe administration of these potential products, including long- term follow- up for all patients who receive the potential products; • sourcing additional clinical and, if approved, commercial supplies for the materials used to manufacture and process the

potential products; • developing a manufacturing process and distribution network with a cost of goods that allows for an attractive return on investment; • establishing sales and marketing capabilities after obtaining any regulatory approval required to gain market access and acceptance; • developing therapies for types of cancers beyond those addressed by the current potential products; • not infringing, misappropriating or otherwise violating the intellectual property rights, in particular, the patent rights, of third parties, including competitors developing alternative CAR T- cell therapies; and • avoiding any applicable regulatory barriers to market, such as data and marketing exclusivities held by third parties, including competitors with approved CAR T- cell therapies. We cannot be sure that T- cell immunotherapy technologies that we may develop will yield satisfactory products that are safe and effective, scalable, or profitable. Clinical development involves a lengthy and expensive process with uncertain outcomes. Results from preclinical studies or previous clinical trials 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 fail to show the desired results in clinical development despite demonstrating positive results in preclinical studies or having successfully advanced through initial clinical trials. There is a high failure rate for drugs and biologics proceeding through clinical trials and failure may occur at any stage due to a multitude of factors both within and outside our control. 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 product candidate development. Any such delays could materially and adversely affect our business, financial condition, results of operations and prospects. If clinical trials result in negative or inconclusive results, we may decide, or regulators may require us, to discontinue trials of the product candidates or conduct additional clinical trials or preclinical studies. As an organization, we have limited experience designing and implementing clinical trials and we have limited experience conducting pivotal clinical trials. Failure to adequately design a trial, or incorrect assumptions about the design of the trial, could adversely affect our ability to initiate the trial, enroll patients, complete the trial, or obtain regulatory approval on the basis of the trial results, as well as lead to increased or unexpected costs and delayed timelines. The design and implementation of clinical trials is a complex process. We have limited experience designing and implementing clinical trials, and we may not successfully or cost- effectively design and implement clinical trials that achieve our desired clinical endpoints efficiently, or at all. A clinical trial that is not well designed may delay or even prevent initiation of the trial, can lead to increased difficulty in enrolling patients, may make it more difficult to obtain regulatory approval for the product candidate on the basis of the study results, or, even if a product candidate is approved, could make it more difficult to commercialize the product successfully or obtain reimbursement from third- party payers. Additionally, a trial that is not well- designed could be inefficient or more expensive than it otherwise would have been, or we may incorrectly estimate the costs to implement the clinical trial, which could lead to a shortfall in funding. We may find it difficult to enroll patients in clinical trials, which could delay or prevent us from proceeding with clinical trials. Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to success. The timing of clinical trials depends on the ability to recruit patients to participate as well as completion of required follow- up periods. If patients are unwilling to participate in our clinical studies for any number of reasons, such as because of negative publicity from adverse events related to the biotechnology or gene therapy fields, the timeline for recruiting patients, conducting clinical trials and obtaining regulatory approval may be delayed. Additionally, any shelter- in- place orders from local, state, or federal governments or clinical trial site policies resulting from pandemics may impact our ability to enroll patients in clinical trials. These delays could result in increased costs, delays in advancing product candidates, or termination of the clinical trials altogether. For example, we experienced delays and suspensions in our trials in 2020 due to the COVID- 19 pandemic ~~and . although~~ **Although** these suspensions did not result in significant overall delay, ~~there is uncertainty regarding the duration and severity of the ongoing pandemic, and we could experience further delays of other pandemic- related events that may adversely impact our clinical as well as preclinical pipeline candidates in the future. Notwithstanding the foregoing, as the COVID- 19 pandemic continues to evolve, or~~ if future pandemics occur, we may experience ~~additional~~ **significant** delays to our clinical trials, including related to enrollment, site closures, reduced availability of key personnel, or our ability to receive the necessary approvals from the FDA or other regulatory agencies to advance our programs. We may be required to suspend, repeat, or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, or the trials are not well designed. Clinical trials must be conducted in accordance with the FDA' s current good clinical practices requirements or analogous requirements of applicable foreign regulatory authorities. Clinical trials are subject to oversight by the FDA, other foreign governmental agencies and IRBs, or ethical committees at the study sites where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates manufactured in accordance with applicable cGMP. Clinical trials may be suspended by the FDA, other foreign regulatory authorities, us, or by an IRB or ethics committee with respect to a particular clinical trial site, for various reasons, including: • deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or study protocols; • deficiencies in the clinical trial operations or trial sites; • unforeseen adverse side effects or the emergence of undue risks to study subjects; • deficiencies in the trial design necessary to demonstrate efficacy; • the product candidate may not appear to offer benefits over current therapies; or • the quality or stability of the product candidate may fall below acceptable standards. If we experience delays in the completion of, or the termination of, any clinical trial of any of our product candidates, the commercial prospects of such product candidate will be harmed, and our ability to generate product revenues from such product candidate will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition, results of operations, cash flows, and prospects significantly. 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. The manufacturing processes that we use to produce our product candidates for human therapeutics are complex, novel and have not been validated for commercial use. Several factors could cause production interruptions, including equipment malfunctions, facility contamination, raw material shortages or contamination, natural disasters, disruption in utility services, human error, or disruptions in the operations of our suppliers. Our synthetic biology product candidates require processing steps that are more complex than those required for most chemical pharmaceuticals. Moreover, unlike chemical pharmaceuticals, the physical and chemical properties of a biologic often cannot be fully characterized. As a result, assays of the finished product may not be sufficient to ensure that the product will perform in the intended manner. Accordingly, it is necessary to employ multiple steps to control our manufacturing process to assure that the product candidate is made strictly and consistently in compliance with the process. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims, or insufficient inventory. We have developed our proprietary electroporation device, UltraPorator, to permit the rapid and cost- effective manufacturing of our UltraCAR- T therapies, but we may face challenges in the production and implementation of this device, which may, in turn, adversely impact the therapeutic candidates. We may encounter problems achieving adequate quantities and quality of clinical- grade materials that meet FDA, EMA, or other applicable standards or specifications with consistent and acceptable production yields and costs. Interim and preliminary results from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit, validation, and verification procedures that could result in material changes in the final data. From time to time, we ~~may~~ publish interim data, including interim top- line results or preliminary results from our clinical trials. Interim data and results from our clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top- line results also remain subject to audit, validation, and verification procedures that may result in the final data being materially different from the interim and preliminary data we previously published. As a result, interim and preliminary data may not be predictive of final results and should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly. Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, delay or prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences. There have been several significant adverse side effects in gene therapy treatments in the past, including reported cases of leukemia and death seen in other trials. While new approaches have been developed to reduce these side effects, gene therapy and synthetic biology therapy in general is still a relatively new approach to disease treatment and additional adverse side effects could develop. There also is the potential risk of delayed adverse events following exposure to these product candidates due to persistent biological activity of the genetic material or other components of products used to carry the genetic material. Other possible adverse side effects that could occur with treatment using cell and gene therapy products include an immunologic reaction early after administration that, while not necessarily adverse to the patient' s health, could substantially limit the effectiveness of the treatment. In previous clinical trials involving adeno- associated virus, vectors for gene therapy, some subjects experienced the development of a T- cell response, whereby after the vector is within the target cell, the cellular immune response system triggers the removal of transduced cells by activated T- cells. If a similar effect occurs with our product candidates, we may decide or be required to halt or delay further clinical development of our product candidates. Additionally, if any of our product candidates receive marketing approval, the FDA could require us to adopt a REMS to ensure that the benefits outweigh its risks, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to healthcare practitioners, and provider certification. Such requirements could prevent us from achieving or maintaining market acceptance of our product candidates and could significantly harm our business, prospects, financial condition, and results of operations. Even if we complete the necessary clinical trials, we cannot be certain when, or if, we will obtain regulatory approval to commercialize a product candidate **,** and the approval may be for a narrower indication than we seek. We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even ~~where~~ **when** product candidates meet their endpoints in clinical trials, the clinical trial results may not support approval of our product candidates if they fail to demonstrate that our product candidates are both safe and effective for their intended uses. Similarly, the regulatory authorities may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or a REMS. These regulatory authorities may require precautions or contraindications with respect to conditions of use or they may grant approval subject to the performance of costly postmarketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and materially and adversely affect our business, financial condition, results of operations, and prospects. We have chosen to prioritize development of certain of our product candidates. We may expend our limited resources on product candidates or indications that do not yield a successful product and fail to capitalize on other opportunities for which there may be a greater likelihood of success or may be more profitable. Because we have limited resources, we are required to strategically prioritize our application of resources to particular development efforts **, as** ~~. Any resources~~ we ~~expend~~ **have done in our strategic reprioritization that we announced** on **August 2024, to focus** ~~one~~ **on the potential commercialization of PRGN- 2012** ~~or~~ **for the treatment of RRP. As part of the strategic prioritization, we decided to minimize UltraCAR- T spend, and have paused enrollment in PRGN- 3005 and PRGN- 3007 UltraCAR- T clinical trials. We have also reduced our focus on preclinical programs, while continuing select projects we believe could provide future near- term validation of our technology platforms. We have also shutdown our ActoBio subsidiary operations. There is no assurance that PRGN- 2012 will successfully be commercialized and be profitable and by deprioritizing the other programs and product candidates, we may be failing to**

capitalize on opportunities for which there may be a greater likelihood of success or be more ~~of these efforts could be at the expense of other potentially~~ profitable ~~opportunities. If we focus our efforts and resources on one or more of these opportunities or markets and they do not lead to commercially viable products~~ , **and** our revenues, financial condition, and results of operations ~~could~~ **may** be adversely affected. Even if a current or future product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third- party payers, and others in the medical community necessary for commercial success. Ethical, social, and legal concerns about gene and cell therapies could result in additional regulations restricting or prohibiting our product candidates. Even with the requisite approvals from the FDA in the United States, the EMA in the European Union, and other regulatory authorities internationally, the commercial success of our product candidates will depend, in part, on their acceptance by physicians, patients, and healthcare payers as medically necessary, cost- effective, and safe. Public perception may be influenced by claims that gene and cell therapies are unsafe, and any product candidate that we commercialize may not gain acceptance by physicians, patients, healthcare payers, and others in the medical community. In particular, our success will depend upon appropriate physicians prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue to make the products profitable. Before we can begin to commercially manufacture our product candidates for human therapeutics, we must obtain regulatory approval from the FDA for the applicable manufacturing process and facility. This **will** likely ~~will~~ require the manufacturing facility to pass a pre- approval inspection by the FDA. A manufacturing authorization must also be obtained from the appropriate European Union regulatory authorities. In order to obtain FDA approval, we will need to ensure that all of the processes, methods, and equipment are compliant with cGMP and perform extensive audits of vendors, contract laboratories, and suppliers. While we currently expect to use our internal cGMP manufacturing capabilities in Germantown, Maryland for the commercial manufacturing of our lead product candidate, PRGN 2012, we may rely on third parties to commercially manufacture our other product candidates. If we, any of our vendors, contract laboratories or suppliers is found to be out of compliance with cGMP, we may experience delays or disruptions in manufacturing while we work with these third parties to remedy the violation (s) or while we work to identify suitable replacement vendors. The cGMP requirements govern, among other things, quality control of the manufacturing process, raw materials, containers / closures, buildings and facilities, equipment, storage and shipment, labeling, laboratory activities, data integrity, documentation policies and procedures, and returns. In complying with cGMP, we will be obligated to expend time, money, and effort in production, record keeping, and quality control to assure that the product meets applicable specifications and other requirements. If we fail to comply with these requirements, we would be subject to possible regulatory action that could adversely affect our business, results of operations, financial condition, and cash flows, including the inability to sell any products that we may develop. Even if we receive marketing approval of a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. If we fail to comply or experience unanticipated problems with our products, we may be subject to administrative and judicial enforcement, including monetary penalties, for non- compliance and our approved products, if any, could be deemed misbranded or adulterated and prohibited from continued distribution. Even if we obtain regulatory approval for our product candidates, these candidates will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record- keeping, and submission of safety and other postmarket information. Regulatory approvals also may 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 postmarketing testing, including Phase 4 clinical trials, and surveillance to monitor the quality, safety and efficacy of the product. 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 FDA guidance advises that patients treated with some types of gene therapy undergo follow- up observations for potential adverse events for as long as 15 years. 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. Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and other government agencies to ensure 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, but we may ultimately be responsible for any of their failures. If we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory authority may take a range of adverse actions, including, among other things, issuing a warning letter, imposing monetary penalties, restricting or suspending manufacturing, or causing us to withdraw the product from the market. In addition, the FDA' s policies, and those of equivalent foreign regulatory agencies, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would materially and adversely affect our business, financial condition, results of operations, and prospects. Obtaining and maintaining marketing approval of our current and future product candidates in one jurisdiction does not mean that we will be successful in obtaining and maintaining marketing approval of our current and future product candidates in other jurisdictions. Obtaining and maintaining marketing approval of our current and future product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction, while a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the marketing approval process in others. For example, even if the FDA grants marketing approval of a

product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing, and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign marketing approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed ~~. As a company, we have never commercialized a product, we currently have no active sales force and we may lack the necessary expertise, personnel and resources to successfully commercialize our product candidates~~ . As a company, we have never commercialized a product for any indication. Even if we receive regulatory approval for one or more of our product candidates from the FDA or comparable regulatory authorities, we will need to develop robust internal sales, marketing and distribution capabilities to commercialize such products, which will be expensive and time- consuming, or enter into collaborations with third parties to perform these services. Although we have begun developing our commercial infrastructure in anticipation of the potential commercialization of PRGN- 2012, these efforts are in an early stage and we currently have no active sales force. There are costs and risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time- consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. We must also compete with other biotechnology companies to recruit, hire, train and retain marketing and sales personnel. Alternatively, we may wish to establish collaborations with third parties to maximize the potential of our product candidates in jurisdictions in which a product candidate has been approved. Our industry is characterized by intense competition. Therefore, we may not be successful in entering into such commercialization arrangements with third parties on favorable terms, or at all. In addition, we may have limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell, market and distribute our products effectively. There can be no assurance that we will be able to develop the necessary commercial infrastructure and capabilities to successfully commercialize PRGN- 2012 or our other product candidates or be able to establish or maintain relationships with third parties necessary to perform these services. As a result, we may not successfully commercialize any product in any jurisdiction. The successful commercialization of our product candidates will depend in part on the extent to which third- party payers, including governmental authorities and private health insurers, provide coverage and adequate reimbursement levels, as well as implement pricing policies favorable for our product candidates. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue. The availability of coverage and adequacy of reimbursement by third-party payers, including managed care plans, governmental healthcare programs, such as Medicare and Medicaid and private health insurers is essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates that receive FDA approval. Our ability to achieve acceptable levels of coverage and reimbursement for our product candidates or procedures using our product candidates by third- party payers will have an effect on our ability to successfully commercialize our product candidates. Obtaining coverage and adequate reimbursement for our product candidates may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Separate reimbursement for the product itself or the treatment or procedure in which our product candidate is used may not be available. A decision by a third- party payer not to cover or not to separately reimburse for our product candidates or procedures using our product candidates could reduce physician utilization of our products once approved. Assuming there is coverage for our product candidates, or procedures using our product candidates by a third- party payer, the resulting reimbursement payment rates may not be adequate or may require co- payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union, or elsewhere will be available for our current or future product candidates, or for any procedures using such product candidates, and any reimbursement that may become available may not be adequate or may be decreased or eliminated in the future. There is significant uncertainty related to the insurance coverage and reimbursement of newly- approved products. The Medicare and Medicaid programs are increasingly used as models in the United States for how private third- party payers and other governmental payers develop their coverage and reimbursement policies for drugs and biologics. Some third- party payers may require pre- approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third- party payers will decide with respect to the coverage and reimbursement for our product candidates. No uniform policy for coverage and reimbursement for products exist among third- party payers in the United States. Therefore, coverage and reimbursement for products can differ significantly from payer to payer. As a result, the coverage determination process is often a time- consuming and costly process that may require us to provide scientific and clinical support for the use of our product candidates to each payer separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely. Moreover, increasing efforts by third- party payers in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both

coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Our business may be adversely affected by current and potential future healthcare reforms. In the United States, federal and state legislatures, health agencies and third- party payers continue to focus on containing the cost of health care. Legislative and regulatory proposals and enactments to reform health care insurance programs could significantly influence the manner in which our product candidates, if approved, are prescribed and purchased. For example, the Affordable Care Act has changed the way health care is paid for by both governmental and private insurers, including increased rebates owed by manufacturers under the Medicaid Drug Rebate Program, annual fees and taxes on manufacturers of certain branded prescription drugs, the requirement that manufacturers participate in a discount program for certain outpatient drugs under Medicare Part D and the expansion of the number of hospitals eligible for discounts under Section 340B of the Public Health Service Act. In addition, the Tax Act eliminated the tax- based shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Code, commonly referred to as the" individual mandate," effective January 1, 2019. Further, the Bipartisan Budget Act of 2018, among other things, amended the Medicare statute to reduce the coverage gap in most Medicare drug plans, commonly known as the" donut hole," by raising the required manufacturer point- of- sale discount from 50 percent to 70 percent off the negotiated price effective as of January 1, 2019. Significant developments that may adversely affect pricing in the United States include proposed drug pricing and Medicare reforms by Congress and regulatory changes to Medicare Part B and Medicare Part D, additional changes to the Affordable Care Act under the ~~Biden~~ **Trump** Administration and trends in the practices of managed care groups and institutional and governmental purchasers, including consolidation of our customers. The Coronavirus Aid, Relief and Economic Security Act (" CARES Act"), which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID- 19 pandemic, suspended the 2 percent Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. The pharmaceutical industry faces uncertainty regarding the continuation of Medicare' s current drug pricing methodology. For example, on November 27, 2020 the Centers for Medicare & Medicaid Services (" CMS"), published an Interim Final Rule (" IFR") that would have imposed a mandatory Most Favored Nation (" MFN") pricing model on the fifty single- source drugs and biologics (including biosimilars) with the highest annual Medicare Part B spending for seven years, beginning January 1, 2021. The MFN model would have ultimately based payment for each of the fifty drugs on the lowest- available, gross domestic product (" GDP")- adjusted drug price available in any Organization for Economic Co- operation and Development country that meets minimum GDP requirements. Pharmaceutical and biotechnology industry organizations as well as several patient support groups filed litigation to enjoin implementation of the IFR. On December 28, 2020, the United States District Court for the Northern District of California imposed a nationwide preliminary injunction on implementation of the IFR pending CMS' s completion of regulatory notice- and- comment rulemaking by CMS. On December 29, 2021, CMS published a final rule that rescinded the IFR, effective February 28, 2022, to address the procedural issues acknowledged in the preliminary injunction. Although the IFR as published will not go into effect, CMS could propose future pharmaceutical pricing changes similar to the IFR, albeit with the required notice and opportunity for stakeholders to participate in the regulatory process. On November 19, 2021, the United States House of Representatives passed the Build Back Better Act, which includes several provisions aimed at lowering prescription drug costs and reducing spending by the federal government and private payers by, among other things, allowing the United States federal government to negotiate prices for certain high- cost drugs covered under Medicare, imposing rebates on manufacturers of single- source drugs and biologics covered by Medicare Part B and nearly all drugs covered under Part D, if drug prices increase faster than the rate of inflation, based on the Consumer Price Index for All Urban Consumers (" CPI- U"). We are actively monitoring legislative developments to understand the likelihood of enactment and how such legislation would impact our business and operations, if enacted. **On August 16, 2022, the Inflation Reduction Act of 2022, was signed into law, which among other things, includes prescription drug provisions that have significant implications for the pharmaceutical industry and beneficiaries, including extending enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025, allowing the federal government to negotiate a maximum fair price for certain high- priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out- of- pocket prescription drug costs for beneficiaries. On August 29, 2023, the Department of Health and Human Services announced the list of the first ten drugs that will be subject to price negotiations, although the drug price negotiation program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated. In December 2023, the Biden administration released a proposed framework that for the first time proposed that a drug' s price can be a factor in determining that the drug is not accessible to the public and, therefore, that the government could exercise" march- in rights" and license it to a third party to manufacture. We cannot predict whether the Trump administration will finalize the draft framework or if the government will propose other drug pricing policy changes. If pursued and finalized these policies could reduce prices and reimbursement for certain of our products and could significantly impact our business and consolidated results of operations.** There is also significant economic pressure on state budgets that may result in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for certain drugs. In recent years, some states have considered legislation and ballot initiatives that would control the prices of drugs, including laws to allow importation of

pharmaceutical products from lower cost jurisdictions outside the United States and laws intended to impose price controls on state drug purchases. State Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. Government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations by Medicaid programs. This may result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding constraint on prices and reimbursement for our product candidates, if approved. In addition, under the Affordable Care Act, as states implement their health care marketplaces or operate under the federal exchange, the impact on drug manufacturers will depend in part on the formulary and benefit design decisions made by insurance sponsors or plans participating in these programs. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States. It is possible that we may need to provide discounts or rebates to such plans in order to maintain favorable formulary access for our future product candidates, if approved, which could have an adverse impact on our sales and results of operations. In addition, if we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained. Our relationships with customers, third- party payers, and others may be subject to applicable anti- kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings. Healthcare providers, physicians, and third- party payers will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our arrangements with third- party payers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include, but are not limited to, the following: • the federal Anti- Kickback Statute, which prohibits persons from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending the purchase, lease or order, of any good or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid; • the federal civil False Claims Act, which imposes liability, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, claims for payment of governmental funds that are false or fraudulent, making a false statement material to an obligation to pay money to the federal government, or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government; • HIPAA' s fraud provisions, which impose criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a health care offense, or knowingly and willfully making false statements relating to healthcare matters; • the federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, which requires manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members. Beginning in 2022, applicable manufacturers are now required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse- midwives; and • analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, which may apply to items or services reimbursed by non- governmental third- party payers, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers in those jurisdictions; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; some states also prohibit certain marketing- related activities including the provision of gifts, meals, or other items to certain health care providers, and others restrict the ability of manufacturers to offer co- pay support to patients for certain prescription drugs; other states and cities require identification or licensing of sales representatives; and state and foreign laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Although compliance programs can help mitigate the risk of investigations and prosecution for violations of these laws, the risks cannot be eliminated entirely. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If 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, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. Defending against actions or investigations for violations of these laws and regulations, even if ultimately successful, will incur significant legal expenses and divert management' s attention from the operation of our business. We or our collaborators may be subject to federal, state and foreign data privacy and security laws and regulations. In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, that govern the collection, use, disclosure, protection and other

processing of health- related and other personal information could apply to our operations or the operations of our collaborators. Many state legislatures have adopted legislation that regulates how businesses operate online, including measures relating to privacy, data security and data breaches. Laws in all 50 states require businesses to provide notice to customers whose personally identifiable information has been disclosed as a result of a data breach. The laws are not consistent, and compliance in the event of a widespread data breach is costly. For example, the CCPA imposes stringent data privacy and data protection requirements for the personal information of California residents, provides for civil penalties for violations, as well as a private right of action for data breaches. **State laws are changing rapidly, as numerous other states have enacted, or are considering enacting, comprehensive data privacy laws that share similarities with the CCPA.** The CCPA and evolving legislation may require us, among other things, to incur additional costs and expenses in an effort to comply. Foreign data protection laws, including the European Union, or EU, General Data Protection Regulation, or the GDPR, may also apply to health- related and other personal information obtained outside of the United States. The GDPR introduced new data protection requirements in the EU, as well as potential fines for noncompliant companies of up to the greater of € 20 million or 4 percent of annual global revenue. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. Further, the vote in the United Kingdom in favor of exiting the EU, referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. The United Kingdom has transposed the GDPR into domestic law with a United Kingdom version of the GDPR, or the U. K. GDPR, which took effect in January 2021, and could expose us to two parallel regimes, each of which potentially authorizes similar fines and other potentially divergent enforcement actions for violations. The GDPR and U. K. GDPR also impose strict rules on the transfer of personal data to countries outside the European Economic Area or the United Kingdom, respectively, including the United States. The European Commission has adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from the European Economic Area to the United Kingdom without additional safeguards. However, the United Kingdom adequacy decision will automatically expire in June 2025 unless the European Commission re- assesses and renews or extends that decision. We and many other companies may need to implement different or additional measures (such as the recently revised European Commission- approved Standard Contractual Clauses or the U. K. Government- approved International Data Transfer Agreement) to establish or maintain legitimate means for the transfer and receipt of personal data from the European Economic Area and the United Kingdom to the United States. Compliance with United States and foreign data protection laws and regulations could require us to take on more onerous obligations in our contracts; restrict our ability to collect, use, and disclose data; or in some cases, impact our ability to operate in certain jurisdictions. Failure by us or our collaborators to comply with United States and foreign data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and / or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity, and could have a material adverse effect on our business, financial condition, results of operations, and prospects. We may incur significant costs complying with environmental, health, and safety laws and regulations, and failure to comply with these laws and regulations could expose us to significant liabilities. We use hazardous chemicals and radioactive and biological materials in our business and are subject to a variety of federal, state, local and international laws and regulations governing, among other matters, the use, generation, manufacture, transportation, storage, handling, disposal of, and human exposure to these materials both in the United States and overseas, including regulation by governmental regulatory agencies, such as the Occupational Safety and Health Administration and the EPA. We have incurred, and will continue to incur, capital and operating expenditures and other costs in the ordinary course of our business in complying with these laws and regulations. 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 or hazardous materials. We are subject to certain United States and foreign anti- corruption, anti- money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations. Among other matters, United States and foreign anti- corruption, anti- money laundering, export control, sanctions and other trade laws and regulations prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Our business is heavily regulated and therefore involves significant interaction with public officials. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities and other organizations. We also expect our non- United States activities to increase in time. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the United States Foreign Corrupt Practices Act of 1977, as amended, or FCPA. We plan to engage third parties for clinical trials and / or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. In particular, our operations will be subject to FCPA, which prohibits, among other things, United States companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments

or anything else of value to foreign government officials, employees of public international organizations and foreign government- owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof. Recently, the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions, including imprisonment, against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, debarment, reputational harm, prohibitions on the conduct of our business, and other consequences. Any such violations could also result in prohibitions on our ability to offer our product candidates in one or more countries as well as difficulties in manufacturing or continuing to develop our product candidates, and could materially damage our reputation, our brand, our ability to attract and retain employees and our business, prospects, operating results, and financial condition. We may rely on third parties to develop and commercialize some of our product candidates **, and we may fail to successfully manage, or disputes may arise from, any such collaborations** . Markets in which collaborators develop product candidates using our technologies will be subject to extensive regulation, and we may rely on our collaborators to comply with all applicable laws and regulations. We have **previously** entered **into** , and may in the future enter into **,** collaboration arrangements to develop product candidates enabled by our technologies **. For example, because of our strategic reprioritization of our pipeline to focus on development of our lead program, PRGN- 2012, we plan to minimize UltraCAR- T spend and focus on strategic partnerships to further advance such UltraCAR- T programs. We may face significant competition in seeking appropriate partners for our product candidates, and the negotiation process may be time- consuming and complex** . There can be no guarantee that we can successfully manage these relationships **, as they involve complex interests and our interests and our collaborators' interests may diverge. Our collaborators may fail to perform their obligations under the collaboration agreements or may not perform their obligations in a timely manner** . If our collaborators are not able to successfully develop product candidates enabled by our technologies, none of these enabled product candidates will become commercially available, and we will receive no back- end payments under these arrangements. ~~We a timely manner.~~ If conflicts arise between our collaborators and us,the other party may act in a manner adverse to us and could limit our ability to implement our strategies.Furthermore,our collaborators may not properly obtain,maintain,enforce or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation.In addition,we cannot control the amount and timing of resources our collaborators may devote to our product candidates **or other collaborative efforts** .They may separately pursue competing products,therapeutic approaches or technologies to develop treatments for the diseases targeted by us.Competing products,either developed by the collaborators or to which the collaborators have rights,may result in the withdrawal of support for our product candidates.If our collaborators terminate or breach our agreements with them,or otherwise fail to complete their obligations **successfully or** in a timely manner,it ~~may have~~ may have ~~limited~~ **a detrimental effect on** ~~or~~ **our** ~~no control over~~ **financial position by reducing or eliminating** the ~~amount~~ **potential** ~~or~~ **for** ~~timing of resources that any~~ **us to receive anticipated revenues from the** ~~collaborator~~ **collaboration** ~~is able~~ **. In some cases,** ~~or~~ **our** ~~willing to devote to developing product candidates~~ **past strategic collaborations have resulted in disagreements and disputes regarding the relative rights, obligations, and revenues of us and** ~~or~~ **our** ~~collaborative~~ **collaboration** ~~efforts~~ **partners** . ~~Any of our~~ **Disagreements and disputes with future** collaborators may **result in** ~~fail to perform its obligations~~ --- **litigation , unfavorable settlements** ~~. Our collaborators may breach~~ or **concessions by** ~~terminate their agreements with~~ us **, or management distraction, that could harm** ~~or~~ **our business operations** ~~otherwise fail to conduct their collaborative activities successfully and in a timely manner~~ . Our technologies are used in product candidates that are subject to extensive regulation by governmental authorities. We may depend on our collaborators to comply with these laws and regulations with respect to product candidates they produce using our technologies, and we may not independently monitor whether our collaborators comply with applicable laws and regulations. If our collaborators fail to comply with applicable laws and regulations, we may be subject to substantial financial and operating risks because, in addition to our own compliance, we may depend on our collaborators to produce the end products enabled by our technologies for sale . We have previously entered into,....., that could harm our business operations . If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, if required in conjunction with the financial statement audit, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. We face an inherent risk of product liability exposure related to the testing of our product candidates in human trials and may face greater risk if we commercialize any products that we develop. Product liability claims may be brought against us by subjects enrolled in our trials, patients, healthcare providers or others using, administering, or selling our products. Insurance coverage for product liability claims is expensive and may be difficult to obtain, and may not be available to us in the future on acceptable terms, or at all. We cannot assure you that we will have adequate insurance coverage against potential claims. In addition, although we currently maintain

product liability insurance for our technologies in amounts we believe to be commercially reasonable, if the coverage limits of these insurance policies are not adequate, a claim brought against us, whether covered by insurance or not, could have a material adverse effect on our business, results of operations, financial condition, and cash flows or even cause us to go out of business. Regardless of the merits or eventual outcome, liability claims may result in: • reduced resources of our management to pursue our business strategy; • decreased demand for products enabled by our technologies; • injury to our reputations and significant negative media attention; • withdrawal of clinical trial participants; • initiation of investigations by regulators; • product recalls, withdrawals or labeling, marketing or promotional restrictions; • significant costs to defend resulting litigation; • substantial monetary awards to trial participants or patients; • loss of revenue; and • the inability to commercialize any products using our technologies. We do not carry insurance for all categories of risks that our business may encounter, and insurance coverage is becoming increasingly expensive. We do not know if we will be able to maintain existing insurance with adequate levels of coverage, and any liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. If we obtain marketing approval for any product candidates, we intend to acquire insurance coverage to include the sale of commercial products, but we may be unable to obtain such insurance on commercially reasonable terms or in adequate amounts. Required coverage limits for such insurances are difficult to predict and may not be sufficient. If potential losses exceed our insurance coverage, our financial condition would be adversely affected. In the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources. Clinical trials or regulatory approvals for any of our product candidates could be suspended, which could adversely affect our results of operations and business, including by preventing or limiting the development and commercialization of any product candidates that we may develop. The livestock products of our Exemplar reporting segment are subject to disease outbreaks that can increase the cost of production and / or reduce production harvests, and the loss of existing livestock would result in the loss of commercial technology. Several of the products of our operating subsidiary, Exemplar, are subject to periodic outbreaks of a variety of diseases. Although Exemplar takes measures to protect their animals, there can be no assurance that a disease will not damage or destroy existing animals. The economic impact of disease to Exemplar can be significant, as we must incur the cost of preventive measures, such as vaccines and antibiotics, and then if infected, the cost of lost or reduced production. The markets in which we are developing candidate products using our technologies are highly competitive. Competitors and potential competitors may develop products and technologies that make ours obsolete or garner greater market share than ours. While we believe that our novel approach to developing the next generation of gene and cell therapies to target the most urgent and intractable challenges in immuno- oncology, autoimmune disorders, and infectious diseases provides us with competitive advantages, our industry is highly competitive and subject to rapid and significant technological change. Many of our competitors have significantly greater financial, technical, and human resource capabilities than we do, and certain of our competitors may also benefit from local government subsidies and other incentives that are not available to us. In addition, mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. As a result of the resources available to our competitors, our competitors may be able to develop competing and / or superior technologies and processes, and compete more aggressively and sustain that competition over a longer period of time than we can. The availability of reimbursement from **the** government and **other third- party payers will also significantly affect the pricing and competitiveness of our products. Our competitors may also obtain FDA 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 before we are able to enter the market.** In the area of infectious diseases, our lead product candidate is PRGN- 2012, which is based on our AdenoVerse immunotherapy platform, for the treatment of RRP. We believe there are competitors in this area, including INOVIO Pharmaceuticals with their investigational DNA vaccine INO- 3107 targeting HPV6 and HPV11 antigens. Our other lead product candidates include ~~PRGN- 3005 for the treatment of ovarian cancer and~~ PRGN- 3006 for the treatment of AML, which are built on our UltraCAR- T platform, and PRGN- 2009, which is based on our AdenoVerse platform. While we are employing a novel approach, there are a number of competitors pursuing CAR- T cell therapies for the treatment of cancer. We believe that, among others, Bristol- Myers Squibb, Tmunity Therapeutics, and Anixa Biosciences are developing CAR- T based treatments for ovarian cancer and TCR2 Therapeutics is developing TCR- T based treatment for ovarian cancer. We believe that Celyad, Mustang Bio, Kite, Amgen, Cellectis S. A., and Allogene Therapeutics are also using CAR- T technology to develop product candidates for the treatment of AML. The CAR- T technology space also has significant other competition including from multiple companies and their collaborators, such as Novartis and University of Pennsylvania, Kite and Gilead, Adaptimmune and GSK, Autolus Therapeutics, Poseida Therapeutics, and Bellicum Pharmaceuticals. We also face competition from non- cell based cancer treatments offered by other companies such as Amgen, AstraZeneca, Incyte, Merck, Abbvie, and Roche. We are also using our suite of proprietary and complementary technologies for the preclinical and clinical development of product candidates for the treatment of autoimmune disorders, including T1D. We believe that our primary competitors with respect to the development of immunotherapies for T1D are Provention Bio, Midatech Pharma, and MerciaPharma. Our ability to compete successfully will depend on our ability to develop proprietary technologies that can be used to produce products that reach the market in a timely manner and are technologically superior to and / or are less expensive than other products on the market. As more companies develop new intellectual property in our markets, a competitor could acquire patent or other rights that may limit products using our technologies, which could lead to litigation. To the extent that any of our competitors are more successful with respect to any key competitive factor or we are forced to reduce, or are unable to raise, the price of any products enabled by our technologies in order to remain competitive, our operating results and financial condition could be materially adversely affected. Our business involves complex operations and requires a management team and employee workforce that is knowledgeable in the many areas in which we operate. The loss of any key members of our management, including our Chief Executive Officer, Helen Sabzevari Ph. D., or the failure to attract or retain other key employees who possess the requisite

expertise for the conduct of our business, could prevent us from developing and commercializing our product candidates for our target markets and executing on our business strategy. In addition, the loss of any key scientific staff, or the failure to attract or retain other key scientific employees, could prevent us from developing our technologies for our target markets or from further developing and commercializing our products and services offerings to execute on our business strategy. We may not be able to attract or retain qualified employees in the future due to the intense competition for qualified personnel among biotechnology, synthetic biology and other technology- based businesses, or due to the unavailability of personnel with the qualifications or experience necessary for our business. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience staffing constraints that will adversely affect our ability to support our internal research and development programs or meet other demands. We have had a number of executive officers depart from our Company over the last several years, and we continually evaluate our leadership structure. Our past or future leadership changes could lead to strategic and operational challenges and uncertainties, distractions of management from other key initiatives, inefficiencies or increased costs, any of which could adversely affect our business, financial condition, results of operations, and cash flows. We depend on sophisticated information technology and infrastructure. We rely on various information systems to manage our operations. These systems are complex and include software that is internally developed, software licensed from third parties, and hardware purchased from third parties. These products may contain internal errors or defects, particularly when first introduced or when new versions or enhancements are released. Failure of these systems could have an adverse effect on our business, which in turn may materially adversely affect our operating results and financial condition. We rely on various information systems to manage our operations and to store information, including sensitive data such as confidential business information and personally identifiable information. These systems have been and continue to be vulnerable to interruption or malfunction, including due to events beyond our control, and to unauthorized access, computer hackers, ransomware, viruses, and other security problems. Failure of these systems or any significant breach of our data security could have an adverse effect on our business and may materially adversely affect our operating results and financial condition. Data security breaches could result in loss or misuse of information, which could, in turn, result in potential regulatory actions or litigation, including material claims for damages, compelled compliance with breach notification laws, interruption to our operations, damage to our reputation or could otherwise have a material adverse effect on our business, financial condition and operating results. Companies throughout our industry have been increasingly subject to a wide variety of security incidents, cyber- attacks and other attempts to gain unauthorized access to networks or sensitive information. While we have implemented and continue to implement cybersecurity safeguards and procedures, these safeguards have been vulnerable to attack. As cyber threats continue to evolve, we may be required to expend additional resources to enhance our cybersecurity measures or to investigate or remediate any vulnerabilities or breaches. Although we maintain insurance to protect ourselves in the event of a breach or disruption of certain of our information systems, we cannot ensure that the coverage is adequate to compensate for any damages that may be incurred. The effects of health epidemics, including the COVID- 19 pandemic, could adversely affect our business operations, which could have a material adverse effect on our results of operations, cash flows, and financial position. The operations of our business could be adversely affected by health epidemics, including, for example, if we are unable to secure necessary supplies, including personal protection equipment for our employees. We also rely on third parties for various aspects of our business, including developing some of our product candidates. These third parties may experience similar disruptions or negative impacts to their businesses due to epidemics, which may result in additional delays or otherwise adversely impact our operations. In addition to the potential impacts to our operations, we may be required to implement, or reinstitute, precautions to mitigate the spread of the illness across our businesses, which may impact our ability to carry out our business as usual, including additional sanitation and cleaning procedures in our laboratories and other facilities, instituting remote working when possible, and implementing social distancing and staggered worktime requirements for our employees that must work on- site. An increase in remote working may also result in elevated susceptibility to cyber security risks. For example, during the COVID- 19 pandemic, we had incurred additional costs as a result of these measures. These measures could also lead to reduced efficiency in our operations. Several of our operations are leanly staffed and rely on key personnel to manage operations. The loss of our key scientific staff, personnel, or other key employees, as a result of illness or otherwise, could negatively impact our business and operations, particularly if we are unable to adequately find or train replacements. A significant outbreak of infectious diseases in the future could result in a widespread health crisis that could adversely affect the economies and financial markets worldwide, resulting in an economic downturn that could impact our business, financial condition and results of operations. We have international operations and assets and may have additional international operations and assets in the future. Our international operations and assets may be subject to various economic, social, and governmental risks. Our international operations and any future international operations may expose us to risks that could negatively impact our future results. Our operations may not develop in the same way or at the same rate as might be expected in a country with an economy similar to the United States. The additional risks that we may be exposed to in these cases include, but are not limited to: • tariffs and trade barriers; • currency fluctuations, which could decrease our revenues or increase our costs in United States dollars; • regulations related to customs and import / export matters; • tax issues, such as tax law changes and variations in tax laws; • limited access to qualified staff; • inadequate infrastructure; • cultural and language differences; • inadequate banking systems; • different and / or more stringent environmental laws and regulations; • restrictions on the repatriation of profits or payment of dividends; • disease outbreaks, environmental catastrophes, crime, strikes, riots, civil disturbances, terrorist attacks or wars; • nationalization or expropriation of property; • law enforcement authorities and courts that are weak or inexperienced in commercial matters; and • deterioration of political relations among countries. Additionally, we are exposed to risks associated with changes in foreign currency exchange rates. We present our consolidated financial statements in United States dollars. Our international subsidiaries have assets and liabilities denominated in currencies other than the United States dollar. Future expenses and revenues of our international subsidiaries are expected to be denominated in currencies other than in United States

dollars. Therefore, movements in exchange rates to translate from foreign currencies may have an impact on our reported results of operations, financial position, and cash flows. We may pursue strategic acquisitions and investments that could have an adverse impact on our business if they are unsuccessful. We have made acquisitions in the past and, if appropriate opportunities become available, we may acquire additional businesses, assets, technologies, or products to enhance our business in the future. In connection with any future acquisitions, we could: • issue additional equity securities, which would dilute our current shareholders; • incur substantial debt to fund the acquisitions; or • assume significant liabilities. Although we conduct due diligence reviews of our acquisition targets, such processes may fail to reveal significant liabilities. Acquisitions involve numerous risks, including: • problems integrating the purchased operations, facilities, technologies, or products; • unanticipated costs and other liabilities; • the potential disruption of our ongoing business and diversion of management resources; • adverse effects on existing business relationships with current and / or prospective collaborators, customers and / or suppliers; • unanticipated expenses related to the acquired operations; • risks associated with entering markets in which we have no or limited prior experience; • potential unknown liabilities associated with the acquired business and technology; • potential liabilities related to litigation involving the acquired companies; • potential periodic impairment of goodwill and intangible assets acquired; and • potential loss of key employees or potential inability to retain, integrate, and motivate key personnel. We cannot be certain that any acquisition will be successful or that we will realize the anticipated benefits of the acquisition. In particular, we may not be able to realize the strategic and operational benefits and objectives we had anticipated. Acquisitions also may require us to record goodwill and non- amortizable intangible assets that will be subject to impairment testing on a regular basis and potential periodic impairment charges, incur amortization expenses related to certain intangible assets, and incur large and immediate write- offs and restructuring and other related expenses, all of which could harm our operating results and financial condition. In addition, we may acquire companies that have insufficient internal financial controls, which could impair our ability to integrate the acquired company and adversely impact our financial reporting. If we fail in our integration efforts with respect to any of our acquisitions and are unable to efficiently operate as a combined organization, our business, and financial condition may be adversely affected. As a result of the Company' s **decision to shutdown Actobio' s operations and Exemplar' s reporting unit' s** annual goodwill impairment test, the Company recorded a $ ~~10~~ **7** . 4 million goodwill impairment charge ~~resulting from our annual test for goodwill in our Exemplar segment~~ in the year ended December 31, ~~2023~~ **2024** . See Note 9 to our consolidated financial statements appearing elsewhere in this Annual Report for additional discussion. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. As of December 31, ~~2023~~ **2024** , we had net operating loss carryforwards of approximately $ ~~891~~ **969** . ~~6~~ **9** million for United States federal income tax purposes available to offset future taxable income, including $ ~~675~~ **757** . 0 million generated after 2017, United States capital loss carryforwards of $ ~~212~~ **100** . ~~5~~ **9** million, and United States federal and state research and development tax credits of $ ~~13~~ **16** . ~~5~~ **2** million, prior to consideration of annual limitations that may be imposed under Section 382 of the Internal Revenue Code of 1986, as amended, or **("** Section 382 **")** . Net operating loss carryforwards generated prior to 2018 **will** ~~began to~~ expire ~~in~~ **if unutilized from** ~~2023~~ **2025 to 2037** , and capital loss carryforwards will expire if unutilized **from** ~~beginning in 2024~~ **2025 to 2027** . As a result of our past issuances of stock, as well as due to prior mergers and acquisitions, certain of our net operating losses have been subject to limitations pursuant to Section 382. As of December 31, ~~2023~~ **2024** , we had utilized all net operating losses subject to Section 382 limitations, other than those losses inherited via acquisitions. As of December 31, ~~2023~~ **2024** , approximately $ ~~39~~ **35** . ~~7~~ **8** million of domestic net operating losses were acquired via acquisition and are limited based on the value of the target at the time of the transaction. Future changes in stock ownership may also trigger an ownership change and, consequently, a Section 382 limitation. As of December 31, ~~2023~~ **2024** , our direct foreign subsidiaries included in continuing operations had foreign loss carryforwards of approximately $ ~~73~~ **69** . 8 million, most of which do not expire. Our ability to compete may decline if we do not adequately protect our proprietary technologies or if we lose some of our intellectual property rights through costly litigation or administrative proceedings. Our success depends in part on our ability to obtain patents and maintain adequate protection of our intellectual property in the United States and abroad for our suite of technologies and product candidates. We have adopted a strategy of seeking patent protection in the United States and abroad with respect to certain of the technologies used in or relating to our technologies and product pipeline. We have also in- licensed rights to additional patents and pending patent applications in the United States and abroad. We intend to continue to apply for patents relating to our technologies, methods, and products as we deem appropriate. For instance, we pursue protection of switch technologies, gene delivery technologies, and genetic componentry related to our pipeline products. In addition, we seek patents covering specific collaborator' s products. We have also filed patents and patent applications in other jurisdictions, such as Australia, Canada, China, Europe, Hong Kong, India, Israel, Japan, Korea and South Africa. In the future we may file in these or additional jurisdictions as deemed appropriate for the protection of our technologies. The enforceability of patents, as well as the actual patent term and expiration thereof, involves complex legal and factual questions and, therefore, the extent of enforceability cannot be guaranteed. Issued patents and patents issuing from pending applications may be challenged, invalidated, or circumvented. Moreover, the United States Leahy- Smith America Invents Act, enacted in September 2011, brought significant changes to the United States patent system, which include a change to a" first to file" system from a" first to invent" system and changes to the procedures for challenging issued patents and disputing patent applications during the examination process, among other things. These changes could increase the costs and uncertainties surrounding the prosecution of our patent applications and the enforcement or defense of our patent rights. Additional uncertainty may result from legal precedent handed down by the United States Court of Appeals for the Federal Circuit and United States Supreme Court as they determine legal issues concerning the scope and construction of patent claims and inconsistent interpretation of patent laws by the lower courts. Accordingly, we cannot ensure that any of our pending patent applications will result in issued patents, or even if issued, predict the breadth of the claims upheld in our and other companies' patents. Given that the degree of future protection for our proprietary rights is uncertain, we cannot ensure that we were the first to invent the inventions covered by our pending

patent applications; we were the first to file patent applications for these inventions; the patents we have obtained, particularly certain patents claiming nucleic acids, proteins, or methods, are valid and enforceable; and the proprietary technologies we develop will be patentable. In addition, unauthorized parties may attempt to copy or otherwise obtain and use our products or technology. Monitoring unauthorized use of our intellectual property is difficult, and we cannot be certain that the steps we have taken will prevent unauthorized use of our technologies, particularly in certain foreign countries where the local laws may not protect our proprietary rights as fully as in the United States. Moreover, third parties could practice our inventions in territories where we do not have patent protection. Such third parties may then try to import into the United States or other territories products, or information leading to potentially competing products, made using our inventions in countries where we do not have patent protection for those inventions. If competitors are able to use our technologies, our ability to compete effectively could be harmed. Moreover, others may independently develop and obtain patents for technologies that are similar to or superior to our technologies. If that happens, we may need to license these technologies, and we may not be able to obtain licenses on reasonable terms, if at all, which could harm our business. We also rely on trade secrets to protect our technologies, especially in cases when we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we require our employees, academic collaborators, collaborators, consultants and other contractors to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary or licensed information. If we cannot maintain the confidentiality of our proprietary and licensed technologies and other confidential information, our ability, and that of our licensors, to receive patent protection and our ability to protect valuable information owned or licensed by us may be imperiled. Enforcing a claim that a third- party entity illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. Moreover, our competitors may independently develop equivalent knowledge, methods, and know- how. Our commercial success also depends in part on not infringing patents and proprietary rights of third parties and not breaching any licenses or other agreements that we have entered into with regard to our technologies, products, and business. We cannot ensure that patents have not been issued to third parties that could block our or our collaborators' ability to obtain patents or to operate as we would like. There may be patents in some countries that, if valid, may block our ability to make, use or sell our products in those countries, or import our products into those countries, if we are unsuccessful in circumventing or acquiring the rights to these patents. There also may be claims in patent applications filed in some countries that, if granted and valid, also may block our ability to commercialize products or processes in these countries if we are unable to circumvent or license them. The biotechnology industry is characterized by frequent and extensive litigation regarding patents and other intellectual property rights. Many companies have employed intellectual property litigation as a way to gain a competitive advantage. Our involvement in litigation, interferences, opposition proceedings or other intellectual property proceedings inside and outside of the United States, to defend our intellectual property rights or as a result of alleged infringement, misappropriation or violation of the rights of others, may divert management' s time from focusing on business operations and could cause us to spend significant amounts of money. Some of our competitors may have significantly greater resources and, therefore, they are likely to be better able to sustain the cost of complex patent or intellectual property litigation than we could. The uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our business or to enter into additional collaborations with others. Furthermore, any potential intellectual property litigation also could force us or our collaborators to do one or more of the following: • stop selling, incorporating or using products that use the intellectual property at issue; • obtain from the third party asserting its intellectual property rights a license to sell or use the relevant technology, which license may not be available on reasonable terms, if at all; or • redesign those products or processes that use any allegedly infringing technology, or relocate the operations relating to the allegedly infringing technology to another jurisdiction, which may result in significant cost or delay to us, or that could be technically infeasible. The patent landscape in the field of biotechnology is particularly complex. We are aware of United States and foreign patents and pending patent applications of third parties that cover various aspects of cell and gene biology including patents that some may view as covering aspects of our technologies. In addition, there may be patents and patent applications in the field of which we are not aware. In many cases, the technologies we develop are early- stage technologies, and we are just beginning the process of designing and developing products using these technologies. Although we will seek to avoid pursuing the development of products that may infringe any patent claims that we believe to be valid and enforceable, we and our collaborators may fail to do so. Moreover, given the breadth and number of claims in patents and pending patent applications in the field of synthetic biology and the complexities and uncertainties associated with them, third parties may allege that we are infringing upon patent claims even if we do not believe such claims to be valid and enforceable. Except for claims we believe will not be material to our financial results, no third party has asserted a claim of infringement against us. Others may hold proprietary rights that could prevent products using our technologies from being marketed. Any patent- related legal action against persons who license our technologies or us claiming damages and seeking to enjoin commercial activities relating to products using our technologies or our processes could subject us to potential liability for damages and require our licensee or us to obtain a license to continue to manufacture or market such products or any future product candidates that use our technologies. We cannot predict whether we or our licensor would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. In addition, we cannot be sure that any such products or any future product candidates or processes could be redesigned to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us or our licensees from developing and commercializing products using our technologies, which could harm our business, financial condition, and operating results. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. If any of our competitors

have filed patent applications or obtained patents that claim inventions also claimed by us, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention and, thus, the right to the patents for these inventions in the United States. These proceedings could result in substantial cost to us even if the outcome is favorable. Even if successful, an interference may result in loss of certain of our important claims. Any litigation or proceedings could divert our management' s time and efforts. Even unsuccessful claims could result in significant legal fees and other expenses, diversion of management' s time, and disruption in our business. Uncertainties resulting from initiation and continuation of any patent or related litigation could harm our ability to compete. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and 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. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other provisions during the patent process. Given the size of our intellectual property portfolio, compliance with these provisions involves significant time and expense. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. If we do not obtain additional protection under the Hatch- Waxman Amendments, other United States legislation, and similar foreign legislation by extending the patent terms and obtaining regulatory exclusivity for our technologies, our business may be materially harmed. Depending upon the timing, duration, and specifics of FDA marketing approval of products using our technologies, one or more of the United States patents we own or license may be eligible for limited patent term restoration under the Hatch- Waxman Amendments. The Hatch- Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our ability to generate revenues could be materially adversely affected. Some of our products may not have patent protection and, as a result, potential competitors face fewer barriers in introducing competing products. We may rely on trade secrets and other unpatented proprietary information to protect our commercial position with respect to such products, which we may be unable to do. In some instances, we may also rely on regulatory exclusivity, including orphan drug exclusivity, to protect our products from competition. Some of our or our collaborators' products may be subject to the BPCIA, which may provide those products exclusivity that prevents approval of a biosimilar product that references the data in one of our BLAs in the United States for 12 years after approval. However, the BPCIA and other regulatory exclusivity frameworks may evolve over time based on statutory changes, FDA issuance of new regulations, and judicial decisions. In addition, the BPCIA exclusivity period does not prevent another company from independently developing a product that is highly similar to an approved product, generating all the data necessary for a full BLA and seeking approval. If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business. We have entered into license agreements with third parties and may need to obtain additional licenses from our existing licensors and others to advance our research or allow commercialization of product candidates we may develop. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. Disputes may arise regarding intellectual property subject to a licensing agreement, including: • the scope of rights granted under the license agreement and other interpretation- related issues; • the extent to which our technology and processes infringe, misappropriate or otherwise violate the intellectual property of the licensor that is not subject to the licensing agreement; • our diligence obligations under the license agreement and what activities satisfy those diligence obligations; • the inventorship and ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and • the priority of invention of patented technology. In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. Enforcing our intellectual property rights may be difficult and unpredictable. If we were to initiate legal proceedings against a third party to enforce a patent claiming one of our technologies, the defendant could counterclaim that our patent is invalid and / or unenforceable or assert that the patent does not cover its manufacturing processes, manufacturing components or products. Proving patent infringement may be difficult, especially where it is possible to manufacture a product by multiple processes. Furthermore, in patent litigation in the United States, defendant counterclaims alleging both invalidity and unenforceability are commonplace. Although we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity of our patent rights, we cannot be certain,

for example, that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would not be able to exclude others from practicing the inventions claimed therein. Such a loss of patent protection could have a material adverse impact on our business. Even if our patent rights are found to be valid and enforceable, patent claims that survive litigation may not cover commercially valuable products or prevent competitors from importing or marketing products similar to our own, or using manufacturing processes or manufacturing components similar to those used to produce the products using our technologies. Although we believe we have obtained assignments of patent rights from all inventors, if an inventor did not adequately assign their patent rights to us, a third party could obtain a license to the patent from such inventor. This could preclude us from enforcing the patent against such third party. We may not be able to enforce our intellectual property rights throughout the world. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to synthetic biology. This could make it difficult for us to stop the infringement of our patents or misappropriation of our other intellectual property rights. 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. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. If our technologies or products using our technologies are stolen, misappropriated, or reverse engineered, others could use the technologies to produce competing technologies or products. Third parties, including our collaborators, contract manufacturers, contractors and others involved in our business, often have access to our technologies. If our technologies, or products using our technologies, were stolen, misappropriated, or reverse engineered, they could be used by other parties that may be able to reproduce our technologies or products using our technologies, for their own commercial gain. If this were to occur, it would be difficult for us to challenge this type of use, especially in countries with limited intellectual property protection. Confidentiality agreements with employees and others may not adequately prevent disclosures of trade secrets and other proprietary information. We have taken measures to protect our trade secrets and proprietary information, but these measures may not be effective. We require our new employees and consultants to execute confidentiality agreements upon the commencement of an employment or consulting arrangement with us. These agreements generally require that all confidential information developed by the individual or made known to the individual by us during the course of the individual' s relationship with us be kept confidential and not disclosed to third parties. These agreements also generally provide that inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Our proprietary information may be disclosed, third parties could reverse engineer our technologies or products using our technologies, and others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets. Costly and time- consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position. **We have failed in the past and may fail in the future to meet all applicable continued listing requirements of Nasdaq Global Select Market, which could result in a delisting of our common stock. Delisting could negatively affect the price of our common stock which, could make it more difficult for us to sell securities in a future financing or for you to sell our common stock. Our common stock is currently listed on the Nasdaq Global Select Market of The Nasdaq Stock Market, LLC (“ Nasdaq ”), which has qualitative and quantitative continued listing criteria. However, we cannot assure you that our common stock will continue to be listed on Nasdaq in the future. In order to continue listing our common stock on Nasdaq, we are required to meet the continued listing requirements of Nasdaq and other Nasdaq rules, including those regarding director independence and independent committee requirements, minimum stockholders’ equity, minimum share price and certain other corporate governance requirements. In particular, we are required to maintain a minimum bid price for our listed common stock of $ 1. 00 per share. We have in the past, and may in the future, be unable to comply with these continued listing requirements; if we do not meet these continued listing requirements, our common stock could be delisted. On November 1, 2024, we received a deficiency letter (the “ Deficiency Letter ”) from the Listing Qualifications Department (the “ Staff ”) of Nasdaq indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum $ 1. 00 per share requirement for continued listing on Nasdaq under Nasdaq Listing Rule 5450 (a) (1) (the “ Bid Price Rule ”). In accordance with Nasdaq Listing Rule 5810 (c) (3) (A), we were provided an initial period of 180 calendar days, or until April 30, 2025, to regain compliance. To regain compliance, the bid price of our common stock must close at $ 1. 00 per share or more for a minimum of ten consecutive business days during such 180- day compliance period. The Deficiency Letter had no immediate effect on the listing or trading of our common stock. On January 16, 2025, we received written notification from Nasdaq indicating that the Company' s common stock had a closing price at or greater than $ 1. 00 per share for the last 10 consecutive business days, from December 31, 2024 to January 15, 2025, and that, as a result, we have regained compliance with the Bid Price Rule and the matter is closed. However, there can be no assurance that we will be able to maintain compliance with the Nasdaq listing requirements, including the minimum bid price requirement. If we fail to maintain compliance with the minimum bid price requirement or to meet the other applicable continued listing requirements in the future and Nasdaq determines to delist our common stock, the delisting could adversely affect the market price and liquidity of our common stock, reduce our ability to raise additional capital and result in operational challenges and damage to investor relations and market reputation. Our quarterly and annual operating**

results may fluctuate in the future. As a result, we may fail to meet or exceed the expectations of research analysts or investors, which could cause our stock price to decline. Our financial condition and operating results have varied significantly in the past and may continue to fluctuate from quarter to quarter and year to year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following factors, as well as other factors described elsewhere in this Annual Report: • our ability to achieve or maintain profitability; • the outcomes of our research programs, clinical trials, or other product development and approval processes; • our ability to develop and successfully commercialize our products; • the timing, receipt, and amount of any payments received in connection with upfront, milestone, and sale and royalty payments, if any; • our ability to successfully scale up production of our commercial products and customer acceptance thereof; • our ability to enter into strategic transactions; • our ability to develop and maintain our technologies; • our ability to manage our growth; • risks associated with the international aspects of our business; • our ability to accurately report our financial results in a timely manner; • our dependence on, and the need to attract and retain, key management, and other personnel; • our ability to obtain, protect and enforce our intellectual property rights; • our ability to prevent the theft or misappropriation of our intellectual property, know- how or technologies; • the costs associated with legal activities, including litigation, arising in the course of our business activities and our ability to prevail in any such legal disputes; • potential advantages that our competitors and potential competitors may have in securing funding or developing competing technologies or products; • our ability to obtain additional capital that may be necessary to expand our business; • business interruptions such as power outages and other natural disasters; • our ability to integrate any businesses or technologies we may acquire with our business; • negative public opinion and increased regulatory scrutiny of gene and cell therapies; • the impact of new accounting pronouncements on our current and future operating results; • our ability to use our net operating loss carryforwards to offset future taxable income; and • the results of our consolidated subsidiaries. Due to the various factors mentioned above, and others, the results of any prior quarterly or annual periods should not be relied upon as indications of our future operating performance. Our stock price is volatile, and purchasers of our common stock could incur substantial losses. Our stock price has been, and is likely to continue to be, volatile. The market price of our common stock could fluctuate significantly for many reasons, including in response to the risks described in this" Risk Factors" section, or for reasons unrelated to our operations, such as reports by media or industry analysts, investor perceptions or negative announcements by our collaborators regarding their own performance, as well as industry conditions and general financial, economic and political instability. From January 1, ~~2022~~ **2023** through February 15, ~~2024~~ **2025** , our common stock has traded as high as $ ~~3~~ **2** . ~~99~~ **19** per share and as low as $ 0. ~~81~~ **67** per share. The stock market in general, as well as the market for biopharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price of our common stock may be influenced by many factors, including, among others: • announcements of acquisitions, collaborations, financings, divestitures, or other transactions by us; • public concern as to the safety of our products; • termination or delay of a development program; • the recruitment or departure of key personnel; and • the other factors described in this" Risk Factors" section. In addition, we believe there has been and may continue to be substantial off- market transactions in derivatives of our stock, including short selling activity or related similar activities, which are beyond our control and which may be beyond the full control of the SEC and Financial Institutions Regulatory Authority, or FINRA. While SEC and FINRA rules prohibit some forms of short selling and other activities that may result in stock price manipulation, such activity may nonetheless occur without detection or enforcement. Significant short selling or other types of market manipulation could cause our stock trading price to decline, to become more volatile, or both. Additionally, we have historically, and may from time to time in the future, own equity interests in our collaborators. Owning equity in our collaborators increases our exposure to the risks of our collaborators' businesses beyond the products of those collaborations. Any equity ownership in our collaborators exposes us to volatility and the potential for negative returns. We may have restrictions on resale and / or limited markets to sell our equity ownership. If our equity position is a minority position, we are exposed to further risk as we will not be able to exert control over the companies in which we hold securities ~~. If we do not meet the continued listing requirements of Nasdaq our common stock may be delisted. Our common stock is listed on Nasdaq Global Select Market (" Nasdaq "). Nasdaq requires us to continue to meet certain listing standards, including standards related to the trading price of our common stock. While we are currently in compliance with the NYSE continued listing requirements, we cannot assure you that we will remain in compliance. If we do not meet Nasdaq' s continued listing standards, we will be notified by Nasdaq and we will be required to take corrective action to meet the continued listing standards; otherwise our common stock will be delisted from Nasdaq. A delisting of our common stock on Nasdaq would reduce the liquidity and market price of our common stock and the number of investors willing to hold or acquire our common stock, which could negatively impact our ability to access the public capital markets. A delisting would also reduce the value of our equity compensation plans, which could negatively impact our ability to retain key employees~~ . We have never declared or paid cash dividends on our capital stock. We do not anticipate paying cash dividends in the future and intend to retain all of our future earnings, if any, to finance the operations, development, and growth of our business. As a result, appreciation of the price of our common stock, which may never occur, will provide a return to shareholders. Investors seeking cash dividends should not invest in our common stock. We have twice distributed equity securities of affiliated entities to our shareholders as a special stock dividend, most recently in 2017, but it is possible that we may never declare a special dividend again, and shareholders should not rely upon potential future special dividends as a source of return on their investment. If securities or industry analysts do not publish research or reports, or publish inaccurate or unfavorable research or reports about our business, our share price and trading volume could decline. The trading market for our shares of common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If securities or industry analysts do not continue to cover us, the trading price for our shares of common stock may be negatively impacted. If one or more of the analysts who covers us downgrades our shares of common stock, changes their opinion of our shares or

publishes inaccurate or unfavorable research about our business, our share price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our shares of common stock could decrease and we could lose visibility in the financial markets, which could cause our share price and trading volume to decline. As of December 31, ~~2023~~ **2024** , Randal J. Kirk controlled approximately ~~39~~ **40** percent of our common stock. If our executive officers and directors choose to act together, they may be able to significantly influence our management and operations, acting in their own best interests and not necessarily those of other shareholders. We have historically been controlled and principally funded by Randal J. Kirk, our Executive Chairman, and affiliates of Mr. Kirk, including Third Security. As of February 15, ~~2024~~ **2025** , Mr. Kirk and shareholders affiliated with him beneficially owned approximately ~~39~~ **40** percent of our voting stock, and our executive officers and directors, as a group, owned approximately ~~41~~ **42** percent of our voting common stock. Mr. Kirk may be able to control or significantly influence all matters requiring approval by our shareholders, including the election of directors and the approval of mergers or other business combination transactions, and he may be able to exert significant influence on other corporate actions as a result of his role as our Executive Chairman and status as a significant shareholder. Further, our executive officers and directors, acting together as shareholders, would be able to significantly influence all matters requiring approval by our shareholders, including the election of directors and the approval of mergers or other business combination transactions, as well as our management and affairs. The interests of this group of shareholders may not always coincide with the interests of other shareholders, and they may act in a manner that advances their best interests and not necessarily those of other shareholders. This concentration of ownership control may: • delay, defer, or prevent a change in control; • entrench our management and / or the board of directors; or • impede a merger, consolidation, takeover, or other business combination involving us that other shareholders may desire. We have engaged in transactions with companies in which Randal J. Kirk, our Executive Chairman, and his affiliates have an interest. We have engaged in a variety of transactions, including collaborations and our sale of our non- healthcare assets to TS Biotechnology, with companies in which Mr. Kirk and affiliates of Mr. Kirk have a direct or indirect interest. Mr. Kirk serves as the Senior Managing Director and Chairman of Third Security and owns 100 percent of the equity interests of Third Security. We believe that each of these transactions was on terms no less favorable to us than terms we could have obtained from unaffiliated third parties, and each of these transactions was approved by at least a majority of the disinterested members of the audit committee of our board of directors. Furthermore, as we execute on these transactions going forward, a conflict may arise between our interests and those of Mr. Kirk and his affiliates. Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. If Mr. Kirk or any of his affiliates were to sell a substantial portion of the shares they hold, it could cause our stock price to decline. In addition, as of December 31, ~~2023~~ **2024** , there were ~~22~~ **25** , ~~057~~ **924** , ~~340~~ **734** shares subject to outstanding options that will become eligible for sale in the public market to the extent permitted by any applicable vesting requirements, other contractual limitations and federal securities law limitations. As of December 31, ~~2023~~ **2024** , there were ~~961~~ **4** , ~~534~~ **004, 057** restricted stock units ~~, or RSUs,~~ **and performance stock units** outstanding. Shares issuable upon the exercise of such options and upon vesting of the ~~RSUs~~ **restricted stock units and performance stock units** can be freely sold in the public market upon issuance and once vested. Additionally, as of December 31, ~~2023~~ **2024** , we had ~~4~~ **2** , ~~502~~ **448** , ~~466~~ **058** shares available for grant under the 2019 Incentive Plan for Non- Employee Service Providers and ~~16~~ **7** , ~~078~~ **043** , ~~137~~ **377** shares available for grant under the 2023 Omnibus Incentive Plan **. In addition, as of December 31, 2024, there were approximately 70, 222, 215 shares of common stock initially underlying the Series A Preferred Stock and 52, 666, 669 shares of common stock initially underlying the Warrants. The exercisability of the Series A Preferred Stock and the Warrants is contingent upon us obtaining stockholder approval to increase the number of authorized shares of common stock** . Our articles of incorporation authorize us to issue, without the approval of our shareholders, one or more classes or series of preferred stock having such designations, preferences, limitations and relative rights, including preferences over our common stock respecting dividends and distributions, as our board of directors may determine. For example, in connection with the ~~formation~~ **issuance in December 2024** of ~~a~~ **79, 000 shares of Series A** Preferred Stock **described elsewhere** ~~Equity Facility, which was subsequently terminated~~ in ~~June 2018~~ **this Annual Report** , we filed an amendment to our articles of incorporation to set the designations of ~~our~~ **the** Series A Preferred Stock. ~~Effective February 1, 2020, the Series A Preferred Stock designations was terminated.~~ In the future, we may ~~enter into similar facilities or~~ issue **additional** preferred stock that has greater rights, preferences, and privileges than our common stock. Certain provisions of Virginia law, the commonwealth in which we are incorporated, and our articles of incorporation and bylaws could hamper a third party' s acquisition of us, or discourage a third party from attempting to acquire control of us. These provisions: • include a provision allowing our board of directors to issue preferred stock with rights senior to those of the common stock without any vote or action by the holders of our common stock. The issuance of preferred stock could adversely affect the rights and powers, including voting rights, of the holders of common stock; • establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at shareholder meetings; • provide for the inability of shareholders to convene a shareholders' meeting without the support of shareholders owning together 25 percent of our common stock; • provide for the application of Virginia law prohibiting us from entering into a business combination with the beneficial owner of 10 percent or more of our outstanding voting stock for a period of three years after the 10 percent or greater owner first reached that level of stock ownership, unless we meet certain criteria; • allow the authorized number of our directors to be changed only by resolution of our board of directors; • limit the manner in which shareholders can remove directors from the board; • require that shareholder actions must be effected at a duly called shareholder meeting and prohibit actions by our shareholders by written consent; and • limit who may call a special meeting of shareholders. These provisions also could limit the price that certain investors might be willing to pay in the future for shares of our common stock. In addition, these provisions make it more difficult for our shareholders, should they choose to do so, to remove our board of directors or management.