

Risk Factors Comparison 2024-03-13 to 2023-02-23 Form: 10-K

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Our business involves **significant material** risks, ~~some of~~ which are described below. Before making investment decisions regarding our common stock, you should carefully consider these risks, as well as the other information in this Annual Report on Form 10-K, including our financial statements and the related notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” The occurrence of any of the events or developments described below could have a material adverse effect on our business, results of operations, financial condition, ~~and~~ **prospects and stock price**. In such event, the market price of our common stock could decline, and you could lose all or part of your investment. In addition, there are additional risks not described below that either are not presently known to us or that we currently deem immaterial, and these additional risks could also materially impair our business, operations or market price of our common stock. Risks Relating to **our Finances** **We have incurred significant operating losses since inception and anticipate that we will incur continued losses for the foreseeable future. We have a history of recurring net losses, including \$ 257.8 million and \$ 192.3 million for the years ended December 31, 2023 and 2022, respectively, and we have otherwise generated operating losses since we began operations in 1995. The extent of our future losses and the timing of profitability are uncertain, and we expect to incur losses for the foreseeable future. We have been engaged in developing our ZF technology since inception, which has and will continue to require significant research and development expenditures. To date, we have generated our funding from issuance of equity securities, revenues derived from collaboration agreements, other strategic partnerships in non-therapeutic applications of our technology, federal government research grants and grants awarded by research foundations. We expect to continue to incur additional operating losses for the next several years as we continue to develop our preclinical core neurology therapeutic programs and capsid engineering platform. If the time required to generate significant product revenues and achieve profitability is longer than we currently anticipate or if we are unable to generate liquidity through equity financing or other sources of funding, we may be forced to further curtail or suspend, or entirely cease, our operations. There is substantial doubt about our ability to continue to operate as a going concern. We need substantial additional funding to execute our operating plan and to continue to operate as a going concern. If adequate funds are not available to us on a timely basis, or at all, we will be required to take additional actions to address our liquidity needs, including additional cost reduction measures such as further reducing operating expenses and delaying, reducing the scope of, discontinuing or altering our research and development activities, which would have a material adverse effect on our business and prospects, or we may be required to cease operations entirely, liquidate all or a portion of our assets, and / or seek protection under the U. S. Bankruptcy Code, and you may lose all or part of your investment. Future sales and issuances of equity securities would also result in substantial dilution to our stockholders. We have incurred significant operating losses and negative operating cash flows since inception and have not achieved profitability. Based on our current operating plan, we estimate that our available cash, cash equivalents and marketable securities as of December 31, 2023, in combination with potential future cost reductions, will be sufficient to fund our planned operations only into the third quarter of 2024. Our financial position raises substantial doubt about our ability to continue to operate as a going concern. Our ability to continue to operate as a going concern is dependent upon our ability to raise substantial additional capital to fund our operations and support our research and development endeavors, including to progress our preclinical and clinical programs as described in this Annual Report on Form 10-K. In this regard, we have been seeking, and continue to actively seek substantial additional capital, including through public or private equity or debt financing, royalty financing or other sources, such as strategic collaborations and other direct investments in our programs. We have been unsuccessful in securing such additional capital to date. If we are unable to secure additional funding in the very near term, we will likely seek protection under the U. S. Bankruptcy Code. We have explored, and continue to explore, whether filing for bankruptcy protection is in the best interest of our Company and our stakeholders. Additional capital may not be available on acceptable terms or at all. In particular, the perception of our ability to continue to operate as a going concern may make it more difficult to obtain financing for the continuation of our operations, particularly in light of currently challenging macroeconomic and market conditions. Further, we may be unable to attract new investments as a result of the speculative nature of our newly reprioritized core neurology preclinical programs. If adequate funds are not available to us on a timely basis, or at all, we will be required to take additional actions to address our liquidity needs, including additional cost reduction measures such as further reducing operating expenses and delaying, reducing the scope of, discontinuing or altering our research and development activities, which would have a material adverse effect on our business and prospects, or we may be required to cease operations entirely, liquidate all or a portion of our assets, and / or seek protection under the U. S. Bankruptcy Code, and you may lose all or part of your investment. In this regard, in April 2023, we announced a restructuring of operations and a reduction in force and a significant reduction in our internal manufacturing and allogeneic research footprints in California, or the April Restructuring, and in November 2023, we announced a further restructuring of operations and reduction in force, or the November Restructuring, including a strategic transformation to focus resources on our proprietary neurology- focused epigenetic regulation programs and AAV capsid delivery technology and move all U. S. operations, including our headquarters, to our Richmond, California facility. On March 1, 2024, our board of directors approved the wind- down of our operations in France and closure of our facility in Valbonne France by the end of 2024, or the France Restructuring. While we expect the April, November and France**

Restructurings to be complete by the third quarter of 2024, the second quarter of 2024 and the fourth quarter of 2024, respectively, we may also incur other charges or cash expenditures not currently contemplated due to events that may occur as a result of, or associated with, each of the restructurings. In addition, we may not achieve the expected benefits of these cost reduction measures and other cost reduction plans on the anticipated timeline, or at all, or we may use our available capital more quickly than we expect, which could otherwise accelerate our liquidity needs and could force us to further curtail or suspend, or entirely cease, our operations. Moreover, we have historically relied in part on collaboration partners to provide funding for and otherwise advance our preclinical and clinical programs. However, in June 2022, our collaboration agreement with Sanofi terminated, in June 2023 our collaboration agreements with Biogen and Novartis terminated, and our collaboration agreement with Kite expires by its terms in April 2024, and we do not expect such agreement to be extended. While we may identify new collaboration partners who can progress some of the programs that were the subject of these collaborations as well as our Fabry disease gene therapy program and our CAR-Treg cell therapy programs, we have not yet been, and may never be, successful in doing so in a timely manner, on acceptable terms or at all, and we may otherwise fail to raise sufficient additional capital in order to progress these and our other programs ourselves, in which case, we will not receive any return on our investments in these programs. In any event, we need substantial additional funding in order to progress the programs that were the subject of these collaborations as well as our Fabry disease and CAR-Treg cell therapy programs, and to advance our core neurology programs and otherwise execute on our current operating plan. If we raise additional capital through public or private equity offerings, including sales pursuant to our at-the-market offering program with Jefferies LLC, the ownership interest of our existing stockholders will be diluted, and such dilution may be substantial given our current stock price decline, and the terms of any new equity securities may have a preference over, and include rights superior to, our common stock. If we raise additional capital through royalty financings or other collaborations, strategic alliances or licensing arrangements with third parties, we may need to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable. If we raise additional capital through debt financing, we may be subject to specified financial covenants or covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or pursuing certain transactions, any of which could restrict our ability to commercialize our product candidates or operate as a business. In addition, as we focus our efforts on proprietary human therapeutics, we will need to seek regulatory approvals of our product candidates from the FDA or other comparable foreign regulatory authorities, a process that could cost in excess of hundreds of millions of dollars per product. We may experience difficulties in accessing the capital markets due to external factors beyond our control, such as volatility in the equity markets for emerging biotechnology companies and general economic and market conditions both in the United States and abroad. In particular, our ability to raise the substantial additional capital we need in order to fund our business may be adversely impacted by global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide, such as has been experienced recently. We cannot be certain that we will be able to obtain financing on terms acceptable to us, or at all. Our failure to obtain adequate and timely funding will adversely affect our ability to continue to operate as a going concern and our ability to develop our technology and products candidates. If we seek to reorganize under the U. S. Bankruptcy Code, our future operations are uncertain, and such reorganization could be unsuccessful and / or result in no recovery for holders of our common stock. If we are unable to successfully reorganize, we may be forced to pursue a liquidation of some or all of our assets. Based on our current operating plan, our cash, cash equivalents and marketable securities as of December 31, 2023 are expected to allow us to meet our liquidity requirements only into the third quarter of 2024. Although we have been actively seeking, and continue to actively seek, substantial additional capital, including through public or private equity or debt financing, royalty financing or other sources, such as strategic collaborations and other direct investments in our programs, we have been unsuccessful in securing any such additional capital to date. As a result, we have explored, and continue to explore, whether filing for bankruptcy protection is in the best interest of our Company and our stakeholders. In the event we file for relief under the U. S. Bankruptcy Code, our operations, our ability to develop our product candidates and execute on our operating plan, and our ability to continue as a going concern will be subject to the risks and uncertainties associated with bankruptcy proceedings, including, among others: our ability to execute, confirm and consummate a plan of reorganization; the additional, significant costs of bankruptcy proceedings and related fees; our ability to obtain sufficient financing to allow us to emerge from bankruptcy and execute our business plan thereafter, and our ability to comply with terms and conditions of any such financing; our ability to continue our operations in the ordinary course; our ability to maintain our relationships with our collaborators, counterparties, employees and other third parties; our ability to obtain, maintain or renew contracts that are critical to our operations on reasonably acceptable terms and conditions or at all; our ability to attract, motivate and retain key employees; the ability of third parties to use certain provisions of the U. S. Bankruptcy Code to terminate contracts without first seeking Bankruptcy Court approval; the ability of third parties to seek and obtain court approval to terminate or shorten the exclusivity period for us to propose and confirm a plan of reorganization, to appoint a trustee, or to convert a proceeding under Chapter 11 of the U. S. Bankruptcy Code to a proceeding under Chapter 7 of the U. S. Bankruptcy Code; and the actions and decisions of our stakeholders and other third parties who have interests in our bankruptcy proceedings that may be inconsistent with our operational and strategic plans. Any delays in our bankruptcy proceedings would increase the risks that we may not be able to reorganize our business and emerge from bankruptcy proceedings and may increase our costs associated with the bankruptcy process or result in prolonged operational disruption. In addition, we would need the prior approval of the Bankruptcy Court for transactions outside the ordinary course of business during the

course of any bankruptcy proceedings, which may limit our ability to respond timely to certain events or take advantage of certain opportunities. Because of the risks and uncertainties associated with any bankruptcy proceedings, we cannot accurately predict or quantify the ultimate impact of events that could occur during any such proceedings. There can be no guarantees that if we seek protection under the U. S. Bankruptcy Code, we will emerge from any such proceedings as a going concern or that holders of our common stock will receive any recovery from any bankruptcy proceedings. In the event we are unable to pursue protection under Chapter 11 of the U. S. Bankruptcy Code, or, if pursued, successfully emerge from such proceedings, it may be necessary for us to pursue protection under Chapter 7 of the U. S. Bankruptcy Code for all or a part of our businesses. In such event, a Chapter 7 trustee would be appointed or elected to liquidate our assets for distribution in accordance with the priorities established by the U. S. Bankruptcy Code. We believe that liquidation under Chapter 7 would result in significantly smaller distributions being made to our stakeholders than those we might obtain under Chapter 11, or no distribution at all, primarily because of the likelihood that the assets would have to be sold or otherwise disposed of in a distressed fashion over a short period of time rather than in a controlled manner and as a going concern. In such event, you may lose part or all of your investment. We have fully impaired our goodwill and indefinite-lived intangible assets, have recorded significant impairment of our long-lived assets, and may be required to record significant additional charges if our long-lived assets become further impaired in the future. We test goodwill, indefinite-lived intangible assets and long-lived assets for impairment annually or more frequently if changes in circumstances or the occurrence of events suggest impairment exists. Any significant change in market conditions, including a sustained decline in our stock price, that indicates a reduction in carrying value may give rise to impairment in the period that the change becomes known. For example, during the year ended December 31, 2023, we recognized an impairment charge of \$ 155. 0 million. We have now fully impaired our goodwill and indefinite-lived intangible assets and have significantly impaired our long-lived assets. For additional information regarding these impairment charges, see Note 6 – Impairment of Goodwill, Indefinite-lived Intangible Assets and Other Long-lived Assets in the accompanying notes to the Consolidated Financial Statements included in Part II, Item 8, “ Financial Statements and Supplementary Data ” of this Annual Report on Form 10- K. It is possible that changes in circumstances, many of which are outside of our control, or in the numerous variables associated with the assumptions and estimates used in assessing the appropriate valuation of our long-lived assets, could in the future result in significant additional impairment charges to our long-lived assets, which could adversely affect our results of operations. Our ability to use net operating losses to offset future taxable income may be subject to limitations. Although a certain amount of our federal net operating loss carryforwards carry forward indefinitely (but are subject to a percentage limitation), a significant amount of our federal and all of our state net operating loss carryforwards will begin to expire, if not utilized, beginning in 2024 and 2029, respectively. The net operating loss carryforwards subject to expiration could expire unused and be unavailable to offset future income tax liabilities. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an “ ownership change, ” which is generally defined as a greater than 50 percentage point change in its equity ownership value over a three- year period, the corporation’s ability to use its pre- change net operating loss carryforwards and other pre- change tax attributes to offset its post- change income or taxes may be limited. We have experienced an ownership change in the past and we may also experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, if we earn net taxable income, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could potentially result in increased future tax liability to us and adversely affect our future cash flows.

Risks Relating to Research, Development, Regulatory Approval and Commercialization of Our Product Candidates and Technologies We are a biotechnology company with a reprioritized preclinical focus and no approved products or product revenues. Our success depends substantially on preclinical studies supporting advancement of product candidates into the clinic and subsequent clinical trial results demonstrating safety and, efficacy and durability of our product candidates to the satisfaction of regulatory authorities. Obtaining We may be unable to obtain positive clinical trial results and regulatory approvals is expensive, lengthy, challenging and unpredictable and may never occur for any of our product candidates. We are a clinical-stage biotechnology company with no approved products or and no product revenues. We Following our strategic reprioritization in 2023, we expect to focus substantially all of our efforts on our core preclinical neurology programs. As a result, we may find that we reduce spending and resources on product candidates or indications that later prove to have greater commercial potential than our core preclinical neurology programs. Our spending on current and future research and development programs may not yield any commercially viable products. Should we be successful in raising additional funds necessary to execute our operating plan and to continue to operate as a ongoing-- going concern, we anticipate initiating clinical trials evaluating in the future on our product candidates if that use our platform technologies in gene therapy and cell therapy and we anticipate initiating additional clinical preclinical studies are supportive trials in the future on other product candidates . We are and will be substantially dependent on the results of these our preclinical studies and subsequent clinical trials, and there is no guarantee that final results of clinical trials conducted on our product candidates now or in the future will demonstrate the safety and efficacy of any of our product candidates. In addition, none of our product candidates have has obtained regulatory approval. Obtaining positive clinical trial results and regulatory approvals is expensive, lengthy, challenging and unpredictable and may never occur for any of our product candidates. If we fail to obtain positive results from our

preclinical studies and subsequent clinical trial results and regulatory approvals for our product candidates, our anticipated revenues from our product candidates and our prospects for profitability would be adversely affected, which would likely cause the market price of our common stock to significantly decline. Conducting clinical trials and obtaining regulatory approvals is complex and exposes our business to numerous risks, including potential unexpected costs and delays. We must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates to the satisfaction of regulatory authorities in order to obtain regulatory approvals necessary for commercialization. We have limited experience in conducting later stage clinical trials and may not possess the necessary resources and expertise to complete such trials. Clinical trials are expensive, lengthy and unpredictable. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage. Events that may delay or prevent successful or timely completion of clinical development and regulatory approval include, among others: • delays in reaching a consensus with regulatory authorities on clinical trial design; • delays in reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites; • delays in opening clinical trial sites or obtaining required **institutional review board, or IRB**, ethics committee or national competent authority approval at each clinical trial site, ~~such as the delays we have experienced opening the clinical trial sites in the United Kingdom for our Phase 1/2 STAAAR clinical study evaluating isralgagene civaparvovec, our wholly-owned gene therapy product candidate for the treatment of Fabry disease, due to the COVID-19 pandemic~~; • delays or interruptions in recruiting, screening and enrolling suitable patients to participate in our clinical trials and dosing enrolled patients, such as ~~(i) the delays we have experienced in recruiting, screening and enrolling patients and experienced and continue to experience in dosing patients for our Phase 1/2 STAAAR clinical study evaluating isralgagene civaparvovec due to challenges related to the COVID-19 pandemic, including due to patients testing positive for COVID-19, patients reconsidering their participation in the study and the limited number of screening sites, among other reasons and (ii) the pause in dosing of additional patients in the Phase 3 AFFINE trial of giroctocogene fitelparvovec implemented by Pfizer in March 2022 and lifted in September 2022~~; • the imposition of clinical holds by regulatory authorities on our clinical trials or those of our collaborators, such as the clinical hold imposed by the FDA on the Phase 3 AFFINE trial of giroctocogene fitelparvovec imposed in November 2021 and lifted in March 2022; ~~• delays in clinical trial activities due to the COVID-19 global pandemic, including delays associated with certain patients testing positive for COVID-19 prior to enrollment or dosing in the study, which have previously impacted clinical trial timelines for our Fabry and TX200 programs~~; • ~~delays or difficulties we may experience in enrolling and dosing the final patients in our Phase 1/2 PRECIZN-1 study evaluating BIVV003, our ZFN gene-edited autologous cell therapy product candidate for the treatment of sickle cell disease~~; • failure by us, any CROs we engage or any other third parties to adhere to clinical trial requirements; • failure to perform in accordance with the Good Clinical Practice and Good Laboratory Practice regulations of the FDA, or applicable comparable foreign regulations in the EU and other countries; • delays in the testing, validation, manufacturing and delivery of our product candidates to the clinical sites, including delays by third parties with whom we have contracted to perform certain of those functions, or as a result of manufacturing or formulation changes to our product candidates; • delays in having patients complete participation in a trial or return for post-treatment follow-up; • clinical trial sites or patients dropping out of a trial; • selections of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data; • occurrences of serious adverse events or other safety concerns associated with product candidates that are viewed to outweigh their potential benefits, result in approval delays or other regulatory restrictions, or harm our reputation; • occurrences of serious adverse events or other safety concerns in clinical trials of the same class of agents conducted by other sponsors; • failures to demonstrate that product candidates are safe and effective for their proposed indication; • changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; • unexpected costs and expenses and lack of sufficient funding to develop our product candidates; and • losses of licenses to critical intellectual properties. We have not yet reached agreement with regulatory authorities on the complete development pathway for certain product candidates, and such authorities have the ability to change decisions or guidance with respect to approvable endpoints, particularly as the technology continues to develop in these areas. For example, we are aware of another company developing a gene therapy to treat hemophilia A that the FDA recommended complete its Phase 3 study and submit two-year follow-up safety and efficacy data on all study participants notwithstanding the company's contention that it and the FDA had previously agreed on the extent of data necessary to support a **biologics license application, or BLA**. While we and Pfizer anticipate pivotal data readouts for our Phase 3 AFFINE trial to be based on full analyses of all study participants, when the first 50 patients are twelve months past reaching a steady-state of FVIII expression, the FDA or other comparable foreign regulatory authorities could determine that we need to treat more patients in this trial than expected or follow patients for longer than expected to generate the required data, or that we need to make other modifications to the trial, any of which could negatively impact the ability to complete the trial and seek regulatory approvals for giroctocogene fitelparvovec, which could in turn materially and adversely affect its competitive position and commercial viability and therefore our business, prospects and market price of our stock. Due to the novelty of certain product candidates and their technologies, the endpoints needed to support regulatory approvals will likely be different from those originally anticipated. Any inability to successfully complete preclinical and clinical development of our product candidates, or complete such trials in the timeframes anticipated, could result in additional costs to us or impair our ability to generate revenues from product sales or achieve regulatory and commercialization milestones and royalties, or shorten any periods during which we may have exclusivity. Even if a product candidate successfully obtains approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. Also, any regulatory approval of our product candidates, once obtained, may be withdrawn, varied or suspended. If we are unable to obtain and maintain regulatory approvals for our product candidates in one or more jurisdictions, or if any approval contains significant limitations, we would not be able to generate anticipated revenues and may struggle to

become profitable, which would have an adverse effect on our business operations and financial condition. ~~acceptable terms with the licensors or sellers. Further, there may be risks and liabilities associated with the product candidates which our due diligence efforts fail to discover, that are not disclosed to us,~~ that we inadequately assess, or that we are unable to manage effectively. Additionally, we may not realize the anticipated benefits of such licenses or acquisitions for a variety of reasons, including the possibility that the product candidates prove not to be safe or effective in clinical trials, that we are unable to successfully integrate the product candidate into our operations, or that the anticipated benefits will not otherwise be realized within the expected timeframe. **Additionally, because we have limited resources, we may forego or delay pursuit of opportunities with certain product candidates or indications that later prove to have greater commercial potential. Our spending on current** Success in research and preclinical studies or early clinical trial results may not be indicative of results obtained in later trials. Likewise, preliminary, initial or interim data from clinical trials may be materially different from final data. Results from research and preclinical studies or early clinical trials are not necessarily predictive of future clinical trial results, and preliminary, initial and interim results of a clinical trial are not necessarily indicative of final results. Our product candidates may fail to show the desired safety and efficacy in clinical trials despite demonstrating positive results in preclinical studies or having successfully advanced through initial clinical trials or preliminary stages of clinical trials. **For example, there can be no assurance that the effects demonstrated by the STAC- BBB capsid variant in our recent preclinical study in NHPs will translate into similar results in any clinical trial of human subjects. Our inability to demonstrate positive results in clinical trials using the STAC- BBB capsid could result in delays and difficulties in furthering development of our capsid platform and the epigenetic regulation therapies that incorporate or depend on the use of the STAC- BBB capsid or other capsids we may discover, or may require us to cease development of such therapies entirely**. From time to time, we have and may in the future publish or report preliminary, initial or interim data. Preliminary, initial or interim data from our clinical trials and those of our collaborators may not be indicative of the final results of the trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and / or more patient data become available. In this regard, such data may show initial evidence of clinical benefit, but as patients continue to be followed and more patient data becomes available, there is a risk that any therapeutic effects will not be durable in patients and / or will decrease over time, or cease entirely. Preliminary, initial or interim data also remain subject to audit and verification procedures that may result in the final data being materially different from such preliminary, initial or interim data. As a result, preliminary, initial or interim data should be considered carefully and with caution until the final data are available. For example, there can be no assurance that the FVIII levels shown in the updated data announced in December ~~2022~~ **2023** by Pfizer and us from the Phase 1 / 2 Alta study of giroctocogene fitelparvovec will persist in future follow- up or any other data from the Alta study or the Phase 3 AFFINE trial. Mean FVIII levels shown in the Alta study, after an initial peak, have ~~trended- tended~~ **tended downward from to fall to lower levels post peak and the then stabilize** time of treatment through each week of follow- up. We cannot anticipate whether and to what extent this trend will continue downward over time. ~~Similarly, there can be no assurance that the sustained elevated α - Gal A levels or the reduction of lyso- Gb3 levels observed in patients treated in the STAAR study will persist in future follow- up or in any other data from the STAAR study, or that such patients or any other future patients in the study, who are withdrawn from ERT will remain off ERT. In addition, patients in the STAAR study may experience more serious AEs, or SAEs.~~ For this reason and potentially other reasons, giroctocogene fitelparvovec and isaralgagene civaparvovec may not ultimately demonstrate a durable, safe and effective clinical benefit to the satisfaction of regulatory authorities in the final results of the Alta study ~~and~~ **and** the Phase 3 AFFINE clinical trial ~~or Phase 1 / 2 STAAR study~~, as applicable, and even if satisfactory to regulatory authorities, such benefit may not be sufficient to yield a commercially- viable product. There is no guarantee that any of our pending clinical trials will be successful. Many of our product candidates currently use our ZF technology platform, including ~~ZF- ZFN nuclease~~ and ZF- transcriptional regulator- technologies, which has not yet yielded any approved therapeutic products. Moreover, ~~many most~~ **many most** of our product candidates are **still in preclinical development** and have never demonstrated any clinical benefit. In addition, our ~~viral delivery systems~~ **engineered capsids, including STAC- BBB,** continue to evolve and have not been used in any approved products. If our product candidates using our ZF technology platform and viral delivery systems are not able to demonstrate ~~the safe, effective and durable results we are hoping to see in clinical trials,~~ we may be forced to suspend or terminate development of some or all of our product candidates or seek alternative technologies to develop or deliver product candidates. In addition, there is a high failure rate for product candidates proceeding through clinical trials. Many companies in the biopharmaceutical industry 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. Any such setbacks could adversely affect our business, financial condition, results of operations and prospects. Our product candidates are subject to a lengthy and unpredictable regulatory approval process in each jurisdiction where approval is sought. A regulatory authority such as the FDA, the European Commission or comparable foreign regulatory authorities must approve any human therapeutic product before it can be marketed in the jurisdiction it governs. The process for receiving regulatory approval is lengthy and unpredictable, and a product candidate may not withstand the rigors of testing under the process. Before commencing clinical trials in humans in the United States, we must submit an IND to the FDA. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the EU, for example, an application for the approval of a clinical trial must be submitted for each clinical trial to each national competent authority and relevant ethics committee of EU Member States in which sponsor wishes to conduct the clinical trial. Only after an IND becomes effective and / or the **CTA clinical trial authorization** has been obtained may clinical trials begin. See “ Business — Government Regulation ” for details regarding the regulatory approval processes applicable to our product candidates. While there is some overlap, the regulatory requirements to conduct clinical trials and seek marketing approval vary by jurisdiction. There is no guarantee that the safety studies and other

data generated will be sufficient to permit us to conduct clinical trials in all jurisdictions where planned, or once generated, that such clinical trial data will be sufficient to obtain marketing approval in all jurisdictions in which we intend to seek such approval. If we are not able to obtain the necessary regulatory approvals to conduct our clinical trials and commercialize our product candidates, or if such approvals are delayed or suspended, our business, prospects and market price of our common stock would be adversely affected. We may not be able to identify, qualify and enroll sufficient patients for our clinical trials or complete our clinical trials in a timely manner, which could delay or prevent us from proceeding with the development of our product candidates. Identifying, qualifying and enrolling patients in clinical trials of our product candidates, and completing these clinical trials, is critical to our success. Patient enrollment and trial completion is affected by factors including: • size of the patient population and process for identifying patients; • design of the trial protocol; • eligibility and exclusion criteria; • perceived risks and benefits of the product candidate under study; • perceived risks and benefits of genomic approaches to treatment of diseases; • availability of competing therapies and clinical trials; • **potential additional delays related to the COVID-19 global pandemic, including the impact of certain patients testing positive for COVID-19 prior to enrolling or dosing in the study**; • delays or interruptions related to voluntary pauses of our clinical trials or those of our collaborators, such as the prior voluntary pause in March 2022 in enrolling and dosing additional patients in the Phase 3 AFFINE trial of giroctocogene fitelparvovec, which pause was lifted in September 2022, and the activation of trial sites; • the imposition of clinical holds by regulatory authorities on our clinical trials or those of our collaborators, such as the prior clinical hold imposed by the FDA on the Phase 3 AFFINE trial of giroctocogene fitelparvovec, which hold has since been lifted, and the potential inability of Sangamo and our collaborators to lift clinical holds imposed by regulatory authorities in a timely manner or on acceptable terms, or at all; • ~~delays or difficulties we may experience in enrolling and dosing additional patients in our Phase 1/2 PRECIZN-1 study~~; • severity of the disease under investigation; • availability of genetic testing for potential patients; • proximity and availability of clinical trial sites for prospective patients; • required and desired characteristics of patients; • ability to obtain and maintain patient consent; • risk that enrolled patients will drop out before completion of the trial; • patient referral practices of physicians; and • ability to monitor patients adequately during and after treatment. The timing of our clinical trials depends on our ability to recruit patients to participate as well as completion of required follow-up periods. There are also a number of other product candidates in development by our competitors, who compete for the same limited patient populations. If we are not able to enroll the necessary number of patients in a timely manner, we may not be able to complete our clinical trials on our desired timelines or at all, which could negatively impact the competitive position and commercial viability of our product candidates or delay or reduce the product revenues, milestone payments or royalty payments we expect to earn from our product candidates. ~~For example, we have experienced delays and challenges in recruiting, screening, enrolling and dosing patients for our Phase 1/2 STAAR clinical study evaluating isaratragene civalparvovec, our wholly-owned gene therapy product candidate for the treatment of Fabry disease, due to challenges related to the COVID-19 pandemic, patients testing positive for COVID-19, patients reconsidering their participation in the study and the limited number of screening sites, among other reasons. Our Phase 1/2 STEADFAST clinical study evaluating TX200 has experienced similar delays and challenges.~~ In addition, we and Pfizer also previously announced that some of the patients treated in the Phase 3 AFFINE trial of giroctocogene fitelparvovec have experienced FVIII activity greater than 150 % following treatment, and that Pfizer had decided to voluntarily pause screening and dosing of additional patients in this trial to implement a proposed protocol amendment intended to provide guidelines for the clinical management of elevated FVIII levels. Subsequent to the voluntary pause, the FDA put this trial on clinical hold, which was subsequently lifted in March 2022. While the voluntary pause initiated by Pfizer was lifted, the trial re-opened, and recruitment, enrollment and dosing resumed **was completed**, we cannot assure you ~~that the dosing will be completed in a timely manner, or at all, or~~ that the presentation of data from such trial will be published in a timely manner, if at all. Continued delays or additional pauses to the Phase 3 AFFINE trial could negatively impact the projected timelines for conducting and completing the trial and seeking regulatory approvals for giroctocogene fitelparvovec, which could in turn materially and adversely affect giroctocogene fitelparvovec's competitive position and commercial viability and therefore our business, prospects and market price of our common stock. In addition, if fewer patients are willing to participate in our clinical trials because of negative publicity from adverse events related to genomic medicines, competitive clinical trials for similar patient populations or for other reasons, the timelines for conducting clinical trials of our product candidates and presenting clinical data may be delayed. These delays could result in increased costs, limitation or termination of clinical trials, and delays in product development timelines. If we are forced to expand to additional jurisdictions to address these challenges, it could impose additional costs, delays and risks. If we are not successful in conducting our clinical trials as planned, it would have an adverse effect on our business, financial condition, results of operations, prospects and market price of our common stock. **We may encounter difficulties in advancing product..... of our common stock to decline.** Special regulatory designations, such as RMAT ~~or~~, orphan drug designations, **fast track designation, or PRIME** may not be available for our product candidates or may not lead to a faster development or regulatory review or approval process. We have received RMAT designation for our product ~~candidate candidates~~ to treat severe hemophilia A **and Fabry disease**. Additionally, some of our product candidates, including our product candidate to treat Fabry disease, have also been granted Orphan Drug Designation by the FDA **and PRIME eligibility by the EMA**, and some have also been designated Orphan Medicinal Products by the EMA. Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs for relatively small patient populations as orphan drugs. **In addition, our product candidate to treat Fabry disease was granted FDA Fast Track Designation in May 2023.** For additional information regarding these special regulatory designations, see “Business — Government Regulation.” If we request such designations for our other current or future product candidates, there can be no assurances that the FDA, the European Commission or comparable foreign regulatory authorities will grant any of our product candidates such designations. Additionally, such designations do not guarantee that any regulatory agency will accelerate regulatory review of, or ultimately approve, those product candidates, nor does it limit the ability of any regulatory agency to

grant such designations to product candidates of other companies that treat the same indications as our product candidates prior to our product candidates receiving marketing approval. Such designations can also be revoked. RMAT designation can be revoked if the criteria for eligibility cease to be met as clinical data emerges. Orphan drug exclusivity may be revoked if any regulatory authority determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition. **In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.** Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the approved indications or commercial potential, or result in significant negative consequences following any potential marketing approval. During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions, particularly as many of the diseases we are studying have complex comorbidities. If clinical experience indicates that a product candidate has side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, or, if the product candidate has received regulatory approval, such approval may be revoked, which would severely harm our business, prospects, operating results and financial condition. 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 using other genomic therapies. Gene therapy is still a relatively new approach to disease treatment and additional adverse side effects could develop. There also is the potential risk of significantly delayed adverse events following exposure to gene therapy products due to persistent biologic activity of the genetic material or other components of products used to carry the genetic material. Possible adverse side effects that could occur with treatment with 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. **For example, one patient in the STAAR study expansion phase experienced a Grade 3 SAE of shoulder enthesopathy in December 2022 requiring hospitalization that occurred 14 days following infusion of israltagene civalparvoec. The Principal Investigator and the Safety Monitoring Committee for the study assessed the SAE as possibly related to the israltagene civalparvoec treatment, and the SAE was reported to regulatory authorities. While the Safety Monitoring Committee has since determined that the study may proceed without modification, the patient remains enrolled in the STAAR study, and this event was reported to other investigators for awareness, possible** **Possible** adverse side effects **in this or other studies**, including additional SAEs, could develop in the future, which could delay or halt any further development or potential commercialization of the applicable product candidate. Even if our product development efforts are successful and even if the requisite regulatory approvals are obtained, our products may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Even if we obtain regulatory approval for any of our product candidates that we may develop or acquire in the future, the approved product may not gain market acceptance among physicians, healthcare payors, patients or the medical community. Market acceptance of approved products depends on a number of factors, including: • the efficacy and safety of the product as demonstrated in clinical trials; • the clinical indications and patient populations for which the product is approved; • acceptance by physicians, treatment centers and patients of the product as a safe and effective treatment; • the adoption of novel genomic therapies by physicians, hospitals and third-party payors; • the potential and perceived advantages of the product over alternative treatments; • the safety of the product seen in a broader patient group, including its use outside the approved indications; • any restrictions on product use together with other medications; • the prevalence and severity of any side effects; • product labeling or product insert requirements of the FDA or other comparable foreign regulatory authorities; • the timing of market introduction of the product as well as competitive products; • the development of manufacturing and distribution processes for the product; • the cost of treatment in relation to alternative treatments; • the availability of coverage and adequate reimbursement and the willingness of patients to pay out-of-pocket in the absence of coverage or inadequacy of reimbursement by third-party payors and government authorities; • relative convenience and ease of administration; and • the effectiveness of our sales and marketing efforts and those of our collaborators. If any of our product candidates are approved but fail to achieve market acceptance among physicians, patients, healthcare payors or treatment centers, we will not be able to generate significant revenues from the approved product, which would compromise our ability to become profitable. Even if we are able to commercialize any approved products, such products may not receive coverage and adequate reimbursement from third-party payors in the United States and in other countries in which we seek to commercialize them, which could harm our business. Our ability to commercialize any product successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels, which can affect demand for, or the price of, any approved product. Given the nature of the product candidates that we are developing, some patients may require treatment only one-time (e. g., single dose administration), and there is substantial uncertainty about the pricing structure for such products, and the level of coverage and reimbursement that will be available for a shift to single-dose treatment as compared to chronic therapy over a patient's lifetime. If other companies establish a new pricing structure or business model, including payment based on demonstration of long-term efficacy, our ability to price or obtain reimbursement for our products may be adversely affected. If such pricing structure or business model do not adequately fund the costs of our research and development, manufacturing and commercialization efforts, our business may be adversely affected. In addition to uncertainty about the potential pricing structure for certain of our product candidates, cost containment is a recurrent trend in the healthcare industry. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for certain medications. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of

reimbursement will be. If reimbursement is not available or is available only at limited levels, we may be unable to successfully commercialize any product candidate for which we obtain regulatory approval. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have an adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. Many EU Member States periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in the EU Member States will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and / or branded products available through parallel import to keep healthcare costs down ~~particularly due to the financial strain that the COVID-19 pandemic has placed on national healthcare systems of the EU Member States~~. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of EU and other foreign countries use prices for medicinal products established in other countries as “reference prices” to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. HTA of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. In December 2021, the EU HTA Regulation was adopted, which will enter into application in 2025 and is intended to harmonize the clinical benefit assessment of HTA across the EU. However, individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social and ethical) aspects of health technologies and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected. Recently enacted and future legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain regulatory approval of and commercialize our product candidates and affect the prices we may obtain. The regulations that govern, among other things, regulatory approvals, coverage, pricing and reimbursement for new drug products vary widely from country to country. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, restrict or regulate post-approval activities and affect our ability to successfully sell any product candidates for which we obtain regulatory approval. Also, there has been heightened governmental scrutiny recently over biopharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for biopharmaceutical products. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, have been designed to encourage importation from other countries and bulk purchasing. For a discussion of health reform activity and the current pricing framework, see “Business — Government Regulation — Healthcare Reform” and “Business — Government Regulation — Pricing, Coverage and Reimbursement.” The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and / or impose price controls may adversely affect: • the demand for our product candidates, if we obtain regulatory approval; • our ability to set a price that we believe is fair for our products; • our ability to generate revenue and achieve or maintain profitability; • the level of taxes that we are required to pay; and • the availability of capital. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. In addition, the policies of the FDA, the competent authorities of the EU Member States, the EMA, the European Commission and other comparable regulatory authorities with respect to clinical trials may change, and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State along with a harmonized assessment procedure, leading to a single decision for each EU Member State. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our development plans. It is currently unclear to what extent the ~~UK-U.K.~~ will seek to align its regulations with the EU in the future. A decision by the ~~UK-U.K.~~ not to closely align its regulations with the new approach that will be adopted in the EU may have an effect on the cost of conducting clinical trials in the ~~UK-U.K.~~ as opposed to other countries and / or make it harder to seek a marketing authorization in the EU for our product candidates on the basis of clinical trials conducted in the ~~UK-U.K.~~ If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted. Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny. Even if

we obtain regulatory approval in a jurisdiction, the competent regulatory authority may still impose significant restrictions on the indicated uses or marketing of our product candidates or impose ongoing requirements for potentially costly post-approval studies, post-market surveillance or patient or drug restrictions. For example, the FDA typically advises that patients treated with gene therapy undergo follow-up observations for potential adverse events for a 15-year period. Additionally, the holder of an approved BLA is required to comply with FDA rules and is subject to FDA review and periodic inspections, in addition to other potentially applicable federal and state laws, to ensure compliance with cGMP and adherence to commitments made in the BLA. If we or a regulatory authority discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. Moreover, product labeling, advertising and promotion for any approved product will be subject to regulatory requirements and continuing regulatory review. Failure to comply with such requirements, when and if applicable, could subject us to a number of actions ranging from warning letters to product seizures or significant fines, among other actions. Any government investigation of alleged violations of laws or regulations could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenues. Failure to comply with EU and EU Member State laws that apply to the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products and marketing of such products, both before and after grant of the marketing authorization, or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties. See “Business — Government Regulation — Post-approval Requirements” for more information. Our employees or contractors may engage in misconduct or other improper activities, including noncompliance with research, development, manufacturing or regulatory standards and requirements, which could cause significant liability for us and harm our reputation. We are exposed to the risk of fraud or other misconduct by our employees and contractors, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Misconduct by our employees and contractors could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter such misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, personal imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, or comparable foreign programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on other programs or product candidates that may be more profitable or for which there is a greater likelihood of success. We have limited resources and may forego or delay pursuit of certain research programs or product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities or pursue collaborations rather than retain sole responsibility for development. Our current and future research and development programs for **core neurology program** product candidates may not yield any commercially viable products. The evaluation of the commercial potential or target market for a particular product candidate is forward-looking and based upon assumptions involving, for example and not limited to, market evolution, advances in disease standard of care, competition and reimbursement. This reliance on assumptions means that, if our assumptions prove to be inaccurate or incomplete, we may pursue opportunities that end up having a number of competitors that are more advanced than our product candidates, or we may relinquish valuable rights to a product candidate through strategic collaboration, licensing or other royalty arrangements in cases where it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. **For example, we have implemented several strategic decisions to reallocate resources among our various clinical and preclinical development programs, including most recently made our restructurings, including decisions to defer new investments in our Fabry disease gene therapy program and our CAR-Treg cell therapy programs unless and until we are able to successfully secure a collaboration partner or external investment in these programs. Although we are actively seeking collaboration partners or a direct external investment, as applicable, to progress our Fabry disease and CAR-Treg cell therapy programs, there can be no assurance that such efforts will be successful in a timely manner, or at all, in which case, we will not receive any return on our investments in these programs. As part of our restructurings and the related strategic decision-reprioritization, we have determined to focus substantially all of our efforts on our core preclinical neurology programs. Investment in preclinical programs is highly speculative, as it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect and / or an acceptable safety profile. In addition, we are developing, and may in the future develop certain product candidates**

designed to treat neurological diseases using our novel capsid delivery technology. If our capsid development efforts are not successful, we may be required to defer, or cease entirely, development of such product candidates. In the last several years, we have also paused further material investments—investment in the our BIVV003 SCD program beyond completion of the Phase 1 / 2 PRECIZN- 1 study , as well as in order to prioritize deployment of resources to our Fabry and TX200 programs previously the subject of collaborations with Biogen and Novartis . While we may potentially identify new intend to launch a search for a collaboration partner partners who can progress this some of the program programs to a potential Phase 3 trial that were the subject of these collaborations as well as our Fabry disease and CAR- Treg cell therapy programs , we may not be successful in doing so in a timely manner, on acceptable terms or at all, and as we may otherwise fail to raise sufficient additional capital in order to progress these programs ourselves. As a result of these strategic decisions , we could miss valuable opportunities to capitalize on the potential of the BIVV003 our discontinued and halted program programs . We may also allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a collaboration or that does not prove to have viable commercial opportunities. Any failure to use our financial and human resources efficiently could harm our business and operations. ZF technology is novel and has never been used to develop any approved, commercially viable therapeutic products. Our ZF technology is a novel technology which to date has not yielded any approved commercially viable therapeutic products, and there can be no guarantee that our product development efforts using ZF technology will be fruitful. We have invested heavily in development of this technology, and our failure to develop approved, commercially viable products using ZF technology would significantly limit our business and prospects and would adversely impact the market value of our common stock. Risks Relating to Manufacturing We recently completed the construction of several facilities for clinical trial supplies. We have limited experience manufacturing biopharmaceutical products, and there can be no assurance that we will be able to maintain compliant manufacturing facilities ; build additional facilities and manufacture our product candidates as intended. We In connection with our restructurings and the anticipated closure of our Brisbane, California and Valbonne, France facilities in 2024, we expect to rely solely on use both contract manufacturing organizations, or CMOs , and our own facilities to manufacture meet our projected needs for clinical trial supply . We operate an AAV manufacturing facility in Brisbane, California to manufacture Phase 1/2 clinical study supplies for our gene therapy product candidates, and in 2021 we completed construction of cell therapy manufacturing facilities in Brisbane, California and Valbonne, France to manufacture supplies for our cell therapy product candidates. Operationalizing these new facilities requires us to transition manufacturing processes and know- how of our product candidates from our CMOs to our own facilities. Transferring manufacturing processes and know- how is complex and involves review and incorporation of both documented and undocumented processes that may have evolved over time. In addition, transferring production to different facilities may require utilization of new or different processes and equipment to meet the specific requirements of a given facility. Additional studies may also need to be conducted to support the transfer of certain manufacturing processes and process improvements. We cannot be certain that all relevant know- how and data has have been adequately incorporated into the manufacturing process until the completion of studies and evaluations intended to demonstrate the comparability of material previously produced by CMOs our facilities with that generated by our CMOs facilities. Although some of our employees have experience in the manufacturing of biopharmaceutical products from prior employment at other companies, we, as a company, have no prior experience in biopharmaceutical product manufacturing, and operating these facilities will require us to comply with complex regulations and to continue to hire and retain experienced scientific, quality control, quality assurance and manufacturing personnel. In addition, government approvals are required for us to operate manufacturing facilities and are time- consuming to obtain and maintain. As a manufacturer of biopharmaceutical products, we also will be required to demonstrate and maintain cGMP compliance. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Furthermore, establishing manufacturing operations will require a reallocation of other resources, particularly the time and attention of our senior management. Even if we are able to establish our own manufacturing capabilities, we could encounter challenges in operating the manufacturing facilities in compliance with cGMP, regulatory or other applicable requirements, resulting in potential negative consequences, including regulatory actions, which could undermine our ability to use these facilities for our own manufacturing needs. Any failure or delay in the development of our manufacturing capabilities could adversely impact the development of our product candidates. The manufacture, storage and transport of our product candidates is complex, expensive, highly regulated and risky, which could hamper their commercial viability. There are significant risks associated with manufacturing, storing and transporting our product candidates including, among others, cGMP compliance, cost overruns, technical problems with process scale- up, specialized facilities, process reproducibility, stability issues, lot consistency, yields and timely availability of highly specific raw materials. Even though product batches released for use in clinical trials undergo sample testing, some defects may only be identified following release. In addition, process deviations or unanticipated effects of approved process changes may result in these intermediate products not complying with stability requirements or specifications. Also, our product candidates must be stored and transported at temperatures within a certain range. If these environmental conditions deviate, our product candidates' remaining shelf- lives could be impaired or their efficacy and safety could be adversely affected, making them no longer suitable for use. Moreover, product candidates that are biologics involve complex processes, including the development of cell lines or cell systems to produce the biologic, with the challenge of significant variability. There are difficulties in growing large quantities of such cells, consistently and sufficiently isolating certain types of cells and harvesting and purifying the biologic produced by them. The cost to manufacture biologics is generally far higher than traditional small molecule chemical compounds, and the manufacturing process can be difficult to reproduce. Moreover, manufacturing, storing and transporting our product candidates is subject to strict regulatory standards, which adds additional production risk. Even if efficacy and safety data from our clinical trials would otherwise support regulatory approval of a product candidate, there is no assurance that we or our CMOs will be able to manufacture our product candidates to specifications at levels necessary to support or maintain

regulatory approval by the FDA or other comparable foreign regulatory authorities. Thus, there is no guarantee we will be successful in establishing a larger- scale commercial manufacturing process for our product candidates or obtaining the needed manufacturing capacity. Due to these manufacturing challenges, there is risk that some of our product candidates could be subject to inventory outages, reputational damage and product liability risks, and result in additional expense and delays to clinical trials and commercialization. Supply interruptions or shortages could result in potential negative impacts to our business, prospects and market price of our common stock. If we use chemical, biological or hazardous materials in a manner that causes injury or violates laws, we may be liable for damages. Our research and development activities involve the controlled use of potentially harmful biological materials as well as hazardous materials, chemicals, and various radioactive compounds typically employed in the study of molecular and cellular biology. We routinely use cells in culture and gene delivery vectors, and we employ small amounts of radioisotopes in trace experiments. Although we maintain up- to- date licensing and training programs, we cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling, or disposal of these materials. In the event of contamination or injury, we could be held liable for damages that result, and any liability could exceed our resources. We currently carry insurance covering certain claims arising from our use of these materials. However, if we are unable to maintain our insurance coverage at a reasonable cost and with adequate coverage, our insurance may not cover any liability that may arise. We are subject to federal, state, and local laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. Failure to comply with these laws and regulations could result in fines, penalties and additional liabilities and restrictions on our operations. We ~~currently rely~~ **are reliant** on third parties ~~to conduct some or~~ **for the all aspects of manufacturing manufacture** of our product candidates for preclinical and clinical development. If one of our third- party manufacturers fails to perform adequately or fulfill our needs, we may be required to incur significant costs and devote significant efforts to find new suppliers or manufacturers. ~~We currently have limited experience~~ **In connection with our restructurings and the closure of our Brisbane, California facility in 2024, we now rely solely on CMOs to manufacture preclinical and clinical – scale manufacturing of our product candidates, and we rely in large part upon third- party CMOs to manufacture and supply drug product for our preclinical studies and clinical trials. Although we have in- house manufacturing facilities in Brisbane, California and Valbonne, France, these facilities will only manufacture limited quantities of our product candidates for our early- stage clinical trials-** We intend to continue to rely on third parties for the manufacture of product candidates for later stage clinical trials, and for commercial- scale manufacturing for any approved product. The manufacture of biopharmaceutical products in compliance with the FDA’ s cGMP, or comparable foreign GMP regulations, requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of biopharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced cGMP requirements, other federal and state regulatory requirements and foreign regulations. If our manufacturers were to encounter any of these difficulties or otherwise fail to comply with their obligations to us or under applicable regulations, our ability to conduct ~~later- stage~~ clinical trials could be jeopardized. Any delay or interruption in the supply of clinical trial materials could delay the completion of our clinical trials, increase the costs associated with developing our product candidates and, depending upon the period of delay, require us to commence new clinical trials at significant additional expense or terminate the clinical trials completely. We and our CMOs must comply with cGMP requirements enforced by the FDA through its facilities inspection program and comparable foreign regulatory authorities. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. We and our CMOs may be unable to comply with these cGMP requirements and with other FDA, state and comparable foreign regulatory requirements. The FDA or similar foreign regulatory agencies may also implement new standards at any time or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of products. We have limited control over our manufacturers’ compliance with these regulations and standards. Failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension, variation or delay in product approval, product seizure or recall or withdrawal of product approval. If the safety of any product supplied is compromised due to our manufacturers’ failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of our product candidates, entail higher costs or impair our reputation. Our current agreements with our CMOs do not provide for the entire supply of the drug product necessary for all anticipated clinical trials or for full scale commercialization. If we and our CMOs cannot agree to the terms and conditions for them to provide the drug product necessary for our clinical and commercial supply needs, we may not be able to manufacture the product candidate until a qualified alternative manufacturer is identified, which could also delay the development of, and impair our ability to commercialize our product candidates. The number of third- party CMOs with the necessary manufacturing and regulatory expertise and facilities is limited, and it could be expensive and take a significant amount of time to arrange for alternative CMOs, which could have an adverse effect on our business. New manufacturers of any product candidate would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing the product candidate. Obtaining the necessary approvals or other qualifications under applicable regulatory requirements and ensuring non- infringement of third- party intellectual property rights could result in a significant interruption of supply and could require the new manufacturer to bear significant additional costs which may be passed on to us. We and third parties on which we rely may be adversely affected by natural disasters and catastrophic or other events outside of our control, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster or event. Natural disasters could severely disrupt our operations and our facilities, ~~including our current manufacturing facilities in Brisbane, California and Valbonne, France~~ and the manufacturing facilities of our CMOs, and any

disruption would likely have a negative impact on our business, financial condition, results of operations and prospects. If a natural disaster, pandemic or epidemic, **geopolitical crisis**, including the **COVID-19 pandemic**, **political crisis** **ongoing conflict between Russia and Ukraine and conflicts in the Middle East**, power outage or any other event that is out of our control occurred that prevented us or third parties on which we rely from using all or a significant portion of our or their facilities, that damaged critical infrastructure or that otherwise disrupted our or their operations, it may be difficult or, in certain cases, impossible for us to continue our business and operations for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and may not prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have an adverse effect on our business, financial condition, results of operations and prospects. Such disasters or events occurring at facilities of third parties on which we rely could also negatively impact our business and operations. Risks

Relating to our Industry Our product candidates are based on novel genomic medicine technologies, which makes it difficult to predict the timing and costs of development and of subsequently obtaining regulatory approval. We have concentrated our research and development efforts on genomic medicine, consisting of gene therapy, gene-edited cell therapy and genome engineering. The regulatory approval process for novel product candidates such as ours is unclear and may be lengthier and more expensive than the process for other, better-known or more extensively studied product candidates. Regulatory review committees and advisory groups, and any new guidelines they promulgate, may lengthen the regulatory review process, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our current or future product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory and advisory groups and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of our product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue, and our business, financial condition, results of operations and prospects would be harmed. Even if our product candidates are approved, we expect that the FDA, or comparable foreign regulatory authorities, will require us to submit follow-up data regarding our clinical trial patients for a number of years after any approval. If this follow-up data shows negative long-term safety or efficacy outcomes for these patients, the FDA, or comparable foreign regulatory authorities, may revoke their approval or change the label of our products in a manner that could have an adverse impact on our business. In addition, adverse developments in clinical trials of genomic medicines conducted by others may cause the FDA or other comparable foreign regulatory authorities to change the requirements for approval of our product candidates. The FDA and European Commission have only very recent and limited experience in the approval of in vivo gene therapy products. As a result, it is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates. If we or our competitors develop, acquire, or market technologies or products that are more effective than ours, our financial condition and ability to successfully market or commercialize our product candidates or be profitable would be adversely affected. The biopharmaceutical industry is highly competitive and subject to significant and rapid technological change. We are aware of several companies focused on other methods for editing cells, editing genes and regulating gene expression and a growing number of commercial and academic groups pursuing the development of genome engineering technology. The field of genomic medicine is highly competitive, and we expect competition to persist and intensify in the future from a number of different sources, including biopharmaceutical companies, academic and research institutions, and government agencies that will seek to develop competing products as well as technologies that will compete with our ZF technology platform. For example, in genome engineering and gene therapy products, competing proprietary technologies with our product development focus include but are not limited to, recombinant proteins, other gene therapy / cDNAs, nuclease and base editing technologies, antisense therapeutics and RNA interference technologies, siRNA, RNAi and microRNA approaches, exon skipping, small molecule drugs, monoclonal antibodies, CRISPR / Cas technology and TALE proteins, meganucleases, and MegaTALs. A growing number of companies are also developing rival cell therapy technologies and product candidates. See “Business — Competition” for more information on the competition we may face. Any products that we or our collaborators or strategic partners develop will enter into highly competitive markets. Even if we are able to generate products that are safe and effective for their intended use, competing technologies may prove to be more effective or less expensive, which, to the extent these competing technologies achieve market acceptance, will limit our revenue opportunities. In some cases, competing technologies have proven to be effective and less expensive. Competing technologies may include other methods of regulating gene expression or modifying genes. **ZFNs** **ZF nucleases** and **ZF-TRs** **transcriptional regulators** have broad application in the life sciences industry and compete with a broad array of new technologies and approaches being applied to genetic research by many companies. In addition to possessing competing technologies, our competitors include biopharmaceutical companies with:

- substantially greater capital resources than ours;
- larger research and development staffs and facilities than ours; and
- greater experience in product development and in obtaining regulatory approvals and patent protection.

These organizations also compete with us to attract qualified personnel, attract parties for acquisitions, joint ventures or other collaborations and license the proprietary technologies of academic and research institutions that are competitive with our technology, which may preclude us from pursuing similar opportunities. Accordingly, our competitors may succeed in obtaining patent protection or commercializing products before **us we do**. Even if our product candidate is more effective, it may be disadvantaged if it is not first to market. In addition, any products that we develop may compete with existing products or services that are well established in the marketplace. Further, some of our product candidates in development are designed for use once. Any success in developing one-time use therapeutics could cause us to lose potential recurring revenues from therapeutics that are designed to be taken over a patient’s lifetime. **The COVID-19 pandemic has adversely impacted and**

could continue to adversely impact our business and operations and the business and operations of our collaborators, manufacturers and other business partners. We have experienced and continue to experience impacts from the COVID-19 pandemic on our business and operations and could continue to experience these or potentially more severe impacts as the pandemic evolves in the United States, France, the United Kingdom and locations of our clinical studies and trials, including the new sites for our STAAR study in Canada, Italy and Australia. For example, we have experienced periodic short-term disruptions to our onsite operations while addressing positive cases of COVID-19 in clinical trial patients, and our operations could experience longer term disruptions in the future in the event of a significant outbreak of COVID-19 among clinical trial patients. Moreover, from time to time, we have been required to reorganize and prioritize our resources to mitigate moderate supply constraints due to the impact of COVID-19. If our programs encounter longer-term disruptions, it could impact our ability to support our biopharmaceutical partners as contemplated in our collaboration agreements and could result in adjustments to our timelines, although we do not believe that the short-term disruptions to date have resulted in any such impacts. Additionally, our Phase 1/2 STAAR clinical study previously experienced delays in its timeline due in part to COVID-19 impacts and the diversion of healthcare resources to fight the pandemic. For example, the April 2021 opening of the first clinical trial site in the United Kingdom for this study experienced a delay of approximately one year due to the significant prevalence of COVID-19 in the United Kingdom. Additionally, we have experienced delays in recruiting, enrolling and dosing patients for this study, due in part to the hesitation of patients to travel by plane to trial sites not within driving distance and to enter medical facilities during the pandemic and also due in part to trial sites prioritizing COVID-19 clinical care over research activities such as the STAAR study. The study has also experienced delays when certain patients have decided to take the COVID-19 vaccine or tested positive for COVID-19 prior to enrollment or dosing in the study. Moreover, we previously experienced some short-term delays in sourcing the necessary raw materials to manufacture supplies for the STAAR study and transporting clinical trial materials due to COVID-19 impacts. We estimate that these challenges set back our 2021 STAAR study timelines by approximately three to six months. Clinical timelines for this study could be revised again if COVID-19 impacts to our recruitment, screening, enrollment and dosing of patients and to our sourcing of raw materials for this study intensify because of vaccination delays, new COVID-19 variants or unexpected events. In addition, our STEADFAST study had previously experienced delays in its timeline due to COVID-19 impacts related to manufacturing and technology transfer challenges with our CMOs and due to patients and donors testing positive for COVID-19. We estimate that these challenges set back our overall clinical study timeline in total by approximately three months. COVID-19 impacts may affect guidance on future dosing timelines. With respect to our partnered programs, the timelines for the studies and trials managed by our collaborators are also subject to potential delay in the future if these studies and trials experience similar challenges that we have experienced and continue to experience in our STAAR and STEADFAST studies. The extent to which the COVID-19 pandemic will impact our business, operations and financial condition, either directly or indirectly, will also depend on future developments that remain highly uncertain at the present time. These developments include the ultimate duration and severity of the pandemic, the impacts of new COVID-19 variants, travel restrictions, public health restrictions in the United States, France, the United Kingdom, Australia, Taiwan and other countries, business closures or business disruptions and the effectiveness and timeliness of actions taken in the United States, France, the United Kingdom, Australia, Taiwan and other countries to contain and treat the disease, including the effectiveness of vaccination programs. The surge of new variants of the virus has resulted and may in the future result in new or the return of prior orders and restrictions. Disruptions to our operations, and possibly more severe disruptions in the future that could arise due to the restrictions applicable in the places we operate or our industry generally or to us and our facilities specifically, could impede our ability to conduct research in a timely manner, comply with our research obligations to our collaborators and advance the development of our therapeutic programs. These delays and disruptions could result in adverse material impacts to our business, operating results and financial condition. As our understanding of events evolves and additional information becomes available, we may materially change our guidance relating to our revenues, expenses and timelines for manufacturing, clinical trials and research and development. In addition, to the extent the COVID-19 pandemic continues to adversely affect our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this “Risk Factors” section. Negative public opinion and increased regulatory scrutiny of genomic medicines may damage public perception of the safety of our product candidates and adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates. Genetically modified products are currently subject to public debate and heightened regulatory scrutiny. Gene therapy remains a novel technology, with only two in vivo gene therapy products approved for a genetic disease to date in the United States and only a few in vivo gene therapy products for genetic diseases approved to date in the EU. Public perception may be influenced by claims that gene therapy is unsafe, and gene therapy may not gain the acceptance of the public or the medical community. For example, reports of serious adverse events in a retroviral gene transfer trial for infants with X-linked severe combined immunodeficiency (, or X-linked SCID), in France and subsequent FDA actions putting related trials on hold in the United States had a significant negative impact on the public perception and stock price of certain companies involved in gene therapy, whether or not the specific company was involved with retroviral gene transfer, or whether the specific company’s clinical trials were placed on hold in connection with these events. Other adverse events could occur in the field of genomic medicine that could result in increased regulatory scrutiny, potential regulatory delays or negative impact on public perception genomic medicines, which could cause our stock price to decline. In particular, our success will depend upon physicians who specialize in the treatment of genetic diseases targeted by our product candidates, prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are familiar and for which greater clinical data may be available. Even if the regulatory approval for genetically modified products developed using our technology is obtained, our success will also depend on public acceptance of the use of genetically modified products including medicines, plants and plant products. Claims that genetically modified products are unsafe for consumption or pose a danger to the environment may

influence public attitudes. Our genetically modified products may not gain public acceptance. More restrictive government regulations or negative public opinion would have an adverse effect on our business, financial condition, results of operations and prospects and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. For example, earlier gene therapy trials led to several well-publicized adverse events, including cases of leukemia and death seen in other trials using other vectors. Serious adverse events in our clinical trials, or other clinical trials involving gene therapy products or our competitors' products, even if not ultimately attributable to the relevant product candidates, and the resulting publicity, could result in increased government regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates. Our current and future relationships with healthcare providers, customers and third-party payors subject us to applicable anti-kickback, fraud and abuse, privacy, data security and other healthcare laws and regulations. If we fail to comply with such regulations, we could face regulatory investigations or actions, litigation **(including class claims) and mass arbitration demands**, and substantial fines and penalties, and our business, reputation, results of operations, financial condition and prospects could be adversely affected. Healthcare providers, including physicians, and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Arrangements with healthcare providers, third-party payors 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 would market, sell and distribute our products. As a biotechnology company, even though we will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse, transparency, health privacy and security and patients' rights and comparable foreign legislation are and will be applicable to our business. Outside the United States, interactions between pharmaceutical companies and health care professionals are also governed by strict laws, such as national anti-bribery laws of EU Member States, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. If we fail to comply with these, or to comply with these adequately or appropriately, we could be subject to significant penalties. For details regarding the restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate see "Business — Government Regulation — Additional Regulation." The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Scrutiny has also increased, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time- and resource-consuming and can divert management's attention from the business. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. If our operations or if any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws or applicable regulations, we and they could be subjected to significant civil, criminal and administrative enforcement actions, see "Business — Government Regulation — Additional Regulation." Further, we are required to comply with domestic and international privacy and data security laws, such as the EU GDPR and the CCPA, which apply to the collection, use, disclosure, transfer, or other processing of personal data, including data we collect about trial participants in connection with clinical trials. **In Other— the past few years, numerous U. S. states — including California, such as Virginia, Colorado, Connecticut and Utah — and Connecticut, have enacted also passed comprehensive privacy and data security laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and similar affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance are being considered in several other states, as well as at the federal and local levels.** Certain jurisdictions have enacted data localization and cross-border data transfer laws, which could make it more difficult to transfer information across jurisdictions. **Existing mechanisms that may facilitate cross-border transfers of personal data may change or be invalidated.** In particular, the EEA and the ~~UK~~ **U. K.** have significantly restricted the transfer of personal data to the United States and other countries whose privacy and data security laws they believe to be inadequate. **If we** ~~Although there are currently various~~ **unable to implement a legal mechanism mechanisms to ensure that our may be used to transfers— transfer of personal data from the EEA and United Kingdom to the United States in compliance with law, such as the EEA standard contractual clauses, the U. K.' s International Data Transfer Agreement / Addendum and the EU- U. S. Data Privacy Framework and the U. K. extension thereto (which allows or for transfers to relevant U. S.- based organizations who self-certify compliance and participate in the Framework), the these UK mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If we are unable to implement a legal mechanism to ensure that our transfers of personal data from the EEA or the U. K. are lawful, we could face adverse consequences, including increased exposure to regulatory actions, substantial fines and injunctions against processing or transferring personal data, and could be required to increase our data processing capabilities in the EEA, the UK U. K. or elsewhere at significant expense. Restrictions on our ability to transfer personal data from the EEA, the UK U. K. or elsewhere could impact our clinical trial activities in the EEA or the UK U. K. and limit our ability to collaborate with CROs and other third parties. For more information regarding these regulations, see "Business — Government Regulation — Privacy Regulation."** **We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the**

CCPA, require our customers to impose specific contractual restrictions on their service providers. We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences. In addition, privacy advocates and industry groups have proposed, and may propose, standards with which we are legally or contractually bound to comply, or may become subject to in the future. Our obligations related to privacy and data security (and consumers' expectations regarding them) are quickly changing and becoming increasingly stringent, creating regulatory uncertainty. These obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources. These obligations may also necessitate changes to our information technologies, systems and practices and those of third parties upon which we rely. Moreover, despite our efforts, our personnel or third parties upon which we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. Any failure or alleged failure (including as a result of deficiencies in our policies, procedures or measures relating to privacy, data security, marketing or communications) by us or our third-party partners to comply with laws, regulations, policies, legal or contractual obligations, industry standards or regulatory guidance relating to privacy or data security, may result in significant consequences. These consequences may include, but are not limited to, governmental investigations and enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar), litigation (including class-related claims) and mass arbitration demands, additional reporting requirements and / or oversight, fines and penalties, bans on processing personal data, orders to destroy or not use personal data, civil and criminal liability and adverse publicity imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business or financial condition, including but not limited to interruptions or stoppages in business operations (including clinical trials), inability to process personal data or to operate in certain jurisdictions, limited ability to develop or commercialize our products, expenditure of time and resources to defend any claim or inquiry or revision or restructuring of our operations. Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop. We face inherent risks of product liability exposure related to the testing of our product candidates in human clinical trials and will face even greater product liability risks if we commercially sell any approved products. Product liability claims may be brought against us by subjects-patients enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • decreased demand for any product candidates or products that we may develop; • termination of clinical trial sites or entire trial programs; • injury to our reputation and significant negative media attention; • withdrawal of clinical trial participants; • significant costs to defend the related litigation; • substantial monetary awards to clinical trial patients; • loss of revenue; • diversion of management and scientific resources from our business operations; and • the inability to commercialize any products that we may develop. We currently hold product liability insurance coverage at a level that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, but which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain regulatory approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products that receive regulatory approval. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business. Unfavorable global economic conditions could have a negative impact on our operations, which could materially and adversely affect our ability to continue to operate as a going concern and otherwise have a material adverse effect on our business, financial condition, results of operations, prospects and market price of our common stock. Financial instability or and a general decline in economic conditions in the United States and other countries caused by political instability and conflict, including the ongoing conflict between Russia and Ukraine and conflicts in the Middle East, and economic or financial challenges caused by recent and potential future bank failures or by general health crises, such as the COVID-19 pandemic have led to market disruptions, including significant volatility in commodity prices, credit and capital market markets instability, including disruptions in access to bank deposits and lending commitments, supply chain interruptions, rising interest rates and which have caused record inflation globally-- global inflationary pressures. These macroeconomic factors could materially and adversely affect our ability to continue to operate as a going concern and could otherwise have a material adverse effect on our business, operations, operating results and financial condition as well as the price of our common stock. For example, the recent closures of Silicon Valley Bank, or SVB, Signature Bank and First Republic Bank have resulted in broader financial institution liquidity risk and concerns. Although we were able to access all of the funds we had in deposit with SVB, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages. The failure of any bank in which we deposit our funds could reduce the amount of cash we have available for our operations or delay our ability to access such funds. Any such failure may increase the possibility of a sustained deterioration of financial market liquidity, or illiquidity at clearing, cash management and / or custodial financial institutions. In the

event we have a commercial relationship with a bank that has failed or is otherwise distressed, we may experience delays or other issues in meeting our financial obligations. If other banks and financial institutions fail or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our cash and cash equivalents and investments may be threatened and our ability to raise additional capital when needed could be substantially impaired, which could have a material adverse effect on acceptable terms our business, operations, operating results and financial condition as well as the price of our common stock. In particular, Failure failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our stock price and could require us to delay or abandon clinical development plans or we may be forced to further curtail or suspend, or entirely cease, our operations. In addition, any or all of these effects factors could disrupt our and our collaborators' supply chains and adversely affect our and our collaborators' ability to conduct ongoing and future clinical trials of our product candidates. The extent and duration of the..... stock price and trading volume to decline. Risks Relating to our Reliance on Third Parties If conflicts arise with our contractors, collaborators or other business partners, these conflicts may limit our ability to implement our strategies and may harm our business and prospects. If conflicts arise with our contractors, collaborators or other business partners, the other party will likely act in its self- interest, which may limit our ability to implement our strategies. For example, some of our collaborators are conducting multiple product development efforts within each area that is the subject of their collaboration with us. Our collaborators may develop, either alone or with others, product candidates in related fields that are competitive with the product candidates that are the subject of their collaborations with us. Competing products, either developed by the collaborators or to which the collaborators or have rights, may result in the withdrawal of their support for our product candidates. Some of our collaborators could also become our competitors in the future. Our collaborators could develop or invest in competing products, preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate or breach their agreements with us unexpectedly or prematurely, or fail to devote sufficient resources to the development and commercialization of product candidates covered by the collaboration. In addition, conflicts could arise between us and our collaborators resulting from disputes regarding our or our collaborators' or strategic partners' performance under the applicable agreement, including disputes arising from alleged breaches of our agreements with our collaborators. Any of these conflicts could harm our product development efforts and otherwise adversely affect our business and prospects. Our collaborators control certain aspects of our product development efforts, including a certain of our clinical trials trial, which could result in unanticipated delays and other obstacles in the commercialization of our product candidates. We depend on Our lack of control over aspects of product development in our collaborators collaborations could cause delays to design and conduct certain of our or clinical trials for some other difficulties in the development and commercialization of our product candidates. As a result, these clinical trials may not be conducted in the manner or on the timeline we desire, which may negatively impact our product development efforts prevent us from receiving any milestone, royalty payments and other benefits under the agreement. For example, Pfizer is the trial sponsor of the Phase 3 AFFINE trial of giroctocogene fitelparovec and we depended on the efforts of Pfizer to diligently seek to lift the clinical hold on the Phase 3 AFFINE trial and resume the trial. Although dosing in the AFFINE trial has is now resumed complete, we cannot guarantee that we will not experience future delays in this trial or that the trial will be completed on the anticipated timeframe or at all. Our lack of control over aspects of product development in our agreements with Novartis, Biogen, Kite, Takeda and Pfizer could cause delays or other difficulties in the development and commercialization of our product candidates, which may prevent us from completing the intended IND filings in a timely fashion and receiving any milestone, royalty payments and other benefits under the agreement. In addition, under their respective agreements, our third- party collaborators have certain rights to terminate the agreements by providing us with advance notices, therefore, the actual milestone payments that we may receive under these agreements may be substantially lower than the full amounts provided for under these agreements. For example, in June 2022, our collaboration agreement with Sanofi terminated, in June 2023, our collaborations with Biogen and Novartis terminated, and our collaboration agreement with Kite expires by its terms in April 2024 and we do not expect such agreement to be extended. As a result, we will not be entitled to any further milestone payments or royalties from any of Sanofi, Biogen, Novartis, or Kite. Our collaborators licensing our ZF technologies or AAV capsid technologies may decide to adopt alternative technologies or products or may be unable or unwilling to develop commercially viable products with our ZF technologies or AAV capsid technologies, which would negatively impact our revenues and our strategy to develop product candidates using ZF technologies. Several of our or AAV capsid technologies. Some of our ongoing collaborations leverage our ZF technology and AAV capsid technology platform. These collaborators may elect to adopt alternative technologies in the future, which could decrease the value of either or both of our ZF technology platform and AAV capsid. These collaborators may elect to adopt alternative technologies in the future, which could decrease the value of our ZF technology platform and impede the development of product candidates using the these platform platforms. Additionally, because many of our collaborators are likely to be working on more than one development project, they could choose to shift their resources to projects other than those they are working on with us. If they do so, this would delay our ability to test and develop our ZF technology platform and AAV capsid technology platform and would delay or terminate the development of our product candidates using the such platform. Further, our collaborators may elect not to develop product candidates arising out of our collaborations or not to devote sufficient resources to the development, manufacturing, marketing or sale of these product candidates. If they terminate the collaborations with us or allow them to expire, such as the terminations for convenience of our collaboration agreements with Biogen and Novartis and the anticipated expiration of our collaboration agreement with Kite by its terms in April 2024, and we wish to continue developing the product candidates, we will be required to seek the support of other collaborators or develop the products ourselves. We Particularly as a result of the November Restructuring, we do not expect to have sufficient resources and expertise internally to allow us to continue the development of these product candidates and we may not be able to identify a suitable partner or negotiate a

favorable collaboration agreement, and we may not have sufficient resources and expertise internally, to allow us to continue the development of these product candidates. Commercialization of our technologies will depend, in part, on collaborations with other companies. If we are not able to find collaborators in the future or if our collaborators do not diligently pursue product development efforts, we may not be able to develop our technologies or product candidates, which could slow our growth and decrease the market value of our common stock. We do not have financial resources ourselves to fully develop, obtain regulatory approval for and commercialize our product candidates. We **have relied, and expect to continue to** rely significantly on our collaborations with other biopharmaceutical companies to provide funding for our research and development efforts, including preclinical studies and clinical tests, and expect to rely significantly on such collaborations to provide funding for the lengthy regulatory approval processes required to commercialize our product candidates. **We were party to** For example, we ~~have collaborations-~~ **collaboration agreements** with Novartis to develop product candidates to treat certain neurodevelopment disorders, including autism and intellectual disability, and with Biogen to develop product candidates to treat tauopathies including Alzheimer's disease, alpha-synuclein related diseases including Parkinson's disease and other neurological diseases. **In June 2023, our collaboration agreements with Novartis and Biogen terminated. We are also party to a collaboration agreement** with Kite to develop product candidates to treat engineered cell therapies for cancer, which we expect to expire by its terms and without an extension in April 2024. As a result of these terminations and expirations, we are no longer entitled to any milestone payments or royalties from Novartis, Biogen or Kite, and such counterparties have no further obligations to develop or to reimburse the costs of any of the programs under the applicable agreement. In connection with Pfizer the Restructurings, we made the strategic decision to pause further development product candidates to treat hemophilia A and amyotrophic lateral sclerosis and frontotemporal lobar degeneration linked to mutations of the programs that were the subject of the these collaborations C9ORF72 gene. In June 2022, we completed the future transition of the rights and obligations of Sanofi S. A. or Sanofi, under our prior collaboration agreement back to us. Although we expect **may identify alternative options** to advance some complete the Phase 1/2 PRECIZIN-1 study of the programs BIVV003, our product candidate to treat SCD, we cannot guarantee that **were subject** we will be able to **such agreements** complete this study in a timely manner or at all. Also, **including** we do not expect to make additional material investments in our SCD program and, accordingly, do not plan to continue developing BIVV003 beyond completion of this study. Although we are currently seeking a potential **development internally or with a** collaboration partner. **However** to advance the development of BIVV003 beyond this study, we cannot guarantee that we will be able to successfully secure any such **options, including identifying an alternative suitable** collaboration **partner** in a timely manner, on acceptable terms or at all, **negotiate a favorable alternative collaboration agreement**. In such case, **we may be unable or unwilling to** continued- **continue** development-**developing** of BIVV003 could be further delayed or precluded altogether, in which case may choose to discontinue the BIVV003 program-**programs subject**. Any further delays to or discontinuance **these collaboration agreements due to the lack of adequate capital resources** this program could have an adverse impact on our- **or otherwise** business, results of operations, financial condition and prospects. If we are unable to secure additional collaborations or if our collaborators are unable or unwilling to diligently advance the development, regulatory approval and commercialization of our product candidates, our growth may slow and adversely affect our ability to generate funding for development of our technologies and product candidates **as well as our ability to continue to operate as a going concern, and we may be required to cease operations. For example, although we have decided to defer new investments in our Fabry disease gene therapy program and our CAR- Treg cell therapy programs unless and until we are able to successfully secure a collaboration partner or external investment in these programs, there can be no assurance that such efforts will be successful in a timely manner, or at all, in which case, we will not receive any return on our investments in these programs and our ability to continue to operate as a going concern may be materially and adversely affected.** In addition, our **ongoing** collaborators may sublicense or abandon development programs with little advance notice, or we may have disagreements or disputes with our collaborators, which would cause associated product development to slow or cease. In addition, the business or operations of our collaborators may change significantly through restructurings, acquisitions, other strategic transactions that may negatively impact their ability to advance our programs. Under typical collaborations, we expect to receive revenue for the research and development of our product candidates based on achievement of specific milestones, as well as royalties based on a percentage of sales of any commercialized products. Achieving these milestones will depend, in part, on the efforts of our collaborators, which we have no control over, as well as our own efforts. In addition, business combinations, changes in a collaborator's business strategy and financial difficulties or other factors could result in that collaborator abandoning or delaying development of any product candidates covered by our collaboration agreement with that collaborator. For example, the transition back to us of the rights and obligations of Sanofi related to BIVV003 and the related termination for convenience by Sanofi of our prior collaboration agreement followed a change in Sanofi's strategic direction to focus on allogeneic universal genomic medicine approaches rather than autologous personalized cell therapies. **In addition, Novartis's and Biogen's decisions to terminate their respective collaboration agreements with us each related to a recent strategic review.** Further, if we fail or any collaboration partner fails to meet specific milestones, then the collaboration agreement may be terminated, which would preclude our ability to earn any additional milestone payments under that collaboration agreement and would reduce our revenues. In addition, even if a collaboration product candidate is successfully developed and approved for marketing by relevant regulatory authorities, if sales of the commercialized product fails to meet expectations, we could receive lower royalties than expected. In any event, the milestone and royalty payment opportunities associated with our collaborations involve a substantial degree of risk to achieve and may never be received. Accordingly, investors should not assume that we will receive all of the potential milestone payments provided for under our **ongoing** collaborations, and it is possible that we may never receive any further significant milestone payments or any royalty payments under our collaborations. Risks Relating to our Intellectual Property Because it is difficult, time consuming and costly to obtain,

maintain and enforce patent protections for our technologies and product candidates, and because third parties may have made inventions that are similar to ours, we may not be able to secure optimal patent protections of our technologies and product candidates. Our commercial success may depend in part on obtaining, maintaining and enforcing patent protection for our technologies and product candidates and successfully defending any of our patents that may be challenged. Obtaining, maintaining and enforcing biopharmaceutical patents is costly, time consuming and complex, and we may not be able to file and prosecute all necessary or desirable patent applications in all desired jurisdictions, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner or at all. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent positions of biopharmaceutical companies can be highly uncertain and can involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. In addition, future patent laws, regulations, rules, and court decisions may affect the scope, validity, enforceability, and associated remedies of our current and future patent claims. Accordingly, we cannot predict the breadth of claims that may issue from any patent applications that we own or license, nor are we able to predict whether any third-party patents might issue with claims that are relevant to our product candidates or technologies. Even if patents do successfully issue and even if such patents cover our technologies and product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or deemed unenforceable. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, the existence of which could invalidate a patent or prevent a patent from issuing from a pending patent application. Furthermore, if third parties have made similar inventions, there are multiple ways they could impact the coverage of our own applications. We are a party to various license agreements that grant us rights under specified patents and patent applications. We are also party to various license agreements by which we grant third parties rights under specified patents and patent applications. Our current licenses contain performance obligations. If we fail to meet those obligations, the licenses could be terminated. If we are unable to continue to license these technologies on commercially reasonable terms, or at all, we may be forced to delay or terminate aspects of our product development and research activities. We are unable to exercise the same degree of control over intellectual property that we license from third parties as we exercise over our internally developed intellectual property. We do not control the prosecution of certain of the patent applications that we license from third parties; therefore, the patent applications may not be prosecuted as we desire or in a timely manner. The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- we or our licensors were the first to conceive and / or reduce to practice the inventions covered by each of our pending patent applications;
- we or our licensors were the first to file patent applications for these inventions;
- the patents of others will not have an adverse effect on our ability to do business;
- others will not independently develop similar or alternative technologies or reverse engineer any of our products, processes or technologies;
- any of our pending patent applications will result in issued patents;
- any patents issued or licensed to us, our collaborators or strategic partners will provide a basis for commercially viable products or will provide us with any competitive advantages;
- any patents issued or licensed to us will not be challenged and invalidated by third parties;
- the laws, regulations, rules, or court decisions in the United States and foreign countries will not change or be interpreted in a way that modifies our patent rights or impacts our ability to enforce or maintain our patent rights; or
- we will develop additional products, processes or technologies that are patentable. Others have filed and in the future are likely to file patent applications that are similar to ours. We are aware that there are academic groups and other companies that are attempting to develop technology that is based on the use of zinc finger, TALE, CRISPR / Cas and other DNA-binding proteins, and that these groups and companies have filed patent applications. Several patents with claims directed to **this these technology technologies** have issued, although we have no current plans to use the claimed inventions. If these or other patent applications issue as patents, it is possible that the holder of any patent or patents granted on these applications may bring an infringement action against us, our collaborators, or strategic partners claiming damages and seeking to enjoin research, development or commercial activities relating to the affected products and processes. The costs of litigating the claim could be substantial regardless of outcome. Moreover, we cannot predict whether we, our collaborators, or strategic partners would prevail in any actions. In addition, if the relevant patent claims were upheld as valid and enforceable and our products or processes were found to infringe a patent or patents, we or our collaborators may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, and we may be prevented from making, using, selling, offering to sell, or importing into the United States the relevant product or process unless we or our collaborators could obtain a license or were able to design around the patent claims. We can give no assurance that such a license would be available to us or our collaborators on commercially reasonable terms, or at all, or that we would be able to successfully design around the relevant patent claims. There may be significant litigation in the genomics or cell therapy industry regarding patent and other intellectual property rights, which could subject us to costly, lengthy and distracting litigation with unpredictable results. We rely on trade secrets to protect technology where we believe patent protection is not appropriate or obtainable. Trade secrets, however, are difficult to protect. While we require employees, academic collaborators and consultants to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary information or enforce these confidentiality agreements. Our collaborators, strategic partners, and scientific advisors have rights to publish data and information in which we may have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations and strategic partnerships, then we may not be able to receive patent protection or protect our proprietary information. Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time and may vary based on jurisdiction. Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years from its earliest U. S. non-provisional filing date or from the filing date of the corresponding international application. Various means to extend this expected expiration date may be available. Regardless, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life

has expired for a product, we may be open to competition from generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. **Further, recent judicial decisions in the United States have raised questions regarding the award of PTA for patents in families where related patents have issued without PTA. Therefore, we cannot be certain how PTA will be viewed in the future and whether our patent expiration dates may be impacted.** If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be adversely affected, and our business would be harmed. We rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, collaborators, partners and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures have been and may in the future be breached, and we may not have adequate remedies for any breach. See also the risk factor titled “ If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences, including but not limited to regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations and reputational harm. ” In addition, our trade secrets may otherwise become known or be independently discovered by competitors. Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors, collaborators, partners and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have an adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could adversely affect our business, results of operations and financial condition. We may not be successful in obtaining or maintaining necessary rights to product components, platforms and processes for our development pipeline through acquisitions and in-licenses. Presently, we believe we have rights to the intellectual property, through licenses from third parties and under patents that we own, to develop our gene and cell therapy product candidates. Because our programs may involve additional product candidates, such as TX200 and potential future CAR-Treg therapies that may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, our product candidates may require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify on commercially reasonable terms, if at all. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights, including from other companies and academic institutions, that we may consider attractive. Other companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Once an intellectual property right that we desire is licensed to another company, we may be precluded from obtaining our own license to such rights. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition and prospects for growth could suffer. 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 are a party to a number of intellectual property license agreements that are important to our business and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone, royalty and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license. We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist that might be enforced against our current product candidates or future products, resulting in either an

injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and / or other forms of compensation to third parties. In many cases, patent prosecution of our in- licensed technology is controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. The agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have an adverse effect on our business, financial condition, results of operations and prospects. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have an adverse effect on our business, financial condition, results of operations and prospects. As an example, Sangamo France has exclusively licensed the right to the CAR for use in TX200 from the University of British Columbia, or UBC. Should UBC terminate this license agreement, we may have to develop or acquire the appropriate CAR which would extend our anticipated development timeline and add expense, and which could result in our failure to realize the anticipated benefits of the acquisition of Sangamo France. We may be involved in patent or intellectual property lawsuits or similar disputes involving patents under our control or patents of third parties claiming infringement, which lawsuits could be expensive, time- consuming and impair or prevent development and commercialization activities. Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, declaratory judgment lawsuits, invalidity proceedings, interferences, oppositions, ex parte or inter partes reexaminations, post- grant reviews and inter partes review proceedings before the U. S. PTO, and corresponding foreign patent offices. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization, and such parties may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. There may be third- party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. For example, we are aware of certain patents held by third parties related to certain vector and vector manufacturing methods that are related to certain of our product candidates. We have not yet finalized the commercial scale manufacturing process for any of our product candidates. If our commercial scale manufacturing process utilizes these vector manufacturing methods, and if these third- party patents are valid and in force at the time of commercialization, we may need to challenge these patents, use or develop non- infringing alternatives or seek a license to these patents. In any event, if any third- party patents were held by a court of competent jurisdiction to cover our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block or hinder our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third- party patents were held by a court of competent jurisdiction to cover aspects of our formulations or processes for manufacture or methods of use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license, or until such patents expires. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In some instances, third parties may allege that we are infringing their patents or other proprietary rights even if they are not competitors or have an associated business. Such litigants would bring such infringement actions or threats of action with the goal of obtaining settlement money from us instead of engaging in costly and time- consuming litigation. Defense of these claims, regardless of their merit, would involve substantial litigation expense, could expose proprietary information and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Competitors may also infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid, is unenforceable, in whole or in part, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing. Moreover, if we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and / or unenforceable. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidate. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot

be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have an adverse impact on our business. Interference or derivation proceedings provoked by third parties or brought by us or declared by the U. S. PTO may be necessary to determine the priority of inventions or other matters of inventorship with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could expose us to significant monetary damages, result in the loss of valuable intellectual property, require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non- exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation, interference, derivation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. We employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee' s former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. We may be unable to license gene transfer technologies that we may need to commercialize our ZF technology and potential products, if approved. In order to regulate or modify a gene in a cell, the ZFP must be efficiently delivered to the cell. We have licensed certain gene transfer technologies for our ZFP in research, including AAV and mRNA technology, and we are evaluating these systems and other technologies that may need to be used in the delivery of ZFP into cells for in vitro and in vivo applications. We have not fully developed our own gene transfer technologies, and we rely on our ability to enter into license agreements to provide us with rights to the necessary gene transfer technology. Our approach has been to license appropriate technology as required. For example, in addition to our own vector manufacturing methods currently being used in our product candidates, we are aware of certain patents held by a third party related to certain vector manufacturing methods that are currently being used in certain of our product candidates. We have not yet finalized the commercial scale manufacturing process for any of our product candidates. If our commercial scale manufacturing process utilizes these vector manufacturing methods, and if these third- party patents are in force at the time of commercialization, we may need to use or develop a non- infringing manufacturing method or seek a license to these patents. However, we may not be able to license the gene transfer technologies on reasonable terms, if at all, required to develop and commercialize our product candidates. The inability to obtain a license to use gene transfer technologies with entities that own such technology on reasonable commercial terms, if at all, could delay or prevent the preclinical evaluation, drug development collaborations, clinical testing and / or commercialization of our therapeutic product candidates. **We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending all current and future patents and patent applications in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive or more difficult to enforce than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use, make, sell, or import our technologies in or into jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protections, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Further, the complexity and uncertainty of European patent laws have increased in recent years. In Europe, the new unitary patent system that came into effect in June 2023 would significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the newly formed Unified Patent Court, or UPC. As the UPC is a new court system, there is no precedent or established body of case law on which the court can base its decisions, thus increasing the uncertainty of any litigation before the UPC. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC- based revocation challenge that, if successful, could invalidate the patent in all**

countries who are signatories to the UPC. We cannot predict with certainty the long- term effects of any potential changes. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We, our licensors and collaborators may be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an interest in our patents or other intellectual property as an owner, co- owner, inventor or co- inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable or invalid. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co- ownership of potential joint inventions. In addition, while it is our policy to require our employees, consultants, advisors, contractors and other third parties who may be involved in the conception or development of intellectual property rights to execute agreements assigning such intellectual property rights to us, we, our licensors and collaborators may be unsuccessful in executing or perfecting such agreements with each party who, in fact, conceives or develops intellectual property rights that we regard as our own. The assignment of intellectual property rights may not be self- executing or sufficient in scope, or the assignment agreements may be breached. Furthermore, individuals executing agreements with us may have competing obligations to a third party, such as an academic institution, and thus an agreement with us or our licensors may be ineffective in perfecting ownership of inventions developed by that individual. Litigation may be necessary to resolve these and other claims challenging inventorship and / or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use or enforce against third parties, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Risks Relating to our Business Operations Our recent restructurings may not result in anticipated savings or operational efficiencies, could result in total costs and expenses that are greater than expected and could disrupt our business. Our recent restructurings are designed to reduce costs and increase focus on our key strategic priorities. We may incur additional expenses not currently contemplated due to events associated with the reduction in force, and our restructuring activities may subject us to reputational risks and litigation risks and expenses. We may not fully realize the anticipated benefits and savings from these restructurings due to unforeseen difficulties, disruptions, delays or unexpected costs, which could adversely affect our financial condition. In addition, we may need to undertake additional workforce reductions or restructuring activities in the future. Furthermore, our restructurings may be disruptive to our operations. For example, in connection with the November Restructuring, we expect to close our Brisbane, California facility in 2024 and move all U. S. operations, including our headquarters, to our Richmond, California facility, and in connection with the France Restructuring, we expect to close our Valbonne, France facility and eliminate all 93 roles in France in 2024. We may experience delays or other difficulties in effectuating the transition of certain research and other operations, which could result in significant disruptions to our business and delays in our development efforts and related timelines. In addition, our workforce reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, increased difficulties in our day- to- day operations, loss of institutional knowledge and expertise and increased risk to our internal controls and disclosure controls. Our workforce reductions could also harm our ability to attract and retain qualified personnel who are critical to our operations.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm and other adverse consequences. We are increasingly dependent on information technology systems and infrastructure to operate our business, which are large and complex. In the ordinary course of our business, we and the third parties upon which we rely, may collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, share and transmit large amounts of proprietary, confidential and sensitive information, including intellectual property, trade secrets and personal data (such as health- related information). It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such sensitive information. We have also outsourced elements of our operations (including elements of our information technology infrastructure) to third parties, and as a result, we manage a number of third- party vendors who may have access to our computer networks or our confidential information. Many of those third parties in turn subcontract or outsource some of their responsibilities to other third parties. Our ability to monitor third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. While all information technology operations are inherently vulnerable to inadvertent or intentional security breaches, incidents, attacks and exposures, the size, complexity, accessibility and distributed nature of our information technology systems, and the large amounts of sensitive information stored on those systems, make such systems potentially vulnerable to unintentional or malicious, internal and external attacks on our technology environment. Attacks of this nature are increasing in their frequency, levels of persistence, sophistication and intensity. Threats to information systems and data are

increasingly difficult to detect and come from a variety of sources, including traditional computer “hackers,” threat actors, “hacktivists,” organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation-states and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties on which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems, operations and supply chain. We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, natural disasters (such as earthquakes, fires, floods), war, terrorism, **attacks enhanced or facilitated by artificial intelligence, or AI**, and other similar threats. Ransomware attacks are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm and diversions of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. In addition, ~~the effects of the COVID-19 pandemic and~~ our updated work from home policies have intensified our dependence on information technology systems and could increase our cybersecurity risk as many of our critical business activities are currently being conducted remotely utilizing network connections, computers and devices outside our premises or network and our increased reliance on personnel working from home, while in transit and in public locations. ~~Any of the previously identified or similar threats could cause a data security incident or other interruption of our, our third-party vendors’ and/or business partners’ information technology systems that could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, sensitive information, which could result in financial and reputational harm to us.~~ While we have implemented security measures designed to protect against data security incidents, there can be no assurance that these measures will be effective. We have not always been able in the past and may be unable in the future to detect vulnerabilities in our information technology systems ~~because~~. **We take steps designed to detect, mitigate and remediate vulnerabilities in our information security systems (such threats as our hardware and techniques change frequently/ or software, are often sophisticated in nature and including that of third parties upon which we rely), but we** may not be **able to** ~~detect~~ **detect until after, mitigate and remediate all such vulnerabilities on a timely basis** ~~data security incident has occurred~~. For example, in April 2018, we announced a data security incident involving the compromise of a senior executive’s company email account. Our investigation of the incident did not reveal any evidence that our systems were otherwise compromised in connection with the incident or that personal data about patients or other individuals besides the executive were accessed or disclosed. However, proprietary, confidential and other sensitive information of ours and that of other entities was accessed and may have been compromised as a result of the incident. Unforeseen developments related to this incident could occur, which could have a further adverse impact on us. Any litigation or regulatory review or investigation arising from this incident could result in significant legal exposure to us. A security incident or other interruption could also result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. While we are aware of the company email incident described above, there is no way of knowing with certainty whether we have experienced any other data security incidents that have not been discovered. While we have no reason to believe this to be the case, attackers have become very sophisticated in the way they conceal access to systems, and many companies that have been attacked are not aware that they have been attacked. Any delay in the discovery of an attack may result in increased expense and may harm our reputation. Any security incident or interruption that we, or a third-party upon which we rely, experience (including the company email incident described above) could lead to adverse consequences, including government enforcement actions (for example, investigations, fines, penalties, audits and inspections), additional reporting requirements and / or oversight, restrictions on processing **sensitive** data (including personal data), litigation (including class claims), indemnification obligations, harm to our reputation, monetary fund diversions, **diversion of management attention, interruptions in our operations (including availability of data)** and financial loss. Applicable data privacy and security obligations may require us to notify relevant stakeholders, **including affected individuals, customers, regulators and investors**, of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. In addition, failure to maintain effective internal accounting controls related to security breaches and cybersecurity in general could impact our ability to produce timely and accurate financial statements and subject us to regulatory scrutiny. We may expend significant resources or modify our business activities in an effort to protect against security incidents or other interruptions. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages or claims related to our data privacy and security obligations. While we may be entitled to damages if our third-party partners fail to satisfy their privacy or data security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. Additionally, we cannot be sure that our insurance coverage, if any, will be adequate or sufficient to protect us from or mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms, or at all, or that such coverage will pay future claims. **In addition to experiencing a security incident, third parties may gather, collect or infer sensitive information about us from public sources, data brokers or other means that reveals competitively sensitive details about our organization and**

could be used to undermine our competitive advantage or market position. Additionally, our sensitive information could be leaked, disclosed or revealed as a result of or in connection with our employees', personnel' s or vendors' use of generative AI technologies. We have business operations in France and the United Kingdom, which exposes us to additional costs and risks. Our business operations in France and the United Kingdom subject us to certain additional costs and risks associated with doing business outside the United States, including: • the increased complexity and costs inherent in managing international operations in geographically disparate locations; • challenges of complying with diverse regulatory, financial and legal requirements, which are subject to change at any time; • potentially adverse tax consequences, including changes in applicable tax laws and regulations; • potentially costly trade laws, tariffs, export quotas, custom duties or other trade restrictions, and any changes to them; • compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; • liabilities for activities of, or related to, our international operations; • challenges inherent in efficiently managing employees in diverse geographies, including the need to adapt systems, policies, benefits and compliance programs to differing labor and other regulations; • natural disasters, political and economic instability, including wars, terrorism and political unrest, including the conflict between Russia and Ukraine and in the Middle East, outbreak of health epidemics, including the COVID-19 pandemic, and the resulting global economic and social impacts; • workforce uncertainty in countries where labor unrest is more common than in the United States; and • differing laws and regulations relating to data security and the unauthorized use of, or access to, commercial and personal information. In addition, our international operations in France and the United Kingdom expose us to fluctuations in currency exchange rates between the Euro and the U. S. dollar and between the Pound Sterling and the U. S. dollar. Given the volatility of currency exchange rates, there is no assurance that we will be able to effectively manage currency transaction and / or conversion risks. To date, we have not entered into derivative instruments to offset the impact of foreign exchange fluctuations, which fluctuations could have an adverse effect on our financial condition and results of operations. In any event, difficulties resulting from these and other risks related to our operations outside of the United States could expose us to increased expenses, impair our development efforts, adversely affect our financial condition and results of operations and harm our competitive position. Although we intend to wind down our operations and close our facility in France pursuant to the France Restructuring, we do not expect such restructuring to be complete until the end of 2024. In addition, in connection with the France Restructuring, we are subject to local laws regarding facility closures and workforce reductions, and any failure to comply with such laws could delay our plans to implement, and / or result in additional costs related to, our France Restructuring. We have experienced and may continue to experience difficulties in hiring, integrating and retaining qualified skilled employees. The stability and potential growth and stability of our organization is critical to our ability to successfully achieve our strategic objectives. We may not be able to hire, integrate and retain a sufficient number of qualified employees with the appropriate levels of experience and skills to accomplish our growth objectives. There currently is a shortage of skilled individuals with substantial experience discovering, developing and manufacturing genomic medicines, which is likely to continue. As a result, competition for these individuals is intense and the turnover rate can be high. We have experienced, and may continue to experience, difficulty hiring, integrating and retaining employees with these skills on acceptable terms given the uncertainty regarding our ability to obtain sufficient additional funding and to continue to operate as a going concern as well as the competition among numerous biopharmaceutical companies and academic institutions for individuals with these skills. In this regard, as a result of the April and November Restructurings, approximately 272 roles at our Company were eliminated, and as a result of the France Restructuring, 93 roles will be eliminated. Accordingly, we have been and are operating with a shortage of resources and may not be able to effectively conduct our operations with our substantially reduced number of employees. In addition, our history of implementing significant workforce reductions, along with the potential for future workforce reductions, may negatively affect our ability to retain or attract talented employees. Moreover, any negative or unexpected results in our preclinical studies or clinical trials or applications for marketing approval would make it more challenging to hire and retain qualified skilled employees. If we do not obtain sufficient additional funding in the near term so that we can continue to operate as a going concern and to potentially achieve our growth objectives, the progress of our research, development, manufacturing and regulatory efforts will slow down or halt altogether, which will would materially and adversely impact affect our business, financial condition, results of operations and prospects, and we may be required to cease operations. We are dependent on certain key members of our executive team and certain of our scientific, clinical development and manufacturing personnel, the loss of whose services may impede the progress of our research, development, manufacturing and regulatory efforts. For example, in 2022-2024, our former Senior Vice President, Head of Development, and Chief People Officer and our former Chief Medical Officer resigned from Sangamo, and we have experienced similar departures in recent years among connection with our Restructurings, the employment of each of our former Executive Vice President, Technical Operations, Executive Vice President, Chief Operating Officer, and senior Senior Vice President, Chief Scientific Officer, was terminated finance and legal employees to pursue opportunities at various other biotechnology companies. We could experience resignations of other executives and employees in the future given the uncertainty regarding our ability to obtain sufficient additional funding and to continue to operate as a going concern as well as the intensity of the competition for talent in the biotechnology industry, particularly in the San Francisco Bay Area. Additional resignations or workforce reductions could result in more significant disruptions and threats to our stability and potential growth and stability. While we have entered into employment agreements with each of our executive officers, any of them could leave our employment at any time, as all of our employees are "at will" employees. We do not have "key person" insurance on any of our employees. Risks Relating to our Common Stock and Corporate Organization We have may not be successful in the past, and may in the future, be unable to comply with the listing standards of the Nasdaq Stock Market LLC, our or Nasdaq. If we efforts to discover, license or acquire new potential product candidates and may fail to comply with listing standards in the future, our common stock may be delisted. Delisting could adversely affect the liquidity of our common

stock and the market price of our common stock could decrease, and our ability to obtain sufficient additional capital to fund our operations and to continue to operate as a going concern would be substantially impaired. Our common stock is currently listed on product candidates the Nasdaq Global Select Market, which has minimum requirements that a company must meet in order to remain listed. These requirements include maintaining a minimum closing bid price of \$ 1.00 per share, which closing bid price cannot fall below \$ 1.00 per share for a period of more than 30 consecutive trading days, or the Bid Price Requirement. On October 27, 2023, we received a deficiency notice from the Listing Qualifications Staff, or the Staff of Nasdaq, notifying us that, for the last 30 consecutive business days, the bid price of our common stock had closed below \$ 1.00 per share, thereby failing to satisfy the Bid Price Requirement set forth in the continued listing requirements of Nasdaq Listing Rule 5450 (a) (1). On March 1, 2024, we received a notice from the Staff of Nasdaq notifying us that, for the prior 10 consecutive business days, the bid price of our common stock had closed at \$ 1.00 per share or greater, thereby satisfying the Bid Price Requirement set forth in the continued listing requirements of Nasdaq Listing Rule 5450 (a) (1). However, since receiving such notice of compliance, closing prices of our common stock on Nasdaq have fluctuated to below \$ 1.00 and, accordingly, there can be no assurance that we will be able to maintain compliance with a greater commercial opportunity or for which there is a greater likelihood of success. In the event we fail to comply with existing listing standards in the future, and we do not receive regulatory approval to regain compliance with the Bid Price Requirement prior to the expiration of the compliance period, unless Nasdaq exercises its discretion to extend this period, our common stock may be subject to a delisting action by Nasdaq. If we again fail to satisfy the Bid Price Requirement, a reverse stock split may allow us to meet the Bid Price Requirement, but we cannot assure you that a reverse stock split will be approved by our stockholders or that any reverse stock split, if implemented, will be sufficient to enable us to maintain our Nasdaq listing. Additionally, if a reverse stock split is implemented, there can be no assurance that the market price per new share of our common stock following the reverse stock split will remain unchanged or will increase in proportion to the reduction in the number of shares of our common stock outstanding before the reverse stock split. The liquidity of the shares of our common stock may be affected adversely by any reverse stock split given the reduced number of shares of our common stock that will be outstanding following such reverse stock split. Furthermore, following any reverse stock split, the resulting market price of our common stock may not successfully commercialize, attract new investors and may not satisfy the investing requirements of the those success investors. In the event that our common stock is delisted from Nasdaq as a result of our failure to comply with the Bid Price Requirement, as a result of Nasdaq not granting us an extension or business the panel not granting us a favorable decision or due to our failure to continue to comply with any other requirement for continued listing on Nasdaq, trading of our common stock could be conducted in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board, but there can be no assurance that our common stock will be eligible for trading on such alternative exchange or market. Additionally, if our common stock is delisted from Nasdaq, the liquidity of our common stock would be adversely affected, the market price of our common stock could decrease, our ability to obtain sufficient additional capital to fund our operations and to continue to expand our product pipeline through discovery, operate as a going concern would be substantially impaired and transactions in our common stock could lose federal preemption of state securities laws. Furthermore, there could also be a further reduction in our coverage by securities analysts and the news media and broker-dealers licensing or acquisitions. We may be deterred from making a market in our acquisition common stock, we may be unable to reach acceptable terms with the licensors or sellers. Further, there may be risks and liabilities associated with the product candidates which could cause the price of our common stock due diligence efforts fail to discover decline further. Moreover, that are not disclosed to delisting may also negatively affect our collaborators', vendors', suppliers' and employees' confidence in us, that we inadequately assess, or..... commercial potential. Our spending on current and employee future research and development programs may not yield any commercially viable products. If we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other arrangements in cases in which it would have been more morale advantageous for us to retain sole development and commercialization rights to such product candidate. Alternatively, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a collaboration arrangement.

Risks Relating to our Common Stock and Corporate Organization—Our stock price has been volatile and will likely continue to be volatile, which could result in substantial losses for investors and potentially class action securities litigation against us, and could be influenced by public perception of genomic medicines and the biotechnology sector. Our stock price has been volatile and may continue to be volatile, which could cause stockholders to incur substantial losses. An active public market for our common stock may not be sustained, and the market price of our common stock may continue to be volatile. The market price of our common stock has fluctuated significantly in response to various factors, some of which are beyond our control, including but not limited to the following:

- announcements by us or collaborators providing updates on the progress or development status of product candidates or data from clinical trials;
- initiation or termination of clinical trials;
- changes in market valuations of similar companies;
- overall market and economic conditions, including the equity markets for emerging biotechnology companies;
- deviations in our results of operations from the guidance given by us;
- announcements by us or our competitors of new or enhanced products or technologies or significant contracts, acquisitions, strategic relationships, joint ventures or capital commitments;
- announcement of changes in business and operations by our collaborators, or changes to our existing collaboration agreements;
- changes in public opinions of genomic medicines;
- regulatory developments, including increased regulatory scrutiny of genomic medicines;
- changes by one or more of our securities analysts in recommendations, ratings or coverage of our stock;
- additions

or departures of key personnel; and • sales of our common stock or other securities by us, officers or directors, liquidation of institutional funds that comprised large holdings of our stock and decreases in our cash balances. In addition, **the emerging biotechnology stock markets** have recently experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many **biotechnology** companies, which has resulted in decreased stock prices for many **emerging biotechnology** companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. These fluctuations have often been unrelated or disproportionate to the operating performance of those **biotechnology** companies. Broad market and industry factors, including worsening macroeconomic conditions and other adverse effects or developments relating to **current the COVID-19 pandemic, and** political, geopolitical, regulatory and other market conditions, may negatively affect the market price of shares of our common stock, regardless of our actual operating performance. **Additionally, holders of our stock may seek to bring class action securities litigation claims against us as a result of the volatility in our stock price. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit and the time and attention of our management could be diverted from other business concerns, either of which could seriously harm our business.** Actual or potential sales of significant amounts of shares of our common stock into the market could cause the market price of our common stock to fall or prevent it from increasing for numerous reasons. 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 holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Our outstanding shares of common stock generally may be freely sold in the public market at any time to the extent permitted by Rules 144 and 701 under the Securities Act of 1933, as amended, or the Securities Act, or to the extent the issuance of such shares has already been registered under the Securities Act and are held by non-affiliates of ours. In 2022, the restrictions applicable to the sale of the shares that we issued to Biogen lapsed, and accordingly, may be sold in the public market without restriction. **We Further, we also** agreed, subject to certain limitations, to register for resale under the Securities Act any of the shares we issued to Biogen **in connection with our prior collaboration**. We have also filed registration statements registering the shares of common stock that we may issue under our equity compensation plans. Such shares can be freely sold in the public market upon issuance, subject to volume limitations and black-out periods applicable to affiliates. Additionally, we are party to a sales agreement with Jefferies LLC which permits us from time to time at our discretion to sell up to \$ 325. 0 million of shares of our common stock in the public markets at prevailing market prices. **As of February 22, 2023, we have sold 22, 953, 199 shares of our common stock under the sales agreement for net proceeds of approximately \$ 117. 7 million.** In addition, in accordance with the guidelines specified under Rule 10b5- 1 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and our policies regarding stock transactions, certain of our employees, executive officers and directors have adopted, and may continue to adopt, stock trading plans pursuant to which they have arranged to sell shares of our common stock from time to time in the future. Generally, sales under such plans by our executive officers and directors require public **filings disclosure**. Our employees, executive officers, directors and affiliated stockholders also may buy or sell additional shares outside of a Rule 10b5- 1 plan when they are not in possession of material, nonpublic information. Actual or potential sales of our common stock by such persons could be viewed negatively by other investors and could cause the price of our common stock to fall or prevent it from increasing. We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock. We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock **cash flows**. If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. The market price of our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. In the event securities or industry analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume **to decline**. Anti- takeover provisions in our certificate of incorporation, Delaware law and our bylaws could make an acquisition of our company more difficult and could prevent attempts by our stockholders to remove or replace current management. Anti- takeover provisions of Delaware law and in our certificate of incorporation and our bylaws may discourage, delay or prevent a change in control of our company, even if a change in control would be beneficial to our stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. In particular, under our certificate of incorporation our board of directors may issue up to 5, 000, 000 shares of preferred stock with rights and privileges that might be senior to our common stock, without the consent of the holders of the common stock. Moreover, without any further vote or action on the part of the stockholders, the board of directors would have the authority to determine the price, rights, preferences, privileges, and restrictions of the preferred stock. This preferred stock, if it is ever issued, may have preference over, and harm the rights of, the holders of common stock. Although the issuance of this preferred stock would provide us with flexibility in connection with possible acquisitions and other corporate purposes, this issuance may make it more difficult for a third party to acquire a majority of our outstanding voting stock. Similarly, our authorized but unissued common stock is available for future issuance without stockholder approval. Our certificate of incorporation further provides that stockholders may not take action by written consent. In addition, our amended and restated bylaws: • establish advance notice requirements for nominations for election to the board of directors or proposing matters that can be acted upon at stockholders' meetings; and • prohibit stockholders from calling a special meeting of stockholders. We are also subject to Section 203 of the General Corporation Law of the State of Delaware, which provides, subject to certain exceptions, that if a person acquires 15 % of our voting stock, the person is an " interested stockholder " and may not engage in

“ business combinations ” with us for a period of three years from the time the person acquired 15 % or more of our voting stock. The application of Section 203 may, in some circumstances, deter or prevent a change in control of our company even when such change may be beneficial to our stockholders. Our amended and restated bylaws designate exclusive forums for the adjudication of certain disputes, which could limit our stockholders’ ability to bring claims in a judicial forum it finds favorable for disputes with us or our directors, officers, or employees. Our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware or, if such court does not have subject matter jurisdiction, the federal district court of the State of Delaware, will be the sole and exclusive forum for: • any derivative action or proceeding brought on our behalf; • any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee or stockholder of Sangamo to us or our stockholders; • any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware, our charter or our bylaws, as to which the General Corporation Law of the State of Delaware confers jurisdiction on the Court of Chancery of the State of Delaware; and • any action asserting a claim governed by the internal affairs doctrine. Our amended and restated bylaws further provide that a federal district court of the United State is the sole and exclusive forum for any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. These provisions further provide that any person or entity that acquires any interest in shares of our capital stock will be deemed to have notice of and consented to these provisions. These provisions may limit a stockholder’ s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If a court were to find any of these provisions to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.