Risk Factors Comparison 2024-02-28 to 2023-02-27 Form: 10-K

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You should carefully consider the risks described below together with the other information set forth in this Annual Report on Form 10- K, which could materially affect our business, financial condition or future results. The risks described below are not the only risks facing our company. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and / or operating results. **Additional discussion of the material risks and uncertainties summarized in this risk factor summary, as well as certain other risks and uncertainties that we face, can be found in this section.** RISK FACTORS SUMMARY The following is a summary of the principal factors that cause an investment in the ~~company~~ **Company** to be speculative or risky: • We have a history of net losses and we may not achieve or maintain profitability. • ~~We are dependent on our collaborators, and our failure to successfully manage these relationships could prevent us from developing and commercializing many of our products. • Our biotherapeutic~~ **Biotherapeutic** programs are ~~early stage,~~ highly regulated and expensive ~~. • If either Nestlé Health Science or Takeda terminate their development programs under their respective license agreements with us, any potential revenue from those license agreements will be significantly reduced or non- existent. • We may need additional capital in the future in order to expand our business~~ . • We are dependent on a limited number of customers. • Our product supply agreements with customers have finite duration and may not be extended or renewed. • **The demand for our product depends in part on our customers' research and development and the clinical and market success of their products. •** With respect to customers purchasing our products for the manufacture of API, the termination or expiration of such patent protection may materially and adversely affect our revenues, financial condition or results of operations. • We are dependent on a limited number of contract manufacturers for large scale production of substantially all of our enzymes ~~, including CDX- 616~~ . • If we are unable to develop and..... on a quarterly or annual basis. We are dependent on our collaborators, and our failure to successfully manage these relationships could prevent us from developing and commercializing many of our products **. • If we are unable to develop** and ~~achieving~~ **commercialize new products** ~~or~~ **for** ~~sustaining profitability~~ **the target markets** , **our business** and **prospects will be harmed. • We have invested significant resources to enable fully enzymatic nucleic acid synthesis, which is based on novel ideas and technologies that are largely unproven. • Future revenues from our sales of CDX- 616 to Pfizer are subject to a number of factors which are outside of our control and may not materialize. • Ethical, legal and social concerns about genetically engineered products and processes** could ~~lead~~ **limit or prevent the use of our products, processes, and technologies and limit our revenues. • We have recently enhanced our strategic focus** to **concentrate on certain programs and business lines. As a result of this refined focus on returning the foundational, revenue- generating pharmaceutical manufacturing business and the ECO SynthesisTM manufacturing platform, we may fail to capitalize on other opportunities that may be more profitable or for which there is a greater likelihood of success. • Given our recent change in strategic direction, we may receive limited revenue or no future value from certain of our existing license** ~~disagreements~~ **agreements. • We use hazardous materials in our business, and we must comply** with **environmental laws and regulations. • As a public reporting company, we are subject to rules and regulations established from time to time by the SEC and Nasdaq regarding our internal controls over financial reporting. We may not complete needed improvements to our internal controls over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may adversely affect investor confidence in our company and, as a result, the value of our common stock and** ~~our~~ **your** ~~current~~ **investment. • We may need additional capital in the future in order to expand** ~~or~~ **our** ~~former~~ **business. • We may not be able to comply with the terms of our five- year loan and security agreement (our " Loan Agreement ") with Innovatus Life Sciences Lending Fund, I, LP, an affiliate of Innovatus Capital Partners (" Innovatus "). • Our ongoing efforts to deploy our technology in the life science tools market may fail. • Even if our customers or** collaborators **obtain regulatory approval for any products utilizing our enzymes, such products will remain subject to ongoing regulatory requirements, which may result in significant additional expense** . **• If we or our customers fail to comply with certain healthcare laws, including fraud and abuse laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected. • Our efforts to prosecute, maintain, protect and / or defend our intellectual property rights may not be successful. •** Our ability to **compete may decline if we do not adequately prosecute,** maintain ~~,maintain~~ ,protect and / or defend our proprietary technology,products or services or our intellectual property rights.• Third parties may claim that we are infringing,violating or misappropriating their intellectual property rights,which may subject us to costly and time- consuming litigation and prevent us from developing or commercializing our technology,products or services.• We may be involved in lawsuits to protect or enforce our intellectual property rights,which could be expensive,time- consuming and unsuccessful.• We may not be able to enforce our intellectual property rights throughout the world.• If our biocatalysts are stolen,misappropriated or reverse engineered,others could use these biocatalysts to produce competing products.• ~~Confidentiality~~ **We are subject to anti- takeover provisions in our certificate of incorporation** and **bylaws** ~~non- use agreements with employees,consultants,advisors,~~ and ~~other third parties may not adequately~~ **under Delaware law that could delay or** prevent ~~disclosures and~~ **an** ~~manage~~ **acquisition of** ~~risks associated with~~ our **company** ~~international business~~ .• Market and economic conditions may negatively impact our business,financial condition,and share price.• Business interruptions resulting from disasters or other disturbances could delay us in the process of developing our products and could disrupt our sales.• ~~We are dependent on information technology systems,infrastructure and data,and any failure of these systems could harm our business.• Actual or perceived failures to comply with applicable data~~

~~protection,privacy and security laws,regulations,standards and other requirements could adversely affect our business,results of operations and financial condition.~~ ~~•~~ Evolving expectations around environmental,social and governance matters may expose us to reputational and other risks.Risks ~~Relating~~ **Related** to Our Business and Strategy We have incurred net losses since our inception,including losses of $ **76.2 million,$** 33.6 million ~~in 2022~~ , **and** $ 21.3 million ~~in~~ **for the years ended December 31,2023,2022,and** 2021 **,respectively** ~~and $ 24.0 million in 2020~~ .As of December 31, ~~2022~~ **2023** ~~and 2021~~ ,we had an accumulated deficit of $ ~~421~~ **497** . ~~3~~ **5** million **.If we are unable to continue to successfully develop** and ~~$~~ **commercialize products in our pharmaceutical manufacturing business,increase sales of existing products and services,develop and commercialize our ECO Synthesis ™ manufacturing platform,and or develop new products or services,or otherwise expand our business,whether through new or expanded** collaborations ~~in our~~ **or** ~~markets is fundamental to the~~ **other** ~~success of~~ **products and services,** our ~~business~~ **net losses may increase and we may never achieve profitability** . ~~We currently have license~~ **In addition, some of our** agreements, **including the** ~~research and development agreements, supply agreements and / or distribution agreements with various collaborators. For example, we have ongoing collaborations and~~ agreements with GSK, Merck, Novartis, Nestlé Health Science **, Aldevron** and ~~Takeda that are important to~~ **Roche provide for milestone payments, usage payments, and /** ~~our~~ **or** ~~business~~ **future royalty or other payments, which we will only receive if we** and ~~financial results~~ **/ or our collaborators develop and commercialize products or achieve technical milestones** . We ~~may have limited~~ **also intend to continue to fund the development of additional proprietary performance enzyme products and advance new technologies like** ~~or~~ **our ECO Synthesis ™ manufacturing platform. There can be** no **assurance** ~~control over the amount or timing of resources~~ that any ~~collaborator is able or willing to devote to our partnered products or collaborative efforts. Any of our collaborators may fail to perform its obligations. These collaborators may breach or terminate their agreements with us or otherwise fail to conduct their collaborative activities successfully and in a timely manner. Further, our collaborators may not develop products arising out of our collaborative arrangements or devote sufficient resources to the development, manufacture, marketing or sale~~ of these products ~~. Moreover, disagreements with~~ **or services will become commercially viable or that we will ever achieve profitability on** a **quarterly** ~~collaborator could develop, and any conflict with a collaborator could lead to litigation and could reduce our~~ **or annual basis** ~~ability to enter into future collaboration agreements and negatively impact our relationships with one or more existing collaborators~~ . If ~~any of these events occur~~ **we fail to achieve profitability** , ~~especially~~ **or** if ~~they~~ **the time required** ~~occur in our collaborations with GSK, Merck, Novartis, Nestlé Health Science or Takeda, or if we fail~~ to ~~maintain our agreements with our collaborators~~ **achieve profitability is longer than we anticipate** , we may not be able to **continue** ~~commercialize our existing and potential products or grow~~ our business ~~or generate sufficient revenues to support our operations, we may not receive contemplated milestone payments and royalties under the collaboration, and we may be involved in litigation~~ . **Even** ~~Our collaboration opportunities could be harmed and our financial condition and results of operations could be negatively affected~~ if ~~: •~~ we do ~~not~~ achieve **profitability** ~~our research and development objectives under our collaboration agreements in a timely manner or at all; • we develop products and processes or enter into additional collaborations that conflict with the business objectives of our other collaborators; • we~~ , ~~our collaborators and / or our contract manufacturers do not receive the required regulatory and other approvals necessary for the commercialization of the applicable product; •~~ we disagree with our collaborators as to rights..... in expensive arbitration or litigation, which may not be ~~resolved in~~ **able to sustain** ~~our~~ **or increase profitability on** ~~favor. Finally, our business could be negatively affected if any of our collaborators or suppliers undergoes~~ a **quarterly** ~~change of control or were to otherwise assign the rights or obligations under any of our~~ **or** ~~agreements~~ **annual basis** . ~~Our biotherapeutic~~ **Biotherapeutic** programs are ~~early stage,~~ highly regulated and expensive **, and our enzyme products are complex and subject to quality control requirements** . ~~Our~~ **The** ability **of** ~~to obtain additional development partners or our additional funding~~ **customers, future customers** ~~for~~ **or** ~~the programs~~ **collaborators, including any company developing RNAi therapeutics** , to advance ~~our~~ product candidates **utilizing our products** to clinical trials and to ultimately receive regulatory approvals is highly uncertain. ~~We~~ **Although we** are **no longer** developing ~~and have~~ **our own portfolio of biotherapeutics product candidates, we continue to** ~~developed~~ **develop** ~~novel~~ **enzyme products, including our ECO Synthesis ™ manufacturing platform, that may be used by our customers, future customers or collaborators in connection with their** biotherapeutic **product** candidates ~~, including CDX-6114, the novel oral enzyme product candidate for the treatment of PKU that we licensed to Nestlé Health Science. We are also developing protein sequences for use in gene therapy products for Fabry Disease, Pompe Disease, an undisclosed blood factor deficiency and a certain undisclosed rare genetic disorder for Takeda~~ . The successful development of biotherapeutic candidates involves many risks and uncertainties, requires long timelines and may lead to uncertain results. ~~In addition, drug development is highly regulated~~ **Our customers are subject to extensive regulations by the FDA** and **similar regulatory authorities in other countries for conducting clinical trials and commercializing products for therapeutic, vaccine or diagnostic use. These regulations result in our customers imposing quality** ~~requires~~ **requirements** ~~areas~~ **on us for the manufacture** of **our enzyme products through supplier qualification** ~~expertise and capital resources we do not currently possess~~ **processes** ~~.~~ **and customer contracts and specifications** In order to market a biologic **or drug** product in the United States, ~~we or~~ **our customers, future customers** ~~our~~ **or** collaborators must undergo the following process required by the FDA: • completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with ~~GLP~~ **the FDA' s Good Laboratory Practice** requirements; • submission to the FDA of an **Investigational New Drug Application (“** IND **”)** , which must become effective before human clinical studies may begin in the United States; • approval by an independent **institutional review board (“** IRB **”)** representing each clinical site before the clinical study may be initiated at the site; • performance of adequate and well- controlled human clinical studies ~~(generally divided into three phases)~~ in accordance with **Good Clinical Practice (“** GCP **”)** requirements to establish the safety, purity and potency (or efficacy) of the product candidate for each proposed indication; • preparation of and submission to the FDA of a **Biologics License Application (“** BLA **”) or New Drug Application (“ NDA ”)** after completion of all clinical studies; • potential review of the product candidate by an FDA advisory

committee; • satisfactory completion of an FDA pre- approval inspection of the manufacturing facilities where the product candidate is produced to assess compliance with **current Good Manufacturing Practice (“** cGMP **”)** requirements; ~~and~~ • FDA review and approval of a BLA **or NDA** prior to any commercial marketing or sale of the product in the United States **; and • any post- approval requirements, if applicable. The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and the results are inherently unpredictable** . If ~~we~~ **our customers, future customers or collaborators are ultimately unable to obtain regulatory approval for their biotherapeutic product candidates utilizing our enzyme products, our business may be harmed. In addition, if our customers, future customers or collaborators** fail to comply with applicable FDA or other regulatory requirements at any time during the drug development process, clinical testing, the approval process or after approval, ~~we~~ **they** may become subject to administrative or judicial penalties, including the FDA’ s refusal to approve a pending application, withdrawal of an approval, warning letters, product recalls and additional enforcement actions **, any of which may have an adverse effect on our financial condition. We believe our enzyme products are exempt from compliance with the Food, Drug, and Cosmetic Act (“ FDCA ”) and the current GMP (“ cGMP ”) regulations of the FDA, as our products are further processed and incorporated into final drug or biologic products by our customers and we do not make claims related to their safety or effectiveness** . Our ~~efforts to advance~~ **products are manufactured following the voluntary quality standards of ISO 9001: 2015. In the event we,** ~~our~~ **or** ~~biotherapeutic candidates~~ **our suppliers, produce products** that **fail to comply with required quality standards,** we ~~develop~~ **may incur delays in fulfilling orders, write- downs, damages resulting from product liability claims and harm to our reputation. In the future, our products could become subject to more onerous regulation, or the FDA could disagree with our assessment that our enzyme products** are **exempt from current GMP regulations. In addition, the FDA could conclude that the products we provide to our customers are actually** subject to ~~numerous risks~~ **the pharmaceutical, drug or biologic quality- related regulations for manufacturing, processing, packing or holding of drugs, biologics, or finished pharmaceuticals, and could take enforcement action against us** , including **requiring us to stop distribution** ~~the following: • The regulatory approval processes~~ of **our products until we** ~~the FDA and comparable foreign authorities~~ are **in compliance with applicable** ~~lengthy, time consuming and the results are inherently unpredictable. If we are ultimately unable to obtain regulatory~~ **regulations** ~~approval for biotherapeutic product candidates, our business will be harmed. To obtain regulatory approval to market any product candidate, preclinical studies and costly and lengthy clinical trials are required, and the results of the studies and trials are highly uncertain. A failure of one or more preclinical or clinical trials can occur at any stage, and many companies that have believed their drug candidates performed satisfactorily in preclinical and clinical testing have nonetheless failed to obtain marketing approval of their product candidates. • We may find it difficult to enroll patients in our clinical trials for product candidates. Any enrollment difficulties could delay clinical trials and any potential product approval. • We may experience difficulty or delay in obtaining the FDA’ s acceptance of an IND for product candidates we may seek to enter into clinical development~~ , which would **reduce** ~~delay initiation of Phase 1 clinical testing. Delays in the commencement or~~ **our** ~~completion of clinical testing could significantly~~ **revenue, increase our costs and adversely** affect our **business** ~~product development costs or the product development costs of our present and any future collaborators. We do not know whether planned clinical trials will begin on time or be completed on schedule~~ , **prospects** ~~if at all. The commencement and completion of clinical trials can be delayed for a number of reasons. For example~~ , ~~a clinical trial may be suspended or terminated by us, by the IRB of the institution in which such trial is being conducted, or by the FDA due to a number of factors, including unforeseen safety issues, changes in governmental regulations or lack of adequate funding to continue the clinical trial. • We have limited experience in drug development or regulatory matters related to drug development. As a result, we rely or will rely on third parties to conduct our preclinical and clinical studies, assist us with drug manufacturing and formulation and perform other tasks for us. If these third parties do not successfully carry out their responsibilities or comply with regulatory requirements, we may receive lower quality products or services, suffer reputational harm and not be able to obtain regulatory approval for product candidates. • Our efforts to use CodeEvolver ® protein engineering technology platform to generate new lead biotherapeutic candidates, whether under our collaborations with Nestlé Health Science, Takeda or otherwise, may not be successful in creating candidates of value. • We will be exposed to potential product liability risks through the testing of experimental therapeutics in humans, which may expose us to substantial uninsured liabilities. • Third parties may develop intellectual property that could limit our ability to develop, market and commercialize product candidates. • Changes in methods of treatment of disease, such as gene therapy, could cause us to stop development of our product candidates or reduce or eliminate potential demand for CDX- 6114, if approved, or any other product candidates that we may develop in the future. If either Nestlé Health Science or Takeda terminate their development programs under their respective license agreements with us, any potential revenue from those license agreements will be significantly reduced or non- existent, and our~~ results of operations and financial condition ~~will be materially and adversely affected~~ . **Although** ~~We have invested significant time and financial resources in the development of CDX- 6114 and other product candidates for the treatment of hyperphenylalaninemia now included in the Nestlé License Agreement as well as in the development of candidates for the treatment of Fabry disease and Pompe disease which are now included in the Takeda Agreement. Under the Nestlé License Agreement, we are eligible to receive payments from Nestlé Health Science that include (i) development and approval milestones of up to $ 85. 0 million, (ii) sales- based milestones of up to $ 250. 0 million in the aggregate, which aggregate amount is achievable if net sales exceed $ 1. 0 billion in a single year, and (iii) tiered royalties, at percentages ranging from the mid- single digits to low double- digits, of net sales of product. Under the Takeda Agreement, we are eligible to earn potential payments that include (i) reimbursement of research and development fees and preclinical development milestone payments for the three initial programs of $ 10. 5 million, in aggregate, and $ 3. 4 million for the fourth program, (ii) clinical development and commercialization- based milestone, per target gene, of up to $ 104. 0 million, and (iii) tiered royalty payments based on net sales of applicable products at percentages ranging from the mid- single digits to low single- digits. While we have received milestone payments under the Nestlé License Agreement to date there is no~~

~~guarantee that we will receive further milestone payments under the Nestlé Agreement or Takeda Agreement in the future. Under the Nestle Agreement and the Takeda Agreement, either Nestlé Health Science and Takeda, as applicable, may each terminate the entire agreement or specified programs thereunder at will under certain circumstances as described in more detail under " Item 1. Business-- Our Market Opportunities-- Pharmaceutical Market-- Our Solutions for the Pharmaceutical Market-- Biotherapeutic Product Discovery and Development " in this Annual Report on Form 10- K. If Nestlé Health Science terminates its rights and obligations with respect to the Nestlé License Agreement and / or Takeda terminates its rights and obligations with respect to the Takeda Agreement, then depending on the timing of such event: • the development of our product candidates subject to the respective agreements may be terminated or significantly delayed; • our cash expenditures could increase significantly if it is necessary for us to hire additional employees and allocate scarce resources to the development and commercialization of product candidates; • we would bear all of the risks and costs related to the further development and commercialization of product candidates that were previously the subject of the respective agreements, including the reimbursement of third parties; and • in order to fund further development and commercialization of new product candidates or programs, we may need to seek out and establish alternative collaboration arrangements with third- party partners; this may not be possible, or we may not be able to do so on terms which are acceptable to us, in which case it may be necessary for us to limit the size or scope of one or more of our programs or increase our expenditures and seek additional funding by other means. Our future capital requirements may be substantial, particularly as~~ we continue to ~~develop~~ **expand** our **customer** ~~business. Although we believe that, based~~ **base** ~~on our current level of operations~~, our existing cash, cash equivalents and..... acquisitions of other businesses, technologies or **our** facilities that we may make or develop..... plan or continue our business. Our current revenues are derived from a limited number of key customers. For the years ended December 31, **2023 and** 2022 ~~and 2021~~, customers that each individually contributed 10 % or more of our total revenue accounted for **35 % and** 56 % ~~and 44 %~~ of our total revenues ~~in 2022 and 2021~~, respectively. We expect a limited number of customers to continue to account for a significant portion of our revenues for the foreseeable future. This customer concentration increases the risk of quarterly fluctuations in our revenues and operating results. The loss or reduction of business from one or a combination of our significant customers could, materially adversely affect our revenues, financial condition and results of operations. Our product supply agreements with customers have finite duration, may not be extended or renewed and generally do not require the customer to purchase any particular quantity or quantities of our products. Our product supply agreements with customers generally have a finite duration, may not be extended or renewed and generally do not require the customer to purchase any particular quantity or quantities of our products. While our products are not considered commodities and may not be easily substituted for by our customers, particularly when our products are used in the manufacture of active pharmaceutical ingredients, our customers may nevertheless terminate or fail to renew their product supply agreements with us or significantly curtail their purchases thereunder under certain circumstances. **We are working to develop new relationships with existing or new customers, but despite these efforts we may not, at the time that any of our existing product supply agreements expire or are terminated, or purchases thereunder curtailed, have other contracts in place generating similar or material revenue.** Any such **expiration,** termination or reduction could materially adversely affect our revenues, financial condition and results of operations. For the year ended December 31, ~~2022~~ **2023**, we derived a majority of our product revenue from these product supply agreements. **The demand for our products depends in part on our customers' research and development and the clinical and market success of their products. Our business, financial condition, and results of operations may be harmed if our customers spend less on, or are less successful in, these activities. In addition, customer spending may be affected by, among other things, general market and economic conditions beyond our control. Our customers are engaged in research, development, production, and marketing of pharmaceutical products and intermediates. The amount our customers spend on research, development, production, and marketing, as well as the outcomes of such research, development, and marketing activities, have a large impact on our sales and profitability, particularly the amount our customers choose to spend on our offerings. Available resources, the need to develop new products, and consolidation in the industries in which our customers operate may have an impact on such spending. Our customers and potential customers finance their research and development spending from private and public sources. A reduction in available financing for and spending by our customers, for these reasons or because of continued unstable or unpredictable economic and marketplace conditions, could have a material adverse effect on our business, financial condition, and results of operations. If our customers are not successful in attaining or retaining product sales due to market conditions, reimbursement issues, or other factors, our results of operations may be materially adversely affected.** With respect to customers purchasing our products for the manufacture of ~~active pharmaceutical ingredients (" API~~ **APIs** ~~")~~ for which they have exclusivity due to patent protection, the termination or expiration of such patent protection and any resulting generic competition may materially and adversely affect our revenues, financial condition or results of operations. With respect to customers purchasing our products for the manufacture of API, or lead to the manufacture of API, for which exclusivity due to patent protection has or is about to expire, we can expect that the quantity of our products sold to such customers for such products may decline as generic competition for the API increases. While we anticipate that we may, in some cases, also be able to sell products to these generic competitors for the manufacture of these APIs, or lead to the manufacture of these APIs, the overall effect on our revenues, financial condition and results of operations could be materially adverse. We are dependent on a limited number of contract manufacturers for large scale production of substantially all of our enzymes ~~, including CDX- 616~~. We are working to qualify new contract manufacturers to produce certain of our enzymes ~~, including CDX- 616~~, however those efforts may not be successful and therefore we may experience limitations on our ability to supply our enzymes to customers. Manufacturing of our enzymes is conducted primarily in four locations: our in- house facility in Redwood City, California, and at three third- party contract manufacturing organizations, Lactosan ~~GmbH & Co. KG~~ **in Kapfenberg, Austria, ACSD** (~~" Lactosan "), in Kapfenberg, Austria, ACS Dobfar S. p. A. (" ACSD ") (formerly known as DPhar S. p. A.),~~ in Anagni, Italy, and

Alphazyme ~~LLC~~ in **Jupiter,** Florida, United States. Generally, we perform smaller scale manufacturing in- house and outsource the larger scale manufacturing to these contract manufacturers. We have limited internal capacity to manufacture enzymes. As a result, we are dependent upon the performance and capacity of third- party manufacturers for the larger scale manufacturing of the enzymes used in our pharmaceutical and life sciences businesses. Accordingly, we face risks of difficulties with, and interruptions in, performance by third party manufacturers, the occurrence of which could adversely impact the availability, launch and / or sales of our enzymes in the future. Enzyme manufacturing capacity limitations at our third- party manufacturers and manufacturing delays could negatively affect our business, reputation, results of operations and financial condition. The failure of any contract manufacturer to supply us our required volumes of enzyme on a timely basis, or to manufacture our enzymes in compliance with our specifications or applicable quality requirements or in volumes sufficient to meet demand, would adversely affect our ability to sell pharmaceutical and ~~fine and~~ complex chemicals products, could harm our relationships with our **customers or** collaborators ~~or customers~~ and could negatively affect our revenues and operating results. We may be forced to secure alternative sources of supply, which may be unavailable on commercially acceptable terms, and could cause delays in our ability to deliver products to our customers, increase our costs and decrease our profit margins. We currently have supply agreements in place with Lactosan, ACSD and Alphazyme. In the absence of a supply agreement, a contract manufacturer will be under no obligation to manufacture our enzymes and could elect to discontinue their manufacture at any time. If we require additional manufacturing capacity and are unable to obtain it in sufficient quantity, we may not be able to increase our product sales, or we may be required to make substantial capital investments to build that capacity or to contract with other manufacturers on terms that may be less favorable than the terms we currently have with our suppliers. If we choose to build our own additional manufacturing facility, it could take ~~two~~ **several** years or longer before our facility is able to produce commercial volumes of our enzymes. Any resources we expend on acquiring or building internal manufacturing capabilities could be at the expense of other potentially more profitable opportunities. In addition, if we contract with other manufacturers, we may experience delays of several months in qualifying them, which could harm our relationships with our **customers or** collaborators ~~or customers~~ and could negatively affect our revenues or operating results ~~and processes or enter into additional collaborations that conflict with the business objectives of our other collaborators;• our collaborators and / or our contract manufacturers do not receive the required regulatory and other approvals necessary for the commercialization of the applicable product;• we~~ disagree with our collaborators as to rights to intellectual property that are developed during the collaboration,or their research programs or commercialization activities;• we are unable to manage multiple simultaneous collaborations;• our collaborators or licensees are unable or unwilling to implement or use the technology or products that we provide or license to them;• our collaborators become competitors of ours or enter into agreements with our competitors;• our collaborators become unable or less willing to expend their resources on research and development or commercialization efforts due to general market conditions,their financial condition or other circumstances beyond our control;or • our collaborators experience business difficulties,which could eliminate or impair their ability to effectively perform under our agreements. ~~Takeda recently confirmed that it will~~ **Even after collaboration relationships expire or terminate,some elements of the collaboration may survive.For instance,certain rights,licenses and obligations of each party with respect to intellectual property and program materials may survive the expiration or termination of the collaboration.Disagreements or conflicts between and among the parties could develop even though the collaboration has** ~~end~~ **ended** ~~research,discovery and preclinical work~~ **.These disagreements or conflicts could result** in **expensive arbitration or litigation,** ~~certain rare disease areas that may overlap with the programs on~~ which ~~we collaborate under~~ . If we are unable to develop and commercialize new products for the pharmaceutical, biotherapeutics, diagnostics and life science tools markets, our business and prospects will be harmed. We plan to launch new products for the pharmaceutical, biotherapeutics, diagnostics and other life science tools markets **such as our ECO Synthesis ™ manufacturing platform** . These efforts are subject to numerous risks, including the following: • customers in these markets may be reluctant to adopt new manufacturing processes that use our enzymes; • we may be unable to successfully develop the enzymes or manufacturing processes for our products in a timely and cost- effective manner, if at all; • we may face difficulties in transferring the developed technologies to our customers and the contract manufacturers that we may use for commercial scale production of intermediates and enzymes in these markets **; • the biotherapeutics products that use our tools may not receive regulatory approval or be commercially viable** ; • the contract manufacturers that we may use may be unable to scale their manufacturing operations to meet the demand for these products and we may be unable to secure additional manufacturing capacity; • customers may not be willing to purchase these products for these markets from us on favorable terms, if at all; • we may face product liability litigation, unexpected safety or efficacy concerns and product recalls or withdrawals; • our customers' products may experience adverse events or face competition from new products, which would reduce demand for our products; • we may face pressure from existing or new competitive products; and • we may face pricing pressures from existing or new competitors, some of which may benefit from government subsidies or other incentives. **Our ECO Synthesis ™ manufacturing platform is currently in development to enable the commercial- scale manufacture of RNAi therapeutics through an enzymatic route. While we believe fully enzymatic nucleic acid synthesis will offer certain improvements over phosphoramidite chemistry, including with respect to required infrastructure investments, batch size limitations and waste disposal challenges, the enzymatic route is novel and has not yet been commercialized. As such, we may be faced with unforeseen results, delays and setbacks, in addition to the other foreseeable risks and uncertainties associated with the ongoing development of the ECO Synthesis ™ manufacturing platform and other products. Other challenges with a new technology such as our ECO Synthesis ™ manufacturing platform include having an unknown and unproven regulatory path, uncertainly around the value that we can realize from the technology, uncertainty around the timeline for adoption of the technology by customers, and uncertainly around our ability to manufacture and partner with customers on manufacturing and utilizing the technology. There can be no assurance that these events we may experience in the future related to enzymatic synthesis**

will not cause significant delays or unanticipated costs, or that such development problems can be solved. Any delay or difficulties in developing and commercializing our ECO Synthesis ™ manufacturing platform or any of our other current or future products could adversely affect our business and operations. Competitors and potential competitors who have greater resources and experience than we do may develop products and technologies that make ours obsolete or may use their greater resources to gain market share at our expense. The biocatalysis **and performance enzyme** ~~industry~~ **industries** and each of our target markets are characterized by rapid technological change. Our future success will depend on our ability to maintain a competitive position with respect to technological advances. In addition, as we enter new markets, we will face new competition and will need to adapt to competitive factors that may be different from those we face today. We are aware that other companies, including ~~Royal~~ DSM ~~, N. V. (" DSM ")~~, BASF, Bayer and Novozymes have alternative methods for obtaining and generating genetic diversity or use mutagenesis techniques to produce genetic diversity. Academic institutions such as the California Institute of Technology, the Max Planck Institute and the Austrian Centre of Industrial Biotechnology are also working in this field. Technological development by others may result in our technology, products and services, as well as products developed by our customers using our biocatalysts, becoming obsolete. Our primary competitors in the performance enzymes for **the** pharmaceutical products ~~are~~ **markets include (i)** companies marketing either conventional, non- enzymatic processes or biocatalytic enzymes ~~to~~ **; (ii)** manufacturers of pharmaceutical intermediates and APIs ~~,~~ **;** and ~~also~~ **(iii)** existing in-house technologies (both biocatalysts and conventional catalysts) within our client and potential client companies. The principal methods of competition and competitive differentiation in this market are price, product quality and performance, including manufacturing yield, safety and environmental benefits, and speed of delivery of product. Pharmaceutical manufacturers that use biocatalytic processes can face increased competition from manufacturers that use more conventional processes and / or manufacturers that are based in regions (such as India and China) with lower regulatory, safety and environmental costs. The market for the manufacture and supply of APIs and intermediates is large with many established companies. These companies include many of our large innovator and generic pharmaceutical customers, such as Merck, GSK, Novartis, Pfizer, Bristol-Myers, Kyorin, Urovant **,** and Teva which have significant internal research and development efforts directed at developing processes to manufacture APIs and intermediates. The processes used by these companies include classical conventional organic chemistry reactions, chemo catalytic reactions, biocatalytic reactions or combinations thereof. Our biocatalytic based manufacturing processes must compete with these internally developed routes. Additionally, we also face competition from companies developing and marketing conventional catalysts such as Solvias Inc., BASF and Takasago International Corporation. The market for supplying enzymes for use in pharmaceutical manufacturing is quite fragmented. There is competition from large industrial enzyme companies, such as Novozymes and DuPont, as well as subsidiaries of larger contract research / contract manufacturing organizations, such as DSM, Cambrex Corporation, Lonza, WuXi STA and Almac Group Ltd. Some fermentation pathway design companies, like Ginkgo Bioworks (who recently acquired Zymergen), whose traditional focus has been to design microorganisms that express small molecule chemicals, could extend into designing organisms that express enzymes. There is also competition in the enzyme customization and optimization area from several smaller companies, such as BRAIN AG, Arzeda, c- LEcta GmbH and Evocatal GmbH. We ~~entered the fine chemicals market in 2013, by applying our protein engineering technology in the food market. We~~ face ~~similar forms of competition~~ **competitive challenges related to our ECO Synthesis ™ manufacturing platform. Phosphoramidite chemistry is the current and long- established industry standard for the manufacture of RNA therapeutics. Primary competitors** in this **space** ~~market as in the pharmaceutical markets with the exception that the risk of losing opportunities to larger competitors in fine chemicals is greater given the larger scale of opportunities available in the fine chemicals market compared to the pharmaceutical market. Our significant competitors in the fine chemicals markets~~ include **CDMOs** ~~companies that have been in these marketplaces for many years~~, such as **Agilent Technologies** ~~DuPont Industrial Biosciences (" DuPont Genencor ")~~, ~~DSM, Novozymes and A~~ **which has made significant capital investment to expand their RNA manufacturing capabilities using phosphoramidite chemistry** . ~~B. Enzymes. These~~ **In addition, CDMOs and large pharmaceutical** companies ~~have greater resources in~~ **are seeking to make incremental improvements to phosphoramidite chemistry, including** ~~these~~ -- **the development of ligation** ~~markets than we do and have long-~~ **based** ~~term supply arrangements already in place with customers. Our ability to compete in these markets may be limited by our relatively late entrance. We also face competition in both the fine chemicals and pharmaceutical markets from emerging companies offering whole cell metabolic pathway~~ approaches ~~to these markets~~ **, liquid- phase synthesis, and solvent recycling** . There are ~~numerous~~ **also multiple early- stage competitors who are pursuing fully enzymatic approaches to the manufacture of RNA, including EnPlusOne, a private startup company, and a UK- based consortium led by CPI and consisting of multiple academic and research organizations, including The University of Manchester and large pharmaceutical** companies ~~that participate in the biotherapeutics market generally and the PKU market specifically. Many of these companies are large~~ , **including AstraZeneca plc** ~~successful and well- capitalized. BioMarin Pharmaceutical Inc. (" BioMarin ") and Daiichi Sankyo Company market Kuvan ® in the United States, Europe and Japan for the treatment of a certain type of PKU. In addition, BioMarin gained US FDA approval in 2018 and began commercial sales of PalynziqTM as an~~ **and Novartis** ~~injectable enzyme substitution therapy for the potential treatment of PKU. Several companies, i. e., Synlogic, Homology Medicines and Rubius have reported clinical efforts to develop biotherapeutic candidates for PKU. Beyond targeting PKU, Takeda (who acquired Shire Plc in 2019), Genzyme / Sanofi S. A., BioMarin and other companies market or are actively developing new enzyme therapeutics. There are numerous companies that are developing other forms of therapeutics, such as small molecules, gene therapies, as well as therapies based on gene editing, which could compete with biotherapeutics~~ . Our ability to compete successfully in any of these markets will depend on our ability to develop proprietary products that reach the market in a timely manner and are technologically superior to and / or are less expensive than other products on the market. Many of our competitors have substantially greater production, financial, research and development, personnel and marketing resources than we do. They also started developing products earlier than we did, which may allow them to establish blocking

intellectual property positions or bring products to market before we can. In addition, certain of our competitors may also benefit from local government subsidies and other incentives that are not available to us. As a result, our competitors may be able to develop competing and / or superior technologies and processes ~~,~~ and compete more aggressively and sustain that competition over a longer period of time than we could. Our technologies and products may be rendered obsolete or uneconomical by technological advances or entirely different approaches developed by one or more of our competitors. We cannot be certain that any products we develop in the future will compare favorably to products offered by our competitors or that our existing or future products will compare favorably to any new products that are developed by our competitors. As more companies develop new intellectual property in our markets, the possibility of a competitor acquiring patent or other rights that may limit our products or potential products increases, ~~which~~ **and** could **additionally** lead to litigation. Our limited resources relative to many of our competitors may cause us to fail to anticipate or respond adequately to new developments and other competitive pressures. This failure could reduce our competitiveness and market share, adversely affect our results of operations and financial position, and prevent us from obtaining or maintaining profitability. ~~The COVID~~ **Revenues in future years from our sales of CDX - 616** ~~19 pandemic has had, and continues to have,~~ **Pfizer are subject to** a **number** ~~significant impact globally, prompting governments and businesses to take unprecedented measures in response. In the United States, the COVID- 19 pandemic has and may continue in the future to, directly or indirectly, adversely affect our business, results of~~ **factors which** operations and financial condition, including as..... and other measures. Organizations and individuals are ~~taking additional steps to avoid or reduce infection, including limiting travel and staying home from work. These measures are disrupting normal business operations both in and outside of affected areas and have had significant negative impacts on businesses and financial markets worldwide. The potential impact and duration of COVID- 19 or~~ **our control** ~~another pandemic or public health crisis has had and could continue to have, significant repercussions across regional, national and global economies and financial markets, and could trigger a period of regional, national and global economic slowdown or regional, national or global recessions. The outbreak of COVID- 19 in many -~~ **may not materialize** ~~countries continues to adversely impact regional, national and global economic activity and has contributed to significant volatility and negative pressure in financial markets. As a result, we may experience difficulty accessing debt and equity capital on attractive terms, or at all, due to the severe disruption and instability in the global financial markets. In addition, our customers may terminate or amend their agreements for the purchase of our technology, products and services due to bankruptcy, lack of liquidity, lack of funding, operational failures or other reasons~~ . Starting the first and second quarters of 2021, we began to receive purchase orders from Pfizer ~~, Inc. (" Pfizer ")~~ for large quantities of our proprietary enzyme product, CDX- 616, for use by Pfizer in the manufacture of a critical intermediate for its proprietary active pharmaceutical ingredient, nirmatrelvir. Pfizer markets, sells and distributes nirmatrelvir, in combination with the active pharmaceutical ingredient ritonavir, as its PAXLOVID ™ (nirmatrelvir tablets; ritonavir tablets) product, which received ~~emergency use authorization (" EUA ") by the U. S. Food and Drug Administration (" FDA~~ **approval** ~~")~~ in ~~late~~ **May** ~~2021~~ **2023** for the treatment of mild- to- moderate COVID- 19 in adults ~~and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (" SARS- CoV- 2 ") viral testing, and~~ who are at high risk for progression to severe COVID- 19, including hospitalization or death. ~~The FDA has the authority to issue an EUA under certain circumstances, such as during a public health emergency, pursuant to a declaration by the Secretary of the Department of Health and Human Services (" HHS "), that an emergency exists justifying the issuance of EUAs for certain types of products (referred to as EUA declarations). On March 27, 2020, the Secretary of HHS declared that circumstances exist justifying authorization of drugs and biologics during the COVID- 19 pandemic, subject to the terms of any EUA that is issued for a specific product. Once an EUA declaration has been issued, the FDA can issue EUAs for products that fall within the scope of that declaration. To issue an EUA, the FDA Commissioner must conclude that (1) the chemical, biological, radioactive or nuclear agent (" CBRN ") that is referred to in the EUA declaration can cause serious or life- threatening diseases or conditions; (2) based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing the disease or condition attributable to the CBRN and that the product' s known and potential~~ **Potential** ~~benefits outweigh its known and potential risks; and (3) there is no adequate, approved, and available alternative to the product. the authorization to market products under an EUA is limited to the period of time the EUA declaration is in effect, and the FDA can revoke an EUA in certain circumstances. The FDA' s policies regarding an EUA can change unexpectedly. We cannot predict how long Pfizer' s EUA will remain in place. The FDA' s policies regarding products used to diagnose, treat or mitigate COVID- 19 remain in flux as the FDA responds to new and evolving public health information and clinical evidence. Therefore, it is possible that Pfizer' s EUA may be revoked, which could adversely affect our financial condition and results of operations. Revenues~~ **revenues** ~~in 2023 and~~ in future years from our sales of CDX- 616 to Pfizer and other potential customers (including sublicensees of Pfizer technology from The Medicines Patent Pool (the " MPP ")) are subject to a number of factors which are outside of our control, including, without limitation, the following, all of which could reduce or eliminate our sales of CDX- 616, and therefore materially and adversely affect our business, results of operations and financial condition: • Pfizer has no future binding commitment to purchase any particular quantity or quantities of CDX- 616 from us, and we are dependent upon Pfizer continuing to place orders with us (whether on a spot basis or under a long ~~-~~ term agreement, when and if executed) for their requirements, if any, for CDX- 616; • to our knowledge, sublicensees of Pfizer technology from the MPP have no obligation to purchase CDX- 616 from us under their sublicenses with the MPP; • ~~the EUA granted by the FDA for the use of PAXLOVID ™ for the treatment of COVID- 19 infections in humans could be withdrawn at any time; •~~ future vaccine development and usage and the development and usage of other new therapies for the treatment or elimination of COVID- 19 may eliminate or reduce demand for PAXLOVID ™; • new variants of COVID- 19 may emerge which PAXLOVID ™ is not effective in treating; • Pfizer ~~may not ultimately receive full marketing authorization for PAXLOVID ™ from the FDA and other international regulatory authorities; • Pfizer~~ could reformulate or make changes in the manufacturing process for nirmatrelvir which would eliminate or reduce demand for the use

of CDX- 616 in its manufacture; • sublicensees of Pfizer technology for the manufacture, sale and distribution of PAXLOVID ™ from the MPP may not utilize CDX- 616 in the manufacture of nirmatrelvir; • national and regional governmental authorities (including those of the United States government) may mandate that raw materials and intermediates used in the manufacture of PAXLOVID ™ to be marketed, sold and distributed within the borders of that country be domestically produced, which could eliminate or reduce demand for the use of CDX- 616 in such country; and • we may be unable (because of lack of available manufacturing capacity at our contract manufacturers, supply chain disruptions or an inability to obtain applicable regulatory approvals) to manufacture the quantities of CDX- 616 that Pfizer may desire to purchase from us. We have investments in **non-marketable securities, which may subject us to significant impairment charges. We have investments in** illiquid **or** non-marketable equity securities acquired in private transactions. ~~At~~ **As of** December 31, ~~2022~~ **2023** , ~~8~~ **7** . ~~2~~ **1** % of our consolidated assets consisted of investment securities, which are illiquid investments. Investments in ~~illiquid, or~~ non- marketable, securities are inherently risky and difficult to value. We account for our non- marketable equity securities under the measurement alternative. Under the measurement alternative, the carrying value of our non- marketable equity investments is adjusted to fair value for observable transactions for identical or similar investments of the same issuer or impairment. We evaluate our investment in non- marketable securities when circumstances indicate that we may not be able to recover the carrying value. We may impair these securities and establish an allowance for a credit loss when we determine that there has been an " other- than-temporary " decline in estimated fair value of the equity security compared to its carrying value. The impairment analysis requires significant judgment to identify events or circumstances that would likely have a material adverse effect on the fair value of the investment. Because over 5 % of our total assets consisted of non- marketable investment securities, any future impairment charges from the write down in value of these securities could have a material adverse effect on our financial condition or results of operations. Ethical, legal and social concerns about genetically engineered products and processes could limit or prevent the use of our technology, products and processes and limit our revenues. Some of our technology, products and services **, such as our ECO Synthesis ™ manufacturing platform,** are genetically engineered or involve the use of genetically engineered products or genetic engineering technologies. If we and / or our collaborators are not able to overcome the ethical, legal, and social concerns relating to genetic engineering, our technology, products and services may not be accepted. Any of the risks discussed below could result in increased expenses, delays, or other impediments to our programs or the public acceptance and commercialization of products and processes dependent on our technologies or inventions. Our ability to develop and commercialize one or more of our technologies, products, or processes could be limited by the following factors: • public attitudes about the safety and environmental hazards of, and ethical concerns over, genetic research and genetically engineered products and processes, which could influence public acceptance of our technologies, products and processes; • public attitudes regarding, and potential changes to laws governing ownership of **,** genetic material, which could harm our intellectual property rights with respect to our genetic material and **/ or** discourage collaborators from supporting, developing, or commercializing our technology, products and services; and • governmental reaction to negative publicity concerning genetically modified organisms, which could result in greater government regulation of genetic research and derivative products. The subject of genetically modified organisms has received negative publicity, which has aroused public debate. This adverse publicity could lead to greater regulation and trade restrictions on imports of genetically altered products. The biocatalysts that we develop have significantly enhanced characteristics compared to those found in naturally occurring enzymes or microbes. While we produce our biocatalysts only for use in a controlled industrial environment, the release of such biocatalysts into uncontrolled environments could have unintended consequences. Any adverse effect resulting from such a release could have a material adverse effect on our business and financial condition, **damage our reputation,** and **/ or** ~~we may have exposure~~ -- **expose us** to liability for any resulting harm **. We have recently enhanced our strategic focus to concentrate on certain programs and business lines. As a result of this refined focus, we may fail to capitalize on other opportunities that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we have recently focused our efforts on developing certain programs and business lines. As a result, we may forego or delay pursuit of business opportunities that later prove to have greater commercial potential. Further our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. In addition, our spending on current and future research and development programs, such as ECO Synthesis ™ manufacturing platform that is in development, may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular program or business line, our business and results of operations could be harmed. While we have historically invested significant time and financial resources in the development of biotherapeutics assets, including candidates for the treatment of Fabry disease and Pompe disease, which are included in the Takeda Agreement, in July 2023, we announced we are terminating investment in our biotherapeutics business and in other programs. As a result, we are renegotiating some of these, along with other license agreements for product candidates in our biotherapeutics, food and feed, and non- core life science assets. For example, we entered into the Acquisition Agreement with Nestlé under which they acquired rights to our co- developed lipase enzyme CDX- 7108 and we received an upfront payment and the right to downstream milestones and royalties, terminating our prior SCA and development agreement with Nestlé. While we are working to amend or terminate some of our agreements and enter into new agreements in such a way that we may be able to receive future revenue or other benefits, we may be unsuccessful in doing so. As a result, it remains uncertain as to whether we will receive any value or benefit from these license agreements going forward. Further, renegotiating these agreements may be costly and could divert management attention, which could have an adverse impact on our business and results of operations** . We use hazardous materials in our business and we must comply with environmental laws and regulations. Any claims relating to improper handling, storage or disposal of these materials or noncompliance of applicable laws and regulations could be time consuming and costly and could adversely affect our business and results of operations. Our research and development and

commercial processes involve the use of hazardous materials, including chemical, radioactive and biological materials. Our operations also produce hazardous waste. We cannot eliminate entirely the risk of accidental contamination or discharge and any resultant injury from these materials. Federal, state, local and foreign laws and regulations govern the use, manufacture, storage, handling and disposal of, and human exposure to, these materials. We may ~~be sued~~ **face liability** for any injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed our total assets. Although we believe that our activities comply in all material respects with environmental laws, there can be no assurance that violations of environmental, health and safety laws will not occur in the future as a result of human error, accident, equipment failure or other causes. Compliance with applicable environmental laws and regulations may be expensive, and the failure to comply with past, present or future laws could result in the imposition of fines, third party property damage, product liability and personal injury claims, investigation and remediation costs, the suspension of production or a cessation of operations, and our liability may exceed our total assets. Liability under environmental laws can be joint and several and without regard to comparative fault. Environmental laws could become more stringent over time imposing greater compliance costs and increasing risks and penalties associated with violations, which could impair our research, development or production efforts and harm our business. In addition, we may ~~have~~ **be required** to indemnify some of our customers or suppliers for losses related to our failure to comply with environmental laws, which could expose us to significant liabilities **. Our ability to use our net operating loss carryforwards to offset future taxable income may be subject to certain limitations** . In general, under Section 382 of the Internal Revenue Code of 1986, as amended (the " Code "), a corporation that undergoes an " ownership change " is subject to limitations on its ability to utilize its pre- change net operating loss carryforwards (" NOLs "), to offset future taxable income. If the Internal Revenue Service challenges our analysis that our existing NOLs are not subject to limitations arising from previous ownership changes, our ability to utilize NOLs could be limited by Section 382 of the Code. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Code. Furthermore, our ability to utilize NOLs of companies that we may acquire in the future may be subject to limitations. For these reasons, we may not be able to utilize a material portion of the NOLs reflected in our financial statements, even if we attain profitability. We are subject to the rules and regulations established from time to time by the **SEC** ~~Securities and Exchange Commission,~~ and Nasdaq. These rules regulations require, among other things, that we establish and periodically evaluate procedures with respect to our internal controls over financial reporting. As part of these evaluations, material weaknesses in our internal controls over financial reporting may be identified. A material weakness is a deficiency, or a combination of deficiencies, in internal controls over financial reporting such that there is a reasonable possibility that a material misstatement of a company' s annual or interim consolidated financial statements will not be prevented or detected on a timely basis. While we were able to remediate previously identified material weaknesses in our internal controls over financial reporting, there can be no guarantee we will not identify similar or other material weaknesses in the future and if such material weaknesses are identified, there can be no guarantee we would be able to remediate such material weaknesses. Any material weaknesses in our internal controls may adversely affect our ability to record, process, summarize and accurately report timely financial information and, as a result, our consolidated financial statements may contain material misstatements or omissions. Reporting obligations as a public company place a considerable strain on our financial and management systems, processes and controls, as well as on our personnel. In addition, as a public company we are required to document and test our internal controls over financial reporting pursuant to Section 404 of the Sarbanes- Oxley Act so that our management can certify as to the effectiveness of our internal controls over financial reporting. Likewise, our independent registered public accounting firm is required to provide an attestation report on the effectiveness of our internal controls over financial reporting in our Annual Reports on Form 10- K. If our management is unable to certify the effectiveness of our internal controls or if our independent registered public accounting firm cannot deliver a report attesting to the effectiveness of our internal controls over financial reporting, or if we identify or fail to remediate material weaknesses in our internal controls, we could be subject to regulatory scrutiny and a loss of public confidence, which could seriously harm our reputation and the market price of our common stock. In addition, if we do not maintain adequate financial and management personnel, processes and controls, we may not be able to manage our business effectively or accurately report our financial performance on a timely basis, which could cause a decline in our common stock price and may seriously harm our business. ~~platform~~ **facilities that we may make or develop in the future,our spending on new market opportunities,including opportunities in the biotherapeutics markets** ,and the filing,prosecution,enforcement and defense of patent claims.If our capital resources are insufficient to meet our capital requirements,and we are unable to enter into or maintain collaborations with partners that are able or willing to fund our development efforts or commercialize any ~~enzyme~~ products that we develop or enable,we will have to raise additional funds to continue the development of our technology and products and complete the commercialization of products,if any,resulting from our technologies.In addition,we may choose to raise additional capital due to market conditions or strategic considerations,such as funding **investments in** ~~the ongoing commercialization of~~ our **biotherapeutics business** ~~ECO Synthesis ™ manufacturing platform~~ ,even if we believe we have sufficient funds for our current or future operating plans.We may seek to obtain such additional capital through equity offerings, ~~including pursuant to the EDA,~~ debt financings,credit facilities and / or strategic collaborations.If future financings involve the issuance of equity securities,our existing stockholders would suffer dilution. ~~In addition,under~~ **If we raise debt financing** ~~our~~ **or** ~~Loan Agreement~~ **enter into credit facilities** ,we ~~are~~ **may be** subject to restrictive covenants that limit our ability to conduct our business ~~and could be subject to additional covenants to the extent we seek other debt financing in the future~~ .Strategic collaborations may also place restrictions on our business.We may not be able to raise sufficient additional funds on terms that are favorable to us,if at all.If we fail to raise sufficient funds and fail to generate sufficient revenues to achieve planned gross margins and to control operating costs,our ability to fund our operations,take advantage of strategic opportunities,develop products or technologies,or otherwise respond to competitive pressures could be significantly limited.If this happens,we may be forced to delay or terminate research or development programs or the

commercialization of products resulting from our technologies,curtail or cease operations or obtain funds through collaborative and licensing arrangements that may require us to relinquish commercial rights,or grant licenses on terms that are not favorable to us.If adequate funds are not available,we will not be able to successfully execute our business plan or continue our **business.Our** We have made acquisitions in the past, and if appropriate opportunities become available, we expect to acquire additional businesses, assets, technologies, or products to enhance our business in the future. For example, in October 2010, we acquired substantially all of the patents and other intellectual property rights associated with Maxygen' s directed evolution technology. In connection with any future acquisitions, we could: • issue additional equity securities, which would dilute our current stockholders; • incur substantial debt to fund the acquisitions; • use our cash to fund the acquisitions; or • assume significant liabilities including litigation risk. Acquisitions involve numerous risks, including problems integrating the purchased operations, technologies or products, unanticipated costs and other liabilities, diversion of management' s attention from our core businesses, adverse effects on existing business relationships with current and / or prospective collaborators, customers and / or suppliers, risks associated with entering markets in which we have no or limited prior experience and potential loss of key employees. We do not have extensive experience in managing the integration process and we may not be able to successfully integrate any businesses, assets, products, technologies or personnel that we might acquire in the future without a significant expenditure of operating, financial and management resources, if at all. The integration process could divert management' s time from focusing on operating our business, result in a decline in employee morale and cause retention issues to arise from changes in compensation, reporting relationships, future prospects or the direction of the business. Acquisitions may also require us to record goodwill and non- amortizable intangible assets that will be subject to impairment testing on a regular basis and potential periodic impairment charges, incur amortization expenses related to certain intangible assets, and incur large and immediate write offs and restructuring and other related expenses, all of which could harm our operating results and financial condition. In addition, we may acquire companies that have insufficient internal financial controls, which could impair our ability to integrate the acquired company and adversely impact our financial reporting. If we fail in our integration efforts with respect to any of our acquisitions and are unable to efficiently operate as a combined organization, our business and financial condition may be adversely affected. ~~and businesses to take unprecedented measures in response.In the United States,COVID- 19 has and may continue in the future to,directly or indirectly,adversely affect our business,results of~~ operations and financial condition **,including as a result of compliance with governmental orders governing the operation of businesses during the pandemic,the temporary closure of our Redwood City,California facilities from mid- March 2020 through the end of April 2020 and disruption of our research and development operations** .In the future,our business could be materially adversely affected,directly or indirectly,by the widespread outbreak of contagious disease, ~~such as~~ **including the ongoing** COVID- 19 **pandemic** ~~or any resurgence thereof~~ . ~~If national~~ **National** ,state and local governments in affected regions **have implemented and may continue to** implement safety precautions ~~,similar to those implemented in response to COVID- 19~~ ,including quarantines,border closures,increased border controls,travel restrictions,governmental orders and shutdowns,business closures,cancellations of public gatherings and other measures **.Organizations** ~~,such precautions could,~~ and ~~for~~ **individuals** Risks Related to Government Regulation ~~and Clinical Product Development We or our customers may not be able to obtain regulatory approval for the use of our products in food and food ingredients, if required, and, even if approvals are obtained, complying on an ongoing basis with the numerous regulatory requirements applicable to these products will be time- consuming and costly. The products that we develop for our food and food ingredient customers are, and any other products that we may develop for the food and food ingredients market will likely be, subject to regulation by various government agencies, including the FDA, state and local agencies and similar agencies outside the United States, as well as religious compliance certifying organizations. Food ingredients are regulated by the FDA either as food additives or as substances generally recognized as safe (" GRAS "). A substance can be listed or affirmed as GRAS by the FDA or self- affirmed by its manufacturer upon determination that independent qualified experts would generally agree that the substance is GRAS for a particular use. While we generally self- affirm GRAS status for the ingredients used in the products that we develop for the food market, our customer (s) may be required to submit a GRAS notification to FDA to establish that ingredients in a final commercial product may be considered GRAS. There can be no assurance that our customer (s) will not receive any objections from the FDA with respect to any GRAS notification our customer (s) may submit. If the FDA were to disagree with our customer' s determination that their commercial product and / or its ingredients are GRAS or otherwise compliant, the FDA could ask such customer to voluntarily withdraw the final commercial product from the market or could initiate legal action to halt its sale. Such actions by the FDA could have an adverse effect on our business, financial condition, and results of our operations. Food ingredients that are not GRAS are regulated as food additives and require FDA approval prior to commercialization or must be the subject of an existing food additive regulation. The food additive petition process for ingredients that are not already authorized by regulation is generally expensive and time consuming, with approval, if secured, potentially taking years.** Our ongoing efforts to deploy our technology in the life science tools markets may fail. We have ~~recently begun to use~~ **used** our CodeEvolver ® ~~protein engineering~~ **directed evolution** technology platform to develop new products for customers using NGS and PCR / qPCR for in vitro molecular diagnostic applications. ~~while~~ **While** we have entered into ~~some~~ license agreements for products in this market, we do not know if we can successfully compete in this new market. This new market is well established and consists of numerous large, well- funded entrenched market participants who have long and established track records and customer relationships. **We have also developed a newly engineered** ~~In December 2019, we licensed our first proprietary enzyme for this market, EvoT4 ™ DNA~~ ligase ~~, which is~~ designed to **address sequencing challenges** ~~improve library preparation for NGS users, to Roche~~ . ~~This~~ **These** ~~enzyme~~ **enzymes** , and any **additional** products that we may develop in the future for this market, may not succeed in displacing current products. If we succeed in commercializing new products for this market, we may not generate significant revenues and cash flows from these activities. The failure to successfully deploy products on **a** timely basis in this space may limit our growth and have a material adverse effect on our financial condition, operating results and business

prospects. The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed. We and any collaborators are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Foreign regulatory authorities impose similar requirements. 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 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 and any collaborators must complete additional preclinical or nonclinical studies and clinical trials to demonstrate the safety, purity and potency (or efficacy) of our product candidates in humans to the satisfaction of the regulatory authorities before we will be able to obtain these approvals. Our product candidates could fail to receive regulatory approval for many reasons, including the following: • the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our or our collaborators' clinical trials; • we or our collaborators 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 its 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; • we or our collaborators may be unable to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks; • the FDA or comparable foreign regulatory authorities may disagree with our or our collaborators' interpretation of data from preclinical studies or clinical trials; • the data collected from clinical trials of product candidates may not be sufficient to support the submission of a BLA to obtain regulatory approval in the United States or elsewhere; • the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third- party manufacturers with which we or our collaborators contract for clinical and commercial supplies; • the FDA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing with collaborators; and • the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our or our collaborators' clinical data insufficient for approval. This 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 impose significant limitations in the form of narrow indications, warnings, or a REMS. Regulatory authorities may not approve the price we or our collaborators intend to charge for products we may develop, 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. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates. Clinical trials are difficult to design and implement, expensive, time- consuming and involve an uncertain outcome, and the inability to successfully conduct clinical trials and obtain regulatory approval for our product candidates would substantially harm our business. Clinical testing is expensive and usually takes many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process, and 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. 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, suspended or terminated for a variety of reasons, including in connection with: • the inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of clinical trials; • applicable regulatory authorities disagreeing as to the design or implementation of the clinical trials; • obtaining regulatory authorization to commence a trial; • reaching an agreement on acceptable terms with prospective contract research organizations (" 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 IRB approval at each site; • developing and validating the companion diagnostic to be used in a clinical trial, if applicable; • insufficient or inadequate supply or quality of product candidates or other materials necessary for use in clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials; • recruiting and retaining enough suitable patients to participate in a trial; • having enough patients complete a trial or return for post- treatment follow- up; • adding a sufficient number of clinical trial sites; • inspections of clinical trial sites or operations by applicable regulatory authorities, or the imposition of a clinical hold; • clinical sites deviating from trial protocol or dropping out of a trial; • the inability to demonstrate the efficacy and benefits of a product candidate; • discovering that product candidates have unforeseen safety issues, undesirable side effects or other unexpected characteristics; • addressing patient safety concerns that arise during the course of a trial; receiving untimely or unfavorable feedback from applicable regulatory authorities regarding the trial or requests from regulatory authorities to modify the design of a trial; • non- compliance with applicable regulatory requirements by us or third parties or changes in such regulations or administrative actions; • suspensions or terminations by IRBs of the institutions at which such trials are being conducted, by the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities due to a number of factors, including those described above; • third parties being unable or unwilling to satisfy their contractual obligations to us; or • changes in our financial priorities, greater than anticipated costs of completing a trial or our inability to continue funding the trial. 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. Additionally, we or our collaborators may experience unforeseen events during or resulting from clinical trials that could delay or prevent receipt of marketing approval for or commercialization of product candidates. For example, clinical trials of product candidates may produce negative, inconsistent or inconclusive results, and we may decide, or regulators may require us, to

conduct additional clinical trials or abandon development programs. Regulators may also revise the requirements for approving the product candidates, or such requirements may not be as we anticipate. If we or our collaborators are required to conduct additional clinical trials or other testing of product candidates beyond those that we or our collaborators currently contemplate, if we or our collaborators are unable to successfully complete clinical trials or other testing of such product candidates, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may: • incur unplanned costs; • be delayed in obtaining or fail to obtain marketing approval for product candidates; • obtain marketing approval in some countries and not in others; • obtain marketing approval for indications or 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 to additional post- marketing testing requirements; • be subject to changes in the way the product is administered; • have regulatory authorities withdraw or suspend their approval of the product or impose restrictions on its distribution; • be sued; or • experience damage to our reputation. If we or our collaborators experience delays in the commencement or completion of our clinical trials, or if we or our collaborators terminate a clinical trial prior to completion, we may experience increased costs, have difficulty raising capital and / or be required to slow down the development and approval process timelines. Furthermore, the product candidates that are the subject of such trials may never receive regulatory approval, and their commercial prospects and our ability to generate product revenues from them could be impaired or not realized at all. Results of preclinical studies and early clinical trials of product candidates may not be predictive of results of later studies or trials. Our product candidates may not have favorable results in later clinical trials, if any, or receive regulatory approval. Preclinical and clinical drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the drug development process. Despite promising preclinical or clinical results, any product candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for product candidates in our industry is high. The results from preclinical studies or early clinical trials of a product candidate may not be predictive of the results from later preclinical studies or clinical trials, and interim results of a clinical trial are not necessarily indicative of final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. Many companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks at later stages of development after achieving positive results in early stages of development, and we may face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including previously unreported adverse events. Moreover, non- clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain regulatory approval. Even if any product candidates progress to clinical trials, these product candidates may fail to show the safety and efficacy in clinical development required to obtain regulatory approval, despite the observation of positive results in animal studies. Our or **our customers, future customers** our **or** collaborators ' failure to replicate positive results from early research programs and preclinical or greenhouse studies may prevent us from further developing and commercializing those or other product candidates, which would limit our potential to generate revenues from them and harm our business and prospects. For the foregoing reasons, we cannot be certain that any ongoing or future preclinical studies or clinical trials will be successful. Any safety or efficacy concerns observed in any one of our preclinical studies or clinical trials in a targeted area could limit the prospects for regulatory approval of product candidates in that and other areas, which could have a material adverse effect on our business and prospects. Regulatory authorities in some jurisdictions, including the U. S. and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product candidate as an orphan product if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals in the U. S., or a patient population of greater than 200, 000 individuals in the U. S., but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U. S. The FDA has granted orphan drug designation to CDX- 6512 for the treatment of HCU and to CDX- 6210 for the treatment of Maple Syrup Urine Disease (MSUD). In the U. S., orphan designation entitles a party to financial incentives such as opportunities for grant funding for clinical trial costs, tax advantages and user- fee waivers. In addition, if a product candidate that has orphan designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same drug for the same disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same disease condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same disease condition if such regulatory authority concludes that the later drug is clinically superior if it is shown to be safer, more effective or makes a major contribution to patient care. 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. We have obtained rare pediatric disease designation for CDX- 6512 and CDX- 6120, however, there is no guarantee that such designation will result in approval of CDX- 6512 or CDX- 6210, and even if we obtain approval of CDX- 6512 or CDX- 6210 for the indications for which we have been awarded rare pediatric disease designation, there is no guarantee that such approval will result in an aware of a rare pediatric disease priority review voucher. In 2012, Congress authorized the FDA to award priority review vouchers to sponsors of certain rare pediatric disease product applications. This program is designed to encourage development of new drug and biological products for the prevention and treatment of certain rare pediatric diseases. Specifically, under this program, a sponsor who receives an approval for a drug or biologic for a " rare pediatric disease " that meets certain criteria may qualify for a voucher that can be redeemed to

~~receive a priority review of a subsequent marketing application for a different product, even if that subsequent marketing application would not otherwise qualify for priority review on its own. The sponsor of a rare pediatric disease product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application. The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the U. S. within one year following the date of approval. We have obtained rare pediatric disease designation for CDX- 6512 for the treatment of HCU and for CDX- 6210 for the treatment of MSUD. Even though we have obtained rare pediatric disease designations, there is no guarantee that we will be able to obtain a priority review voucher, even if CDX- 6512 and / or CDX- 6210 are approved by the FDA. Moreover, Congress included a sunset provision in the statute authorizing the rare pediatric disease priority review voucher program. On December 27, 2020, the Rare Pediatric Disease Priority Review Voucher Program was extended, and under the current statutory sunset provisions, after September 30, 2024, FDA may only award a voucher for an approved rare pediatric disease product application if the sponsor has rare pediatric disease designation for the drug, and that designation was granted by September 30, 2024. After September 30, 2026, FDA may not award any rare pediatric disease priority review vouchers (unless Congress amends the law to extend the program further). The ability of the FDA and other government agencies to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, a government agency' s ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the government agency' s ability to perform routine functions. Average review times at the FDA and other government agencies 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 may also slow the time necessary for new drugs and biologics or modifications to approved drugs or 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 United States 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. Separately, in response to the COVID- 19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID- 19 pandemic, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID- 19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Even if we~~ obtain regulatory approval for any products **utilizing** ~~that we develop alone or~~ **our enzymes** ~~with collaborators~~, such products will remain subject to ongoing regulatory requirements, which may result in significant additional expense. **Any** ~~Even if~~ products **that** ~~we develop alone or with collaborators receive~~ **receives** ~~regulatory~~ **FDA** approval ~~, they~~ will ~~be~~ **remain** subject to ongoing regulatory requirements for manufacturing, labeling, packaging, distribution, storage, advertising, promotion, sampling, record- keeping and submission of safety and other post- market information, among other things. Any regulatory approvals received for such products may also be subject to limitations on the approved indicated uses for which they may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing testing and surveillance studies. For example, the holder of an approved **NDA or** BLA in the United States is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the **NDA or** BLA. In the United States, the holder of an approved **NDA or** BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Similar provisions apply in the European Union (the " EU "). Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. Similarly, in the EU any promotion of medicinal products is highly regulated and, depending on the specific jurisdiction involved, may require prior vetting by the competent national regulatory authority. In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the **NDA,** BLA or foreign marketing application. If ~~we~~ **our customers** , **future customers or** our collaborators or a regulatory agency discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured or disagrees with the promotion, marketing or labeling of that product, a regulatory agency may impose restrictions relative to that product, the manufacturing facility or ~~us or~~ **our customers** ~~our~~ **or** collaborators, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. ~~Moreover~~ **In addition** , if ~~any of our product candidates are approved, our product labeling, advertising, promotion and distribution will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product' s approved labeling. If we or~~ **our customers** ~~our~~ **or** collaborators fail to comply with applicable regulatory requirements ~~following approval of any potential products we may develop~~ , **the FDA and other regulatory** authorities may: • issue an untitled ~~enforcement~~ letter or a warning letter asserting a violation of the law; • seek an injunction, impose civil ~~and~~ **or** criminal penalties, and impose monetary fines, restitution or disgorgement of profits or revenues; • suspend or withdraw regulatory approval; • **issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product; • mandate modification of**

promotional materials and labeling and issuance of corrective information; • issue consent decrees or corporate integrity agreements, or debar or exclude from federal healthcare programs; • suspend or terminate any ongoing clinical trials or implement requirements to conduct post- marketing studies or clinical trials; • refuse to approve a pending **NDA,** BLA or comparable foreign marketing application (or any supplements thereto) ~~submitted by us or our collaborators~~ ; • restrict the labeling, marketing, distribution, use or manufacturing of products; • seize or detain products or otherwise require the withdrawal or recall of products from the market; • refuse to approve pending applications or supplements to approved applications ~~that we or our collaborators submit~~ ; • refuse to permit the import or export of products; or • refuse ~~to allow us or our collaborators to enter into~~ government contracts. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may **also** inhibit our ~~or~~ **customers** ~~our~~ -- **or** collaborators' ability to commercialize products and our ability to generate revenues. In addition, the FDA' s policies, and policies of foreign regulatory agencies, may change, and additional regulations may be enacted that could prevent, limit or delay regulatory approval of product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or 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. ~~Our~~ **The healthcare industry is highly regulated. We, and our customers, are subject to various local, state, federal, national, and international laws and regulations, which include laws and regulations promulgated by the FDA, HHS, state boards of pharmacy, state health departments, and similar regulatory bodies in other countries. Additionally, our** business operations and future arrangements with investigators, healthcare professionals, **and** consultants, **among others** ~~third- party payors, patient organizations and customers~~ , may expose us **and our customers** to broadly applicable fraud and abuse and other healthcare laws and regulations ~~. These laws may constrain the business or financial arrangements and relationships through which we will conduct our operations~~ , including ~~how we research~~ , ~~market~~ **without limitation** , ~~sell and distribute our product candidates, if approved. Such laws include: •~~ the ~~U. S.~~ federal Anti- Kickback Statute, ~~which prohibits, among other~~ -- **the** ~~things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U. S.~~ federal ~~and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • the U. S. federal false claims laws, including the~~ civil False Claims Act, ~~which, among other~~ -- **the** ~~things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U. S.~~ federal ~~government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U. S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U. S. federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act; • the U. S. federal Health Insurance Portability and Accountability Act of 1996 (" HIPAA "), which imposes criminal and civil~~ **Civil** ~~liability for~~ **Monetary Penalties Law** , ~~among other things, knowingly~~ and ~~willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U. S. federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • the U. S. federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children' s Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non- physician practitioners such as physician assistants and nurse practitioners, and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members; and •** analogous ~~U. S.~~ state laws **. These** ~~and regulations, including: state anti- kickback and false claims~~ laws ~~,~~ **may constrain the business or financial arrangements and relationships through** which **we will conduct** ~~may apply to our future business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or~~ **our operations. Because of the breadth of these** ~~services reimbursed by any third- party payor, including private insurers; state~~ laws ~~that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines~~ and **narrowness of available statutory** ~~the relevant compliance guidance promulgated by the U. S. federal government, or otherwise restrict payments that may be made to healthcare providers~~ and ~~other potential referral sources; and state laws and regulations~~ - **regulatory exceptions** ~~that require drug manufacturers to file reports relating to pricing and marketing information~~ , **it** ~~which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It~~ is possible that ~~governmental authorities~~ **some of our business activities could be regulated by or subject to challenge under one or more of such laws. We cannot ensure that our compliance controls, policies, and procedures** will ~~conclude~~ **in every instance protect us from acts of our employees, agents, contractors, or collaborators** that **turn out to violate any of** ~~our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other~~ -- **the** ~~healthcare~~ laws ~~and regulations~~ **described above** . If **we or** our operations are found to be in violation of any of the laws described above or any

other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil , and criminal and administrative penalties, damages, fines, exclusion from government- funded imprisonment and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. Ongoing healthcare legislative programs, such as Medicare and regulatory reform measures may Medicaid or similar programs in other countries or jurisdictions, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. The successful commercialization of product candidates developed by us or our partners 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 such product candidates, if approved, could limit our or our partners' 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 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 a material adverse effect on our business and ability to successfully commercialize our product candidates. Assuming we obtain coverage for our product candidates by a third- party payor, the resulting results of operations reimbursement payment rates may not be adequate or may require co- payments that patients find unacceptably high . In 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. 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 biologics 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 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. 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 from payor to payor. 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 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. 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 health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In the United States and some foreign jurisdictions , there have been, and we expect there will continue to be, a number of legislative and regulatory initiatives to contain healthcare costs. Some of these initiatives, such as ongoing healthcare reform, including with respect to reforming drug pricing, adverse changes to the in governmental or private funding of healthcare system products and services , including legislation or regulations governing patient access to care, and the delivery, coverage, pricing, and reimbursement of pharmaceuticals and healthcare services may cause our customers to change the amount of our offerings that they purchase from us or the price they are willing to pay us for these offerings. If cost- containment efforts measures that may reduce or limit coverage and reimbursement for - or newly approved drugs and affect our ability to profitably sell any product candidates for which we develop and our partners obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U. S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Affordable Care Act (the " ACA ") was enacted in the United States. The ACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers' Medicaid rebate liability to covered drugs

~~dispensed to individuals who are enrolled in Medicaid managed care organizations; expanded eligibility criteria for Medicaid programs; expanded the entities eligible for discounts under the 340B drug pricing program; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; established a new Patient- Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and establishes a Center for Medicare & Medicaid Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending. Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA, and on June 17, 2021, the U. S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court' s decision, President Biden had issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the healthcare reform measures will impact our business. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In March 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory cap on the Medicaid drug rebate, currently set at 100 % of a drug' s average manufacturer price, beginning January 1, 2024. Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient assistance programs, and reform government program reimbursement methodologies for products. Most recently, the Inflation Reduction Act of 2022 (the " IRA "), included a number of significant drug pricing reforms, which include the establishment of a drug price negotiation program within the U. S. Department of Health and Human Services (" HHS ") (beginning in 2026) that requires manufacturers to charge a negotiated " maximum fair price " for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers under Medicare Parts B and D to penalize price increases that outpace inflation (first due in 2023), and a redesign of the Part D benefit, as part of which manufacturers are required to provide discounts on Part D drugs (beginning in 2025). The IRA permits the HHS Secretary to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Additional drug pricing proposals could appear in future legislation. Further, it is possible that additional governmental action is taken in response to the COVID- 19 pandemic. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third- party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for any product candidate we develop, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects. We expect that these new laws and~~ other healthcare reform measures **limit our customers' profitability, they may decrease research and development spending, which could decrease the demand for our products and services and materially adversely affect our growth prospects. Any of these factors could harm our customers' businesses, which, in turn, could materially adversely affect our business, financial condition, results of operations, cash flows, and prospects. We cannot predict the likelihood, nature, or extent of other health reform initiatives** that may **arise from future legislative, administrative, or other action. Any substantial revision of applicable healthcare legislation could have a material adverse effect on the demand for our customers' products, which in turn could have a negative impact on our results of operations, financial condition, or business. Changes in the healthcare industry' s pricing, selling, inventory, distribution, or supply policies or practices, or in public or government sentiment for the industry as a whole, could also significantly reduce our revenue and results of operations. Compliance with European Union chemical regulations could** be ~~adopted in the future may costly and adversely affect our business and result~~ **results** ~~in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation~~ of **operations** ~~cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize any product candidates we develop, if approved~~ . Some of our products are subject to the EU regulatory regime known as The Registration, Evaluation and Authorization of Chemicals (" REACH "). REACH mandates that certain chemicals manufactured in, or imported into, the EU be registered and evaluated for their potential effects on human health and the environment. Under REACH, we and our contract manufacturers located in the EU are required to register certain of our products based on the quantity of such product imported into or manufactured in the EU and on the product' s intended end- use. The registration, evaluation and authorization process under REACH can be costly and time consuming. Problems or delays in the registration, evaluation or authorization process under REACH could delay or prevent the manufacture of some of our products in, or the importation of some of our products into, the EU, which could adversely affect our business and results of operations. In addition, if we or our contract manufacturers fail to comply with REACH, we may be subject to penalties or other enforcement actions, which could have a material adverse effect on our business and results of operations. Risks Related to ~~our Dependence on Third Parties We rely on third parties to~~

conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects. We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. As a result, we are and expect to remain dependent on third parties to conduct clinical trials of our product candidates. Specifically, we expect CROs, clinical investigators, and consultants to play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, we will not be able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the 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. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to stop and / or repeat clinical trials, which would delay the marketing approval process. There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow- up information on subjects enrolled in such clinical trials unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. In addition, clinical trial investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or comparable foreign regulatory authorities concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit by the FDA or any comparable foreign regulatory authority. Any such delay or rejection could prevent us from commercializing our product candidates. We contract with third parties for the manufacturing and supply of product candidates for use in preclinical testing and clinical trials and related services, which supply may become limited or interrupted or may not be of satisfactory quality and quantity. We do not have any manufacturing facilities. We produce in our laboratory relatively small quantities of products for evaluation in our research programs. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacture if any of our product candidates are approved. We currently have limited manufacturing arrangements and expect that each of our product candidates will only be covered by single source suppliers for the foreseeable future. This reliance increases the risk that we will not have sufficient quantities of our product candidates or products, if approved, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. Furthermore, all entities involved in the preparation of therapeutics for clinical trials 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 clinical trials must be manufactured in accordance with cGMP requirements. 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 contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a BLA on a timely basis and must adhere to the FDA's cGMP regulations enforced by the FDA through its facilities inspection program. Comparable foreign regulatory authorities may require compliance with similar requirements. The facilities and quality systems of our third- party contractor manufacturers must pass a pre- approval inspection for compliance with the applicable regulations as a condition of marketing approval of our product candidates. We do not control the manufacturing activities of, and are completely dependent on, our contract manufacturers for compliance with cGMP regulations. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do on commercially reasonable terms, if at all. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. 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 transferring such skills or technology to another third party and a feasible alternative may not exist. In addition, certain of our product candidates and our own proprietary methods have never been produced or implemented outside of our company, and we may therefore experience delays to our development programs if and when we attempt to establish new third party manufacturing arrangements for these product candidates or methods. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new

~~manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget. Our or a third party' s failure to execute on our manufacturing requirements, do so on commercially reasonable terms and comply with cGMP could adversely affect our business in a number of ways, including: • an inability to initiate or continue clinical trials of our product candidates under development; • delay in submitting regulatory applications, or receiving marketing approvals, for our product candidates; • loss of the cooperation of future collaborators; • subjecting third- party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities; • requirements to cease development or to recall batches of our product candidates; and • in the event of approval to market and commercialize our product candidates, an inability to meet commercial demands for our product or any other future product candidates. Risks Related to~~ Intellectual Property and Information Technology We will continue to file and prosecute patent applications and maintain trade secrets in an ongoing effort to protect our intellectual property rights. It is possible that our current patents, or patents which we may later acquire, may be successfully challenged or invalidated, in whole or in part. It is also possible that we may not obtain issued patents from our pending patent applications. We sometimes permit certain patents or patent applications to lapse or go abandoned under appropriate circumstances. Due to uncertainties inherent in prosecuting patent applications, sometimes patent applications are rejected, and we subsequently abandon them. It is also possible that we may develop proprietary technology, products or services in the future that are not patentable or that the patents of others will limit or altogether preclude our ability to conduct business. In addition, any patent issued to us or to our licensor may provide us with little or no competitive advantage, in which case we may abandon such patent ~~or~~ **,** license it to another entity ~~,~~ or terminate the license agreement. Our means of protecting our proprietary rights may not be adequate and our competitors may independently develop technologies, products or services that are identical or similar to ours or that compete with ours. Patent, trademark, copyright and trade secret laws afford only limited protection for our technology, products and services. The laws of many countries do not protect our proprietary rights to as great **of** an extent as do the laws of the United States. Despite our efforts to protect our proprietary rights, unauthorized parties have in the past attempted, and may in the future attempt, to operate under the aspects of our intellectual property rights, or proprietary technology, products or services or products, or to obtain and use information that we regard as proprietary. Third parties may also design around our proprietary rights, which may render our protected technology, services and products less valuable, if the design around is favorably received in the marketplace. In addition, if any of our technology, products and services ~~is~~ **are** covered by third- party patents or other intellectual property rights, we could be subject to various legal actions. We cannot assure that our technology products and / or services do not infringe, violate or misappropriate any patents or other intellectual property rights owned or controlled by others or that they will not in the future. Litigation may be necessary to enforce our intellectual property rights, to protect our trade secrets, to determine the validity and scope of the proprietary rights of others, or to defend against claims of infringement, invalidity, misappropriation, or other claims. Any such litigation could result in substantial costs and diversion of our resources. Moreover, any settlement of or adverse judgment resulting from litigation relating to intellectual property rights could require us to obtain a license to continue to make, use, import, sell or offer for sale the technology, products or services that is the subject of the claim, or otherwise restrict or prohibit our use of the technology, products or services. Our success depends in part on our ability to obtain patents and maintain adequate protection of our intellectual property rights directed to our technology, products and services in the United States and other countries. We have adopted a strategy of seeking patent protection in the United States and in foreign countries with respect to certain of the technology used in or relating to our products, services, and processes. As such, as of December 31, ~~2022~~ **2023** , we owned or controlled approximately ~~2~~ **1** , ~~090~~ **990 active** issued patents and pending patent applications in the United States and in various foreign jurisdictions. ~~Our~~ **As of December 31, 2023, our** patents and patent applications, if issued ~~, as of December 31, 2022~~ , have terms that expire between ~~2023~~ **2024** and approximately ~~2043~~ **2044** . We also have license rights to a number of issued patents and pending patent applications in the United States and in various foreign jurisdictions. Our owned and licensed patents and patent applications include those directed to our enabling technology and to the methods and products that support our business in the **pharmaceutical** ~~biotherapeutics, pharma~~ manufacturing, life sciences, ~~food~~ **oligonucleotide synthesis,** and other markets. We intend to continue to apply for patents relating to our technology, methods, services and products as we deem appropriate. Issuance of claims in patent applications and enforceability of such claims once issued involve complex legal and factual questions and, therefore, we cannot predict with any certainty whether any of our issued patents will survive invalidity claims asserted by third parties. Issued patents and patents issuing from pending applications may be challenged, invalidated, circumvented, rendered unenforceable or substantially narrowed in scope. In addition, the inventorship and ownership of the patents and patent applications may be challenged by others. Moreover, the United States Leahy- Smith America Invents Act (" AIA "), enacted in September 2011, brought significant changes to the United States patent system, which include a change to a " first to file " system from a " first to invent " system and changes to the procedures for challenging issued patents and disputing patent applications during the examination process, among other things. While interference proceedings are possible for patent claims filed prior to March 16, 2013, many of our filings will be subject to the post- and pre- grant proceedings set forth in the AIA, including citation of prior art and written statements by third parties, third party pre- issuance submissions, ex parte reexamination, inter partes review, post- grant review, and derivation proceedings. We may need to utilize the processes provided by the AIA for supplemental examination or patent reissuance. These proceedings could result in substantial cost to us even if the outcome is favorable. Even if successful, any proceeding may result in loss of certain claims. Any litigation or proceedings could divert our management' s time and efforts. Even unsuccessful claims brought by third parties could result in significant legal fees and other expenses, diversion of management time, and disruption in our business. Uncertainties resulting from initiation and continuation of any patent or related litigation could harm our ability to compete. Additional uncertainty may result from legal precedent handed down by the United States Federal Circuit Court and Supreme Court as they determine legal issues concerning the scope and

construction of patent claims and inconsistent interpretation of patent laws by the lower courts. Accordingly, we cannot ensure that any of our pending patent applications will result in issued patents, or even if issued, predict the breadth of the claims upheld in our **, our licensors',** and other companies' patents. Given that the degree of future protection for our proprietary rights is uncertain, we cannot ensure that: (i) we **or our licensors** were the first to invent the inventions covered by each of our pending applications, (ii) we **or our licensors** were the first to file patent applications for these inventions, or (iii) the proprietary technology, products or services we develop will be patentable. In addition, unauthorized parties may attempt to copy or otherwise obtain and use our technology, products and services. Monitoring unauthorized use of our intellectual property rights is difficult, and we cannot be certain that the steps we have taken will prevent unauthorized use of our technology, products or services, particularly in certain foreign countries where the local laws may not protect our proprietary rights as fully as in the United States. Moreover, third parties could practice our inventions in territories where we do not have patent protection. Such third parties may then try to import products made using our inventions into the United States or other countries. If competitors are able to use our proprietary technology, products or services, our ability to compete effectively could be harmed. In addition, others may independently develop and obtain patents for technologies, products or services that are similar to or superior to our technologies, products or services. If that happens, we may need to license these technologies, products or services, and we may not be able to obtain licenses on reasonable terms, if at all, which could cause harm to our business. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. Changes in patent laws and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them, or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or may obtain in the future **. For example, in some cases, we have filed for unitary patent protection under the rules implemented on June 1, 2023, in the European Patent Office. We will continue to assess this route of protection on a case- by- case basis, as applications are filed and patents are granted through the European Patent Office. This may alter our ability to protect our patents in some European countries** . Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. For example, in some foreign jurisdictions, governments have the right to compel patent owners to grant others licenses to their intellectual property under certain circumstances. In addition, any protection afforded by foreign patents may be more limited than that provided under U. S. patent and intellectual property laws. We may encounter significant problems in enforcing and defending our intellectual property both in the United States and abroad. For example, if the issuance in a given country of a patent covering an invention is not followed by the issuance in other countries of patents covering the same invention, or if any judicial interpretation of the validity, enforceability or scope of the claims or the written description or enablement in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in other countries, our ability to protect our intellectual property rights in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property rights or narrow the scope of our patent protection. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U. S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects ~~. Third parties may claim that we are infringing, violating or misappropriating their intellectual property rights, which may subject us to costly and time consuming litigation and prevent us from developing or commercializing our technology, products or services~~ . Our commercial success also depends in part on our ability to operate without infringing, violating or misappropriating patents and other intellectual property rights of third parties, and without breaching any licenses or other agreements that we have entered into with regard to our technologies, products or services. We cannot ensure that patents have not been issued, or will not be issued, to third parties that could block our ability to obtain patents or to operate as we would like. There may be patents in some countries that, if valid, may block our ability to make, use, sell, or offer for sale our technology, products or services in those countries, or import our products into those countries, if we are unsuccessful in circumventing or acquiring rights to these patents. There also may be claims in patent applications filed in some countries that, if granted and valid, may also block our ability to commercialize technology, products, services or processes in these countries if we are unable to circumvent or obtain rights to them. The industries in which we operate and the biotechnology industry, in particular, are characterized by frequent and extensive litigation regarding patents and other intellectual property rights. Many biotechnology companies have employed intellectual property litigation as a way to gain a competitive advantage. **We are aware of some patents and patent applications relating to aspects of our technologies, products or services filed by, and issued to, third parties. We cannot assure that if such third- party patents rights are asserted against us that we would ultimately prevail.** Any involvement in litigation or other intellectual property proceedings inside and **/ or** outside of the United States to defend against claims that we infringe, misappropriate or violate the intellectual property ~~of the~~ rights of others may divert our management' s time from focusing on business operations and could cause us to spend significant amounts of money. Any potential intellectual property litigation also could force us to do one or more of the following: • stop making, using, selling or importing our technologies, products and services that use the subject intellectual property; • pay monetary damages to the third party asserting claims against us; • grant or transfer rights to third parties relating to our patents or other intellectual property rights; • obtain from the third party asserting its intellectual property rights a license to make, sell, offer for sale, import or use the relevant technology, product or service, which license may not be available on reasonable terms, or at all; or • redesign those technologies, products, services or processes that use any allegedly infringing, ~~misappropriating~~ **misappropriated** or ~~violating~~ **violated** intellectual property rights, or relocate the operations relating to the allegedly infringing **,** ~~misappropriating~~ **misappropriated** or ~~violating~~ **violated** intellectual property rights to another jurisdiction, which may result in significant cost or delay to us, could be technically infeasible or could prevent us from making,

selling, offering for sale, using or importing some of our technologies, products or services in the United States or other jurisdictions ~~. We are aware of some patents and patent applications relating to aspects of our technologies, products or services filed by, and issued to, third parties. We cannot assure that if such third party patents rights are asserted against us that we would ultimately prevail~~ . Competitors may infringe, violate or misappropriate our intellectual property rights or those of our licensors. To prevent infringement, violation, misappropriation or other unauthorized use, we have in the past filed, and may in the future be required to file, enforcement claims, which can be expensive and time- consuming. In addition, in an enforcement proceeding, a court may decide that the intellectual property right that we own or control is not valid, is unenforceable and / or is not infringed, violated or misappropriated. In addition, in legal proceedings against a third party to enforce a patent directed at one of our technologies, products or services, the defendant could counterclaim that our patent is invalid and / or unenforceable in whole or in part. In patent enforcement litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are commonplace. Grounds for a patent validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non- enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the United States Patent and Trademark Office (" USPTO ") or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of enforcement litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents or those of our licensors invalid. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on the respective technology, products or services. Such a loss of patent protection could have a material adverse impact on our business. Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses ~~,~~ and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our expenses and reduce the resources available for operations and research and development activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace. Furthermore, because of the substantial amount of discovery required in connection with U. S. intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. The laws of some foreign countries where we do business do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and enforcing intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property rights, particularly those relating to biotechnology technologies. Accordingly, our efforts to protect and enforce our intellectual property rights in such countries may be inadequate. This could make it difficult for us to stop the infringement, violation or misappropriation of our patents or other intellectual property rights. Additionally, proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. If our biocatalysts, or the genes that code for our biocatalysts, are stolen, misappropriated or reverse engineered, others could use these biocatalysts or genes to produce competing products. Third parties, including our contract manufacturers, customers and those involved in shipping our biocatalysts, often have custody or control of our biocatalysts. If our biocatalysts, or the genes that code for our biocatalysts, were stolen, misappropriated or reverse engineered, they could be used by other parties who may be able to reproduce these biocatalysts for their own commercial gain. If this were to occur, it may be difficult for us to challenge this type of use, especially in countries with limited intellectual property rights protection or in countries in which we do not have patents covering the misappropriated biocatalysts. Confidentiality and non- use agreements with employees, consultants, advisors and other third parties may not adequately prevent disclosures and non- use of trade secrets and other proprietary information. In addition to patent protection, we also rely on other intellectual property rights, including protection of copyright, trade secrets, know- how and / or other proprietary information that is not patentable or that we elect not to patent. However, trade secrets can be difficult to protect, and some courts are less willing or unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and proprietary information, we rely in part on trade secret law and contractual agreements to protect our confidential and proprietary information and processes. We generally enter into confidentiality and invention assignment agreements with our employees, consultants and third parties working on our behalf upon their commencement of a relationship with us. However, trade secrets and confidential information are difficult to protect and we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes and we may not enter into such agreements with all employees, consultants and third parties who have been involved in the development of our intellectual property rights. Nevertheless, without our permission or awareness, our confidential and proprietary information may be disclosed to third parties, used by the respective individuals for purposes other than for the Company' s business, or obtained through illegal means, such that third parties could reverse engineer our biocatalysts, **enzyme** ~~product~~ **products** ~~candidates,~~ and processes, to attempt to develop the same technology or develop substantially equivalent technology. Costly and time- consuming litigation could be necessary to enforce and determine the scope of our confidential and proprietary rights, and failure to protect our trade secrets could adversely affect our competitive business position. If any of our trade secrets were lawfully obtained, we may be unable to prevent them, or those to whom they communicate it, from using that technology or information to compete with us or disclosing it publicly. Therefore, these events could have a material adverse effect ~~ob~~ **on** our business, financial condition and results of operations. In particular,

a failure to protect our proprietary rights may allow competitors to copy our technology, which could adversely affect our pricing and market share. In addition to contractual measures, we try to protect the confidential nature of our proprietary information by maintaining physical security of our premises and electronic security of our information technology systems. Such security measures may not, for example, in the case of misappropriation of a trade secret by an employee, consultant or other third party with authorized access or with unauthorized access but an intent to steal, provide adequate protection for our proprietary information. Our security measures may not prevent such employee, consultant or other third party from misappropriating our trade secrets and using them or providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. While we use commonly accepted security measures, trade secret violations are often a matter of state law in the United States, and the criteria for protection of trade secrets can vary among different jurisdictions. If the steps we have taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. Risks Related to Owning our Common Stock We are subject to anti- takeover provisions in our certificate of incorporation and bylaws and under Delaware law that could delay or prevent an acquisition of our company, even if the acquisition would be beneficial to our stockholders. Provisions in our amended and restated certificate of incorporation and our bylaws may delay or prevent an acquisition of ~~us~~ **the Company** . Among other things, our amended and restated certificate of incorporation and bylaws provide for a board of directors which is divided into three classes, with staggered three- year terms and provide that all stockholder action must be effected at a duly called meeting of the stockholders and not by a consent in writing, and further provide that only our board of directors, the chairman of the board of directors, our chief executive officer or president may call a special meeting of the stockholders. In addition, our amended and restated certificate of incorporation allows our board of directors, without further action by our stockholders, to issue up to 5, 000, 000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These provisions may also 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, who are responsible for appointing the members of our management team. Furthermore, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law **(" DGCL ")** which prohibits, with some exceptions, stockholders owning in excess of 15 % of our outstanding voting stock from merging or combining with us. Finally, our charter documents establish advanced notice requirements for nominations for election to our board of directors and for proposing matters that can be acted upon at stockholder meetings. Although we believe these provisions together provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if an offer to acquire our company may be considered beneficial by some stockholders. Our **bylaws designate a state or federal court located within the State of Delaware as the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us our current or former directors, officers, stockholders, or other employees. Our bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of us under Delaware law, (ii) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer, or other employee of the Company to us or our stockholders, (iii) any action asserting a claim against us or any of our directors, officers, or other employees arising pursuant to any provision of the DGCL or our certificate of incorporation or bylaws (as either may be amended from time to time), (iv) any action asserting a claim against us governed by the internal affairs doctrine, or (v) any other action asserting an " internal corporate claim, " as defined under Section 115 of the DGCL. The forgoing provisions do not apply to any claims arising under the Securities Act and, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States will be the sole and exclusive forum for resolving any action asserting a claim arising under the Securities Act. These choice of forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our current or former directors, officers, or other employees, which may discourage lawsuits with respect to such claims. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find the choice of forum provision to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations or financial condition. Our** quarterly or annual operating results may fluctuate in the future. As a result, we may fail to meet or exceed the expectations of research analysts or investors, which could cause our stock price to decline. Our financial condition and operating results have varied significantly in the past and may continue to fluctuate from quarter to quarter and year to year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following factors, as well as other factors described elsewhere in this report: • our ability to achieve or maintain profitability; • our ~~relationships with, and dependence on, collaborators in our principal markets; • our~~ dependence on a limited number of customers ~~,~~ ; • our product supply agreements with customers have finite duration, may not be extended or renewed and generally do not require the customer to purchase any particular quantity or quantities of our products; • with respect to customers purchasing our products for the manufacture of active pharmaceutical ingredients for which they have exclusivity due to patent protection, the termination or expiration of such patent protection and any resulting generic competition may materially and adversely affect our revenues, financial condition or results of operations; • our dependence on a limited number of products in our performance enzymes business; • our reliance on a limited number of contract manufacturers for large scale production of substantially all of our enzyme products; • our **relationships with, and dependence on, collaborators in our principal markets; • our** ability to **successfully and timely** develop and ~~successfully~~

commercialize new products **, including our ECO Synthesis ™ manufacturing platform,** for the markets we serve; • ~~our ability to obtain additional development partners for our novel biotherapeutic programs; • potential of Nestlé Health Science or Takeda terminating any development program under their~~ -- **the** ~~license agreements with us; •~~ potential of GSK, Merck, Novartis or any other performance enzyme customer terminating their agreements with us; • the success of our customers' products in the market and the ability of such customers to obtain regulatory approvals for products and processes; • our ~~or our customers' ability to obtain regulatory approval for the sale and manufacturing of food products using our enzymes; • our~~ ability to deploy our technology platform in life science tools markets; • our ~~ability to successfully achieve domestic and foreign regulatory approval for product candidates; • our ability to successfully design and execute clinical testing at a reasonable cost and on an acceptable time- frame; • our~~ dependence on **our collaborators or customers'** product candidates which could unexpectedly fail at any stage of preclinical or clinical development; • our dependence on **our collaborators or customers'** product candidates which may lack the ability to work as intended or cause undesirable side effects ~~; • our dependency on third parties to conduct clinical trials, research, and preclinical studies~~ ; • our ability to successfully prosecute and protect our intellectual property; • our ability to compete if we do not adequately protect our proprietary technologies or if we lose some of our intellectual property rights; • our ability to avoid infringing the intellectual property rights of third parties; • our involvement in lawsuits to protect or enforce our patents or other intellectual property rights; • our ability to enforce our intellectual property rights throughout the world; • our dependence on, and the need to attract and retain, key management and other personnel; • our ability to prevent the theft or misappropriation of our biocatalysts, the genes that code for our biocatalysts, know- how or technologies; • our ability to protect our trade secrets and other proprietary information from disclosure by employees and others; • our ability to obtain substantial additional capital that may be necessary to expand our business; • our ability to comply with the terms of our ~~credit facility~~ **Loan Agreement** ; • our ability to timely pay debt service obligations; • our customers' ability to pay amounts owed to us in a timely manner; • our ability to avoid charges to earnings as a result of any impairment of goodwill, intangible assets or other long- lived assets; • changes in financial accounting standards or practices may cause adverse, unexpected financial reporting fluctuations and affect our reported results of operations; • our ability to maintain effective internal control over financial reporting; • our dependency on information technology systems, infrastructure and data; • our ability to control and to improve product gross margins; • our ability to protect against risks associated with the international aspects of our business; • the cost of compliance with EU chemical regulations; • potential advantages that our competitors and potential competitors may have in securing funding or developing products; • our ability to accurately report our financial results in a timely manner; • results of regulatory tax examinations; • market and economic conditions may negatively impact our business, financial condition, and share price; • business interruptions due to natural disasters, disease outbreaks or other events beyond our control; • public concerns about the ethical, legal and social ramifications of genetically engineered products and processes; • our ability to integrate our current business with any businesses that we may acquire in the future; • our ability to properly handle and dispose of hazardous materials in our business; • potential product liability claims; • changes to tax law and related regulations could materially affect our tax obligations and effective tax rate; and • our ability to use our NOLs to offset future taxable income. Due to the various factors mentioned above, and others, the results of any prior quarterly or annual periods should not be relied upon as indications of our future operating performance. We **do not intend to pay cash dividends for the foreseeable future. We** currently intend to retain our future earnings, if any, to finance the further development and expansion of our business and do not intend to pay cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, restrictions contained in future agreements and financing instruments, business prospects and such other factors as our board of directors deems relevant. General Risk Factors **If securities or industry analysts do not publish research or reports about our business, or publish negative reports about our business, our stock price and trading volume could decline.** The trading market for our common stock will be influenced by the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our stock or change their opinion of our stock in a negative manner, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline. **We face risks associated with our international business.** While we have a limited number of employees located outside of the United States, we are and will continue to be dependent upon contract manufacturers located outside of the United States. In addition, we have customers and partners located outside of the United States. Conducting business internationally exposes us to a variety of risks, including: • changes in or interpretations of **U. S. or** foreign **laws or** regulations that may adversely affect our ability to sell our products, repatriate profits to the United States or operate our foreign- located facilities; • the imposition of tariffs; • the imposition of limitations on, or increase of, withholding and other taxes on remittances and other payments by foreign subsidiaries or joint ventures; • the imposition of limitations on genetically- engineered **or other** products or processes and the production or sale of those products or processes in foreign countries; • currency exchange rate fluctuations; • uncertainties relating to foreign laws, regulations and legal proceedings including **pharmaceutical,** tax, import / export, anti-corruption and exchange control laws; • the availability of government subsidies or other incentives that benefit competitors in their local markets that are not available to us; • increased demands on our limited resources created by our operations may constrain the capabilities of our administrative and operational resources and restrict our ability to attract, train, manage and retain qualified management, technicians, scientists and other personnel; • economic or political instability in foreign countries; • difficulties associated with staffing and managing foreign operations; and • the need to comply with a variety of United States and foreign laws applicable to the conduct of international business, including import and export control laws and anti-corruption laws. Concerns about inflation, energy costs, geopolitical issues, the United States mortgage market and a declining real estate market, unstable global credit markets and financial conditions, and volatile oil prices have led to periods of

significant economic instability, diminished liquidity and credit availability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth going forward, increased unemployment rates, and increased credit defaults in recent years. Our general business strategy may be adversely affected by any such economic downturns, volatile business environments and continued unstable or unpredictable economic and market conditions **. Recently, the closures of Silicon Valley Bank (" SVB ") and Signature Bank (" Signature ") and their placement into receivership with the Federal Deposit Insurance Corporation, and the government- brokered sale of the deposits and majority of assets of First Republic Bank to JPMorgan Chase, created bank- specific and broader financial institution liquidity risk and concerns. Although government intervention ensured that depositors at these banks have access to their funds, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market- wide liquidity shortages, impair the ability of companies to access near- term working capital needs, and create additional market and economic uncertainty. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur, and we cannot predict the impact or follow- on effects of these insolvencies more broadly or on our business in particular. Further, we cannot guarantee that the government will intervene to provide depositors with access to funds if similar events occur in the future. If other banks and financial institutions enter receivership or become insolvent in the future, our ability to access our existing cash, cash equivalents, and investments may be threatened, which could have a material adverse effect on our business and financial condition** . In addition, if the market and economic conditions described above continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and stock price. Additionally, rising rates of inflation have increased the costs associated with conducting our business, including by causing substantial increases in the costs of materials, including raw materials and consumables, equipment, services, and labor. Moreover, given the unpredictable nature of the current economic climate, including future changes in rates of inflation, it may be increasingly difficult for us to predict and control our future expenses, which may harm our ability to conduct our business. Business interruptions resulting from disasters or other disturbances could delay us in the process of developing our products and could disrupt our sales. Our business continuity and disaster recovery plans may not adequately protect us from a serious disaster or other disturbance. Our headquarters and other facilities are located in the San Francisco Bay Area, which in the past has experienced both severe earthquakes and wildfires. Earthquakes, wildfires or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. We are also vulnerable to other types of disasters and other events that could disrupt our operations, such as riot, civil disturbances, war, terrorist acts, **public health emergencies, domestic or foreign conflicts,** infections in our laboratory or production facilities or those of our customers or contract manufacturers and other events beyond our control. If a natural disaster or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event ~~. We~~ **, and we** may incur substantial expenses as a result of the limited nature of **such** ~~our disaster recovery and business continuity~~ plans. We do not carry insurance for earthquakes and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our cash flows and success as an overall business. We are dependent on information technology systems, infrastructure and data, and any failure of these systems could harm our business. Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations and financial condition. Information technology helps us operate efficiently, interface with customers, maintain financial accuracy and efficiency and accurately produce our financial statements. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology infrastructure, we could be subject to transaction errors, processing inefficiencies, the loss of customers, business disruptions or the loss of or damage to intellectual property through security breach. If our information technology systems do not effectively collect, store, process and report relevant data for the operation of our business, whether due to equipment malfunction or constraints, software deficiencies, or human error, our ability to effectively plan, forecast and execute our business plan and comply with applicable laws and regulations will be impaired, perhaps materially. Our information technology systems and those of our external vendors, strategic partners and other contractors or consultants are vulnerable to attack and damage or interruption from computer viruses and malware (e. g. ransomware), malicious code, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation- state and nation- state- supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. Any such impairment could materially and adversely affect our financial condition, results of operations, cash flows and the timeliness with which we report our internal and external operating results. Our business may require us to use and store personal information of our customers, employees, and business partners. This may include names, addresses, phone numbers, email addresses, contact preferences, tax identification numbers and payment account information. We require usernames and passwords in order to access our information technology systems. We also use encryption and authentication technologies to secure the transmission and storage of data. However, these security measures may be compromised as a result of security breaches by unauthorized persons, employee error, malfeasance, faulty password management or other irregularity, and result in persons obtaining unauthorized access to our data or accounts. Third

parties may attempt to fraudulently induce employees or customers into disclosing usernames, passwords or other sensitive information, which may in turn be used to access our information technology systems. For example, our employees have received " phishing " emails and phone calls attempting to induce them to divulge passwords and other sensitive information. In addition, unauthorized persons may attempt to hack into our products or systems to obtain personal data relating to employees and other individuals, our confidential or proprietary information or confidential information we hold on behalf of third parties. We also rely on external vendors to supply and / or support certain aspects of our information technology systems. The systems of these external vendors may contain defects in design or manufacture or other problems that could unexpectedly compromise information security of our own systems, and we are dependent on these third parties to deploy appropriate security programs to protect their systems. If we or our third- party vendors were to experience a significant cybersecurity breach of our or their information systems or data, the costs associated with the investigation, remediation and potential notification of the breach to **counterparties** ~~counter- parties~~ and data subjects could be material. Our remediation efforts may not be successful. Further, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss, corruption or unauthorized disclosure of our trade secrets, personal information or other proprietary or sensitive information or other similar disruptions. Attacks upon information technology systems are also 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. As a result of the **remote work policies we initiated in response to the** COVID- 19 pandemic **, and our continued hybrid working environment** , 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. We have programs in place to detect, contain and respond to data security incidents, and we make ongoing improvements to our information- sharing products in order to minimize vulnerabilities, in accordance with industry and regulatory standards. However, because the techniques used to obtain unauthorized access to or sabotage systems change frequently and may be difficult to detect, we may not be able to anticipate and prevent these intrusions or mitigate them when and if they occur. Even if identified, we may be unable to adequately **and timely** investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection and to remove or obfuscate forensic evidence. We and certain of our external vendors 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, it could result in the unauthorized access to or unauthorized use, disclosure, release or other processing of personal information, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media and other parties pursuant to privacy and security laws. Any security compromise affecting us, our service providers, vendors, strategic partners, other contractors, consultants or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures and lead to regulatory scrutiny. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary or personal information, we could incur liability, including litigation exposure, penalties and fines, **which may not be covered by insurance or may be in excess of our insurance coverage. Additionally,** we could become the subject of regulatory action or investigation, our competitive position could be harmed and the further development of our products could be delayed. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our business ~~. Furthermore, federal, state~~ and ~~international laws and regulations can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties, fines and significant legal liability, if our information technology security efforts fail. We may also be exposed to a risk of loss or litigation and potential liability, which~~ could materially and **adversely affect our business, results of operations and financial condition. Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could** adversely affect our business, results of operations and financial condition. The global data protection landscape is rapidly evolving, and we are or may become subject to state, federal and foreign laws, regulations, decisions and directives governing the privacy, security, collection, storage, transmission, use, processing, retention and disclosure of personal information. Any failure or perceived failure by us to comply with applicable laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business. In the United States, HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of **certain** individually identifiable health information. Certain states have also adopted ~~comparable~~ **and continue to adopt new** privacy and security laws and regulations, which govern the privacy, processing and protection of health- related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act (" CCPA ") went into effect on January 1, 2020 ~~, and introduces new compliance burdens on organizations doing business in California that collect personal information about California residents~~ . ~~It~~ **The CCPA** creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA also provides for civil penalties for violations, as well as a private right of action for data breaches **(which has** ~~that is expected to increase~~ **increased the likelihood of, and risks associated with,** data breach litigation **)** . Further, the California ~~Consumer~~ Privacy **Rights** Act (" ~~CCPA~~ **CPRA** ") **significantly amended the** ~~recently passed in California. The CPRA~~ **CCPA** ~~will~~ **, which went into effect in January 2023. It** ~~impose~~ **imposes** additional data ~~protection~~ **privacy** obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data and opt outs for certain uses of sensitive data. It ~~will~~ also ~~create~~ **created** a new California ~~data~~ **privacy** protection agency authorized to issue substantive

regulations and could result in increased privacy and information security enforcement. ~~The majority of the provisions went into effect on January 1, 2023, and additional~~ **Additional** compliance investment and potential business process changes may **also** be required. Similar laws **regulating personal information generally or health information in particular** have passed in **more than a dozen states** ~~Virginia, Colorado, Connecticut and Utah~~ and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. These developments increase our compliance burden and our risk, including risks of regulatory fines, litigation and associated reputational harm. Any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. Furthermore, the Federal Trade Commission (" FTC ") and many state Attorneys General continue to enforce federal and state consumer protection laws against companies for ~~online~~ **the** collection, use, ~~dissemination~~ **sharing** and security ~~practices~~ **of personal information** that appear to be unfair or deceptive. For example, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5 (a) of the Federal Trade Commission Act. The FTC expects a company' s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. In **the** ~~Europe~~ **European Union (" EU ")**, the **EU** General Data Protection Regulation (" **EU** GDPR ") ~~went into effect in May~~ **governs the processing of personal data. The UK has implemented the EU GDPR as the UK GDPR which sits alongside the UK Data Protection Act** 2018 **(the " UK GDPR ",** and **together with the EU GDPR, the " GDPR "). The GDPR** imposes ~~strict~~ requirements for **controllers, including (among others) specific requirements for obtaining valid consent where consent is the legal basis for** processing **, requirements around accountability and transparency,** the **obligation to consider data protection when any new products or services are developed, the obligation to comply with individuals' data protection rights, and the obligation to notify relevant data supervisory authorities of notifiable** personal data **breaches without undue delay (and no later than 72 hours) after becoming aware** of **the personal data breach (and affected data subjects where the personal data breach is likely to result in a high risk to their rights and freedoms). The EU GDPR provides that EU member states may enact their own additional national laws and regulations regarding the processing of genetic, biometric or health data, which could affect our ability to use and share personal data or could cause our costs to increase and potentially harm our business and financial condition. Failure to comply with the requirements of the GDPR can result in (among other things) fines of up to the greater of € 20 million (under the EU GDPR) or £ 17. 5 million (under the UK GDPR) or 4 % of an organization' s total worldwide annual turnover of the preceding financial year and other administrative penalties. To the extent that we are subject to the GDPR, compliance with the GDPR may require substantial amendments to our procedures and policies and these changes could adversely impact our business by increasing operational and compliance costs or impact business practices. Further, there is a risk that the amended policies and procedures will not be implemented correctly or that** individuals within **the business will not be fully compliant with the new procedures. There is a risk that we could be impacted by a cybersecurity incident that results in loss or unauthorized disclosure of personal data, potentially resulting in us facing harms similar to those described above. Among other requirements, the EU GDPR prohibits the international transfer of personal data subject to the GDPR from** the European Economic Area (" EEA ") ~~. The GDPR imposes stringent requirements for controllers and processors of personal data and increases our obligations, for example, by imposing higher standards when obtaining consent from individuals to process their personal data, requiring more robust disclosures to individuals, strengthening individual data rights, shortening timelines for data breach notifications, limiting retention periods and secondary use of information, increasing requirements pertaining to health data as well as pseudonymized (i. e., key- coded) data and imposing additional obligations when we contract with third- party processors in connection with the processing of personal data. The GDPR provides that EEA member states may make their own additional laws and regulations limiting the processing of genetic, biometric or health data, which could limit our ability to use and share personal data or could cause our costs to increase and harm our business and financial condition. Failure to comply with the requirements of the GDPR can result in fines of up to the greater of € 20 million and 4 % of the total worldwide annual turnover of the preceding financial year and other administrative penalties. If we are required to comply with the new data protection rules imposed by GDPR, such compliance may be onerous and adversely affect our business, financial condition, and results of operations. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR~~ to third countries that ~~have~~ **the European Commission does** not **recognize as having an ' adequate' level of data protection, unless a data transfer mechanism has** been **put in place or a derogation under** ~~found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between~~ the EU **GDPR can be relied on** ~~and the United States remains uncertain~~ . **In** ~~For example, in~~ July 2020, the Court of Justice of the EU ~~(" CJEU ")~~ **in its Schrems II judgement** limited how organizations could lawfully transfer personal data from the ~~EU /~~EEA to the United States by invalidating the **EU- U. S.** Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses (" **EU** SCCs ") **, including a requirement for companies to carry out a transfer privacy impact assessment (" TIA ")** . ~~In March~~ **A TIA, among other things, assesses laws governing access to personal data in the recipient country and considers whether supplementary measures that provide privacy protections additional to those provided under the EU SCCs will need to be implemented to ensure an ' essentially equivalent' level of data protection to that afforded in the EEA. On October 7,** 2022, ~~the United States~~ **U. S. President Biden introduced** ~~and~~ - **an** ~~EU announced~~ **Executive Order to facilitate** a new **Trans** ~~regulatory regime intended to replace the invalidated regulations; however, this new EU~~ - ~~US~~ **Atlantic** Data Privacy Framework ~~has not been implemented beyond~~ **(" DPF ")** ~~an~~ **and in July** ~~executive order signed by President Biden on October 7, 2022~~ **2023** ~~on Enhancing Safeguards for~~ **, the European Commission adopted its Final Implementing Decision granting the** United States **adequacy (" Adequacy Decision ")** ~~Signals Intelligence Activities. The European Commission issued revised SCCs on June 4, 2021 to account~~ for **EU- U** ~~the~~

~~decision of the CJEU and recommendations made by the European Data Protection Board~~ . **S.** ~~The revised SCCs must be used for relevant new data~~ transfers ~~from September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. The new SCCs apply only to the transfer~~ of personal data ~~outside of~~ **for entities self- certified to the DPF. Entities relying on EU SCCs for transfers to the United States are also able to rely on the analysis in the Adequacy Decision as support for** ~~the~~ **their** ~~EEA~~ **TIA regarding the equivalence of U. S. national security safeguards** and **redress. The UK GDPR also imposes similar restrictions on transfers of personal data from the UK to jurisdictions that the UK Government does** not **consider adequate, including** the United ~~Kingdom;~~ **States. The UK Government has published its own form of** the ~~United Kingdom' s~~ **EU SCCs, known as the International Data Transfer Agreement and an International Data Transfer Addendum to the new EU SCCs. The UK** Information Commissioner' s Office **has also published** ~~launched a public consultation on~~ its **own version** ~~draft revised data transfers mechanisms in August 2021. There is some uncertainty around whether the revised clauses can be used for all types~~ of ~~data transfers, particularly whether they~~ **the TIA and** ~~can be relied on for data transfers to non- EEA entities subject to the GDPR. As supervisory authorities issue further~~ guidance on ~~personal~~ **international transfers, although entities may choose to adopt either the EU or UK- style TIA. Further, on September 21, 2023, the UK Secretary of State for Science, Innovation and Technology established a UK- U. S.** data ~~export mechanisms~~ **bridge (i. e.** , ~~including circumstances where~~ **a UK equivalent of** the **Adequacy Decision)** ~~SCCs cannot be used,~~ and **adopted UK** ~~/ or start taking enforcement action, we could suffer additional costs, complaints and / or regulatory~~ **regulations** ~~investigations or fines, and / or if we are otherwise unable~~ to ~~transfer personal~~ **implement the UK- U. S.** data **bridge** ~~between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results. Further, from January 1, 2021, companies have had to comply with the GDPR and also the United Kingdom GDPR~~ (" UK ~~GDPR~~ **Adequacy Regulations** ") ~~, which, together with~~ **. Personal data may now be transferred from** the ~~amended~~ UK **under** ~~Data Protection Act 2018, retains~~ the ~~GDPR in~~ UK ~~national law~~ **- U** . ~~The~~ **S. data bridge through the** UK ~~GDPR mirrors~~ **extension to** the ~~fines~~ **DPF to organizations self- certified** under the ~~GDPR, i. e., fines up to the greater of € 20 million (or up to £ 17. 5 million for~~ UK **extension to DPF** ~~) or 4 % of global turnover~~ . ~~The relationship between~~ **As we continue to expand into** ~~the~~ **other** ~~United Kingdom~~ **foreign countries** and ~~the EU in relation~~ **jurisdictions, we may be subject** to **additional** ~~certain aspects of data protection law~~ **laws** ~~remains unclear,~~ and ~~it is unclear~~ **regulations that may affect** how **we conduct business** ~~United Kingdom data protection laws and regulations will develop in the medium to longer term. The European Commission has adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re- assesses and renews or extends that decision. In September 2021, the United Kingdom government launched a consultation on its proposals for wide- ranging reform of United Kingdom data protection laws following Brexit and the response to this consultation was published in June 2022. There is a risk that any material changes which are made to the United Kingdom data protection regime could result in the European Commission reviewing the United Kingdom adequacy decision, and the UK United Kingdom losing its adequacy decision if the European Commission deems the United Kingdom to no longer provide adequate protection for personal data~~ . Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Various federal, state and foreign legislative or regulatory bodies may enact new or additional laws and regulations concerning privacy, data- retention and data- protection issues, including laws or regulations mandating disclosure to domestic or international law enforcement bodies, which could adversely impact our business or our reputation with customers. For example, some countries have adopted laws mandating that certain personal information regarding customers in their country be maintained solely in their country. Having to maintain local data centers and redesign product, service and business operations to limit processing of personal information to within individual countries could increase our operating costs significantly. Any failure, or perceived failure, by us to comply with federal, state or international privacy, data- retention or data- protection- related laws, regulations, orders or industry self- regulatory principles could result in proceedings or actions against us by governmental entities or others, a loss of customer confidence, damage to our brand and reputation and a loss of customers, any of which could have an adverse effect on our business. Evolving expectations around corporate responsibility practices, specifically related to environmental, social and governance (" ESG ") matters, may expose us to reputational and other risks. Investors, stockholders, customers, suppliers and other third parties are increasingly focusing on ESG and corporate social responsibility endeavors and reporting. Companies that do not adapt to or comply with the evolving investor or stakeholder expectations and standards, or ~~which~~ **that** are perceived to have not responded appropriately, may suffer from reputational damage ~~and~~ **, which could** result in the business, financial condition and / or stock price of a company being materially and adversely affected **. For example, certain customers have inquired about our ESG practices and may impose ESG guidelines, procurement policies, sustainability standards, mandates or reporting requirements for, and may scrutinize relationships more closely with, their suppliers, including us, which may lengthen sales cycles, increase our costs or impair our ability to attract and retain customers** . Further, this increased focus on ESG issues may result in new regulations **, international accords** and / or third- party requirements that could adversely impact our business, or certain shareholders reducing or eliminating their holdings of our stock. **An** ~~Additionally, an~~ allegation or perception that we have not taken sufficient action in these areas could negatively harm our reputation. ~~59~~ **Additionally, the subjective nature and wide variety of methods and processes used by various stakeholders, including investors, to assess environmental, social, and governance criteria could result in a negative perception or misrepresentation of the company' s sustainability policies and practices. 43**