Risk Factors Comparison 2025-03-11 to 2024-03-13 Form: 10-K

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~~Investing in our common stock involves a high degree of risk.~~ You should consider carefully the risks **and uncertainties** described below, together with **all of** the other information ~~included or incorporated by reference~~ in this Annual Report on Form 10- K **and in our** ~~. If any of the~~ **other** ~~following~~ **filings with the Securities and Exchange Commission, or SEC. We operate in a dynamic and rapidly changing industry that involves numerous** risks ~~occur, our business, financial condition, results of operations~~ and **uncertainties** ~~future growth prospects could be materially and adversely affected~~ . ~~In~~ **The risks and uncertainties described below are not** ~~these -- the only ones we face~~ ~~circumstances, the market price of our common stock could decline~~ . Other ~~events~~ **risks and uncertainties, including those** that we do not currently **consider** ~~anticipate or that we currently deem immaterial --~~ **material,** may **impair** ~~also affect~~ our business **. If any of the risks discussed below actually occur** , ~~prospects~~ **our business** , financial condition ~~and~~ **, operating** results **or cash flows could be materially adversely affected. Our actual results could differ materially from those anticipated in these forward- looking statements as a result** of ~~operations~~ **certain factors, including the risks we face as described below and elsewhere in this Annual Report on Form 10- K** . Risks Related to **Our Business Risks Related to Our Limited Operating History, Financial Position and Need for Capital We have incurred significant losses since inception, expect to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future. We have no products for sale, have not generated any product revenue and may never generate product revenue or become profitable. Investment in biotechnology product development is a highly speculative undertaking and entails substantial upfront expenditures and significant risks that any program will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale nor have we generated any revenue from product sales to date and we continue to incur significant research and development and other expenses related to our ongoing operations. We do not expect to generate product revenue unless or until it successfully completes clinical development and obtains regulatory approval of, and** ~~the~~ **then** ~~Merger~~ **successfully commercializes, at least one product candidate. We may never succeed in these activities and, even if it does, may never generate product revenue or revenues that are significant or large enough to achieve profitability. If we are unable to generate sufficient revenue through the sale of any approved products, it may be unable to continue operations without additional funding. We have incurred recurring operating losses since inception. Our net loss for the years ended December 31, 2024 and 2023 was $ 47. 7 million and $ 53. 7 million, respectively. We expect to continue to incur significant losses for the foreseeable future. Our operating expenses and net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if and as we: • advance our existing and future programs through preclinical and clinical development, including expansion into additional indications; • seek to identify additional programs and additional product candidates; • maintain, expand, enforce, defend and protect our intellectual property portfolio; • seek regulatory and marketing approvals for product candidates; • seek to identify, establish and maintain additional collaborations and license agreements; • ultimately establish a sales, marketing and distribution infrastructure to commercialize any drug products for which we may obtain marketing approval, either by ourselves or in collaboration with others; • commence commercial sales of products for which we receive marketing approval; • hire additional personnel including research and development, clinical and commercial; • add operational, financial and management information systems and personnel, including personnel to support product development; • acquire or in- licenses products, intellectual property and technologies; and • establish commercial- scale current good manufacturing practices, or cGMP, capabilities through a third- party or our own manufacturing facility. In addition, our expenses will increase if, among other things, we are required by the U. S. Food and Drug Administration, or the FDA, or other regulatory authorities to perform trials or studies in addition to, or different than, those that we currently anticipate, there are any delays in completing our clinical trials or the development of any product candidates, or there are any third- party challenges to our intellectual property or we need to defend against any intellectual property- related claim. Even if we obtain marketing approval for, and are successful in commercializing, one or more product candidates, we expect to incur substantial additional research and development and other expenditures to develop and market additional programs and / or to expand the approved indications of any marketed product. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.** The ~~Merger~~ **size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our failure to become profitable would decrease our value and could impair our ability to raise capital, maintain our research and development efforts, expand our business and / or continue our operations. A decline in our value could also cause you to lose all or part of your investment. We will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate clinical trials, product development programs or future commercialization efforts. Developing biotechnology products is a very long, time- consuming, expensive and uncertain process that takes years to complete. Since inception, we have funded our operations primarily through private equity and debt financings and have incurred significant recurring losses. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our clinical trials for bempikibart, initiate additional clinical trials, and continue to research, develop and conduct preclinical studies of our other potential product**

candidates, and continue to operate as a public company. In addition, if we obtain regulatory approval for any product candidate for commercial sale, we anticipate incurring significant commercialization expenses related to product manufacturing, marketing, sales and distribution activities to launch any such product. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies to perform preclinical studies or clinical trials in addition to those that we currently anticipate. Because the design and outcome of our current, planned and anticipated clinical trials are highly uncertain, and ~~may~~ **many of our near- term plans are subject to regulatory feedback, we cannot reasonably estimate the actual amount of funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. Our future capital requirements depend on many factors, including factors that are** not ~~be completed and the Merger Agreement may be terminated in accordance~~ **within our control. We will also incur additional costs associated** with ~~its~~ **operating as a public company. We will require substantial additional funding to continue our operations. Based on our current operating plan, we believe that our existing cash, cash equivalents and short- term investments should be sufficient to fund our operations to the second half of 2026. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including: • the timing and progress of preclinical and clinical development activities, including our ongoing Phase 2 clinical trial for bempikibart in alopecia areata, or AA; • the number and scope of preclinical and clinical programs we pursue; • our ability to establish an acceptable safety profile with IND- enabling toxicology studies to enable clinical trials; • successful patient enrollment in, and the initiation and completion of, larger and later- stage clinical trials; • per subject trial costs; • the number and extent of trials required for regulatory approval; • the countries in which the trials are conducted; • the length of time required to enroll eligible subjects in clinical trials; • the number of subjects that participate in the trials; • the drop- out and discontinuation rate of subjects; • potential additional safety monitoring requested by regulatory agencies; • the duration of subject participation in the trials and follow- up; • the extent to which we encounter any serious adverse events in our clinical trials; • the timing of receipt of regulatory approvals from applicable regulatory authorities; • the timing, receipt and** terms ~~. The Merger is subject to a number~~ of ~~conditions~~ **any marketing approvals and post- marketing approval commitments from applicable regulatory authorities; • the extent to which we establish or maintain collaborations, strategic partnerships, or other strategic arrangements with third parties, if any, and the performance of any such third parties in connection therewith; • hiring and retaining research and development personnel; • our arrangements with our contract development and manufacturing organizations, or CDMOs, and contract research organizations, or CROs; • development and timely delivery of clinical and commercial- grade drug formulations** that ~~must~~ **can** be ~~satisfied~~ **used in** ~~or~~ **our** ~~waived~~ **planned clinical trials and for commercial launch , respectfully; •** ~~in each case, prior to~~ the ~~completion~~ **impact** of **any business interruptions** ~~the Merger, as specified in the Merger Agreement. These conditions~~ to **our operations** ~~the completion of the Merger, some of which are beyond our~~ **or** ~~control~~ **to those of the third parties with whom we work; and • obtaining , maintaining, defending and enforcing patent claims and other intellectual property rights. Adequate additional financing** may not be ~~satisfied or waived in a timely manner~~ **available to us on acceptable terms,** or at all, and ~~, accordingly, the Merger may be delayed or not completed. If the Merger is not completed, we are subject to the following risks: • if the Merger Agreement is terminated under specified circumstances,~~ we may be required to ~~pay Q32 a termination fee of $ 2. 4 million; • the price of~~ **seek additional funds sooner than planned through public equity offerings, debt financings, collaborations and licensing arrangements** ~~our~~ **or** ~~common stock may decline and could fluctuate significantly; and • costs related to the~~ **other** ~~Merger,~~ **sources. Such financing may dilute our stockholders or the failure to obtain** such ~~as financial~~ **financing** ~~advisor, legal and accounting fees~~ **may restrict our operating activities. Any additional fundraising efforts may divert our management from our day- to- day activities** , which **may adversely affect** ~~we estimate will total approximately $ 5. 6 million, which must be paid even if the Merger is not completed. If the Merger Agreement is terminated and~~ our ~~board of directors determines to seek another~~ business ~~combination,~~ **. To** ~~there~~ ~~--~~ **the extent** ~~can be no assurance~~ that we ~~will be able to find a partner with whom a business combination would yield greater benefits than the benefits to be provided under the Merger Agreement. If we and Q32 complete the Merger, the combined company will need to~~ raise additional capital ~~by issuing~~ **through the sale of** equity **or convertible debt** securities **, your ownership interest will be diluted, and the terms may include liquidation** or ~~additional~~ **other preferences and anti- dilution protections that adversely affect your rights as a stockholder. Debt financing or refinancing may result in imposition of** debt **covenants** ~~or through licensing arrangements~~ , **increased fixed payment obligations or** ~~which may cause significant dilution to the~~ **other** ~~combined company' s stockholders or restrict~~ **restrictions** ~~the combined company' s operations. Additional financing may not be available to the combined company when it is needed or may not be available on favorable terms. To the extent~~ that ~~the combined company~~ **may affect our business. If we** ~~raises~~ ~~--~~ **raise** ~~additional capital by issuing equity securities, such financing will cause additional dilution to all securityholders of the combined company, including our pre- Merger stockholders and Q32' s former securityholders. It is also possible that the terms of any new equity securities may have preferences over the combined company' s common stock. Any debt financing the combined company enters into may involve covenants that restrict its operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of the combined company' s assets, as well as prohibitions on its ability to create liens, pay dividends, redeem its stock or make investments. In addition, if the combined company raises~~ additional funds through **upfront payments or milestone payments pursuant** ~~licensing arrangements, it may be necessary~~ to **future collaborations with third parties, we may have to relinquish valuable rights to product development programs, or** grant licenses on terms that are not favorable to **us** ~~the combined company~~ . Our ~~stockholders~~ **ability to raise additional capital** may **be adversely impacted by global macroeconomic conditions and volatility in** ~~not realize a benefit from the Merger commensurate with the ownership dilution they~~ ~~-~~ **the credit** ~~will experience in connection with~~

~~the Merger. If the combined company is unable to realize the full strategic~~ and financial **markets in** ~~benefits currently anticipated from~~ the ~~Merger~~ **U. S. and worldwide** , ~~our stockholders will~~ **over which we may** have ~~experienced substantial dilution of their ownership interests without receiving any commensurate benefit,~~ **no or little control. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on** ~~or~~ **our** ~~only receiving part of the commensurate benefit to the extent the combined company is able to realize only part of the strategic and~~ financial **condition and ability** ~~benefits currently anticipated from the Merger. Certain provisions of the Merger Agreement may discourage third parties from submitting competing proposals, including proposals that may be superior~~ to **pursue** ~~the transactions contemplated by the Merger Agreement. The terms of the Merger Agreement prohibit us from soliciting competing proposals or~~ **our business strategy** ~~cooperating with persons making unsolicited takeover proposals~~ , ~~except in~~ **and we may have to delay, reduce the scope of, suspend or eliminate clinical trials, product development programs or future commercialization efforts. We have a** limited ~~circumstances. In addition, if we terminate the Merger Agreement under specified circumstances, we may be required to pay Q32 a termination fee of $ 2. 4 million. This termination fee may discourage third parties from submitting competing~~ -- **operating history** ~~proposals to us or our stockholders,~~ and **have no products approved** ~~may cause our board of directors to be less inclined to recommend a competing proposal. Because the lack of a public market~~ for ~~Q32' s stock~~ **commercial sale which may** ~~makes~~ - **make** it difficult **for you** to evaluate ~~the fair market value of Q32' s stock, we may pay more than the fair market value of Q32' s stock and / or~~ **our current business** ~~the stockholders of Q32 may receive consideration in the Merger that is less than the fair market value of Q32' s stock. The outstanding Q32 common stock is privately held~~ and **likelihood** ~~is not traded in any public market. The lack~~ of ~~a public market makes it difficult to determine the fair market value of Q32' s stock. Because the percentage of our equity to be issued to Q32 stockholders was determined based on negotiations between the parties, it is possible that the value of our common stock to be received by Q32 stockholders will be less than the fair market value of Q32' s stock, or we may pay more than the aggregate fair market value for Q32' s stock. Stockholders could file lawsuits relating to the Merger. As of the date of this Annual Report on Form 10- K, there are no pending lawsuits challenging the Merger. However, potential plaintiffs may file lawsuits challenging the Merger. The outcome of any future litigation is uncertain. Such litigation, if not resolved, could prevent or delay consummation of the Merger and result in substantial costs to us, Q32, or the combined company, including any costs associated with the indemnification of directors and officers. One of the closing conditions is the absence of any order or legal requirement that restrains, enjoins, or otherwise prevents the consummation of the Merger. Therefore, if a plaintiff were successful~~ --- **success** ~~in obtaining an~~ **and viability** ~~injunction prohibiting the consummation of the Merger on the agreed- upon terms, then such injunction may prevent the Merger from being consummated, or from being consummated within the expected time frame. Risks Related to Our Financial Position and Need for Additional Capital We have incurred significant losses since inception and anticipate that we will incur continued losses for the foreseeable future. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline. We may never achieve or maintain profitability~~ . We are a clinical- stage **biotechnology** ~~genetic medicines~~ company with ~~a~~ limited operating history. Since **our** inception **in 2017** , we have incurred significant operating losses **and have utilized substantially all of our resources to conduct research and development activities (including with respect to our bempikibart and ADX- 097 programs) and undertake preclinical studies of product candidates, as well as for conducting clinical trials of our most advanced product candidates and the manufacturing of such product candidates, business planning, developing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these activities. We have limited significant experience as a company in initiating, conducting or completing clinical trials. In part because of this lack of experience, we cannot be certain that our current and planned clinical trials will begin or be completed on time, if at all. We have not yet demonstrated our ability to successfully complete Phase 3 or other pivotal clinical trials, obtain regulatory or marketing approvals, manufacture a commercial- scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from period to period due to a variety of factors, many of which are beyond our control. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history. In addition, as our business grows, we may encounter unforeseen expenses, restrictions, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with an early research and development focus to a company capable of supporting larger scale clinical trials and eventually commercial activities. We may not be successful in such a transition. Risks Related to Discovery, Development and Commercialization We face competition from entities that have developed or may develop programs for the diseases we plan to address with bempikibart or other product candidates. The development and commercialization of drugs and biologics is highly competitive** . Our ~~net~~ **affect** the **value of** ~~agreements if we fail to meet our diligence obligations,including using commercially reasonable efforts to meet diligence milestones by specified dates.If we fail to comply with our obligations to our licensors or collaborators,our counterparties may have~~ the ~~right to terminate these~~ **product candidate being developed under any such** ~~agreements~~ - **agreement** .Termination of these agreements or reduction or elimination of our rights under these agreements may result in ~~us~~ **our** having to negotiate new or reinstated agreements with less favorable terms,or cause us to lose our rights under these agreements,including our rights to important intellectual property or technology ~~that~~ **.Risks Related to Our Intellectual Property If we** are ~~necessary~~ **unable to obtain and maintain patent protection** for our ~~business.Certain~~ **technology and products or if the scope of the** patent ~~filings relating~~ **protection obtained is not sufficiently broad,we may not be able** to **compete effectively in our markets** losses **and reduce our resources available** for **development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can. Uncertainties resulting from**

the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace. We may not be able to effectively secure first- tier technologies when competing against other companies or investors. Our future success may require that we acquire patent rights and know- how to new or complementary technologies. However, we compete with a substantial number of other companies that may also compete for technologies we desire. In addition, many venture capital firms and other institutional investors, as well as other biotechnology companies, invest in companies seeking to commercialize various types of emerging technologies. Many of these companies have greater financial, scientific and commercial resources than us. Therefore, we may not be able to secure the technologies we desire. Furthermore, should any commercial undertaking by us prove to be successful, there can be no assurance competitors with greater financial resources will not offer competitive products and / or technologies. If our trademarks and trade names are not adequately protected, ~~the~~ then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our future registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or an equivalent administrative body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, domain name or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects. Numerous factors may limit any potential competitive advantage provided by our intellectual property rights. The degree of future protection afforded by our intellectual property rights, whether owned or in- licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The factors that may limit any potential competitive advantage provided by our intellectual property rights include: • pending patent applications that we may file or license may not lead to issued patents; • patents, should they issue, that we own or license, may not provide us with any competitive advantages, or may be challenged and held invalid or unenforceable • others may be able to develop and / or practice technology that is similar to our technology or aspects of our technology but that is not covered by the claims of any of our owned or in- licensed patents, should any such patents issue; • third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection; • we (or our licensors) might not have been the first to make the inventions covered by a pending patent application that we own or license; • we (or our licensors) might not have been the first to file patent applications covering a particular invention; • others may independently develop similar or alternative technologies without infringing our intellectual property rights; • we may not be able to obtain and / or maintain necessary licenses on reasonable terms or at all; • third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property; • we may not be able to maintain the confidentiality of our trade secrets or other proprietary information; • we may not develop or in- license additional proprietary technologies that are patentable; and • the patents of others may have an adverse effect on our business. Should any of these events occur, they could significantly harm our business and results of operation. Risks Related to Government Regulation The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time- consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, such product candidates, and our ability to generate revenue will be materially impaired. The process of obtaining regulatory approvals, both in the U. S. and abroad, is unpredictable, expensive and typically takes many years following commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. We cannot

commercialize product candidates in the U. S. without first obtaining regulatory approval from the FDA. Similarly, we cannot commercialize product candidates outside of the U. S. without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of our product candidates, including our most advanced product candidate, bempikibart, we must demonstrate through lengthy, complex and expensive preclinical and clinical trials that such product candidates are both safe and effective for each targeted indication. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Further, a product candidate may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. A product candidate could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including: • the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; • we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for our proposed indication; • the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; • serious and unexpected drug- related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to a product candidate, which may result in inquiries from or actions by regulatory authorities to address such events; • we may be unable to demonstrate that a candidate' s clinical and other benefits outweigh our safety risks; • the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; • the data collected from clinical trials of a product candidate may not be acceptable or sufficient to support the submission of a Biologics License Application, or BLA, a new drug application, or NDA, or similar marketing application to obtain regulatory approval in the U. S. or elsewhere, and we may be required to conduct additional clinical trials; • the FDA or the applicable foreign regulatory authority may disagree regarding the formulation, labeling and / or the specifications of a product candidate; • the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third- party manufacturers with which we may contract for clinical and commercial supplies; and • the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in us failing to obtain regulatory approval to market bempikibart or other product candidates, which would significantly harm our business, results of operations and prospects. The FDA' s and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, the U. S. Supreme Court' s July 2024 decision to overturn prior established case law giving deference to regulatory agencies' decisions and interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA' s regulations, policies and decisions may become subject to increasing legal challenges, delays, and / or changes. The U. S. Supreme Court stripped federal agencies of this presumptive deference and held that courts must exercise their independent judgment when deciding whether an agency such as the FDA acted within its statutory authority under the Administrative Procedure Act, or the APA. Decisions such as this could introduce additional uncertainty into the regulatory process and may result in additional legal challenges to actions taken by federal regulatory agencies, including the FDA and CMS, that we rely on. In addition to potential changes to regulations as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays and other impacts, any of which could adversely impact our business and operations. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability. If we were to obtain approval, regulatory authorities may approve any such product candidate for fewer or more limited indications than we request, including failing to approve the most commercially promising indications, may grant approval contingent on the performance of costly post- marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for a product candidate, we will not be able to commercialize, or will be delayed in commercializing, such product candidate and our ability to generate revenue may be materially impaired. With the change in presidential administrations in 2025, there is substantial uncertainty as to how, if at all, the new administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. The impending uncertainty could present new challenges or potential opportunities as we navigate the clinical development and approval process for our product candidates. Inadequate funding for the FDA, the SEC and other government agencies, including from government shutdowns, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. Currently, federal agencies in the U. S. are operating under a continuing resolution that is set to expire on March 14, 2025. Without appropriation of additional funding to federal agencies, our

business operations related to our product development activities for the U. S. market could be impacted. The ability of the FDA to review and approve regulatory submissions can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital to properly capitalize and continue our operations. We may not be able to meet requirements for the chemistry, manufacturing and control of our product candidates. In order to receive approval of our products by the FDA and comparable foreign regulatory authorities, we must show that we and our contract manufacturing partners are able to characterize, control and manufacture our drug and biologic products safely and in accordance with regulatory requirements. This includes synthesizing the active ingredient, developing an acceptable formulation, performing tests to adequately characterize the formulated product, documenting a repeatable manufacturing process and demonstrating that our products meet stability requirements. Meeting these chemistry, manufacturing and control, or CMC, requirements is a complex task that requires specialized expertise. If we are not able to meet the CMC requirements, we may not be successful in advancing our clinical studies or obtaining regulatory approvals for our product candidates. We have and may in the future conduct clinical trials for our product candidates at sites outside the U. S., and the FDA may not accept data from trials conducted in such locations. We have conducted and may in the future choose to conduct clinical trials for our product candidates outside the U. S. Although the FDA may accept data from clinical trials conducted outside the U. S., acceptance of this data is subject to conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U. S. population, and the data must be applicable to the U. S. population and U. S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will depend on its determination that the trials also complied with all applicable U. S. laws and regulations. If the FDA does not accept the data from any trial that we conduct outside the U. S., it would likely result in the need for additional trials, which would be costly and time- consuming and would delay or permanently halt our development of the applicable product candidates. Even if the FDA accepted such data, it could require us to modify our planned clinical trials to receive clearance to initiate such trials in the U. S. or to continue such trials once initiated. Other risks inherent in conducting international clinical trials include: • the need to comply with foreign regulatory requirements, differences in healthcare services, and differences in cultural customs that could restrict or limit our ability to conduct our clinical trials; • administrative burdens of conducting clinical trials under multiple sets of foreign regulations; • foreign exchange fluctuations; • diminished protection of intellectual property in some countries; and • political and economic risks relevant to foreign countries. Our product candidates for which it intends to seek approval as biologics may face competition sooner than anticipated. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, was enacted as part of the ACA to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as " interchangeable " based on its similarity to an approved biologic. Under the BPCIA, an application for a highly similar or " biosimilar " product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12- year **period** ~~ended December 31, 2023 was $ 113. 0 million. As~~ of **exclusivity** ~~December 31, 2023 and December 31, 2022, we had~~ **another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor' s own preclinical data** ~~an~~ **and data from adequate** ~~accumulated deficit of $ 542. 1 million~~ and ~~$ 429. 1 million~~ **well-controlled clinical trials to demonstrate the safety** , ~~respectively~~ **purity and potency of their product** . ~~On March 10~~ **Our investigational biological products** , ~~2022~~ **if approved** , ~~we closed~~ **could be considered reference products entitled to the 12- year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action** ~~our~~ **or** ~~transaction~~ **otherwise, or that the FDA will not consider a product candidate to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of litigation. The approval of a biosimilar of any of our product candidates could have a material adverse impact on our business due to increased competition and pricing pressure. Even if we receive regulatory approval of bempikibart or other product candidates, we will be subject to extensive ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply** with **regulatory requirements or experience unanticipated problems with our product candidates** ~~OXB (US) LLC and recorded a gain of $ 131. 2 million~~ **Any regulatory approvals that we may receive for bempikibart or other product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of such product candidates, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post- approval study or risk management requirements. For**

example, the FDA may require a risk evaluation and mitigation strategy in order to approve a product candidate, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or comparable foreign regulatory authorities approve a product candidate, the products and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export will be subject to comprehensive regulation by the FDA and other regulatory agencies in the U. S. and by comparable foreign regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as ongoing compliance with cGMPs and GCPs for any clinical trials that we conduct following approval. In addition, manufacturers of drug substances and products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMPs. 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 facilities where the product is manufactured, a regulatory authority may impose restrictions on **that product,** the ~~sale of our~~ manufacturing **facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing, restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials, restrictions on the manufacturing process, warning or untitled letters, civil and criminal penalties, injunctions, product seizures, detentions or import bans, voluntary or mandatory publicity requirements and imposition of restrictions on operations, including costly new manufacturing requirements. The occurrence of any event or penalty described above may inhibit our ability to commercialize bempikibart or other product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity. We may face difficulties from healthcare legislative reform measures. Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of bempikibart or other product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U. S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. See the section titled "** ~~business~~ **Business - Government Regulation- Healthcare Reform "** ~~which resulted in which resulted in net income of $ 92. 1 million for the three months ended March 31, 2022 (see Note 6 to our consolidated financial statements included~~ elsewhere in this Annual Report on Form 10- K for **a more detailed description of healthcare reforms measures that may prevent us from being able to generate revenue, attain profitability, or commercialize product candidates. The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect: • the demand for any of our product candidates, if approved; • the ability to set a price that we believe is fair for any of our product candidates, if approved; • our ability to generate revenues and achieve or maintain profitability; • the level of taxes that we are required to pay; and • the availability of capital. Legislative and regulatory proposals have been made to expand post- approval requirements and restrict sales and promotional activities for pharmaceutical and biologic products. We cannot be sure whether** additional **legislative changes will be enacted,** ~~information regarding the OXB (US) LLC Transaction). Our net loss for~~ **or whether FDA regulations** ~~the year ended December 31~~, ~~2022 was $ 5. 0 million~~ **guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be** . In addition, **increased scrutiny** ~~we have not commercialized any products and have never generated any revenue from product sales. We have historically devoted most of our financial resources to research and development, including our preclinical development activities. In July 2023, we completed a review of our business and our board of directors approved a plan to explore, review and evaluate a range of potential strategic options available to us, including, without limitation, an acquisition, merger, reverse merger, sale of assets, strategic partnerships or other transactions. Based on the financing environment and our anticipated clinical development timeline, we stopped further development of our programs and reduced our workforce~~ by ~~86 % to~~ **the U. S. Congress of the FDA' s approval process may** significantly ~~reduce~~ **delay** ~~our~~ **or prevent** ~~ongoing operating costs as we evaluate strategic alternatives. We have incurred and expect to continue to incur costs and expenditures in connection with the process of evaluating our strategic alternatives and will continue to incur costs associated with operating as a public company. The process of continuing to evaluate strategic transactions may be costly, time- consuming and complex, and we may incur significant costs related to these processes, such as legal, accounting and advisory fees and expenses and other related charges. A considerable portion of these costs will be incurred regardless of whether any particular course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in our business. Should we resume development of our product candidates, we would expect to continue to incur significant additional operating losses for the foreseeable future as we seek to advance product candidates through preclinical and clinical development, expand our research and development activities, develop new product candidates, complete clinical trials, seek regulatory approval and, if we receive U. S. Food and Drug Administration, or FDA, or foreign regulatory authorities approval, commercialize our products. Furthermore, the costs of advancing product candidates into each succeeding clinical phase tend to increase substantially over time. The total costs to advance any of our product candidates to~~ marketing approval ~~in even a single jurisdiction would be substantial. Because of the numerous risks and uncertainties associated with genetic medicines product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to begin generating revenue from the commercialization of products or achieve or maintain profitability. Our expenses will also increase substantially if and as we: • continue our current research programs and our preclinical development of product~~

~~candidates from our current research programs; • seek to identify, assess, acquire and / or develop additional research programs and additional product candidates; • initiate preclinical testing and clinical trials for any product candidates we identify and develop; • establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval; • maintain, expand and protect our intellectual property portfolio; • further develop our genetic medicines platform; • hire additional clinical, scientific and commercial personnel; • add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts~~ , as well as **subject us** to ~~support~~ **more stringent product labeling and post- marketing testing and other requirements. We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare** ~~our~~ **or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. Our business** operations ~~as a public reporting company; • acquire or in~~ **and current and future arrangements with investigators, healthcare professionals, consultants, third** ~~- license~~ **party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties. Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third- party payors, patient organizations and customers may expose us to fraud and abuse and** other ~~commercial products~~ **healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations** , **including how we research, market, sell and distribute our** product candidates ~~and technologies; • make royalty~~ , ~~milestone or~~ **if approved. See** ~~other~~ **the section titled " Business** ~~payments under current and any future in~~ **Government** ~~license agreements; and • further expand our Good Manufacturing Practices, or GMP, manufacturing capacity. Furthermore, should we resume development of our product candidates, our ability to successfully develop, commercialize and license our products and generate product revenue would be subject to substantial additional risks and uncertainties. Each of our programs and product candidates will require additional preclinical and clinical development, potential regulatory approval in multiple jurisdictions, securing manufacturing supply, capacity and expertise, building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenue from product sales. These risks are further described under " — Risks Related to Discovery, Development, Clinical Testing, Manufacturing and Regulatory~~ **Regulation** ~~Approval~~ **- Other Healthcare Laws and Compliance Requirements** ~~" and " — Risks Related to Commercialization. " As a result, we expect to continue to incur net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. The amount of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If we are unable to develop and commercialize one or more of our product candidates either alone or with collaborators, or if revenues from any product candidate that receives marketing approval are insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability. If we are unable to achieve and then maintain profitability, the value of our equity securities will be materially and adversely affected. Any financial or strategic option we pursue may not be successful. In July 2023, our board of directors approved a process to explore, review and evaluate a range of potential strategic options available to us, including, without limitation, an acquisition, merger, reverse merger, sale of assets, strategic partnerships or other transactions. The process of continuing to evaluate these strategic options has been and may continue to be costly, time-consuming and complex and we may incur significant costs related to this continued evaluation, such as legal, accounting and advisory fees and expenses and other related charges. There can be no assurance that the proposed Merger with Q32 will be completed, and we can provide no assurance that any other strategic alternative we may pursue will have a positive impact on our results of operations or financial condition. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. Until such time, if ever, as we can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. As of December 31, 2023, we do not have any committed external source of funds. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believes that we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, including under our effective Registration Statement on Form S- 3, the ownership interests of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raises additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts, should we resume development of our product candidates, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our decision to discontinue further program development efforts may not result in the anticipated savings for the Company and may adversely affect our business. In connection with our decision to pursue strategic alternatives and reduce our ongoing operating expenses, in July 2023 we decided to stop further program developments. Based on the anticipated clinical development timeline of HMI-103 and the financing environment, we believe this decision to discontinue further program development efforts will~~

~~significantly reduce our ongoing operating costs. We may not realize, in full or in part, the anticipated benefits and savings in operating expenses from this decision due to unforeseen difficulties, delays or other unexpected costs. For instance, this decision to stop further program developments may include higher than expected costs associated with winding down our clinical programs. Moreover, if we are unable to realize the expected cost savings, our financial condition could be adversely affected, and it may be more difficult to complete the proposed Merger with Q32 or any other potential strategic transaction. We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to continue our operations for more than twelve months after the issuance date of our consolidated financial statements included~~ elsewhere in this Annual Report on Form 10- K **for a more detailed description of the laws that may affect our ability to operate** . ~~We~~ **Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations** will ~~case law involving~~ **involve substantial costs** ~~applicable fraud and abuse or other healthcare laws and regulations~~ .If our operations are found to be in violation of any of ~~the~~ **these** laws ~~described above~~ or any other governmental laws and regulations that may apply to ~~us~~ **it** ,we may be subject to significant penalties,including civil,criminal and administrative penalties,damages,fines,exclusion from government- funded healthcare programs, **integrity oversight** ~~such as Medicare~~ and ~~Medicaid or similar programs in other countries or jurisdictions~~ **reporting obligations to resolve allegations of non- compliance** ,disgorgement,individual imprisonment,contractual damages,reputational harm,diminished profits and the curtailment or restructuring of our operations. ~~If~~ **Further,defending against** any ~~of~~ **such actions can be costly and time- consuming and may** require ~~additional capital~~ **significant personnel resources. Therefore** , ~~which~~ **even if** we **are successful in defending against any such actions that** may ~~raise through equity offerings~~ **be brought against us** , ~~debt financings, marketing and distribution arrangements and~~ **our business may be impaired. Even if we are able to commercialize bempikibart or** other ~~collaborations, strategic alliances and licensing arrangements or other sources to enable us to complete the development and potential commercialization of our~~ product candidates **, due to unfavorable pricing regulations** and ~~any future~~ **/ or third- party coverage and reimbursement policies, we may not be able to offer such products at competitive prices which would seriously harm our business. We intend to seek approval to market bempikibart and other** product candidates ~~, should~~ **in both the U. S. and in selected foreign jurisdictions. If** we ~~resume~~ **obtain approval in one or more foreign jurisdictions for** such **product candidates** ~~activities. In addition~~ , we **will** ~~may not~~ be ~~able~~ **subject** to ~~enter into~~ **rules and regulations in those jurisdictions. Our ability to successfully commercialize** any ~~collaborations~~ **product candidates** that **we may develop** will ~~generate~~ **depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third- party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Government authorities and other third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for medications. These entities may create preferential access policies for a competitor' s product, including a branded or generic / biosimilar product, over our products in an attempt to reduce their costs, which may reduce our commercial opportunity. Additionally, if any of our product candidates are approved and we are found to have improperly promoted off- label uses of those programs, we may become subject to** significant **liability** ~~cash. Adequate additional financing may not be available to us on acceptable terms~~ , **which** ~~or at all. Our failure to raise capital as and when needed~~ would **materially adversely** ~~have a negative effect~~ **affect** ~~on~~ our **business and** financial condition ~~and our ability to pursue our~~ **. See the sections titled "** ~~business~~ **Business** ~~strategy. In addition, attempting to secure additional financing may divert the time and attention of our management from day~~ - ~~to~~ **Government Regulation** - **Coverage** ~~day activities. Based upon our current projections, we believe that our existing cash, cash equivalents,~~ and ~~short~~ **Reimbursement " and "** - **Regulation in** ~~term investments will enable us to fund our operations for at least one year from~~ the **EU "** ~~issuance date of our consolidated financial statements for the year ended December 31, 2023 included~~ elsewhere in this Annual Report on Form 10- K ~~. However, due to considerations of certain qualitative factors, including the discontinuation of all clinical trials and research activities, as well as our significant reduction in force of all but a few custodial employees, our management has concluded that there is substantial doubt regarding our ability to continue as a going concern~~ for **a** more **detailed description** ~~than twelve months after the issuance date~~ of ~~our consolidated financial statements included elsewhere in this Annual Report on Form 10- K. Beyond that, we will need to raise additional capital in order to fund operating expenses and capital expenditure requirements. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. In addition, our resource requirements could materially change depending on the outcome of our ongoing strategic alternative review process. As a result, we are unable to estimate the exact amount of our working capital requirements. Changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control. Should we resume development of our product candidates our future funding requirements, both near and long- term, would depend on many factors, including, but not limited to: • the initiation, progress, timing, costs and results of our planned clinical trials for our product candidates; • the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities; • the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights; • the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates; • the effect of competing technological and market developments; • the cost and timing of completion of commercial- scale manufacturing activities; • the costs of operating as a public company; • the extent to which we in- license or acquire other products and technologies; • the cost of establishing sales, marketing and distribution capabilities for our product candidates in regions where we choose to commercialize our products; and • the initiation, progress, timing and results of our commercialization of our product candidates, if approved for commercial sale. We maintain the majority of our cash and cash equivalents in accounts with major U. S. and multi- national financial institutions, and our deposits at these~~

institutions exceed insured limits. Market conditions can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintains our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position. We cannot be certain that additional funding will be available on acceptable terms, or at all. For example, the trading prices for our and other biopharmaceutical companies' stock have been highly volatile as a result of macroeconomic conditions, developments in the industry and the COVID- 19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock and any such sales may be on unfavorable terms. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of or product candidates or potentially discontinue operations. We have a limited operating history and no history of commercializing genetic medicine products, which may make it difficult to evaluate the prospects for our future viability. We were established and began operations in 2015. Our operations to date have been limited to financing and staffing our company, developing our technology and identifying and developing our product candidates. We have not yet demonstrated an ability to successfully complete any clinical trials, including large- scale, pivotal clinical trials, obtain marketing approval, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Typically, it takes about six to ten years to develop a new drug from the time it enters Phase 1 clinical trials to when it is approved for treating patients, but in many cases, it may take longer. Consequently, should we resume development of our product candidates, predictions about our future success or viability may not be as accurate as they - **the government** could be if we had a longer operating history or a history of successfully developing and commercializing genetic medicine products. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will eventually need to transition from a company with a research focus to a company capable of supporting commercial activities. We may not be successful in such a transition. We expect our financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any particular quarterly or annual period as indications of future operating performance. Should we resume development of our product candidates, we would be heavily dependent on the success of our product candidates, and if none of our candidates receives regulatory approval or is not successfully commercialized, our business may be harmed. We have historically invested a significant portion of our efforts and financial resources in the development of our product candidates. Our future success and ability to generate product revenue is substantially dependent on our ability to successfully develop, obtain regulatory approval for and successfully commercialize our product candidates. We currently have no products that are approved for commercial sale and may never be able to develop marketable products, and we have stopped development activities. Should we resume development of our product candidates, we expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to development of these candidates, which would require additional clinical development, management of clinical and manufacturing activities, regulatory approval in multiple jurisdictions, securing manufacturing supply, building of a commercial organization, substantial investment and significant marketing efforts before we can generate any revenues from any commercial sales. Accordingly, our business has historically depended heavily on the successful development, regulatory approval and commercialization of our product candidates, which may never occur. Therefore, we cannot be certain that any of our product candidates would be successful in future clinical trials, receive regulatory approval or be successfully commercialized even if we receive regulatory approval. Even if we receive approval to market any product candidate from the FDA or other regulatory authorities, we cannot be certain that our product candidates will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. Additionally, the research, testing, manufacturing, labeling, approval, sale, marketing and distribution of genetic medicine products are and will remain subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations . We are not permitted to market any product candidate in the United States until it receives approval of a Biologics License Application, or BLA from the FDA, or in any foreign countries until it receives the requisite approval from such countries. We have not submitted a BLA to the FDA or comparable applications to other regulatory authorities and do not expect to be in a position to do so for the foreseeable future. If any of our product candidates shows unexpected adverse events or a lack of efficacy in the indications we intend to treat, or if we experience other regulatory or developmental issues, our development plans and business could be significantly harmed. Further, competitors may be developing products with similar technology and may experience problems with their products that could identify problems that would potentially harm our business. We may not be successful in our efforts to identify additional product candidates. Historically, part of our strategy involved, and to the extent such activities are resumed in the future may involve, identifying novel product candidates. The process by which we identify product candidates may fail to yield product candidates for clinical development for a number of reasons, including those discussed in these risk factors and also: • we may not be able to assemble sufficient resources to acquire or discover additional product candidates; • competitors may develop alternatives that render our potential product candidates obsolete or less attractive; • potential product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights; • potential product candidates may, on further study, be shown to have harmful side effects, toxicities or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance; • potential product candidates may not be effective in treating their targeted diseases; • the market for a potential product candidate may change so that the continued development of that product candidate is no longer reasonable; • a potential product candidate may not be capable of being produced in commercial quantities at an **and** acceptable cost, or at all; or • the regulatory pathway for a potential product candidate may be too complex and difficult to navigate successfully or economically. In addition, should we resume development of our product candidates, we may choose to focus our efforts and resources on a potential product candidate that

ultimately proves to be unsuccessful. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights. If we are unable to identify additional suitable product candidates for clinical development, this would adversely impact our business strategy and our financial position and share price and could potentially cause us to cease operations. We may be required to make significant payments in connection with our license agreement with the City of Hope. Under our license agreement with the City of Hope, or COH, we are subject to significant obligations, including payment obligations upon achievement of specified milestones and royalties on product sales, as well as other material obligations, including potential payments if we were to sublicense the COH technology to additional strategic collaborators. If these payments become due, we may not have sufficient funds available to meet our obligations or we may have to direct funds from other development efforts, and as a result, our development efforts may be materially harmed. Should we resume development of our product candidates, we intend to identify and develop product candidates based on our novel genetic medicines platform, which makes it difficult to predict the time and cost of product candidate development. There have only been a limited number of human clinical trials involving a gene editing product candidate. Moreover, none of those trials has involved our nuclease-free gene editing technology, prior to our initiated Phase 1 pheEDIT clinical trial. In addition, there have been a limited number of gene therapy products approved in the United States or in Europe and none of these products have utilized our AAVHSC platform. We have historically concentrated our research and development efforts on our genetic medicines platform, which uses both nuclease- free gene editing and gene therapy technologies. Our future success depends on the successful development of this novel therapeutic approach. There have been a limited number of clinical trials of gene editing technologies, and, prior to our Phase 1 pheEDIT clinical trial, none of these clinical trials involved product candidates that utilize our novel gene correction editing technology. Moreover, there have been a limited number of gene therapy products approved in the United States or in Europe and none of these products have utilized our AAVHSC platform. In addition, because our programs, prior to our pausing of further product development, were all in the research, preclinical or early- clinical stage, we have not been able to fully assess safety in humans, and there may be long- term effects from treatment with any of our future product candidates that we cannot predict at this time. Any gene correction editing product candidates we may develop will act at the level of DNA, and, because animal DNA differs from human DNA, it will be difficult for us to test our future product candidates in animal models for either safety or efficacy. Also, animal models may not exist for some of the diseases we expect to pursue, should we resume development of our product candidates. Our genetic medicines platform is based on a family of 15 proprietary AAVHSCs which we can deploy through a nuclease- free gene editing modality, gene therapy, or GTx- mAb, which is designed to produce antibodies throughout the body. All applications rely on the unique ability of our AAVHSCs to efficiently target multiple tissues in the body. The mechanism of action by which these vectors target particular tissues is still not completely understood. Therefore, it is difficult for us to determine that our vectors will be able to properly integrate corrective DNA in or deliver gene transfer constructs to enough tissue cells to reach therapeutic levels. Should we resume development of our product candidates, we cannot be certain that our AAVHSCs will be able to meet safety and efficacy levels needed to be therapeutic in humans or that they will not cause significant adverse events or toxicities. Furthermore, studies conducted by a third party in non- human primates, or NHPs, suggest that intravenous delivery of certain AAV vectors at very high doses may result in severe toxicity of the dorsal root ganglion, or DRG. To date, we have not observed the severe DRG toxicities described in these publications after intravenous administration in NHPs with our naturally occurring AAVHSC vectors, and we have not seen these toxicities in our product candidates. However, we cannot be certain that we will be able to avoid triggering toxicities in our future preclinical or clinical studies we may conduct with our product candidates. Any such results could impact our ability to develop a product candidate. As a result of these factors, it is more difficult for us to predict the time and cost of product candidate development, and we cannot predict whether the application of our genetic medicines platform, or any similar or competitive gene therapy or gene editing platforms, will result in the identification, development, and regulatory approval of any medicines, or that other genetic medicine technologies will not be considered better or more attractive for the development of medicines. There can be no assurance that any development problems we experience in the future related to our genetic medicines platform or any of our research programs will not cause significant delays or unanticipated costs, or that such development problems can be solved. We may also experience delays in developing a sustainable, reproducible, and scalable manufacturing process or transferring that process to commercial partners. Any of these factors may prevent us from completing our preclinical studies or any clinical trials that we may initiate, should we resume development of our product candidates, or commercializing any product candidates we may develop on a timely or profitable basis, if at all. Because gene therapy and gene editing are novel and the regulatory landscape that governs any product candidates we may develop is uncertain and continues to change, we cannot predict the time and cost of obtaining regulatory approval, if we receive it at all, for any product candidates we may develop, to the extent we resume such activities. Regulatory requirements governing products created with genome editing technology or involving gene therapy treatment have changed frequently and will likely continue to change in the future. Approvals by one regulatory authority may not be indicative of what any other regulatory authority may require for approval, and there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of gene therapy products, cell therapy products and other products created with genome editing technology. For example, the FDA maintains the Office of Therapeutic Products within its Center for Biologics Evaluation and Research, or CBER, with responsibility for the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. Should we resume development of our product candidates, these and other regulatory review agencies, committees and advisory groups and any requirements and 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 these treatment candidates or lead to significant post- approval limitations or restrictions. Additionally, under NIH Guidelines supervision of human gene transfer trials includes evaluation and assessment by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. In the European Union, or EU, the European Medicines Agency, or EMA, has a Committee for Advanced Therapies, or CAT, that, in conjunction with the Committee for Medicinal Products for Human Use, or CHMP, is responsible for assessing the quality, safety and efficacy of advanced therapy medicinal products, or ATMPs. ATMPs include gene therapy medicines, somatic- cell therapy medicines and tissue- engineered medicines. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for a gene therapy medicinal candidate that is submitted to the EMA. The CAT' s opinion is considered by the CHMP when giving its final recommendation regarding the authorization of a product in view of the balance of benefits and risks identified. Although the CAT' s draft opinion is submitted to the CHMP for final approval, the CHMP may depart from the draft opinion, if it provides detailed scientific justification. In the EU, the development and evaluation of a gene therapy medicinal product must be considered in the context of the relevant EU guidelines. The CHMP and CAT are also responsible for providing guidelines on ATMPs and have published numerous guidelines, including specific guidelines on gene therapies and cell therapies. These guidelines provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of ATMPs and include, among other things, the preclinical studies required to characterize ATMPs; the manufacturing and control information that should be submitted in a marketing authorization application; and post- approval measures required to monitor patients and evaluate the long term efficacy and potential adverse reactions of ATMPs. Although these guidelines are not legally binding, we believe that our compliance with them is likely necessary to gain and maintain approval for any of our product candidates. In addition, the EMA may issue new guidelines concerning the development and marketing authorization for gene therapy medicinal products and require that we comply with these new guidelines. Similarly complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape. As a result, the procedures and standards applied to gene therapy products and cell therapy products may be applied to any of our gene therapy or genome editing product candidates, but that remains uncertain at this point. The clinical trial requirements of the FDA, the EMA and other regulatory authorities and the criteria these regulators use to evaluate the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for product candidates created with novel genome editing technology such as ours can be more lengthy, rigorous and expensive than the process for other better known or more extensively studied product candidates and technologies. To the extent we resume our activities developing novel treatments for diseases in which there is little clinical experience with new endpoints and methodologies, there is heightened risk that the FDA, the EMA or comparable regulatory authorities may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. This may be a particularly significant risk for many of the genetically defined diseases for which we may develop product candidates alone or with collaborators due to small patient populations for those diseases, and designing and executing a rigorous clinical trial with appropriate statistical power is more difficult than with diseases that have larger patient populations. Regulatory authorities administering existing or future regulations or legislation may not allow production and marketing of products utilizing genome editing technology in a timely manner or under technically or commercially feasible conditions. Even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in statute or regulations or the interpretation of new available data by applicable regulatory agencies. Changes in applicable regulatory guidelines may lengthen the regulatory review process for our product candidates, require additional studies or trials, increase development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of such product candidates, or lead to significant post- approval limitations or restrictions. Additionally, adverse developments in clinical trials conducted by others of gene therapy products or products created using genome editing technology, or adverse public perception of the field of genome editing, may cause the FDA and other regulatory authorities to revise the requirements for approval of any product candidates we may develop or limit the use of products utilizing genome editing technologies, either of which could materially harm our business. Furthermore, regulatory action or private litigation could result in expenses, delays or other impediments to our research programs or the development or commercialization of current or future product candidates. Should we resume development of our product candidates, we would be required to consult with these regulatory and advisory groups and comply with all applicable guidelines, rules and regulations. If we fail to do so, we may be required to delay or terminate development of such product candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a product candidate to market could decrease our ability to generate sufficient product revenue to maintain our business. Clinical trials are expensive, time- consuming, difficult to design and implement, and involve an uncertain outcome. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Should we resume development of our product candidates, the results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later- stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biotechnology and genetic medicines industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Even if our current and

future clinical trials are completed as planned, we cannot be certain that their results will establish the safety, purity, potency and / or effectiveness of any of our product candidates to the satisfaction of the FDA or other regulatory authorities, even if we believe that such trials were successful. To date, we have not completed any clinical trials for our product candidates. Should we resume development of our product candidates, we may experience delays in conducting any clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, recruit and enroll patients on time or be completed on schedule, or at all. Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to: • the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies; • obtaining regulatory approval to commence a trial; • reaching an agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • obtaining institutional review board, or IRB, and ethics committee approval or positive opinion at each site; • recruiting suitable patients to participate in a trial; • developing and validating the companion diagnostic to be used in a clinical trial, if applicable; • having patients complete a trial or return for post- treatment follow- up; • clinical sites deviating from trial protocol or dropping out of a trial; • addressing patient safety concerns that arise during the course of a trial; • adding a sufficient number of clinical trial sites; or • manufacturing sufficient quantities of product candidate for use in clinical trials. Should we resume development of our product candidates, we may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates or significantly increase the cost of such trials, including: • we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials; • clinical trials of our product candidates may produce negative safety and / or efficacy data or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon development programs; • the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate; • our third- party contractors **payor practices that** may **affect** fail to comply with regulatory requirements or **our ability** meet their contractual obligations to **commercialize** us in a timely manner, or at all; • we or our investigators might have to suspend or terminate clinical trials of our product candidates **. We are subject to U. S. and certain foreign export and import controls, sanctions, embargoes, anti- corruption laws, and anti- money laundering laws and regulations. We can face criminal liability and other serious consequences** for **violations, which can harm our business. We are subject to export control and import laws and regulations, including the U. S. Export Administration Regulations, U. S. Customs regulations,** various reasons **economic and trade sanctions regulations administered by the U. S. Treasury Department' s Office of Foreign Assets Controls** , including non **the U. S. Foreign Corrupt Practices Act of 1977, as amended, the U. S. domestic bribery statute contained in 18 U. S. C. § 201, the U. S. Travel Act, the USA PATRIOT Act, and other state and national anti** - compliance with regulatory requirements **bribery and anti- money laundering laws in the countries in which we conduct activities. Anti- corruption laws are interpreted broadly and prohibit companies and their employees** , **agents, contractors, and** a finding that our product candidates have undesirable side effects or other unexpected characteristics **collaborators from authorizing** , **promising, offering,** or a finding that the participants are being exposed to unacceptable health risks; • the cost of clinical trials of our -- **or providing, directly or indirectly, improper payments or anything else of value to or from recipients in the public or private sector. We may engage third parties to sell** product **products outside** candidates may be greater than we anticipate, and we may not have funds to cover the costs; • the supply or quality of our product candidates or other -- **the** materials necessary **U. S.,** to conduct clinical trials **of , and /** our - **or** product candidates may be insufficient or inadequate; • **to obtain necessary permits, licenses, patent registrations, and other** regulators **regulatory** may revise **approvals. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and** the **other** requirements **organizations. We can be held liable** for approving **the corrupt** our -- **or** product candidates, **other illegal activities of** or **our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of** such **activities. Any violations of the laws** requirements may not be as we anticipate; and • **regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. Governments outside the U. S. tend to impose strict price controls, which may adversely affect our revenue, if** any **. In some countries** future collaborators that conduct clinical trials may face any of the above issues , **particularly Member States of** and may conduct clinical trials in ways they - **the EU,** view as advantageous to them - **the pricing** but that are suboptimal for us. If we are required to conduct additional clinical trials or other testing of **prescription drugs is subject** our product candidates beyond those that we currently contemplate, if we are unable to **governmental control. In** successfully complete clinical trials of our product candidates or other testing, if the results of these **countries** trials or tests are not positive or are only modestly positive or if there are safety concerns , **pricing negotiations with governmental authorities can take considerable time after receipt of** we may: • incur unplanned costs; • be delayed in obtaining marketing approval for **a therapeutic. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various Member States and parallel distribution,** our -- **or** product candidates or not **arbitrage between low- priced and high- priced Member States, can further reduce prices. To** obtain marketing **coverage and reimbursement or pricing** approval **approvals** at all; • obtain marketing approval in some countries **, we** and not in others; • obtain marketing approval for - **or** indications **current** or **future collaborators may** patient populations that are not as broad as intended or desired; • obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings; • be subject **required** to **conduct** additional post-

~~marketing testing requirements; or • have the product removed from the market after obtaining marketing approval. We could encounter further delays if~~ a clinical trial ~~is suspended~~ or ~~terminated~~ **other studies that compare the cost- effectiveness of a product to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts** by ~~us, by the IRBs of the institutions in which such trials are being conducted, by the Data Monitoring Committee, or DMC, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Furthermore, we may rely on CROs and clinical trial sites to ensure the proper and timely conduct of clinical trials and while we would have agreements governing their committed activities, we would have limited influence over their actual performance, as described in " — Risks Related to Our Dependence on Third Parties. " To the extent we were to resume such activities, all of our product candidates would require extensive clinical testing before we would be prepared to submit a BLA or similar applications seeking regulatory approval. We cannot predict with any certainty if or when we might complete the development of any of our product candidate and submit a BLA or similar applications or whether any such BLA or similar applications will be approved by the FDA or comparable foreign authorities. We may seek feedback from the FDA or other regulatory authorities on our clinical development program, and the FDA or such regulatory authorities may not provide such feedback on a timely basis, or such feedback may not be favorable, which could further delay our development programs. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be harmed, and our ability to generate revenues from our product candidates may be delayed. In addition, any delays in our clinical trials could increase our costs, slow down the development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and results of operations. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. In addition, the FDA' s and other regulatory authorities' policies 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 EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi- center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state' s decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR provides for a three- year transition period. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the EU Clinical Trials Directive remain governed by said Clinical TrialDirective until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our** third- party **payors** ~~service providers, such as clinical research organizations, or CROs, may impact our~~ - **or authorities may lead** ~~developments plans. It is currently unclear~~ to **further pressure** ~~what extent the United Kingdom, or UK, will seek to align its regulations with the EU. The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). On January 17, 2022, the UK Medicines and Healthcare Regulatory Agency, or MHRA, launched an eight- week consultation~~ on ~~reframing~~ the **prices** ~~UK legislation for~~ - **or reimbursement levels** ~~clinical trials, with~~ **within** the **country** ~~aim to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The UK Government published its response to the consultation is on March 21, 2023 confirming that it would bring forward changes to the legislation. These resulting legislative amendments will be closely watched and will determine how closely the UK regulations are aligned with the CTR. Under the terms~~ of ~~the Protocol on Ireland / Northern Ireland, provisions of the CTR which relate to the manufacture and import of investigational medicinal products and auxiliary medicinal products apply in Northern Ireland. On February 27, 2023, the UK Government and the European Commission reached a political agreement on the " Windsor Framework " which will revise the Protocol on Ireland / Northern Ireland in order to address some of the perceived shortcomings in its operation. Once implemented, this may have further impact on the application~~ - **publication** ~~of the CTR in Northern Ireland. A decision by the UK Government not to closely align any new legislation with the new approach adopted in the EU may have an~~ **and** ~~effect on the cost of conducting clinical trials in the UK as opposed to~~ other countries. If ~~we are slow~~ **reimbursement of any product approved** ~~or~~ **for marketing is unavailable** ~~unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our~~ - **or** ~~development plans may also~~ **limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations or prospects could** be **materially and** adversely ~~impacted~~ **affected** . **We** ~~Adverse public perception of genetic medicine, and gene editing in particular,~~ may ~~negatively impact the length of time required to advance~~ **seek one or more designations or expedited programs for** our product candidates ~~through clinical trials should we resume development of our product candidates~~ , **but may not receive** ~~including the pace at which we advance patient enrollment, and potential regulatory approval of, or demand for, our potential~~

products. Some of our therapeutic candidates involved editing the human genome. If we resume the development of our product candidates in the future, the clinical and commercial success of such potential products would depend in part designations or be allowed to proceed on expedited program pathways public acceptance of the use of gene editing and gene therapy for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that gene therapy and gene editing are unsafe , unethical, or immoral, and , consequently, our products may not gain the acceptance of the public or the medical community. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of product candidates we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available. In addition, gene editing technology is subject to public debate and heightened regulatory scrutiny due to ethical concerns relating to the application of gene editing technology to human embryos or the human germline. For example, in April 2015, Chinese scientists reported on their attempts to edit the genome of human embryos to modify the gene for hemoglobin beta. This is the gene in which a mutation occurs in patients with the inherited blood disorder beta thalassemia. Although this research was purposefully conducted in embryos that were not viable, the work prompted calls for a moratorium or other types of restrictions on gene editing of human eggs, sperm, and embryos. The Alliance for Regenerative Medicine in Washington, D. C. has called for a voluntary moratorium on the use of gene editing technologies in research that involved altering human embryos or human germline cells. Similarly, the NIH has announced that it would not fund any use of gene editing technologies in human embryos, noting that there are multiple existing legislative and regulatory prohibitions against such work, including the Dickey- Wicker Amendment, which prohibits the use of appropriated funds for the creation of human embryos for research purposes or for research in which human embryos are destroyed. Laws in the United Kingdom prohibit genetically modified embryos from being implanted into women, but embryos can be altered in research labs under license from the Human Fertilisation and Embryology Authority. Research on embryos is more tightly controlled in many other European countries. Although we do not use our technologies to edit human embryos or the human germline, should we resume development of our product candidates, such public debate about the use of gene editing technologies in human embryos and heightened regulatory scrutiny could prevent or delay our development of product candidates. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair our development and commercialization of product candidates or demand for any products we may develop. Adverse events in our preclinical studies or clinical trials or those of our competitors or of academic researchers utilizing gene therapy or gene editing technologies, even if not ultimately attributable to product candidates we do receive may discover and develop, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of potential product candidates we may identify and develop, stricter labeling requirements for those product candidates that are approved, a decrease in demand for any such product candidates and a suspension or withdrawal of approval by regulatory authorities of our product candidates. A Breakthrough Therapy Designation designations from and proceed on such expedited program pathways in the FDA future , such designations even if granted for or expedited programs any of our product candidates, may not lead to a faster development or regulatory review or approval process , and it each designation does not increase the likelihood that any of our product candidates will receive marketing regulatory approval in the U . Should we resume development S. We may seek fast track designation for some of our product candidates, we may seek where applicable. If a Breakthrough Therapy Designation drug is intended for the treatment of a serious our or product candidates if the life- threatening condition and nonclinical or clinical data support for the drug demonstrates the potential to address an unmet medical need for such a condition, required user fees upon submission of the first section of the BLA drug sponsor may apply for fast track designation .The FDA has broad discretion whether or not to grant this designation .,so Even even if we believe a particular product candidate is eligible for this designation,we cannot provide assure assurance you that the FDA would decide to grant it this designation .Even if we do our candidates receive Fast fast Track track Designation designation , we these candidates may not experience a faster development process,review or approval compared to conventional FDA procedures.The FDA may withdraw Fast fast Track track Designation designation if it believes that the designation is no longer supported by data from our the clinical development program. Many biologics that have received Fast Track track Designation designation have failed to obtain approval alone does not guarantee qualification for the FDA' s priority review procedures . We In the future,we may seek EMA PRIME a breakthrough therapy designation for one some of or our more product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics , to treat a serious or life- threatening disease or condition , and preliminary clinical evidence indicates that the drug , or biologic in our case, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Biologics Drugs designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval rolling review of a BLA, if the relevant criteria are met . Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough breakthrough Therapy therapy Designation designation for a product candidate may not result in a faster development process, review or approval compared to drugs therapies considered for approval under conventional non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product no..... to the PRIME scheme, the EMA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time

~~period~~ for **FDA** review or approval will not be shortened. **In the future, we may also seek approval of** ~~Product~~ **product** ~~developers that benefit from PRIME designation~~ **candidates under the FDA' s accelerated approval pathway. A product** may be eligible for accelerated **approval if it** ~~assessment (in 150 days instead of 210 days), which may be granted for medicinal products of major interest from a public health perspective or that target an unmet medical need, but this~~ is ~~not guaranteed. We may equally pursue some of the post- Brexit MHRA procedures to prioritize access to new medicines that will benefit patients, such as a 150- day assessment, a rolling review procedure and an innovative licensing and access pathway, or ILAP. ILAP aims to accelerate the time to market and to facilitate patient access to medicines, including new chemical entities, biological medicines, new indications and repurposed medicines. To benefit from ILAP, we must first apply to the MHRA for an innovation passport. An innovation passport allows for enhanced engagement with the MHRA and its partner agencies. Once an innovation passport has been granted, the next step in the pathway is the preparation of a target development profile, or TDP, document by the MHRA and its partner agencies. The TDP sets out the regulatory and development milestones, identifies potential pitfalls and creates a roadmap to achieving early patient access in the UK. Product developers that benefit from ILAP will be provided with advice on clinical trial design to ensure optimal data generation for both regulatory approval and health technology appraisal. The competent regulatory authorities in the EU and the UK have broad discretion whether to grant access to the aforementioned schemes and designations, and even if we were to be eligible for some of these procedures, we may not experience a faster development process, review or authorization compared to conventional procedures. Moreover, the removal or threat of removal of such designation may create uncertainty or delay in the clinical development of our product candidates and threaten the commercialization prospects of our product candidates, if approved. Such an occurrence could materially impact our business, financial condition and results of operations. Should we resume development of our product candidates, we may attempt to secure approval from the FDA or comparable foreign regulatory authorities through the use of accelerated approval pathways or similar expedited approval pathways outside the United States. If we are unable to obtain such approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA or similar expedited approval pathways by foreign regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post- marketing requirements, the FDA or foreign regulatory authorities may seek to withdraw accelerated approval or similar expedited approval. To the extent we resume development of our product candidates, we may in the future seek an accelerated approval for our one or more of our product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate~~ designed to treat a serious or life- threatening **disease or** condition ~~that~~ **and generally** provides **a** meaningful **advantage** ~~therapeutic benefit~~ over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit ~~,~~ but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a **new** drug ~~or biologic~~ over available therapy may not be a direct therapeutic advantage ~~,~~ but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor' s agreement to conduct, in a diligent manner, **additional post-approval** confirmatory studies to ~~verity~~ **verify** and describe the drug ~~or biologic~~ ' s ~~predicted~~ clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA is permitted to require, as appropriate, that a post- approval confirmatory study or studies be underway prior to approval or within a specified time ~~period~~ after the date of accelerated approval was granted. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis ~~,~~ if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if ~~confirmatory~~ **such post-approval** studies fail to ~~confirm such~~ **verify the drug' s predicted** clinical benefit. **Under FDORA, the FDA is empowered to act, such as issuing fines, against companies that fail to conduct with due diligence any post- approval confirmatory study or submit timely reports to the agency on their progress.** In **addition** ~~the EU~~ , ~~a " conditional " marketing authorization may be granted in cases where all the required safety and efficacy data are not yet available. A conditional marketing authorization is subject to conditions to be fulfilled~~ for ~~generating missing data or ensuring increased safety measures. A conditional marketing authorization is valid for one year and has to be renewed annually until fulfillment of all relevant conditions. Once the applicable pending studies are provided, a conditional marketing authorization can become a " standard " marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA, the marketing authorization will cease to be renewed. Furthermore, marketing authorizations may also be granted " under exceptional circumstances " when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to the introduction of specific procedures. This may arise when the intended indications are very rare and, in the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. This type of marketing authorization is close to a conditional marketing authorization as it is reserved to medicinal~~ products **being considered** ~~to be approved for severe diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of a marketing authorization. However, unlike a conditional marketing authorization, the applicant does not have to provide the missing data and will never have to. Although a marketing authorization " under exceptional~~

~~circumstances " is granted definitively, the risk- benefit balance of the medicinal product is reviewed annually and the marketing authorization may be withdrawn where the risk- benefit ratio is no longer favorable. Prior to seeking accelerated approval or similar expedited approval for any of our product candidates, should we resume development of our product candidates, we may seek feedback from the FDA or other comparable regulatory authorities and will otherwise evaluate our ability to seek and receive accelerated approval or similar expedited approval. Furthermore, if we decide to submit an application~~ for accelerated approval **, the FDA generally requires, unless otherwise informed by the Agency, that all advertising and promotional materials intended ~~or~~ for ~~similar expedited~~ dissemination or publication within 120 days of regulatory** approval **~~,~~ be submitted to ~~there~~ -- the Agency ~~can be no assurance that such submission or~~ for ~~application will be accepted or that any expedited development,~~** review **~~or~~ during the pre-** approval **review period ~~will be granted on a timely basis, or at all~~**. **~~The FDA or~~ Thus, even if we seek to utilize ~~other~~ -- the accelerated ~~comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting~~** approval **~~of any type. A failure~~ pathway, we may not be able** to obtain accelerated approval **and, even if we do, we may not experience a faster development, regulatory review or approval process ~~or~~ for that product. Moreover, even if we received accelerated approval,** any **post- ~~other form of expedited development, review or~~** approval **~~for our~~ studies required to confirm and verify clinical benefit may not show such benefit, which could lead to withdrawal of any approvals we have obtained. In addition, receiving accelerated approval does not assure that the product' s accelerated approval will eventually be converted to a traditional approval. If the FDA determines that a** product candidate **offers a treatment for a serious condition and, if approved, the product** would **provide ~~result in~~** a **~~longer time period to commercialization of such~~ significant improvement in safety or effectiveness, the FDA may designate the** product candidate **~~or~~ for ~~make commercialization unfeasible,~~ priority review. A priority review designation means that the goal for the FDA to review ~~and~~ - an ~~could increase~~ application is six months, rather than** the **~~cost~~ standard review period** of **~~development of such~~ ten months. We may request priority review for our product candidates. The FDA has broad discretion with respect to whether to grant priority review status to a** product candidate **~~and could harm~~ , so even if we believe a particular product candidate is eligible for such designation ~~our~~ - or ~~competitive position~~ status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily result** in **an expedited regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six- month review cycle or at all. We may pursue orphan drug designation for certain of our product candidates, but may not be able to obtain such designation, or obtain or maintain the benefits of such designation including orphan drug exclusivity, and even if we do obtain orphan designation for our product candidates, any orphan drug exclusivity it receives may not prevent regulatory authorities from approving ~~the~~ other ~~marketplace~~ competing products** . We may seek orphan drug designation for **some of** our product candidates **; however ~~should we resume our development activities in the future~~ , ~~but~~ we may never receive such designation. Under the Orphan Drug Act, the FDA may designate a product as ~~any~~ - an** orphan drug **if it is a drug or biologic intended to treat a rare disease or condition, defined as a patient population of fewer than 200, 000 in the U. S., or a patient population of 200, 000 or more in the U. S. where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U. S. Orphan drug ~~designations~~ - designation must be requested before submitting an NDA ~~we may receive may not confer marketing exclusivity~~** or **a BLA ~~other expected benefits~~** . **~~In the United States,~~ A similar regulatory scheme governs** orphan **products in the EU. Orphan** drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and **application ~~user-~~** fee waivers. **After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA.** In addition, if a product **~~that has~~ candidate with an** orphan drug designation subsequently receives the first **~~FDA~~ regulatory** approval for the **~~disease~~ indication** for which it has such designation, the product is entitled to **a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same product for the same therapeutic indication for seven years. Even if we obtain** orphan drug exclusivity **for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same product for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care** . Orphan drug exclusivity **~~in~~ may also be lost if** the **FDA determines ~~United States provides~~** that the **request ~~FDA may not approve any other applications, including a full BLA, to market the same drug~~** for **designation was materially defective or if** the **~~same~~ manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare** disease or condition **~~for seven years, except in limited circumstances~~** . **Further ~~The applicable exclusivity period is ten years in the EU. The European exclusivity period can be reduced to six years if, at the end of the fifth year, a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. In the future~~** , even if we **~~, or any prospective collaborators,~~** obtain orphan drug designation **, we may not be the first to obtain regulatory approval** for **~~a product candidate, we, or they, may not be able to obtain or maintain orphan drug exclusivity for that product candidate. We may not be the first to obtain marketing approval of~~** any **indication ~~product candidate for which we have obtained orphan drug designation for the orphan- designated disease or condition~~** due to the uncertainties associated with developing pharmaceutical products. **~~In addition~~ The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. Additionally** , **~~exclusive~~ legislation has been proposed by the European Commission that, if implemented, has the potential in some cases to shorten the ten- year period of orphan** marketing **exclusivity. It is unclear ~~rights in the United States may be limited~~** if **~~we seek approval~~ , when, ~~for~~ - or how ~~a disease or condition broader than the orphan- designated disease or condition or may be lost if~~** the FDA **~~later determines that the request for~~ - or ~~designation was materially defective or if we are unable to assure sufficient quantities of the~~**

other ~~product to meet~~ **regulatory authorities may change** the ~~needs of patients with the rare disease or condition. Further, even if we, or any future collaborators, obtain~~ orphan drug **regulations** ~~exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same disease or condition. Even after an~~ **and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA or other regulatory authorities may make to their** orphan drug ~~is approved~~ **regulations and policies** , ~~the FDA can subsequently approve the same drug for the same disease or~~ **our** ~~condition if~~ **business could be adversely impacted. Risks Related to Our Third Party Relationships We currently rely and expect to rely on third parties in** the **future to conduct our** ~~FDA concludes that the later drug is clinically~~ -- **clinical trials and** ~~superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process, nor does it prevent competitors from obtaining approval of the same~~ **some aspects of** ~~product candidate as ours~~ - **our research,** ~~for diseases or conditions other than those in which we have been granted orphan drug designation. The same principles are valid for the EU~~ as well **as some aspects of** ~~. A Regenerative Medicine Advanced Therapy designation from the FDA, or~~ **our delivery methods, and** ~~Advanced Therapy Medicinal Product classification by the~~ **those** EMA ~~,~~ **third parties may not perform satisfactorily** , ~~even if granted~~ **including failing to meet deadlines** for ~~any~~ **the completion of such trials, research or testing. We currently, and expect to continue to, rely on third parties, such as but not limited to CROs, clinical data management organizations, medical institutions, preclinical laboratories and clinical investigators, to conduct some aspects of our research. For example, we may rely on a third party to supply components** of our product candidates, **or to conduct some of our preclinical animal experiments. Any of these third parties** may **terminate their engagements with us at any time under certain criteria. If we need to enter into alternative arrangements, it may delay our product research and development activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will** not ~~lead~~ **relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the general investigational plan and protocols. Moreover, the FDA, the EMA and other regulatory authorities require us and the study sites and investigators we work with** to ~~a faster~~ **comply with standards, commonly referred to as GLPs and GCPs for conducting, recording and reporting the results of preclinical studies and clinical trials to assure, amongst other things, that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We have collaborations and license agreements with third parties, including our existing license agreements with BMS and Colorado and expect to collaborate with third parties in the future. We may not be successful in finding strategic collaborators for continuing** development **of certain of** ~~or~~ **our future** ~~regulatory review or approval process and does not increase the likelihood that our~~ product candidates ~~will receive marketing approval. Should we resume development of our~~ - **or successfully commercializing or competing in the market for certain indications. We currently collaborate with third- parties with respect to bempikibart and ADX- 097. If any of our collaborators, licensors or licensees experience delays in performance of, or fail to perform their obligations under, their applicable agreements with us, disagree with our interpretation of the terms of such agreement or terminate their agreement with us, our pipeline of** product candidates ~~,~~ **would be adversely affected. If** we ~~may seek a Regenerative Medicine Advanced Therapy,~~ **fail to comply with any of the obligations under** ~~or~~ **our collaborations** ~~RMAT, designation for~~ - **or** ~~HMI~~ **license agreements, including payment terms and diligence terms, our collaborators, licensors or licensees may have the right to terminate our agreements, in which event we may lose intellectual property rights, market or sell the products covered by such agreements or may face other penalties under such agreements. Our collaborators, licensors or licensees may also fail to properly maintain or defend the intellectual property we have licensed from them, or infringe upon other third party intellectual property rights, leading to the potential invalidation of such third party' s intellectual property or subjecting us to litigation or arbitration, any of which would be time** - ~~102~~ **consuming and expensive and could harm** ~~or~~ **our ability to develop or commercialize** our product candidates. **Further** ~~In 2017~~ , ~~the FDA established the RMAT designation as part of its implementation of the 21st Century Cures Act. An investigational drug is eligible for RMAT designation if: (1) it meets the definition of a regenerative medicine therapy, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or~~ any ~~combination product using such therapies~~ **of these relationships may require us to increase** ~~or~~ **our near** ~~products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious disease or condition;~~ and ~~(3) preliminary clinical evidence indicates that the investigational drug has the potential to address unmet medical needs for such disease or condition. In a February 2019 final guidance, the FDA also stated that certain gene therapies that lead to a sustained effect on cells or tissues may meet the definition of a regenerative medicine therapy. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review of BLAs and priority review. Product candidates granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict~~ long- term **expenditures** ~~clinical benefit~~ , **issue securities that dilute** ~~or~~ **our existing stockholders or disrupt our management and business. In** ~~reliance upon data obtained from a meaningful number of sites, including through expansion to additional~~ -- **addition** ~~sites~~ , ~~as appropriate. RMAT- designated~~ **collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our** product candidates **and products if the collaborators believe** that ~~receive accelerated approval may, as appropriate, fulfill their~~ -- **the competitive products are more likely to be successfully developed** ~~post- approval requirements through the submission of clinical evidence, clinical studies, patient registries,~~ or **can be commercialized under terms that are more economically attractive than under** ~~other~~ -- **the** ~~sources of real world evidence (~~ **agreements with us. In the future, we may decide to collaborate with entities** such as **, but not limited to, non** ~~electronic~~

~~health records); through the collection of larger confirmatory data sets; or via post-~~ **profit organizations, universities, pharmaceutical and biotechnology companies for the development and potential commercialization of existing and new product candidates. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of several factors. Those factors may include the design or results of clinical trials, the likelihood of** approval ~~monitoring~~ **by the FDA or similar regulatory authorities outside the U. S., the potential market for the subject product candidate, the costs and complexities** of ~~all~~ **manufacturing and delivering such product candidate to** patients ~~treated~~ **, the potential of competing drugs, the existence of uncertainty** with **respect** ~~such therapy prior~~ to ~~approval~~ **our ownership** of **technology** ~~the therapy. RMAT designation does not change the standards for product approval~~ , ~~and~~ **which can exist if** there is ~~no assurance that~~ **a challenge to** such **ownership without regard** ~~designation or eligibility for such designation will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the RMAT designation. Additionally, RMAT designation can be revoked if the criteria for eligibility cease~~ to ~~be met as clinical data emerges. In the EU, a specific framework has been implemented for ATMPs to facilitate their~~ -- **the** ~~access to~~ **merits of** the ~~EU~~ **challenge and industry and** market **conditions generally** . **The collaborator may also consider alternative** ~~An ATMP can be classified into three main types of medicinal products: (i) gene therapy medicinal products containing genes that lead to a therapeutic, prophylactic or diagnostic effect, (ii) somatic- cell therapy medicinal products containing cells or tissues that have been manipulated to change their biological characteristics or cells or tissues not intended to be used for the same essential functions in the body which can be used to cure, diagnose or prevent diseases, and (iii) tissue- engineered products containing cells or tissues that have been modified so they can be used to repair, regenerate or replace human tissue. Companies developing~~ product candidates **or technologies for similar indications that** may **be available to collaborate** ~~seek a scientific recommendation from the EMA' s CAT~~ on **and** ~~ATMP classification. This optional procedure allows applicants to clarify~~ whether **such** a ~~given~~ **collaboration could be more attractive than the one with us for our** product candidate **. The terms** ~~based on genes, cells or tissues meets the scientific criteria which define ATMPs, in order to address, as early as possible, questions~~ of ~~borderline with~~ **any additional collaborations or** other ~~areas, which~~ **arrangements that we** may **establish may** ~~arise as science develops. ATMP classification recommendation is adopted by the EMA' s CAT, after consultation with the EC. The EMA offers a range of advisory services and incentives to support the development of ATMPs such as contribution of the CAT' s members in the discussion of the scientific advice and fee waivers. Similarly to RMAT designation, ATMP classification in the EU does~~ not **be favorable to us** ~~change the standards for product approval, and there is no assurance that such classification will result in expedited review or approval~~ . **Collaborations** ~~Our contract manufacturers, including Oxford Biomedica (US) LLC,~~ are **complex** ~~subject to significant regulation with respect to manufacturing our former product candidates. The manufacturing facilities which we have historically and may in the future rely may not meet or continue to meet regulatory requirements, as applicable and as imposed to date, and have limited capacity. Historically, we have had relationships with a limited number of suppliers for the manufacturing of our viral vectors and product candidates. In March 2022, we closed an~~ **and** ~~agreement with Oxford to establish a new AAV vector manufacturing company, Oxford Biomedica (US) LLC, that incorporates our proven' plug and play' process development and manufacturing platform, as well as our experienced team and high- quality GMP vector production capabilities that we built and operated since 2019. The related transactions closed on March 10, 2022. Each supplier may require licenses to manufacture such components if such processes are not owned by the supplier or in the public domain and we may be unable to transfer or sublicense the intellectual property rights we may have with respect to such activities. All entities involved in the preparation of therapeutics for clinical studies or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late- stage clinical studies must be manufactured in accordance with GMP or similar requirements outside the United States. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. Our contract manufacturers must supply all necessary documentation in support of a BLA on a timely basis and must adhere to the FDA' s current good laboratory practices, or GLP, and GMP regulations enforced by the FDA through its facilities inspection program. Similar requirements apply in foreign jurisdictions. Some of our contract manufacturers have not produced a commercially- approved product and therefore have not obtained the requisite FDA and foreign regulatory approvals to do so. Our facilities and quality systems and the facilities and quality systems of some or all of our third- party contractors must pass a pre- approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre- approval plant inspection, FDA or foreign regulatory authorities approval of the products will not be granted. The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third- party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and / or~~ time- consuming **to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, it may have to**

curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop ~~or~~ our product candidates or bring them to the market and generate product revenue. The success of any potential collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of such collaboration arrangements. These disagreements can be difficult to resolve if neither of the parties has final decision- making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party ~~to implement and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent closure of a facility~~. Any such ~~remedial measures imposed upon~~ termination or expiration would adversely affect us financially and could harm ~~or~~ our business reputation. Future acquisitions or strategic alliances could disrupt our business and harm our financial condition and results of operations. We may acquire additional businesses or drugs, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets ~~whom we contract could materially harm our~~ or technologies, we may not be able to realize the benefit of acquiring such ~~business~~ businesses if we are unable ~~. If our third- party manufacturers fail~~ to successfully integrate ~~maintain regulatory compliance, the~~ them ~~FDA~~ with ~~or~~ our ~~other regulatory authorities can impose regulatory sanctions including~~ existing operations and company culture. We may encounter numerous difficulties in developing , manufacturing and marketing any ~~among other things, refusal to approve a pending application for a~~ new ~~drug~~ drugs ~~product or biologic product, or revocation of a pre- existing approval. As a result~~ resulting , our business, financial condition and results of operations may be materially harmed. Additionally, if supply from ~~one approved manufacturer is interrupted, there could be~~ a strategic alliance ~~significant disruption in commercial supply. An alternative manufacturer would need to be qualified through a BLA supplement and /~~or acquisition that ~~marketing authorization application supplement which could result in further~~ delay ~~. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for~~ or ~~commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines. These factors could cause the delay of clinical studies, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and~~ prevent us from ~~commercializing~~ realizing their expected benefits ~~our~~ or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction. The risks we face in connection with acquisitions, include: • diversion of management time and focus from operating our business to addressing acquisition integration challenges; • coordination of research and development efforts; • retention of key employees from the acquired company; • changes in relationships with strategic partners because of ~~products~~ product ~~successfully. Furthermore~~ acquisitions or strategic positioning resulting from the acquisition; • cultural challenges associated with integrating employees from the acquired company into our company; • the need to implement or improve controls , procedures, and policies at a business that prior to the acquisition may have lacked sufficiently effective controls, procedures and policies; • liability for activities of the acquired company before the acquisition, including intellectual property infringement claims, violation of laws, commercial disputes, tax liabilities, and other known liabilities; • unanticipated write- offs or charges; and • litigation or other claims in connection with the acquired company, including claims from terminated employees, customers, former stockholders or other third parties. Our failure to address these risks or other problems encountered in connection with our past or future acquisitions or strategic alliances could cause us to fail to realize the anticipated benefits of these transactions, cause us to incur unanticipated liabilities and harm the business generally. There is also a risk that future acquisitions will result in the incurrence of debt, contingent liabilities, amortization expenses or incremental operating expenses, any of which could harm our financial condition or results of operations. We rely, and anticipate that we will rely, on third parties to assist in designing, conducting, supervising and monitoring our preclinical studies and clinical trials, and if those third parties perform in ~~our suppliers fail to meet contractual requirements, and~~ an ~~we are unable to secure one~~ unsatisfactory manner, it may harm ~~or~~ our business. We rely ~~more replacement suppliers capable of production at a substantially equivalent cost~~ , ~~our~~ and anticipate that we will rely, on third party clinical investigators, CROs, clinical data management organizations and consultants to help design, conduct, supervise and monitor preclinical studies and clinical trials ~~may be delayed or we could lose potential revenue. If we resume development~~ of our product candidates ~~and encounter difficulties enrolling~~ . Because we rely on third ~~patients~~ parties ~~in~~ and do not have the ability to conduct preclinical studies ~~our~~ or clinical trials independently , we have less control over the timing, quality and other aspects of preclinical studies and clinical trials than we would if we conducted them on our own, including our inability to control whether sufficient resources are applied to our programs. If any of our CROs are acquired ~~our~~ or consolidated, these concerns are likely to be exacerbated and our preclinical studies or clinical trials may be further impacted due to potential integration, streamlining, staffing and logistical changes. These investigators, CROs and consultants are not our employees and we have limited control over the amount of time and resources that they dedicate to our programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. Further, these third parties may not

be diligent, careful or timely in conducting our preclinical studies or clinical trials, resulting in the preclinical studies or clinical trials being delayed or unsuccessful. If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, satisfy legal and regulatory requirements for the conduct of preclinical studies or clinical trials or meet expected deadlines, our preclinical and clinical development ~~activities~~ **programs** could be delayed ~~or~~ **and** otherwise adversely affected. **In all events** ~~Should we resume development of our product candidates~~, ~~the timely completion~~ **we are responsible for ensuring that each** of **our preclinical studies and** clinical trials ~~would depend, among~~ **is conducted in accordance with the general investigational plan and protocols for the trial. The FDA and** other ~~things, on our ability~~ **health authorities require certain preclinical studies** to ~~enroll a sufficient number of patients who remain in the study until its conclusion. We may encounter delays in enrolling, or~~ be ~~unable to enroll~~ **conducted in accordance with GLP** , **and** ~~a sufficient number of patients to complete any of our~~ clinical trials ~~, and even once enrolled we may be unable~~ to ~~retain a sufficient number~~ **be conducted in accordance with GCP, including conducting, recording and reporting the results** of **clinical** ~~patients to complete any of our~~ trials ~~. The enrollment of patients depends on many factors, including: • the patient eligibility criteria defined in the protocol; • the size of the patient population required for analysis of the trial' s primary endpoints; • the proximity of patients~~ to ~~study sites; •~~ **assure that data and reported results are credible and accurate and that** the ~~design~~ **rights, integrity and confidentiality** of ~~the trial; • our ability to recruit~~ clinical trial ~~investigators~~ **participants are protected. If we or our CROs fail to comply** with ~~the~~ **these requirements,** ~~appropriate competencies and experience; • clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other~~ -- **the data generated** ~~available therapies, including any new products that may be approved for the indications we are investigating; • our ability to obtain and maintain patient consents; and • the risk that patients enrolled~~ in **our** clinical trials ~~will drop out of~~ **may be deemed unreliable or uninterpretable and the FDA and** ~~the~~ **other** ~~trials before completion. In~~ **health authorities may require us to perform** ~~addition~~ **additional** ~~, should we resume development of our product candidates, our~~ clinical trials ~~would compete with~~ **. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. In** ~~other~~ -- **the U. S., we are also required to register certain** clinical trials ~~for product candidates that are in the same therapeutic areas as our product candidates,~~ and **post** ~~this competition would reduce~~ the **results** ~~number and types~~ of **completed** ~~patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our~~ clinical trials **on a government- sponsored database** ~~at the same clinical trial sites that some of our competitors use~~ , ~~which will reduce the number of patients who are available for our clinical trials~~ **ClinicalTrials. gov, within certain timeframes. Failure to do so can result** in **fines, adverse publicity and civil and criminal sanctions. Any** such **event** ~~clinical trial site. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which~~ could **adversely** ~~have a harmful effect~~ **affect our business, financial condition, results of operations and prospects. We rely** on ~~our ability to develop our product candidates, or could render further development impossible. Our product candidates have caused and may in the future cause serious adverse events or undesirable side effects or have other properties which may delay or prevent their~~ **third** ~~regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if any. Serious adverse events or undesirable side effects caused by our product candidates have caused, and could in the future cause, us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects, toxicities or unexpected characteristics, including death. A significant risk in any gene editing product is that the edit will be " off- target " (or " on- target, " but unwanted) and cause serious adverse events, undesirable side effects, toxicities or unexpected characteristics. For example, off- target cuts could lead to disruption of a gene or a genetic regulatory sequence at an unintended site in the DNA, or, in those instances where we also provide a segment of DNA to serve as a repair template, it is possible that following off- target cut events, DNA from such repair template could be integrated into the genome at an unintended site, potentially disrupting another important gene or genomic element. We cannot be certain that off- target editing will not occur in any of our planned or future clinical studies. There is also the potential risk of delayed adverse events following exposure to gene editing and / or gene therapy, due to the potential for persistent biological activity of the genetic material or other product components used to carry the genetic material. Accordingly, the FDA typically recommends an extended follow- up period to monitor for such events in patients~~ -- **parties** ~~who have received investigational gene therapies. Although we have communicated to the FDA our intent to withdraw or inactive our previously open INDs and discontinue development of our product candidates, as well as our determination that such long- term follow- up is not necessary for our product candidates, the FDA may disagree, and may continue to recommend that such follow- up be conducted. If we resume development of our product candidates and unacceptable side effects arise~~ in the **supply and manufacture** ~~development of such product candidates, we, the FDA, the IRBs at the institutions in which our studies are conducted or DMC, could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval~~ of our product candidates for ~~any or~~ **our research, preclinical and clinical activities, and may do the same** ~~all targeted indications. Treatment- related side effects could also affect patient recruitment or~~ **for** ~~the ability~~ **commercial supplies** of ~~enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using~~ our product candidates ~~to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly. If we resume development of our product candidates and any of our product candidates receives marketing approval, and we or others later identify undesirable side~~

effects caused by any such product, including during any long- term follow- up observation period recommended or required for patients who receive treatment using our products, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw approvals of such product; • we may be required to recall a product or change the way such product is administered to patients; • additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product; • regulatory authorities may require additional warnings on the label, such as a " black box " warning or contraindication; • we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients or implement similar risk management measures; • the product could become less competitive; • we could be sued and held liable for harm caused to patients; and • our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects. The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate' s clinical development and may vary among jurisdictions . We have not obtained **yet manufactured our product candidates on a commercial scale and may not be able to do so for any of our product candidates. We currently rely on third parties in the supply and manufacture of materials for our research, preclinical and clinical activities and may continue to do so for the foreseeable future, including if we received** regulatory approval for any product candidate and have communicated to **. We may do** the **same** FDA our intent to withdraw or **for** inactivate **the commercial supply of** our previously open INDs **drug product, if any** . It is possible that neither **We use third parties to perform additional steps in the manufacturing process, such as the filling, finishing and labeling of vials and storage and shipping of** our product candidates previously in **and we expect to do so for the foreseeable future. There can be no assurance that our supply of research, preclinical and clinical** development (should we elect to restart **drug candidates and other materials will not be limited, interrupted** our - **or restricted** development programs), nor - **or will be of satisfactory quality or continue to be available at acceptable prices. Replacement of** any **of the third parties we may engage could require significant effort and expertise because there may be a limited number of qualified replacements. In addition, raw materials, reagents, and components used in the manufacturing process, particularly those for which we have no** other **source or supplier, may not be available, may not be suitable or acceptable for use due to material or component defects, or may introduce variability into the supply of our** product candidates we may seek to **. Furthermore, with the increase of companies** develop **developing fusion protein based antibodies and /** in the future will ever obtain regulatory approval. Neither we nor - **or** any future collaborator is permitted **monoclonal antibodies, there may be increased competition for the supply of the raw materials that are necessary** to market -- **make** any **our fusion protein based antibodies and / or monoclonal antibodies, which could severely impact the manufacturing** of our product candidates in **. We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited, and** the **they must be acceptable to** United States until we receive regulatory approval of a BLA from the FDA . It is possible that the FDA may refuse to file for - **or** substantive review any BLAs, that we submit for our product candidates or may conclude after review of our data that our application is insufficient to obtain marketing approval **approved by** of our product candidates. Similar risks exist in foreign jurisdictions. Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from well- controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory authorities , that such product candidates are safe and effective, or in the case of biologics, safe, pure, and potent, for their intended uses . **Suppliers** Results from nonclinical studies and **manufacturers** clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are promising , **including** such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA and other regulatory authorities may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post- approval , **must meet applicable manufacturing requirements, including compliance with cGMP** or it may object to elements of our clinical development program. Depending on the extent of these or any other FDA- and other regulatory **regulations** authorities - **, and undergo rigorous facility and process validation tests** required studies, approval of any BLA or application that we submit may be delayed by several years, or may require us to expend significantly more resources than we have available. Of the large number of potential products in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects. In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post- marketing clinical trials, including Phase 4 clinical trials, and / or the implementation of a REMS or similar risk management measures, which may be required to ensure safe use of the drug after approval. The FDA or the applicable foreign regulatory agency also may approve a product candidate for a more limited indication or patient population than we originally requested, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates. In addition, changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. For instance, the EU pharmaceutical

legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the EC in November 2020. The EC' s proposal for revision of several legislative instruments related to medicinal products (including potentially revising the duration of regulatory exclusivity and eligibility for expedited pathways) was published on April 26, 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council (not expected before the end of 2024 or early 2025). The revisions may, however, have a significant impact on the pharmaceutical industry and our business in the long term. Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business to the extent we resume such activities. The ability of the FDA and foreign regulatory authorities to review and or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA' s or and foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA' s or foreign regulatory authorities' ability to perform routine functions. Average review times at the agency and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies, such as the EMA following its relocation to Amsterdam and related reorganization, may also slow the time necessary for new drugs and biologics to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. Even if we restart development of our product candidates and obtain FDA approval for our product candidates in the United States in the future, we may never obtain approval for or commercialize them in any other jurisdiction, which would limit our ability to realize their full market potential. In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country- by- country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in any one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory **standards** requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized. **In** Even if we restart development of and receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates. Any product candidate for which we obtain marketing approval, will be subject to extensive and ongoing requirements of and review by the FDA and other -- **the** regulatory authorities, including oversight of the manufacturing processes, post- approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for such product, among other things. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with GMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and GCP requirements for any clinical trials that we conduct post- approval. Manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with GMP or similar regulations and standards. In addition, any marketing approvals that we may receive for our product candidates may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post- approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, including adverse events of unanticipated severity or frequency, or with our third- party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including: • restrictions on manufacturing such products; • restrictions on the labeling or marketing of a product; • restrictions on product distribution or use; • requirements to conduct post- marketing studies or clinical trials; • warning letters or holds on clinical trials; • withdrawal of the products from the market; • refusal to approve pending applications or supplements to approved applications that we submit; • recall of products; • fines, restitution or disgorgement of profits or revenues; • suspension or withdrawal of marketing approvals; • refusal to permit the import or export of our products; • product seizure or detention; or • injunctions or the imposition of civil or criminal penalties. The FDA' s and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future

legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability. The FDA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off- label uses. If we restart development of our product candidates and any of our product candidates are approved, and we are found to have improperly promoted off- label uses of those products, we may become subject to significant liability. The FDA and other regulatory authorities strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product' s approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off- label uses, we may become subject to significant liability. The U. S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off- label use and has enjoined several companies from engaging in off- label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition. Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop. The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in: • impairment of our business reputation and significant negative media attention; • withdrawal of participants from our clinical trials; • significant costs to defend the related litigation and related litigation; • distraction of management' s attention from our primary business; • substantial monetary awards to patients or other claimants; • inability to commercialize our product candidates; • product recalls, withdrawals or labeling, marketing or promotional restrictions; • decreased demand for our product candidates, if approved for commercial sale; and • loss of revenue. Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities. We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, employment practices liability, property, auto, workers' compensation, umbrella, and directors' and officers' insurance. Any additional product liability insurance coverage we acquire in the future, may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for any of our product candidates, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the commercialization of any product candidates we develop. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended. We also expect that operating as a public company will continue to make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers. We do not know if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations. Our employees and independent contractors, including principal investigators, CROs, consultants, vendors, and any third parties we may engage in connection with development and commercialization, to the extent we resume such activities, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business. Misconduct by our employees and independent contractors, including principal investigators, CROs, consultants, vendors, and any third parties we may engage in connection with development and commercialization, could include intentional, reckless or negligent conduct or unauthorized activities that violate: (i) the laws and regulations of the FDA, foreign regulatory authorities rules and regulations and other similar regulatory requirements, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) data privacy, security, fraud and abuse and other healthcare laws and regulations. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, 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 comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U. S. federal healthcare programs or healthcare programs in other jurisdictions, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations. Our business and operations may suffer in the event of information technology system failures, cyberattacks or deficiencies in our cybersecurity. In the ordinary course of our business, we collect and store sensitive data, including intellectual property, clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations. Our information technology systems, as well as those of our CROs and other contractors and consultants, are vulnerable to failure or damage from computer viruses and malware (e. g. ransomware), unauthorized access or other cybersecurity attacks, natural disasters (including hurricanes), international terrorism, conflicts and telecommunication and electrical failures. We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product candidate development programs. For example, should we resume the development of our product candidates, the loss of preclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption **of** or **our suppliers** security breach were to result in a loss of or damage to our **or manufacturers** data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad actors, or breached due to human error (e. g., social engineering, phishing), a technical vulnerability, malfeasance or other disruptions. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. We may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques (including artificial intelligence) that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. Any significant security breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could require significant resources to remediate or recover from the incident, result in legal claims or proceedings (including class actions), liability under laws that protect the privacy of personal information, significant regulatory penalties, and such an event could disrupt our operations, damage our reputation, and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay our clinical development of our product candidates. Further, our insurance coverage may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems. Should we resume development of our product candidates, initial, interim, " top- line " and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. If we resume development of our product candidates, we may publicly disclose initial, interim, top- line or preliminary data from our clinical trials, which would be based on a preliminary analysis of then- available data, and the results and related findings and conclusions would be subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the initial, top- line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Initial, top- line or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the initial, top- line or preliminary data we previously published. Should we resume development of our product candidates, further clinical data from any trials of our candidates may not be consistent with data previously observed and disclosed in preclinical studies or clinical trials. As a result, initial, top- line and preliminary data should be viewed with caution until the final data are available. We may also disclose interim or initial data from our preclinical studies and clinical trials. Interim or initial data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between initial, interim, top- line or preliminary data and final data could significantly harm our business prospects. Further, disclosure of any such data by us or by our competitors could result in volatility in the price of our common stock. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our Company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the top- line or preliminary data that we report differ from

~~actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition. To the extent we resume development of our product candidates, we may expend our limited resources to pursue a particular product candidate or indication and~~ fail to capitalize on product candidates or indications....., collaborators, or other third parties to comply with such requirements or ~~adequately address privacy and security concerns~~ **to perform their obligations to us in relation to quality** , ~~even~~ **timing or otherwise, some of which may be out of their or our control, or** if ~~unfounded~~ **our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to increase the manufacturing of the materials ourselves, for which we currently have limited capabilities and resources, or enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all. Any interruption of the development or operation of the manufacturing of our product candidates, such as order delays for equipment or materials, equipment malfunction, quality control and quality assurance issues, regulatory delays and possible negative effects of such delays on supply chains and expected timelines for product availability, production yield issues, shortages of qualified personnel, discontinuation of a facility or business or failure or damage to a facility resulting from natural disasters** , could result in ~~additional cost and liability~~ **the cancellation of shipments, loss of product in the manufacturing process or a shortfall in available product candidates or materials. In some cases, the technical skills or technology required** to **manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting** us **from** , ~~damage~~ **transferring such skills** ~~our~~ **or technology** ~~reputation, and adversely affect our business and results of operations. We are subject~~ to ~~environmental, health~~ **another third party** and **a feasible alternative** ~~safety laws and regulations, and we~~ may **not exist** ~~become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities. Our operations are subject to numerous environmental, health and safety laws and regulations~~ . These **factors would increase our reliance on** ~~laws and regulations govern, among other things, the controlled use, handling, release and disposal of and the maintenance of a registry for, hazardous materials and biological materials,~~ such **manufacturer or require us to obtain a license from such manufacturer in order to** ~~as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that~~ have ~~a toxic effect on reproduction, laboratory procedures and exposure to blood- borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other~~ **another** ~~sanctions. As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, the production efforts of our~~ third-party **manufacture our product candidates. If we are required to change** manufacturers ~~or~~ **for any reason** ~~our development efforts may be interrupted or delayed. We are currently subject to securities class action litigation and may be subject to similar or other litigation in the future~~ , ~~which~~ **we** will **be** ~~require~~ **required** ~~significant management time~~ **to verify that the new manufacturer maintains facilities** and **procedures that comply with quality standards** ~~attention, result in significant legal expenses~~ and **with all applicable regulations** ~~may result in unfavorable outcomes, which may have a material adverse effect on our business, operating results~~ and ~~financial condition, and~~ **guidelines. The delays associated with the verification of a new manufacturer could** negatively affect ~~the price of our common stock. We are, and may in the future become, subject to various legal proceedings and claims that arise in or~~ **our** ~~outside the ordinary course of business~~ **ability to develop product candidates in a timely manner or within budget** . ~~In the past, securities~~ **Regional or single- source dependencies may in some** ~~class~~ **cases accentuate** ~~action litigation has often been brought against a company following a decline in the~~ **these** ~~market price of its securities. This risk~~ **risks** ~~is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years~~ . For example, **the pharmaceutical industry generally, and in some cases of third parties** on ~~March 25~~ **which we rely** , **depend on China- based suppliers or service producers for** ~~2022, a stockholder of the Company, Michael C. Pizzuto, filed a putative class action complaint alleging violations of Sections 10 (b) and 20 (a) of the Securities and Exchange Act of 1934, as amended, against us and~~ certain ~~of~~ **materials, products and services,** ~~our~~ **or** executives **other activities** . **Our ability or the ability of the third parties** ~~Pizzuto v. Homology Medicines, Inc., No. 2: 22 - CV - 01968 (C. D. Cal 2022). The complaint alleges that~~ we ~~failed~~ **rely on** to ~~disclose~~ **continue to engage these China- based suppliers or service providers for** certain **materials could be restricted due** ~~information regarding efficacy and safety in connection with a Phase 1 / 2 HMI- 102 clinical trial, and seeks damages in an unspecified amount. The Company filed a motion~~ to **geopolitical developments between** ~~transfer the case to~~ the United States ~~District Court~~ **and China, including as a result of the escalation of tariffs or other trade restrictions. In addition, we currently rely on foreign CROs and CDMOs, including WuXi Biologics, and will likely continue to rely on foreign CROs and CDMOs in the future. Foreign CDMOs may be subject to U. S. legislation, including,** for **example** ~~the District of Massachusetts on September 2~~ , **legislation previously considered in** ~~2022, and a motion to dismiss on October 17, 2022. On April 18, 2023,~~ the **U. S. Congress (but** ~~court granted the motion to transfer, finding that venue was~~ not ~~proper in~~ **enacted) called** the **BIOSECURE Act** ~~Central District of California and transferring the case to the District of Massachusetts~~ . ~~Following~~ **If** the ~~transfer,~~ **BIOSECURE Act or similar legislation is passed in** the ~~case number changed~~ **future, it could prohibit the U. S. government from entering contracts or providing grants or loans** to ~~1: 23~~ **procure biotechnology equipment and services provided or produced by so** ~~- cv- 10858- AK (D. Mass.). On May 9, 2023, the Massachusetts court issued an order permitting the parties to submit updated briefs in connection with the motion to dismiss, which were submitted on June 8, 2023, July 13, 2023, and August 3, 2023. The motion to dismiss remains pending. On March 4, 2024, the Massachusetts court held oral argument on the Company' s motion to dismiss, which remains pending. On February 22, 2024, a purported stockholder of the Company, Kevin Welsh, filed a putative class action complaint against the Company and its directors related to the Company' s proposed Merger with Q32, alleging violations of~~

Sections 14 (a) and 20 (a) of the Securities Exchange Act of 1934, as amended. Welsh v. Homology Medicines, Inc., No. 1: 24- cv- 00242 (D. Del.). The complaint alleges that the Company and its directors filed a proxy statement containing material omissions regarding financial forecasts and their respective analysis, and seeks damages in an unspecified amount. The case is in its early stages. The Company believes the claims alleged -- **called " biotechnology companies** lack merit. The results of **concern** the securities class action lawsuit and any future legal proceedings cannot be predicted with certainty . **" It** Also **also** , **could prohibit the U. S. government from entering contracts** our - **or** insurance coverage may be insufficient, and any amounts not covered **providing grants or loans to entities who use biotechnology equipment or services provided or produced** by **" biotechnology** insurance will be borne by the combined company **companies of concern "** . Furthermore, our assets may be insufficient to cover any amounts that exceed our insurance coverage, and we may have to pay damage awards or otherwise may enter into settlement arrangements in connection with such **contracts, grants,** claims. Any such payments or settlement arrangements **loans. WuXi Biologics, along with several other entities, was identified** in current **the legislation as a " biotechnology company of concern. " Even though the final version of the BIOSECURE Act considered by Congress did include a delayed implementation date to permit companies to wind down from impacted relationships, any additional executive action, legislative action** or future litigation **potential sanctions with China** could have a material **materially** adverse effect on our business, operating results or financial condition. Even if the plaintiffs' claims are not successful, current or future litigation could result in substantial costs and significantly and adversely impact **WuXi Biologics** our reputation and divert management' s attention and resources , **and our agreement with them. In addition, foreign CDMOs may be subject to sanctions, trade restrictions and other foreign regulatory requirements** which could have a **increase the cost or reduce the supply of** material adverse effect on **available to us, delay the procurement** our - **or supply** business, operating results and financial condition, and negatively affect the price of our common stock. In addition, such **material** lawsuits may make it more difficult to finance our - **or** operations. Should we resume development of our product candidates, we face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more advanced or effective than ours, which may harm our financial condition and our ability to successfully market or commercialize any product candidates we may develop. The development and commercialization of new genetic medicine products is highly competitive. Moreover, the gene editing field is characterized by rapidly changing technologies, significant competition, and a strong emphasis on intellectual property. Should we resume development of our product candidates, we will face competition with respect to any product candidates that we may seek to develop or commercialize from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we have research programs, including PKU, MLD, Hunter syndrome, hemoglobinopathies and ophthalmological diseases. Some of these competitive products and therapies are based on scientific approaches that are similar to our approach, and others are based on entirely different approaches. Historically, our platform and product focus has been the development of genetic medicines using our proprietary AAVHSCs in vivo through a nuclease- free gene editing modality, gene therapy, or GTx- mAb, which is designed to produce antibodies throughout the body. Should we resume development of such programs, and if our former programs were to be approved for the indications for which we had been conducting clinical trials, they may compete with other products under development, including gene editing and gene therapy products or other types of therapies, such as small molecule, antibody or protein therapies. If our PKU treatments are approved, they may compete with therapies from American Gene Technologies, BioMarin, Censa Pharmaceuticals, Generation Bio, Nestlé Health Science, Sangamo Therapeutics and Synlogic. However, we believe that only gene therapy or gene editing approaches have the potential to restore the normal Phe biochemical pathway with a single administration. If our Hunter syndrome treatment is approved, it may compete with therapies from Shire and / or GC Pharma. If our MLD treatment is approved, it may compete with therapies from Orchard Therapeutics, Passage Bio and / or Shire. In vivo gene therapy approaches provide potential advantages over ex vivo approaches. There are a number of companies developing nuclease- based gene editing technologies using CRISPR / Cas9, TALENs, meganucleases, Mega- TALs and ZFNs, including but not limited to Beam Therapeutics, bluebird bio, Caribou Biosciences, Cellectis, CRISPR Therapeutics, Editas Medicine, Intellia Therapeutics, Precision BioSciences, Prime Therapeutics and Sangamo Therapeutics and non- nuclease- based technology, including LogicBio Therapeutics, a wholly- owned subsidiary of Alexion. Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. We have requested withdrawal or inactivation of our previously open INDs, so we are currently not progressing any product candidates through the development process. Mergers and acquisitions in the pharmaceutical, biotechnology, and gene therapy industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop or that would render any products that we may develop obsolete or non- competitive. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position

before we are able to enter the market. Additionally, technologies developed by our competitors may render our potential product candidates uneconomic or obsolete, and we may not be successful in marketing any product candidates we may develop against competitors. In addition, as a result of the expiration or successful challenge of our patent rights, we could face more litigation with respect to the validity and / or scope of patents relating to our competitors' products. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize. Should we resume development of our product candidates, the successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue. The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third- party payors are essential for most patients to be able to afford prescription medications such as our product candidates, assuming FDA or foreign authorities approval. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our product candidates. Assuming we obtain coverage for our product candidates by a third- party payor, the resulting reimbursement payment rates may not be adequate or may require co- payments that patients find unacceptably high. Moreover, for drugs and biologies administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such products. We cannot be sure that coverage and reimbursement in the United States, the EU or elsewhere will be available for our product candidates or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future. Coverage and reimbursement by a third- party payor may depend upon a number of factors, including the third- party payor' s determination that use of a product is: • a covered benefit under its health plan; • safe, effective and medically necessary; • appropriate for the specific patient; • cost- effective; and • neither experimental nor investigational. Third- party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third- party payors may refuse to provide coverage and reimbursement for particular drugs or biologies when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third- party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing third- party therapeutics may limit the amount we will be able to charge for our product candidates. These third- party payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, and may not be able to obtain a satisfactory financial return on our product candidates. There is significant uncertainty related to the insurance coverage and reimbursement of newly- approved products. In the United States, third- party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologies will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third- party payors may require pre- approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third- party payors will decide with respect to the coverage and reimbursement for our product candidates. No uniform policy for coverage and reimbursement for products exists among third- party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly among third- party payors. As a result, the coverage determination process is often a time- consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each third- party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost- containment initiatives in Europe and other countries have and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially- reasonable revenue and profits. Even if a pharmaceutical product obtains a marketing authorization in the EU, there can be no assurance that reimbursement for such product will be secured on a timely basis or at all. Governments influence the price of medicinal products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Member states are free to restrict the range of pharmaceutical products for which their national health insurance systems provide reimbursement, and to control the prices and reimbursement levels of pharmaceutical products for human use. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed to by the government. Member states may approve a specific price or level of reimbursement for the pharmaceutical product, or alternatively adopt a

system of direct or indirect controls on the profitability of the company responsible for placing the pharmaceutical product on the market, including volume- based arrangements, caps and reference pricing mechanisms. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost- effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription medicines, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross border imports from low- priced markets exert a commercial pressure on pricing within a country. Moreover, increasing efforts by governmental and third- party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. Even if any of our product candidates receives marketing approval in the future, it may fail to achieve market acceptance by physicians, patients, third- party payors or others in the medical community necessary for commercial success. If any of our product candidates receives marketing approval in the future, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors and others in the medical community. If it does not achieve an adequate level of acceptance, we may not generate significant product revenues or become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including but not limited to: • the safety, efficacy and potential advantages compared to alternative treatments; • effectiveness of sales and marketing efforts; • the cost of treatment in relation to alternative treatments, including any similar generic treatments; • our ability to offer our products for sale at competitive prices; • the convenience and ease of administration compared to alternative treatments; • the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; • the strength of marketing and distribution support; • the timing of market introduction of competitive products; • the availability of third- party coverage and adequate reimbursement; • product labeling or product insert requirements of the FDA, EMA or other regulatory authorities, including any limitations or warnings contained in a product' s approved labeling; • the prevalence and severity of any side effects; and • any restrictions on the use of our product together with other medications. Because we expect sales of our product candidates, if approved, to generate substantially all of our product revenues for a substantial period, the failure of this product to find market acceptance would harm our business and could require us to seek additional financing. Should we resume development of our product candidates, if we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing our product candidates, if approved. Moreover, provisions in our agreements with Pfizer may inhibit our ability to enter into future collaborations with third parties. We do not have any infrastructure for the sales, marketing or distribution of our products, and the cost of establishing and maintaining such an organization may exceed the cost- effectiveness of doing so. Should we resume development of our product candidates, there are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any product launch, which would adversely impact the commercialization of our product candidates. Additionally, if the commercial launch of any of our product candidates for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of our product candidates in certain markets overseas. Therefore, our future sales in these markets will largely depend on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator' s strategic interest in the product and such collaborator' s ability to successfully market and sell the product. We intend to pursue collaborative arrangements regarding the sale and marketing of our product candidates, if approved, for certain markets overseas; however, we cannot assure that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. If we are unable to build our own sales force or negotiate a collaborative relationship for the commercialization of our product candidates, we may be forced to delay the potential commercialization of our product candidates or reduce the scope of our sales or marketing activities for our product candidates. If we elect to increase our expenditures to fund commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. We could enter into arrangements with collaborative partners at an earlier stage than otherwise would be ideal and we may be required to relinquish rights to our product candidates or otherwise agree to terms unfavorable to us, any of which may have an adverse effect on our **ability to manufacture our product candidates. We may also be required to enter into long- term manufacturing agreements that contain exclusivity provisions and / or substantial termination penalties which could have a material adverse effect on our** business , operating results and prospects **prior to or after commercialization of any of our product candidates** . If we are unable to establish adequate sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates, and may not become profitable and may incur significant additional losses. We will be competing with many companies that currently have extensive and well- funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies. If we obtain approval to commercialize any products outside of the United States, a variety of risks associated with international operations could materially adversely affect our **or maintain** business. If any of our product candidates are approved for commercialization, we

intend to enter into agreements with third parties to market it in certain jurisdictions outside the United States. We expect that we will be subject to additional risks related to international pharmaceutical operations, including: • different regulatory requirements for drug and biologic approvals and rules governing drug and biologic commercialization and country- specific regulations of gene therapies in foreign countries; • complex and restrictive import / export regulations; • reduced protection for intellectual property rights; • foreign reimbursement, pricing and insurance regimes; • potential noncompliance with the U. S. Foreign Corrupt Practices Act, the U. K. Bribery Act 2010 and similar anti- bribery and anticorruption laws in other jurisdictions; • production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; • political and economic instability, including in light of international terrorism and conflicts; • fluctuations in currency exchange rates; and • higher costs of doing business internationally, including increased accounting, travel infrastructure and legal compliance costs. We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the EU and many of the EU member states with which we will need to comply. Many U. S.- based biotechnology companies have found the process of marketing their own products in Europe to be very challenging. In the future, any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated. The Patient Protection and Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA- licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12- year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor' s own preclinical data and data from adequate and well- controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. There is a risk that any of our product candidates approved as a biological product under a BLA would not qualify for the 12- year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Jurisdictions in addition to the United States have established abbreviated pathways for regulatory approval of biological products that are biosimilar to earlier approved reference products. For example, the EU has had an established regulatory pathway for biosimilars since 2006. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non- biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. We have historically contracted with third parties, including Oxford Biomedica (US) LLC, for the manufacture of certain materials for our research programs, preclinical and clinical studies. This reliance on third parties increases the risk that we will not have sufficient quantities of such materials, product candidates, or any medicines that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost or in compliance with regulatory requirements, which could delay, prevent, or impair our development or commercialization efforts if we were to resume such activities. We have historically relied on third- party manufacturers **manufacturing** for the manufacture of materials for research programs, preclinical and clinical studies. We do not have long- term supply agreements with all of the third- party manufacturers, and we purchase our required supply on a purchase order basis. Furthermore, the raw materials for our product candidates are sourced , in some cases, from a single- source supplier. Should we resume development of our - **or** product candidates, if we were to experience an unexpected loss of supply of any of our product candidates or any of our future product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials. We may be unable to establish any agreements with third- party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third- party manufacturers, reliance on third- party manufacturers entails additional risks, including: • the possible breach of the manufacturing agreement by the third party; • the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; • reliance on the third party for regulatory compliance, quality assurance, safety, and pharmacovigilance and related reporting; • inability to meet our drug specifications and quality requirements consistently; • delay or inability to procure sufficient manufacturing capacity; • issues related to scale- up of manufacturing; • costs and validation of new equipment and facilities required for scale- up; • reliance on single sources for drug components; • lack of qualified backup suppliers for those components that are currently purchased from a sole or single- source supplier; • misappropriation of proprietary information, including our trade secrets and know- how; • the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or study drug or placebo not being properly identified; • clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; • operations of our third- party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier; and • carrier disruptions or increased costs that are beyond our control. We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with GMP regulations for manufacturing both active drug substances and finished drug products. Third- party manufacturers may not be able to comply with GMP regulations or similar regulatory requirements outside the United States. The failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or medicines, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of

~~our medicines and harm our business, financial condition, results of operations, and prospects. Assuming we were to resume the development of our product candidates, any medicines that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under GMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. Our current and anticipated future dependence upon others for the manufacture of any product candidates we may develop or medicines may adversely affect our future profit margins and our ability to commercialize any medicines that receive marketing approval on a timely and competitive basis. Should we resume development of our product candidates, we would rely on third parties to conduct, supervise and monitor our clinical trials. If those third parties did not successfully carry out their contractual duties, or if they performed in an unsatisfactory manner, it may harm our business. Should we resume development of our product candidates, we would rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we expect to have limited influence over their actual performance. We would rely upon CROs to monitor and manage data for our clinical programs, as well as the execution of future nonclinical studies. Our reliance on CROs for clinical development activities limits our control over these activities, but we would remain responsible for ensuring that each of our studies was conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs would not relieve us of our regulatory responsibilities. We and our CROs will be required to comply with GLP and GCP, which are regulations and guidelines enforced by the FDA and are also required by the competent authorities in the EU and comparable foreign regulatory authorities in the form of International Conference on Harmonization guidelines for any of our product candidates that are in preclinical and clinical development. The Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under GMP regulations. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process. Our CROs will not be our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other product development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed. If our relationship with any CROs terminate, we may not be able to enter into arrangements with alternative CROs or~~ do so on commercially reasonable terms ~~. Switching~~ **, we may not be able to develop and commercialize** ~~or~~ **our** ~~adding additional CROs involves substantial cost and~~ **product candidates successfully. Failure to execute our manufacturing** ~~requires~~ **requirements** ~~management time and focus. In addition~~ , **either by us** ~~there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our~~ ~~-~~ **or** ~~ability to meet~~ **by one of** our **third- party vendors, could adversely affect** ~~desired clinical development timelines. Though we intend to carefully manage~~ our **business. Our** relationships with **healthcare providers, physicians, and third- party payors will be subject to applicable anti- kickback, fraud and abuse, anti- bribery and other healthcare laws and regulations, which could expose it to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings. Healthcare providers, physicians, and third- party payors play a primary role in the recommendation and prescription of any product candidates that we may develop for which it obtains marketing approval. Our future arrangements with 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** ~~our~~ ~~-~~ **or financial arrangements and relationships through which we market, sell, and distribute our medicines for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations listed in the section above titled " Risk Factors — Risks Related to Government Regulation, " including certain laws and regulations applicable only if we have marketed products. Some state laws also require pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers or require pharmaceutical companies to report information related to payments to health care providers or marketing expenditures. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Given the breadth of the laws and regulations, limited guidance for certain laws and regulations and evolving government interpretations of the laws and regulations, governmental authorities may possibly conclude that our business practices may not comply with healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition, results of operations, and prospects. The provision of benefits or advantages to**

physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is prohibited in the EU. The provision of benefits or advantages to physicians is also governed by the national anti- bribery laws of EU Member States, such as the U. K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician' s employer, his or her competent professional organization, and / or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. Risks Related to Our Business, Personnel and Operations Our strategic refocus and the associated workforce reduction announced in February 2025 may not result in anticipated cost savings, could result in total costs and expenses that are greater than expected and could disrupt our business. In February 2025, we announced a reduction in workforce in connection with the strategic refocus of our business to prioritize and focus on the advancement of bempikibart in patients with alopecia areata. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our operating structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our results of operation and financial condition would be adversely affected. We expect to incur additional costs as we recognize one- time employee termination- related charges. We also cannot guarantee that we will not have to undertake additional workforce reductions or restructuring activities in the future. Furthermore, our strategic restructuring plan may be disruptive to our operations. For example, our workforce reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, increased difficulties in our day- to- day operations and reduced employee morale. If employees who were not affected by the reduction in force seek alternate employment, this could result in us seeking contract support which may result in unplanned additional expense or harm our productivity. Our workforce reductions could also harm our ability to attract and retain qualified management, scientific, and clinical personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing our product candidates in the future. Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties. Our future growth may depend, in part, on our ability to develop and commercialize bempikibart or other product candidates in foreign markets for which we may rely on collaboration with third parties. We are not permitted to market or promote any product candidates before we receive regulatory approval from the applicable foreign regulatory authority and may never receive such regulatory approval for any product candidates. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of bempikibart or other product candidates, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets or to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of bempikibart or other product candidates will be harmed, and our business will be adversely affected. Moreover, even if we obtain approval of bempikibart or other product candidates and ultimately commercialize such product candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries. Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs , CDMOs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, CDMOs, suppliers and vendors acting for or on our behalf may engage in misconduct or other improper activities. It is not always possible to identify and deter misconduct by these parties 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 comply with these laws or regulations. Our internal computer systems, or those of any of our CROs, manufacturers, other contractors, third party service providers or consultants or potential future collaborators, may fail or suffer security incidents, data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations. Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems and those of our third- party CROs, other contractors (including sites performing our clinical trials), third party service providers and supply chain companies, and consultants, as well as other partners, these systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners and / or other third parties, or from cyber- attacks by malicious third parties, which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data. To the extent that any disruption or security breach were to result in a loss, destruction, unavailability, alteration or dissemination of, or damage to, our data or applications, or for us to be believed or reported that any of these occurred, we could incur liability and reputational damage and the development and commercialization

of bempikibart or other product candidates could be delayed. As our employees work remotely and utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations, there are risks to our information technology systems and data. Additionally, business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity threats, risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies or threats presented by malicious third parties. We, like other organizations in our industry, expect to experience cybersecurity incidents and threats to our infrastructure. While we have implemented security measures designed to protect against security incidents , there can be no assurance that ~~we~~ **these measures** will **be effective. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may** not ~~encounter challenges or~~ **be detected until after a security incident has occurred. Further, we may experience** delays in **developing** ~~the future or that these delays or challenges will not have an~~ **and** ~~adverse impact on our business, financial condition and prospects~~ **deploying remedial measures designed to address any such identified vulnerabilities** . **Applicable data privacy** ~~Should we resume development of our product candidates, we may collaborate with third parties for the development~~ and ~~commercialization~~ **security obligations may require us to notify relevant stakeholders** of **security incidents. Such disclosures** ~~our product candidates in the future, but there~~ are ~~no assurances that we will succeed in establishing and maintaining such collaborative relationships, which may significantly limit our ability to develop and commercialize our product candidates successfully, if at all. Should we resume development of our product candidates, we may seek collaborative relationships for the development and commercialization of our product candidates in the future. Failure to obtain a collaborative relationship for any of our product candidates may significantly impair the potential for the product candidate. We would also need to enter into collaborative relationships to provide funding to support our other research and development programs. The process of establishing and maintaining collaborative relationships is difficult, time- consuming and involves significant uncertainty, such as: • a collaboration partner may shift its priorities and resources away from our product candidates due to a change in business strategies, or a merger, acquisition, sale or downsizing; • a collaboration partner may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons; • a collaboration partner may cease development in therapeutic areas which are the subject of our strategic collaboration; • a collaboration partner may not devote sufficient capital or resources towards our product candidates; • a collaboration partner may change the success criteria for a product candidate thereby delaying or ceasing development of such candidate; • a significant delay in initiation of certain development activities by a collaboration partner will also delay payment of milestones tied to such activities, thereby impacting our ability to fund our own activities; • a collaboration partner could develop a product that competes, either directly or indirectly, with our product candidate; • a collaboration partner with commercialization obligations may not commit sufficient financial or human resources to the marketing, distribution or sale of a product; • a collaboration partner with manufacturing responsibilities may encounter regulatory, resource or quality issues and be unable to meet demand requirements; • a collaboration partner may terminate a strategic alliance; • a dispute may arise between us and a partner concerning the research, development or commercialization of a product candidate resulting in a delay in milestones, royalty payments or termination of an alliance and possibly resulting in** costly **, litigation or arbitration which may divert management attention** and **the disclosure** ~~resources; and • a partner may use our~~ -- **or** ~~products or technology in such a way as to invite litigation from a third party. If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development, manufacturing or commercialization efforts related to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to establish and maintain collaborative relationships on acceptable terms or to successfully transition terminated collaborative agreements, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital. Moreover, any collaborative partners we enter into agreements with in the future may shift their~~ -- **the failure** ~~priorities and resources away from our product candidates or seek to renegotiate or terminate their relationships with us. If we fail~~ to comply with **such requirements** ~~our obligations in the agreements under which we in- license or acquire development or commercialization rights to products, technology or data from third parties, we~~ could **lead** ~~lose such rights that are important~~ to ~~our business. We are a party to agreements with COH for certain AAV vector- related patents and know- how, and we may enter into additional agreements, including license agreements, with other parties in the future that impose diligence, development and commercialization timelines, milestone payments, royalties, insurance and other obligations on us. If we fail to comply with our obligations under the COH License, or any of our other collaborators, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product candidate that is covered by these agreements, which could materially adversely~~ -- **adverse consequences** affect the value of the product candidate..... able to compete effectively in our markets . We rely ~~upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our proprietary technologies, product candidate development programs and product candidates. Our success depends in large part~~ on ~~our ability to secure and maintain patent protection in the United States and other countries with respect to all current and future product candidates. We seek to protect our proprietary position by filing or collaborating with our licensors to file patent applications in the United States and abroad related to our proprietary technologies, development programs and product candidates. The patent prosecution process is expensive and time- consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. 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 applications that we own or in- license may fail to result in issued patents with claims that cover our proprietary products and technology, including our product candidates in the United States or in other foreign~~

countries, in whole or in part. Alternately, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technologies. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application or later invalidate or narrow the scope of an issued patent. Even if patents do successfully issue and even if such patents cover our former product candidates or any future product candidate, third parties may challenge their validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates or companion diagnostic that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate and companion diagnostic under patent protection could be reduced. If the patent applications we hold or have in-licensed with respect to our development programs and product candidates fail to issue, if their validity, breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our former product candidates or any future product candidate, it could dissuade companies from collaborating with us to develop product candidates, encourage competitors to develop competing products or technologies and threaten our ability to commercialize future product candidates. Any such outcome could have a materially adverse effect on our business. The patent position of biotechnology and pharmaceutical companies is highly uncertain, involves complex legal and factual questions, and is characterized by the existence of large numbers of patents and frequent litigation based on allegations of patent or other intellectual property infringement or violation. In addition, the laws of jurisdictions outside the United States may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. Since patent applications in the United States and other jurisdictions are confidential for a period of time after filing, we cannot be certain that we were the first to file for patents covering our inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in the issuance of patents, or may result in the issuance of patents which fail to protect our technology or products, in whole or in part, or which fail to effectively prevent others from commercializing competitive technologies and products. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Thus, even if our patent applications issue as patents, they may not issue in a form that will provide us with meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. 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. Third parties may assert claims against us alleging infringement of their patents and proprietary rights, or we may need to become involved in lawsuits to defend or enforce our patents, either of which could result in substantial costs or loss of productivity, delay or prevent the development and commercialization of our product candidates, prohibit our use of proprietary technology or sale of products or put our patents and other proprietary rights at risk. Our commercial success depends, in part, upon our ability to develop, manufacture, market and sell our product candidates without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. Litigation relating to infringement or misappropriation of patent and other intellectual property rights in the pharmaceutical and biotechnology industries is common, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the U. S. Patent and Trademark Office, or USPTO, and corresponding foreign patent offices. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, many companies in intellectual property- dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors. Numerous United States, EU and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates, and 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 intellectual property rights of third parties. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. We may be subject to third- party claims including infringement, interference or derivation proceedings, post- grant review and inter partes review before the USPTO or similar adversarial proceedings or litigation in other jurisdictions. Even if such claims are without merit, a court of competent jurisdiction could hold that these third- party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize the applicable product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third- party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to

~~prohibit our use of those compositions, formulations, methods of treatment, prevention or use or other technologies, effectively blocking our ability to develop and commercialize the applicable product candidate until such patent expires or is finally determined to be invalid or unenforceable or unless we obtained a license. In addition, defending such claims would cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages if we are found to be infringing a third party's patent rights. These damages potentially include increased damages and attorneys' fees if we are found to have infringed such rights willfully. Further, if a patent infringement suit is brought against us or our~~ third- party service providers **and technologies** ~~, our development, manufacturing or sales activities relating~~ to **operate critical business systems to process sensitive information in a variety of contexts. Our ability to monitor** ~~the~~ **these** ~~product or product candidate that~~ **third parties' information security practices** is **limited, and** ~~the~~ **these** ~~subject of the suit may be delayed or terminated. As a result of patent infringement claims, or in order to avoid potential infringement claims, we may choose to seek, or be required to seek, a license from the~~ third **parties** ~~party, which may require payment of substantial royalties or fees, or require us to grant a cross-license under our intellectual property rights. These licenses~~ may not **have adequate information security measures in place** ~~be available on reasonable terms or at all. Even if a license can be obtained on reasonable terms, the rights may be nonexclusive, which would give our competitors access to the same intellectual property rights~~ . If ~~we are unable to enter into a license on acceptable terms, we could be prevented from commercializing one or~~ **our** ~~more of our product candidates, or forced to modify such product candidates, or to cease some aspect of our business operations, which could harm our business significantly. We might also be forced to redesign or modify our product candidates so that we no longer infringe the~~ third- party **service providers experience a security incident** ~~intellectual property rights, which may result in significant cost~~ or **other interruption** ~~delay to us~~ , **we** ~~or which redesign or modification~~ could **experience adverse consequences** ~~be impossible or technically infeasible~~ . ~~Even~~ **While we may be entitled to damages** if ~~we were ultimately to prevail, any of these events could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. In addition, if the breadth or~~ **our** ~~strength of protection provided the patents and patent applications we own or in- license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. If we or one of our licensors were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States and in Europe, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non- enablement. Third parties might allege unenforceability of our patents because during prosecution of the patent an individual connected with such prosecution withheld relevant information, or made a misleading statement. The outcome of proceedings involving assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity of patents, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution, but that an adverse third party may identify and submit in support of such assertions of invalidity. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Our patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors view these announcements in a negative light, the price of our common stock could be adversely affected. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace. We may not identify relevant~~ third- party ~~patents~~ **service providers fail to satisfy their privacy or security- related obligations to us, any award may be insufficient to cover** ~~or~~ **our damages** ~~may incorrectly interpret the relevance~~ , ~~scope~~ **or we may be unable to recover such award. In addition, supply- chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in** ~~or~~ **our** ~~expiration of a~~ **supply chain or our** third- party ~~patent which might~~ **partners' supply chains have not been compromised. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience** ~~adversely~~ -- **adverse** ~~affect~~ **consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and / or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); increased investigation and compliance costs; financial loss; and other similar harms. Security incidents and attendant consequences may cause stakeholders (including investors and potential customers) to stop supporting our research and development activities, deter new customers from products, and negatively impact** our ability to **grow** ~~develop, manufacture~~ and ~~market~~ **operate our business. 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,** ~~our~~ - **or** ~~product candidates~~ **claims related to our data privacy and security obligations** . We cannot ~~guarantee~~ **be sure** that ~~any of our or~~ **our insurance coverage will be adequate** ~~our~~ - **or sufficient** ~~licensors' patent searches or analyses, including but not limited~~ to

protect us from ~~the identification of relevant patents, analysis of the scope of relevant patent claims or determination of the expiration of relevant patents, are complete or thorough, nor~~ **or** ~~can we be certain that we have identified~~ **to mitigate liabilities arising out of our privacy and security practices or from disruptions in, or failure or security** ~~each~~ **breach** ~~and every~~ **of, our systems or** third- party ~~patent and pending application in the United States~~ **systems where information important to our business operations or commercial development is stored** , **or** ~~Europe and elsewhere~~ that ~~is relevant~~ **such coverage will continue** to ~~or necessary~~ **be available on commercially reasonable terms** ~~for~~ **or** ~~the commercialization of~~ **at all,** ~~our~~ **or** ~~product candidates in any jurisdiction. For example, in the United States, applications filed before November 29, 2000 and certain applications filed after~~ that ~~date that~~ **such coverage** will **pay future claims** ~~not be filed outside the United States remain confidential until patents issue~~. **We** ~~Patent applications in the United States, EU and elsewhere~~ are ~~published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates could be filed by others without our knowledge. Additionally, pending patent applications that have been published can,~~ subject to **stringent** ~~certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. After issuance, the scope of patent claims remains subject to construction as determined by an~~ **and changing** ~~interpretation of the law~~ **laws** , **regulations** ~~the written disclosure in a patent~~ and ~~the patent's~~ **standards, and contractual obligations relating to privacy, data** ~~prosecution~~ **protection** ~~history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect~~ , ~~which may negatively impact~~ **and data security. The actual** ~~our~~ **or perceived** ~~ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third- party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States, the EU or elsewhere that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our~~ failure ~~to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates. If we fail to correctly identify or interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay monetary damages, we may be temporarily or permanently prohibited from commercializing our product candidates. We might, if possible, also be forced to redesign our product candidates in a manner that no longer infringes third- party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology and genetic medicines industries involve both technological complexity and legal complexity. Therefore, obtaining and enforcing biotechnology and genetic medicines patents is costly, time- consuming and inherently uncertain. In addition, the America Invents Act, or the AIA, which was passed in September 2011, resulted in significant changes to the U. S. patent system. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned from a " first- to- invent " to a " first- to- file " system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. Under a " first- to- file " system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application and diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions. Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U. S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings as compared to the evidentiary standard in U. S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. It is not clear what, if any, impact the AIA will have on the operation of our business. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents. We may become involved in opposition, interference, derivation, inter partes review or other proceedings challenging our or our licensors' patent rights, and the outcome of any proceedings are highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our owned or in- licensed patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third- party patent rights. Additionally, the U. S. Supreme Court has ruled on several patent cases in recent years either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations, and there are other open questions under patent law that courts have yet to decisively address. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways and could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. In addition, the European patent system is relatively stringent in the type of amendments that are~~

allowed during prosecution, but, the complexity and uncertainty of European patent laws has also increased in recent years. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. The USPTO and European and other patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and European and other patent agencies over the lifetime of a patent. While an inadvertent failure to make payment of such fees or to comply with such provisions can in **obligations could lead to government enforcement actions (which could include civil or criminal penalties), fines and sanctions, private litigation and / or adverse publicity and could negatively affect our operating results and business. We, and third parties with whom we work, are or** many **may** cases **become subject to numerous domestic and foreign laws, regulations, and standards relating to privacy, data protection, and data security, the scope of which are changing, subject to differing applications and interpretations, and may** be cured **inconsistent among countries, or conflict with other rules. We are or may become subject to the terms of contractual obligations related to privacy, data protection, and data security. Our obligations may also change or expand as our business grows. The actual or perceived failure** by **us** additional payment of a late fee or **third parties related to us to comply** by other means in accordance with the applicable rules, there are situations in which non- compliance with such provisions will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors fail to maintain the patents and patent applications covering our product candidates or if we or our licensors otherwise allow our patents or patent applications to be abandoned or lapse, it can create opportunities for competitors to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize our product candidates in any indication for which they are approved. We enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In- licensing patents covering our product candidates in all countries throughout the world may similarly be prohibitively expensive, if such opportunities are available at all. And in- licensing or filing, prosecuting and defending patents even in only those jurisdictions in which we develop or commercialize our product candidates may be prohibitively expensive or impractical. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection or licensed patents to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection, but enforcement is not as strong as that in the United States or the EU. These products may compete with our product candidates, and our or our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. In addition, we intend to abandon certain national and regional patent applications while they are still pending. The grant proceeding of each national or regional patent is an independent proceeding which may lead to situations in which applications may be rejected by the relevant patent office, while substantively similar applications are granted by others. For example, relative to other countries, China has a heightened requirement for patentability and specifically requires a detailed description of medical uses of a claimed drug. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for and launch generic versions of our products. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology. The laws **,** of some jurisdictions do not protect intellectual property rights to the same extent as the laws or regulations in the United States and **obligations** the EU, and many companies have encountered significant difficulties in protecting and defending proprietary rights in such jurisdictions. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets or other forms of intellectual property, which could make it difficult for us to prevent competitors in some jurisdictions from marketing competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, are likely to result in substantial costs and divert our efforts and attention from other aspects of our business, and additionally could put at risk our or our licensors' patents of being invalidated or interpreted narrowly, could increase the risk of our or **our compliance and operational costs** our licensors' patent applications not issuing , **expose** or could provoke third parties to assert claims against us . We may not prevail in any lawsuits that we initiate, while damages or other remedies may be awarded to **regulatory scrutiny** the adverse party , **actions** which may be commercially significant. If we prevail , **fines** damages or other remedies awarded to us, 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. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an **and** adverse effect on our **penalties, result in reputational harm, lead to a loss of customers, result in litigation and** ability **liability** to successfully commercialize our product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting , **and** or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face

additional competition in those jurisdictions. In some jurisdictions, compulsory licensing laws compel patent owners to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties under patents relevant to our business, or if we or our licensors are prevented from enforcing patent rights against third parties, our competitive position may be substantially impaired in such jurisdictions. If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of marketing exclusivity for our product candidates, our business may be materially harmed. The term of any individual patent depends on applicable law in the country where the patent is granted. In the United States, provided all maintenance fees are timely paid, a patent generally has a term of 20 years from its application filing date or earliest claimed non- provisional filing date. Extensions may be available under certain circumstances, but the life of a patent and, correspondingly, the protection it affords is limited. Even if we or our licensors obtain patents covering our product candidates, when the terms of all patents covering a product expire, our business may become subject to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review and approval of new product candidates, patents protecting such candidates may 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. In the United States, a patent that covers an FDA- approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U. S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch- Waxman Act, which permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. In the EU, our product candidates may be eligible for term extensions based on similar legislation. In either jurisdiction, however, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Even if we are granted such extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be in effect shortened and our competitors may obtain approval to market competing products sooner. The resulting reduction of years of revenue from applicable products could be substantial. Our proprietary rights may not adequately protect our technologies and product candidates, and do not necessarily address all potential threats to our competitive advantage. The degree of future protection afforded by our intellectual property rights is uncertain because -- **cause** intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative: • others may be able to make products that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed; • others, including inventors or developers of our owned or in-licensed patented technologies who may become involved with competitors, may independently develop similar technologies that function as alternatives or replacements for any of our technologies without infringing our intellectual property rights; • we or our licensors or our other collaboration partners might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own, license or will own or license; • we or our licensors or our other collaboration partners might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have obtained a license, or will own or will have obtained a license; • we or our licensors may fail to meet obligations to the U. S. government with respect to in- licensed patents and patent applications funded by U. S. government grants, leading to the loss of patent rights; • it is possible that our pending patent applications will not result in issued patents; • it is possible that there are prior public disclosures that could invalidate our or our licensors' patents; • issued patents that we own or exclusively license may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors; • our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • ownership, validity or enforceability of our or our licensors' patents or patent applications may be challenged by third parties; and • the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business. We depend on proprietary technology licensed from others. If we lose our existing licenses or are unable to acquire or license additional proprietary rights from third parties, we may not be able to continue developing our products. We currently in- license certain intellectual property from COH. In the future we may in- license intellectual property from other licensors. We rely on certain of these licensors to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them. We have limited control over these activities or any other intellectual property that may be related to our in- licensed intellectual property. For example, we cannot be certain that such activities by these licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited control over the manner in which our licensors initiate an infringement proceeding against a third- party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves. The licensing and acquisition of third- party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third- party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a

competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire. If we fail to comply with our obligations under our patent licenses with third parties, we could lose license rights that are important to our business. We are a party to license agreements with COH, pursuant to which we in- license patents and technology for our product candidates. These existing licenses impose various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations or otherwise materially breach a license agreement, our licensors may have the right to terminate the license, in which event we would not be able to develop or market the products covered by such licensed intellectual property. In addition, any claims asserted against us by our licensors may be costly and time-consuming, divert the attention of key personnel from business operations or otherwise have a material adverse effect on our business . Our reliance on third parties may require us to share our trade secrets , which increases the possibility that our trade secrets will be misappropriated or disclosed, and confidentiality agreements with employees and third parties may not adequately prevent disclosure of trade secrets and protect other proprietary information. We consider proprietary trade secrets, confidential know- how and unpatented know- how to be important to our business. We may rely on trade secrets and confidential know- how to protect our technology, especially where patent protection is believed by us to be of limited value. However, trade secrets and confidential know- how are difficult to protect, and we have limited control over the protection of trade secrets and confidential know- how used by our licensors, collaborators and suppliers. Because we expect to rely on third parties to manufacture our current and future product candidates, and we expect to collaborate with third parties on the development of our current and future product candidates, we may, at times, share trade secrets with them. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development collaborations or similar agreements. Under such circumstances, trade secrets and confidential know- how can be difficult to maintain as confidential. To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with us prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. The need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our competitive position is based, in part, on our know- how and trade secrets, a competitor' s discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. Enforcing a claim that a third party obtained illegally and is using trade secrets and / or confidential know-how is expensive, time consuming and unpredictable, and the enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. In addition, these agreements typically restrict the ability of our advisors, employees, third- party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor' s discovery of our trade secrets would impair our competitive position and have an adverse impact on our business. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. As of December 31, 2023 we own four registered trademarks and one pending trademark application in the United States, as well as 39 registered trademarks and five pending trademark applications in other countries around the world. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our unregistered trademarks or trade names. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or **, and** results of operations. **See** We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their -- **the sections titled "** former employers or other third parties. We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business **Business - Government Regulation- Data Privacy** include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an **and Security "** ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and **"** if we fail in defending any such claims, in addition to paying monetary damages, we may lose

~~valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and reputational loss and be a distraction to our management and other~~ **Other Regulatory** ~~employees. Risks Related to Employee~~ Matters **"** ~~and Other Risks Related to Our Business Our recent reduction in force undertaken to significantly reduce our ongoing operating expenses may not result in our intended outcomes and may yield unintended consequences and additional costs. In July 2023, we implemented a reduction in force affecting approximately 80 employees, or 86 % of our workforce, in order to reduce our ongoing operating costs, extend our cash runway and maximize shareholder value as we consider strategic options. In connection with this corporate restructuring, we recorded a restructuring charge for severance and related costs of $ 10. 3 million in the Company' s consolidated statements of operations included~~ elsewhere in this Annual Report on Form 10- K ~~during~~ **for a more detailed description of the laws that may affect our ability to operate. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We are subject to numerous environmental, health and safety laws and regulations, including** ~~the~~ **those** ~~twelve months ended December 31~~ **governing laboratory procedures and the handling** , ~~2023~~ **use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials** . In addition, we **may incur substantial costs** ~~had previously granted certain of the terminated employees restricted stock units that vest~~ in **order** ~~annual installments based on continued service~~ to **comply** ~~the Company, as well as options to purchase shares of the Company' s common stock that typically vest over a period of four years. In connection~~ with **current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with** ~~the~~ **these laws** ~~reduction in workforce, the Company agreed to accelerate the vesting of a portion of the RSUs that were unvested as of the employees' termination dates,~~ and **regulations** also **may** ~~modify the stock options for terminated employees such that subject to the satisfaction of severance conditions, the terminated employees' vested options will remain outstanding and exercisable until the first anniversary of each employee' s termination date. These equity modifications resulted~~ -- **result** in **substantial fines, penalties or** ~~a net reduction to stock- based compensation expense of $ 1. 0 million reflected within restructuring and~~ other ~~charges in the Company' s consolidated statements of operations included elsewhere in this Annual Report on Form 10- K during the twelve months ended December 31, 2023. The reduction in force may result in unintended consequences and additional costs, such as the loss of institutional knowledge and expertise, attrition beyond the intended number of employees, decreased morale among our remaining employees, and the risk that we may not achieve the anticipated benefits of the reduction in force. In addition, while positions have been eliminated certain functions~~ **sanctions** ~~necessary to our operations remain, and we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees. The reduction in workforce could also make it difficult for us to pursue, or prevent us from pursuing, new opportunities and initiatives due to insufficient personnel, or require us to incur additional and unanticipated costs to hire new personnel to pursue such opportunities or initiatives~~ . If we are unable to **attract and retain qualified key management and scientists** ~~realize the anticipated benefits from the reduction in force~~ , **staff, consultants and advisors,** ~~or~~ **our ability to implement** ~~if we experience significant adverse consequences from the reduction in force,~~ our business **plan** ~~, financial condition, and results of operations~~ may be ~~materially~~ adversely affected ~~. Our future success depends on our ability to retain our key personnel and to attract, retain and motivate qualified personnel. Our industry has experienced a high rate of turnover of management personnel in recent years~~ . We are highly dependent **upon our senior management and our scientific, clinical and medical staff and advisors. The loss of the service of any of the members of our senior management or other key employees could delay our research and development programs and materially harm our business, financial condition, results of operations and prospects. In addition, we expect that we will continue to have an increased need to recruit and hire qualified personnel as we advance our programs and expand operations. Failure to successfully recruit and retain personnel could impact our anticipated development plans and timelines. We are dependent** on the ~~development~~ **continued service of our technical personnel because of the highly technical and novel nature of our product candidates** , **platform and technologies and the specialized nature of the** regulatory ~~, commercialization~~ **approval process. Replacing such personnel may be difficult and may take** ~~and~~ **an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully execute our** business ~~development expertise~~ **strategy, and we cannot assure you that we will be able to identify or employ qualified personnel for any such position on acceptable terms, if at all. Many** of ~~certain principal members of~~ **the biotechnology and pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. Because** our management ~~teams~~ **team** ~~. Although we have formal employment agreements~~ **and key employees are not obligated to provide us** with **continued service** ~~our executive officers~~ , ~~these agreements do not prevent them~~ **they** ~~from~~ **could** ~~terminating~~ **terminate** their employment with us at any time **without penalty** . We **do not maintain key person life insurance policies on any of** ~~or~~ **our management team members or key employees. Our future success will depend in large part on our continued ability to attract and retain highly qualified scientific, technical and management personnel, as well as personnel with expertise in preclinical and clinical testing, manufacturing, governmental regulation and commercialization. In order to do so, we may need to pay higher compensation or fees to our employees or consultants than we currently expect, and such higher compensation payments may have a negative effect on our operating results. We face increased competition for personnel from** ~~the~~ **other** ~~third parties~~ **companies, universities, public and private research institutions, government entities and other organizations. If we are unable to attract and retain qualified personnel, the rate and success at which we may be able to discover and develop our product candidates and implement our business plan will be limited. We expect to expand our research, development, delivery, manufacturing, commercialization, regulatory and future sales and marketing**

capabilities over time, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. As of December 31, 2024, we had 42 full- time employees, including 3 who hold Ph. D. degrees and 3 who hold M. D. degrees, and one part- time employee; 31 employees are engaged in research and development and 12 employees in management or general and administrative activities. In connection with the growth and advancement of our pipeline and operating as a public company, we expect to increase the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expected expansion of our operations or recruit and train additional qualified personnel. Moreover, our current physical laboratory space may be insufficient for our near- term research and development hiring plans, and the expected physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. As a growing biotechnology company, we are actively pursuing new platforms and product candidates in many therapeutic areas and across a wide range of diseases. Successfully developing product candidates for and fully understanding the regulatory and manufacturing pathways to all of these therapeutic areas and disease states requires a significant depth of talent, resources and corporate processes in order to allow simultaneous execution across multiple areas. Due to our limited resources, we may not be able to effectively manage this simultaneous execution and the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, legal or regulatory compliance failures, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our potential product candidates. If our management is unable to effectively manage the expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to compete effectively and commercialize any product candidates it may develop will depend in part on our ability to effectively manage the future development and our expansion. General Risk Factors Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all. Our market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. Our estimates and forecasts relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties. Our revenue will be dependent, in part, upon ~~whom~~ **the size of the markets in the territories for which** we **gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. We may become exposed to costly and damaging liability claims, either when testing a product candidate in the clinical or at the commercial stage, and our product liability insurance may not cover all damages from such claims. We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. While we currently have no products that have been approved for commercial sale, the current and future use of a product candidate in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims may be made by patients that use the product, healthcare providers, pharmaceutical companies, or others selling such product. Any claims against us, regardless of their merit, could be difficult and costly to** ~~depend~~ **defend** ~~may be~~ **and could materially and** adversely ~~affected~~ -- **affect** ~~by natural disasters public health emergencies and other~~ -- **the** ~~natural catastrophic events~~ **market for our products or any prospects for commercialization of our products. Although we believe we currently maintain adequate product liability insurance for our product candidates** , **it is possible that our liabilities could exceed our insurance coverage or that in the future we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims** and our business **operations** ~~continuity and disaster recovery plans may not adequately protect us from a serious disaster. Natural disasters~~ could ~~severely disrupt our operations~~ **be impaired. Litigation costs** and **the outcome of litigation could** have a material adverse effect on our business **. From time to time** , ~~results~~ **we may be subject to litigation claims through the ordinary course** of **our business** operations **regarding** , **but not limited to** ~~financial condition and prospects. If a natural disaster~~ , **employment matters** ~~public health emergency~~ , ~~such as the COVID- 19 pandemic~~ **security of patient and employee personal information** , ~~power outage~~ **contractual relations with collaborators and intellectual property rights. Litigation to defend itself against claims by third parties,** or ~~other event occurred~~ **to enforce any rights** that **we** ~~prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our manufacturing facilities, or that otherwise disrupted operations, it~~ may ~~be difficult or~~ **have against third parties** , **may** ~~in certain cases, impossible for us to~~ continue **to be necessary** ~~our business for a substantial period~~

~~of time. The disaster recovery and business continuity plans we have in place may prove inadequate 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~~ **result in substantial costs and diversion of our resources, causing** a material adverse effect on our business **, financial condition, results of operations or cash flows. Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises, political crises, geopolitical events, such as the conflict between Russia and Ukraine and the conflict in Israel and Gaza, or other macroeconomic conditions, which could have a material and adverse effect on our results of operations and financial condition. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates, and uncertainty about economic stability. The Federal Reserve has raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. Similarly, the global geopolitical disruptions, including the military conflict between Russia and Ukraine, the conflict in Israel and Gaza and U. S.' s rising tensions with China have created extreme volatility in the global capital markets and may have further global economic consequences, including disruptions of the global supply chain. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more costly, more dilutive, or more difficult to obtain in a timely manner or on favorable terms, if at all. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs. We may in the future experience disruptions as a result of such macroeconomic conditions, including delays or difficulties in initiating or expanding clinical trials and manufacturing sufficient quantities of materials. Any one or a combination of these events could have a material and adverse effect on our results of operations and financial condition. Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited. Since inception, we have incurred losses and may never achieve profitability. As of December 31, 2024 and December 31, 2023, we had federal and state NOLs of $ 233. 4 million and $ 119. 3 million, respectively. Under current law, our federal NOLs generated in taxable years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80 % of its taxable income annually for tax years beginning after December 31, 2020. Federal NOLs generated in taxable years beginning before January 1, 2018, however, have a 20- year carryforward period, but are not subject to the 80 % limitation. Our state NOLs expire at various dates from 2040 through 2044. As of December 31, 2024, we had federal research and development tax credit carryforwards of $ 6. 2 million that expire at various dates from 2041 through 2044. In addition, as of December 31, 2024, we had state research and development tax credit carryforwards of $ 2. 3 million that expire at various dates from 2038 through 2044. Under Sections 382 and 383 of the Internal Revenue Code of 1986, or the Code, if a corporation undergoes an " ownership change, " generally defined as one or more shareholders or groups of shareholders who own at least 5 percent of the corporation' s equity increasing their equity ownership in the aggregate by more than 50 percentage points (by value) over a rolling three- year period, the corporation' s ability to use our pre- change NOLs and other pre- change tax attributes (such as research and development tax credits) to offset our post- change income or taxes may be limited. Similar rules may apply under state tax laws. Our prior equity offerings and other changes in our stock ownership may have resulted in such ownership changes in the past. We have not conducted a formal study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our inception. In addition, we may experience ownership changes in the future as a result of future securities offering or subsequent shifts in our stock ownership, some of which are outside of our control. As a result, even if we earn net taxable income in the future, our ability to use our pre- change NOLs or other pre- change tax attributes to offset U. S. federal taxable income or income taxes may be subject to limitations, which could potentially result in increased future tax liability to us. There is a risk that due to changes under the tax law, regulatory changes or other unforeseen reasons, our existing NOLs or business tax credits could expire or otherwise be unavailable to offset future income tax liabilities. At the state level, there may also be periods during which the use of NOLs or business tax credits is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed by us. For these reasons, we may not be able to realize a tax benefit from the use of our NOLs or tax credits, even if we attain profitability. The U. S. Congress, the Trump administration, or any new administration may make substantial changes to fiscal, tax, and other federal policies that may adversely affect our business. The rules dealing with U. S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U. S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our business and financial condition. In recent years, many such changes have been made and changes are likely to continue to occur in the future. In 2017, the U. S. Congress and the Trump administration made substantial changes to U. S. policies, which included comprehensive corporate and individual tax reform. In addition, the Trump administration called for significant changes to U. S. trade, healthcare, immigration and government regulatory policy. With the transition to the Biden administration in early 2021, changes to U. S. policy occurred and since the start of the Trump Administration in 2025, U. S. policy changes have been implemented at a rapid pace and additional changes are likely. Changes to U. S. policy implemented by the U. S. Congress, the Trump administration or any new administration have impacted and may in the future impact, among other things, the U. S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U. S. regulatory environment, inflation and other areas. Although we cannot predict the impact, if any, of these changes to our**

business, they could adversely affect our business. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them. Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations. Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to bank failures and market- wide liquidity problems . For example, ~~following Hurricane Maria~~ **on March 10** , ~~shortages in production~~ **2023, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection** and **Innovation, which appointed the Federal Deposit Insurance Corporation, or FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank was also swept into receivership. The U. S. Department of Treasury, the Federal Reserve Board, or the Federal Reserve, and the FDIC released a statement that indicated that all depositors of SVB would have access to all of their funds, including funds held in uninsured deposit accounts, after only one business day of closure. The U. S. Department of Treasury, FDIC and Federal Reserve have announced a program to provide up to $ 25 billion of loans to financial institutions secured by certain government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments and help address liquidity pressures that may arise. There is no guarantee, however, that the U. S. Department of Treasury, FDIC and Federal Reserve will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion. At this time, we hold the majority of our cash on deposit at SVB (which has been assumed by First Citizens) and we have not experienced any adverse impact to our current and projected business operations, financial condition or results of operations as a result of the closure of SVB or any other banks. We have diversified our cash deposit holdings between multiple financial institutions. However, uncertainty remains over liquidity concerns in the broader financial services industry, and our business, business partners, or industry as a whole may be adversely impacted in ways that we cannot predict at this time. If, for example, other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened. Although we have assessed our banking relationships as we believe necessary or appropriate, our access to cash in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the financial institutions with which we have banking relationships, and in turn, us. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; or termination of cash management arrangements and / or** delays in ~~a number~~ **accessing or actual loss** of ~~medical supplies produced in Puerto Rico~~ **funds subject to cash management arrangements. In addition, widespread investor concerns regarding the U. S. or international financial systems could** ~~resulted~~ -- **result in less favorable commercial financing terms** , **including higher interest rates or costs** and **tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and / or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or** any **other impacts resulting from the factors described above or other related or** similar ~~interruption due to a natural disaster affecting us~~ **factors not described above, could have material adverse impacts on** ~~or~~ **our** ~~any of~~ **liquidity and our current and /** ~~our~~ - **or projected business operations and financial condition and results of operations. In addition, one or more of our critical vendors,** third ~~-~~-party manufacturers **, or other business partners** could **be adversely affected by any of the liquidity or other risks that are described above, which in turn, could have a** ~~materially~~ -- **material** ~~delay~~ **adverse effect on our current and /** ~~our~~ - **or projected business** operations **and results of operations and financial condition** . ~~Risks Related~~ **Any business partner bankruptcy or insolvency, or any breach or default by a business partner, or the loss of any significant supplier relationships, could result in material adverse impacts on our current and / or projected business operations and financial condition. We do not anticipate that we will pay any cash dividends in the foreseeable future. The current expectation is that we will retain our future earnings, if any,** to ~~Our~~ **fund the growth of our business as opposed to paying dividends. As a result, capital appreciation, if any, of our** ~~Common~~ **common** ~~Stock~~ **stock will be your sole source of gain, if any, for the foreseeable future. An active trading market for our common stock may not develop and our stockholders may not be able to resell their shares of common stock for a profit, if at all. Prior to the Merger, there had been no public market for shares of Legacy Q32 capital stock. An active trading market for our shares of common stock may never develop or be sustained. If an active market for our common stock does not develop or is not sustained, it may be difficult for our stockholders to sell their shares at an attractive price or at all. Future sales of shares by existing stockholders could cause our stock price to decline. If existing securityholders of Homology and Legacy Q32 sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after legal restrictions on resale lapse, the trading price of our common stock could decline. As of December 31, 2024, we had 12, 197, 615 shares**

of common stock outstanding. Certain of these shares are subject to lock- up agreements between Homology and Legacy Q32 on the one hand and certain securityholders of Homology and Legacy Q32 on the other hand. Following the expiration of these lock- up agreements, the relevant stockholders will not be restricted from selling shares our common stock held by them, other than by applicable securities laws. Stockholders not subject to these lock- up agreements will not be restricted from selling shares of our common stock held by them, other than by applicable securities laws. In addition, shares of common stock that are subject to outstanding options or warrants of Legacy Q32 will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act. If these shares are sold, the trading price of our common stock could decline. Our executive officers ~~and ,~~ directors and **principal stockholders** ~~their respective affiliates, if they choose to act together, will continue to~~ have the ability to control or significantly influence all matters submitted to **our** stockholders for approval. ~~Our~~ **As of December 31, 2024, our** executive officers ~~and ,~~ directors and **principal stockholders** ~~their respective affiliates~~ , in the aggregate, **beneficially own** ~~hold shares representing~~ approximately ~~10~~ **62** . 2 % of our outstanding ~~voting~~ **shares of common** stock ~~as of December 31, 2023~~ . As a result, if these stockholders **were to** choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these ~~persons~~ **stockholders** , if they choose to act together, would control or significantly influence the election of directors ~~, the composition of our management~~ and approval of any merger, consolidation or sale of all or substantially all of our assets. **This concentration** ~~A significant portion~~ of **voting power could delay** ~~our~~ **or prevent an acquisition of** ~~total outstanding shares are eligible, or~~ **our company on terms that other stockholders may desire. If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline. The trading market for our common stock** will ~~soon become eligible, to~~ be ~~sold into~~ **influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect to not provide research coverage of our common stock and such lack of research coverage may adversely affect** the market **price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline. Our quarterly and annual operating results may fluctuate in the future. As a result, we may fail to meet or exceed the expectations of research analysts or investors** , which could cause ~~the market~~ **our stock** price ~~of~~ **to decline and negatively impact our financing** ~~our~~ **or** ~~common~~ **funding ability, as well as negatively impact our ability to exist as a standalone company. Our financial condition and operating results have varied in the past and will continue to fluctuate from quarter- to- quarter and year- to- year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following, as well as other factors described elsewhere in this Annual Report: • We will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate clinical trials, product development programs or future commercialization efforts. • We face competition from entities that have developed or may develop programs for the diseases we plan to address with bempikibart or other product candidates. • Bempikibart and the rest of our pipeline are in early stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. If we or our current or future collaborators are unable to complete development of, or commercialize, our product candidates, or experience significant delays in doing so, our business will be materially harmed. • We are substantially dependent on the success of our most advanced product candidate, bempikibart, and our clinical trials of our lead candidate may not be successful. • Our rights to develop and commercialize our product candidates are, and in the future, may be subject to the terms and conditions of licenses granted to us by others. If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties, or these agreements are terminated, or we otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business. • Our ability to protect our patents and other proprietary rights is uncertain, exposing us to the possible loss of competitive advantage. • If we are unable to attract and retain qualified key management and scientists, staff, consultants and advisors, our ability to implement our business plan may be adversely affected. Due to the various factors mentioned herein, and others, the results of any of our prior quarterly or annual periods should not be relied upon as indications of our future operating performance. Our financial results may fluctuate significantly from quarter- to- quarter and year- to- year, such that a period- to- period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our** stock **price** to **decline** ~~drop significantly, even if our business is doing well~~ . **Our** ~~Sales of a substantial number of shares of our common~~ stock ~~in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market~~ price **may also decline as a result** of **unexpected clinical trial results in one** ~~our~~ **or** ~~common stock~~ **more of our ongoing or future clinical trials** . We have ~~registered~~ **broad discretion in the use of our cash and cash equivalents and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment. We have broad discretion over the use of our cash and cash equivalents. You may not agree with our decisions, and our use of these resources may not yield any return on your investment. Our failure to apply these resources effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. You will not have the opportunity to influence our decisions on how to use our cash**

resources. Unfavorable global economic conditions could adversely affect our business, financial condition, results of operations or cash flows. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all **. A weak** ~~shares of common stock that we may issue under our~~ **or** ~~equity compensation plans~~ **declining economy could also strain our suppliers** , **possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in** which ~~can be freely sold in~~ the ~~public~~ **current economic climate and financial** market **conditions could adversely impact** ~~upon issuance, subject to volume limitations applicable to affiliates. Provisions in~~ our ~~restated~~ **business. Our** certificate of incorporation and ~~amended and restated~~ bylaws and **the provisions** under Delaware law could make an acquisition of our ~~Company~~ **company** ~~, which may be beneficial to our stockholders,~~ more difficult and may prevent attempts by our stockholders to replace or remove **out** ~~our current~~ management. Provisions in our ~~restated~~ certificate of incorporation and ~~our amended and restated~~ bylaws may discourage, delay or prevent a merger, acquisition or other change in control ~~of our Company~~ that stockholders may consider favorable, including transactions in which ~~you~~ **our common stockholders** might otherwise receive a premium **price** for ~~your~~ **their** shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors ~~is~~ **will be** responsible for appointing the members of our management team, 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. Among other things, these provisions ~~include those establishing~~ : • **establish** a classified board of directors **such that all** ~~with three- year staggered terms, which may delay the ability of stockholders to change the membership~~ --- **members** of **the** ~~a majority of our~~ board **are not elected at one time; • do not provide for cumulative voting in the election** of directors; • **allow** ~~no cumulative voting in~~ the ~~election~~ **authorized number** of **our** directors ~~, which limits the ability of minority stockholders~~ to **be changed only** ~~elect director candidates; • the exclusive right of our board of directors to elect a director to fill a vacancy created~~ by **resolution** ~~the expansion~~ of ~~the board of directors or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on~~ our board of directors; • **provide that only** the ~~ability of our~~ board of directors **may fill vacancies on the board of directors created by the expansion of the board of directors or the resignation, death or removal of a director; • limit the manner in which stockholders can remove directors from the board; • establish advance notice requirements for nominations for election** to **the board of directors or for proposing matters that can be acted on at stockholder meetings; • require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent; • limit who may call a special meeting of stockholders; •** authorize ~~the~~ **our board of directors to** ~~issuance~~ --- **issue** ~~of shares of~~ preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the **stock** ownership of a **potential** hostile acquirer **, effectively preventing acquisitions that have not been approved by our board of directors** ; **and** ~~• the ability of our board of directors to alter our bylaws without obtaining stockholder approval; • the required~~ **require the** approval of the holders of at least ~~two- thirds~~ **66. 67 %** of the ~~shares~~ **votes that all our stockholders would be** entitled to **cast** ~~vote at an election of directors~~ to ~~adopt,~~ amend or repeal **certain provisions of our charter** ~~our~~ **or** bylaws ~~or repeal the provisions of our restated certificate of incorporation regarding the election and removal of directors; • a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders; • the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and • advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer' s own slate of directors or otherwise attempting to obtain control of us~~ . Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the **DGCL** ~~General Corporation Law of the State of Delaware~~ , which prohibits **stockholders owning** ~~a person who owns~~ in excess of 15 % of ~~our~~ **the** outstanding voting stock from merging or combining with us **. Although Homology and Legacy Q32 believe these provisions collectively will provide** for ~~a period~~ **an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board** of **directors,** ~~three years after the~~ **they** ~~date of~~ **would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove** ~~the~~ **then** ~~transaction in~~ **current management by making it more difficult for stockholders to replace members of the board of directors,** which ~~the person acquired in excess of 15 % of our outstanding voting stock, unless the merger or combination~~ is ~~approved in a prescribed manner~~ **responsible for appointing the members of management** . Our certificate of incorporation **provides that** ~~designates the Court of Chancery of the State of Delaware~~ , ~~subject~~ **unless we consent in writing** to **the selection of an alternative forum,** certain ~~exceptions, as~~ **designated courts will be** the sole and exclusive forum for certain **legal** ~~types of~~ actions **between us** and ~~proceedings that may be initiated by~~ our stockholders ~~and our bylaws designate the federal district courts of the United States as the exclusive forum for actions arising under the Securities Act of 1933, as amended~~ , which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers ~~or~~ **,** employees **or agents** . Our ~~restated~~ certificate of incorporation ~~specifies~~ **provides** that, unless we consent in writing to ~~the selection of~~ an alternative forum, the Court of Chancery of the State of Delaware **is** ~~will be~~ the sole and exclusive forum for **state law** ~~most legal actions involving~~ claims **for (i) any derivative action or proceeding** brought ~~against us~~ **on our behalf, (ii) any action asserting a claim of or based on a breach of a fiduciary duty owed** by **any of our current or former directors, officers, or other employees of the company or our** stockholders ~~. In addition~~ , **(iii) any action asserting a claim arising pursuant to any**

provision of the DGCL, our certificate of incorporation or our bylaws **, or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein, which for purposes of this risk factor refers to herein as the " Delaware Forum Provision. " The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act and the Exchange Act. Our bylaws further** provide that ~~the~~ **, unless we consent in writing to an alternative forum,** federal district courts of the United States ~~are~~ **will be** the exclusive forum for **resolving** any complaint ~~raising~~ **asserting** a cause of action arising under the Securities Act ~~of 1933~~ , **which for purposes of this risk factor is referred to herein** as ~~amended~~ **the " Federal Forum Provision** . ~~Any~~ **" In addition, our certificate of incorporation and bylaws that any** person or entity purchasing or otherwise acquiring any interest in shares of our capital stock **is** ~~shall be~~ deemed to have notice of and **consented to the foregoing Delaware Forum Provision and Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed** to have ~~consented to~~ **waived its compliance with** the **U. S. federal securities laws and the rules and regulations thereunder. The Delaware Forum** ~~provisions~~ **Provision** ~~of~~ **and the Federal Forum Provision may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in** ~~our~~ **or** ~~restated certificate~~ **near the State** of ~~incorporation and~~ **Delaware. Additionally, the forum selection clauses in our** bylaws ~~described above. We believe these choice of forum provisions benefit us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi- forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors, officers, employees and agents as it~~ may limit ~~any~~ **our** ~~stockholder~~ **stockholders** ' ~~s~~ ability to bring a claim in a judicial forum that **they** ~~such stockholder finds~~ **find** favorable for disputes with us or our directors, officers ~~,~~ **or** employees **, which may discourage such lawsuits against us and** ~~or~~ **our** ~~agents~~ **directors, officers and employees even though an action, if successful, might benefit our stockholders. Risks Related to Our Operations Following the Merger If any of the events described in " Risks Related to Our Business " occur, those events could cause potential benefits of the Merger not to be realized. To the extent any of the events in the risks described in that section occurs, the potential benefits of the Merger may not be realized and our results of operations and financial condition could be adversely affected in a material way. This could cause the market price of our common stock to decline. We may be unable to successfully integrate Homology' s and Legacy Q32' s businesses and realize the anticipated benefits of the Merger** . The **Merger involved** ~~enforceability of similar choice of forum provisions in other~~ **the combination of two** companies **that operated** ~~' certificates of incorporation has~~ **as** ~~been challenged in legal proceedings~~ **independent companies. Following the Merger** , **we are required to devote significant management attention** and ~~it~~ **resources to integrating our business practices and operations. We may fail to realize some or all of the anticipated benefits of the Merger if the integration process takes longer than expected or is more costly than expected. Potential difficulties we may encounter in the integration process include the following: • the inability to successfully combine our businesses in a manner that permits us to achieve the anticipated benefits from the Merger, which would result in the anticipated benefits of the Merger not being realized partly or wholly in the time frame currently anticipated or at all; • creation of uniform standards, controls, procedures, policies and information systems; and • potential unknown liabilities and unforeseen increased expenses, delays or regulatory conditions associated with the Merger. In addition, prior to the Merger, we operated independently. It** is possible that ~~,~~ **the integration process also could result** in ~~connection with~~ **the diversion of our management' s attention, the disruption or interruption of, or the loss of momentum in our ongoing businesses or inconsistencies in standards, controls, procedures and policies,** any ~~applicable action brought against us, a court could find the choice~~ of ~~forum provisions contained in our restated certificate of incorporation or bylaws to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provisions contained in our restated certificate of incorporation or bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions,~~ which could adversely affect our **ability to maintain our** business **relationships or the ability to achieve the anticipated benefits of the Merger** , **or could otherwise adversely affect our business and** financial ~~condition or~~ results ~~of operations~~ . ~~Our ability~~ **Stockholders could file lawsuits relating** to ~~use net operating losses and research and development credits~~ **the Merger. Potential plaintiffs may file lawsuits relating** to ~~offset~~ **the Merger. The outcome of any** future ~~taxable income or income tax liabilities may be subject to certain limitations~~ **litigation** . ~~As of December 31, 2023, we had federal and state net operating loss carryforwards, or NOLs, of approximately $ 326. 2 million and $ 317. 3 million, respectively. Our state NOLs, and federal NOLs generated in taxable years beginning before January 1, 2018, are subject to expiration and will expire at various dates through 2043. Federal NOLs generated in taxable years beginning after December 31, 2017 may be carried forward indefinitely but may only be used to offset 80 % of our taxable income in taxable years beginning after December 31, 2020, which may require us to pay federal income taxes in future years despite generating federal NOLs in prior years. As of December 31, 2023, we also had federal and state research and development and other tax credit carryforwards, or credits, including the orphan drug credit, of approximately $ 65. 5 million and $ 17. 2 million, respectively, available to reduce or offset future taxable income. The federal and state credits expire at various dates through 2043. These NOLs and credits could expire unused and be unavailable to offset future taxable income, to the extent subject to expiration. In addition, in general, under Sections 382 and 383 of the Code, a corporation that undergoes an " ownership change "~~ is ~~subject to~~ **uncertain. Such** ~~limitations~~ **litigation** ~~on its ability to utilize its pre- change NOLs or credits to offset future taxable income. For these purposes, an ownership change generally occurs where the aggregate change in stock ownership of one or more stockholders or groups of stockholders owning at least 5 % of a corporation' s stock exceeds 50 percentage points over a rolling three- year period. Our existing NOLs or credits may be subject to limitations arising from previous ownership changes~~ , if **not resolved** ~~any. In addition, future changes in our stock ownership, many of which are outside of our control~~ , could result in **substantial costs** ~~an ownership change. Our state NOLs or credits may also be impaired~~

~~or subject~~ to **us** ~~limitations under state law. Accordingly~~ , **including** ~~even if we attain profitability, we may not be able to utilize a material portion of our NOLs or credits. Because we do not anticipate paying~~ any **costs associated with** ~~cash dividends on our common shares in~~ the **indemnification** ~~foreseeable future, capital appreciation, if any, would be your sole source~~ of ~~gain~~ **directors and officers** . We ~~have never declared or paid any cash dividends on our common shares~~ **will continue to incur additional costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies** . We ~~currently anticipate that we~~ will **continue** ~~retain future earnings for the development and operation of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common shares would be your sole source of gain on an investment in our common shares for the foreseeable future. General Risk Factors The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock. Our stock price is likely~~ to **incur significant** ~~be volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your shares of common stock at or above the price at which you purchased them. The market price for our common stock may be influenced by many factors, including: • the success of competitive products or technologies; • actual or expected changes in our growth rate relative to our competitors; • results of clinical trials of our product candidates or those of our competitors; • developments related to our existing or any future collaborations; • regulatory actions with respect to our product candidates or our competitors' products and product candidates; • regulatory or~~ legal **, accounting** ~~developments in the United States~~ and other ~~countries; • development of new product candidates that may address our markets and make our product candidates less attractive; • changes in physician, hospital or healthcare provider practices that may make our product candidates less useful; • announcements by us, our collaborators or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments; • developments or disputes concerning patent applications, issued patents or other proprietary rights; • the recruitment or departure of key personnel; • the level of~~ expenses ~~related to any of our product candidates or clinical development programs; • failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public; • the results of our efforts to discover, develop, acquire or in- license additional product candidates or products; • actual or expected changes in estimates as to financial results, development timelines or recommendations by securities analysts; • variations in our financial results or those of companies that are perceived to be similar to us; • changes in the structure of healthcare payment systems; • market conditions in the pharmaceutical and biotechnology sectors; • general economic, industry and market conditions; and • the other factors described in this " Risk Factors " section. We expect to continue to incur increased costs as a result of operating~~ as a public company, ~~and our~~ **including costs associated with public company reporting obligations under the Exchange Act. Our** management ~~is required~~ **team consists of the executive officers of Legacy Q32 prior to the Merger, some of whom have not previously managed and operated a public company. These executive officers and other personnel will need** to devote substantial time to ~~new~~ **gaining expertise related to public company reporting requirements and** compliance ~~initiatives~~ **with applicable laws and regulations to ensure that we comply with all of such requirements. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on the board of directors or on board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms. Once we are no longer a smaller reporting company or otherwise no longer qualify for applicable exemptions, we will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results and cash flows. We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition as well as other disclosure** and corporate governance ~~practices~~ **requirements** . As ~~a public~~ **an emerging growth** company, ~~we~~ **Homology took advantage of exemptions from various requirements such as an exemption from the requirement to** have ~~incurred and expect~~ **our independent auditors attest** to ~~continue to incur significant legal, accounting and~~ **our internal control over financial reporting under Section 404 of** ~~other~~ -- **the** ~~expenses that we did not incur as a private company. The~~ Sarbanes-Oxley Act of 2002 ~~,~~ **as well as an exemption from the " say on pay " voting requirements pursuant to** the Dodd- Frank Wall Street Reform and Consumer Protection Act **of 2010. Homology ceased to qualify as an emerging growth company effective December 31 , 2023. We qualify as a " smaller reporting company, " as such term is defined in Rule 12b- 2 under** the ~~listing~~ **Exchange Act, which allows us to take advantage of many of the same exemptions from disclosure** requirements ~~of The Nasdaq and~~ **, including not being required to comply with** ~~other~~ -- **the auditor attestation** ~~applicable securities rules and regulations impose various~~ requirements ~~on public companies, including establishment and maintenance~~ of ~~effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and have made some activities more time- consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors. We continue to evaluate these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Pursuant to~~ Section 404 of the Sarbanes- Oxley Act ~~of 2002,~~ **and reduced disclosure**

obligations regarding executive compensation in this Annual Report on Form 10- K and in ~~or~~ our ~~Section 404, other~~ periodic reports and proxy statements. Once we are **no longer a smaller reporting company or otherwise no longer qualify for these exemptions, we will be** required to ~~furnish~~ **comply with these additional legal and regulatory requirements applicable to public companies and will incur significant legal, accounting and other expenses to do so. If we are not able to comply with the requirements in** a ~~report by~~ **timely manner** ~~our~~ **or** ~~management on~~ **at all, our financial condition or the market price of our common stock may be harmed. For example, if we identify, or if our independent auditor identifies deficiencies in** our internal control over financial reporting ~~. To achieve compliance with Section 404 within~~ **that are deemed to be material weaknesses, we could face additional costs to remedy** ~~the~~ **those deficiencies** ~~prescribed period~~ , **the market price of our stock could decline** ~~we have engaged in a process to document and evaluate our~~ **or we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources. If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired. Provided we continue to be listed on Nasdaq, we will be subject to the reporting requirements of the Exchange Act, the Sarbanes- Oxley Act and the rules and regulations of Nasdaq. The Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and** internal control over financial reporting ~~, which has been both costly and challenging~~ . We **must perform system** ~~will need to continue to dedicate internal resources, engage outside consultants, adopt a detailed work plan to assess~~ and ~~document the adequacy~~ **process evaluations and testing** of **our** internal control over financial reporting ~~, continue steps~~ to ~~improve~~ **allow management to report on the effectiveness of our internal** ~~control~~ **controls** ~~processes~~ **over financial reporting in our Annual Report on Form 10- K filing for that year,** as ~~appropriate~~ **required by Section 404 of the Sarbanes- Oxley Act. As a private company** , ~~validate through testing whether such~~ **Legacy Q32 was never required to test its internal** controls ~~are~~ **within a specified period. This will require that we incur substantial professional fees and internal costs to expand our accounting and finance** ~~functioning~~ **functions** ~~as documented,~~ and ~~implement a continuous~~ **that we expend significant management efforts. We may experience difficulty in meeting these** reporting **requirements in a timely manner. We may discover weaknesses in our system of internal financial** and ~~improvement process for~~ **accounting controls and procedures that could result in a material misstatement of our financial statements. Our** internal control over financial reporting ~~. Despite our efforts, there is a risk that we~~ will not **prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system' s objectives will** be **met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. If we are not** able to ~~conclude~~ **comply with the requirements of Section 404 of the Sarbanes- Oxley Act, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If** that **were to happen, the market price of our common stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Legacy Q32 and its independent registered public accounting firm identified a material weakness in** our internal control over financial reporting ~~is effective~~ **, which has been remediated** as ~~required by Section 404~~ **of December 31, 2024** . If we identify **additional** ~~one or more~~ material weaknesses **in the future** ~~, it could cause us to need to restate our~~ **or** ~~previously issued~~ **otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business and the market price of our common stock. In preparation of its consolidated** financial statements ~~and result in~~ **to meet the requirements applicable to the Merger, Legacy Q32** ~~an~~ **and** ~~adverse reaction~~ **its independent registered public accounting firm identified a material weakness** in ~~the~~ **its internal control over** financial ~~markets due to~~ **reporting. A material weakness is** a **deficiency,** ~~loss of confidence in the reliability of our~~ **or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim** financial statements ~~. There can be no assurance that we~~ will **not** be **prevented or detected on a timely basis** ~~able to comply with the continued listing standards of Nasdaq~~ . ~~If we fail~~ **The material weakness identified related** to ~~satisfy Nasdaq~~ **deficiencies in Legacy Q32** ' s ~~continued~~ **controls over complex accounting topics. Specifically, Legacy Q32' s accounting and internal control infrastructure did not allow for adequate review processes over complex accounting topics due to lack of sufficient personnel. Due to this material weakness, material errors were identified and corrected in Legacy Q32' s unaudited condensed consolidated financial statements for the nine months ended September 30, 2023. We have implemented measures designed to improve internal controls over financial reporting to remediate the control deficiencies that led to the material weakness, including strengthening reviews by our finance team and expanding our accounting and finance team to add additional qualified accounting and finance resources, which includes augmenting our finance team with third party consultants that possess the required expertise to assist management with its review of complex accounting topics. We implemented and formally documented improved processes and controls, including process narratives and risk and control matrices, to appropriately mitigate risks of material misstatement to the financial statements. We implemented enhanced procedures to make sure all steps are being performed as part of the control procedures to detect any material issues, and that the correct individuals are assigned as control owners to ensure that an appropriate, sufficient, and independent review is taking place. Our remediated controls have been operating for a sufficient period of time and we have concluded, through testing, that these controls are operating effectively and that the material weakness is remediated as of December 31, 2024. We cannot assure you that the measures we have taken to date, and actions we may take in the future, will prevent or avoid potential future material weaknesses. In addition, our independent registered public accounting firm has not performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes- Oxley Act because no such evaluation has been required. Had Legacy Q32 or its**

independent registered public accounting firm performed an evaluation of its internal control over financial reporting in accordance with the provisions of the Sarbanes- Oxley Act, additional material weaknesses may have been identified. If we are unable to successfully remediate any future material weaknesses in our internal control over financial reporting, or identify any additional material weaknesses in the future, or otherwise fail to maintain an effective system of internal controls, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, ~~Nasdaq~~ **investors** may **lose confidence in** ~~take steps to delist our securities. Such a delisting would likely have a negative effect on the price of the securities and would impair stockholders' ability to sell or~~ **our financial reporting** ~~purchase the securities when they wish to do so. In the event of a delisting~~ , **and** ~~we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our securities to become listed again, stabilize~~ the market price ~~or improve the liquidity~~ of ~~our securities, or prevent future non- compliance with Nasdaq's listing requirements. In the future, we may engage in acquisitions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources. In the future, we may enter into transactions to acquire other businesses, products or technologies. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms, or at all. Any acquisitions we make may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue~~ our common stock ~~or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we~~ may ~~obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and nondisruptive manner. Acquisitions may also divert management attention from day- to- day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results. Unstable global political or economic conditions may have serious adverse consequences on our business, financial condition and share price. The global economy, including credit and financial markets, has recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, rising interest and inflation rates, declines~~ **decline** ~~in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. If the equity and credit markets continue to deteriorate, or the United States enters a recession, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. In addition, international terrorism and conflicts could disrupt or otherwise adversely impact our operations and those of third parties upon which we rely. Related sanctions, export controls or other actions have and may in the future be initiated by nations including the U. S., the EU or Russia (e. g., potential cyberattacks, disruption of energy flows, etc.), which could adversely affect our business and / or our supply chain, our CROs, CMOs and other third parties with which we conduct business. Any of the foregoing could harm our business, results of operations and the price of our common stock may be adversely affected. We are exposed to fluctuations in inflation, which could negatively affect our business, financial condition and results of operations. The United States has~~ **as** ~~recently experienced historically high levels of inflation. According to the U. S. Department of Labor, the annual inflation rate for the United States was approximately 8. 0 % for 2022. If the inflation rate continues to increase, it will likely affect our expenses, including, but not limited to, increased cost of drug product from OXB (US) LLC and other future potential contract manufacturing organizations, supplies and employee compensation expenses. To the extent inflation results in rising interest rates and has other adverse effects on the market, it may adversely affect our business, financial condition and results of operations. The increasing focus on environmental sustainability and social initiatives could increase our costs, harm our reputation and adversely impact our financial results. There has been increasing public focus by investors, environmental activists, the media and governmental and nongovernmental organizations on a variety of environmental, social and other sustainability matters. We may experience pressure to make commitments relating to sustainability matters that affect us, including the design and implementation of specific risk mitigation strategic initiatives relating to sustainability. If we are not effective in addressing environmental, social and other sustainability matters affecting our business, or setting and meeting relevant sustainability goals, our reputation and financial results may suffer. In addition, we may experience increased costs in order to execute upon our sustainability goals and measure achievement of those goals, which could have an adverse impact on our business and financial condition. Moreover, this emphasis on environmental, social and other sustainability matters has resulted and may~~ result ~~in the adoption of new laws and regulations, including new reporting requirements~~ . **78** ~~If we fail to comply with new laws, regulations or reporting requirements, our reputation and business could be adversely impacted.~~