Risk Factors Comparison 2025-02-05 to 2024-02-05 Form: 10-K

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We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and / or in the future could affect, our business, prospects, operating results, and financial condition. The risks described below include forward- looking statements, and actual events and our actual results may differ materially from these forward- looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business, prospects, operating results, and financial condition. Furthermore, additional risks and uncertainties are described under other captions in this report and should also be considered by our investors. For purposes of this section (as well as this report in general), references to our products encompass products marketed or otherwise commercialized by us and / or our collaborators or licensees; and references to our product candidates encompass product candidates in development by us and / or our collaborators or licensees (in the case of collaborated or licensed products or product candidates under the terms of the applicable collaboration or license agreements), unless otherwise stated or required by the context. In this section, we first provide a summary of the more significant risks and uncertainties we face and then provide a full set of risk factors and discuss them in greater detail. Summary of Risk Factors As noted above, we are subject to a number of risks that if realized could materially harm our business, prospects, operating results, and financial condition. Some of the more significant risks and uncertainties we face include those summarized below. The summary below is not exhaustive and is qualified by reference to the full set of risk factors set forth in this" Risk Factors" section. Please carefully consider all of the information in this Form 10- K, including the full set of risks set forth in this" Risk Factors" section, and in our other filings with the SEC before making an investment decision regarding Regeneron. Commercialization Risks • We are substantially dependent on the success of EYLEA, EYLEA HD, and Dupixent. • Sales of our products are dependent on the availability and extent of coverage and reimbursement from third- party payors, including private payors and government programs such as Medicare and Medicaid. • Product reimbursement and coverage policies and practices could change due to various factors such as drug price control measures that have been or may be enacted or introduced in the United States by various federal and state authorities. • The commercial success of our products is subject to significant competition from products or product candidates that may be superior to, or more established or cost effective than, our products or product candidates. • We and our collaborators on which we rely to commercialize some of our marketed products may be unable to continue to successfully commercialize or co- commercialize our products, both in and outside the United States. Regulatory and Development Risks • Drug development and obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain. • Serious complications or side effects in connection with the use or development of our products or product candidates could cause our regulatory approvals to be revoked or limited or lead to delay or discontinuation of development of our product candidates or new indications for our marketed products. • We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use, which would delay or prevent continued development of such candidates and / or receipt of regulatory approval or commercial sale. • Many of our products are intended to be used in combination with drug- delivery devices, which may result in additional regulatory, commercialization, and other risks. Intellectual Property and Market Exclusivity Risks • We may not be able to protect the confidentiality of our trade secrets, and our patents or other means of defending our intellectual property may be insufficient to protect our proprietary rights. • Patents or proprietary rights of others may restrict our development, manufacturing, and / or commercialization efforts and subject us to patent litigation and other proceedings that could find us liable for damages. • Loss or limitation of patent rights, and regulatory pathways for biosimilar competition, **have in the past reduced and** could reduce **in the future** the duration of market exclusivity for our products ~~, including EYLEA and EYLEA HD~~ . Manufacturing and Supply Risks • We rely on limited internal and contracted manufacturing and supply chain capacity, which could adversely affect our ability to commercialize our products and to advance our clinical pipeline. As we increase our production in response to higher product demand or in anticipation of a potential regulatory approval, our current manufacturing capacity will likely not be sufficient, and our dependence on our collaborators and / or contract manufacturers may increase, to produce adequate quantities of drug material for both commercial and clinical purposes. • Expanding our manufacturing capacity and establishing fill / finish capabilities **has been and** will **continue to** be costly and we may be unsuccessful in doing so in a timely manner, which could delay or prevent the launch and successful commercialization of our products approved for marketing and could jeopardize our clinical development programs. • Our ability to manufacture products may be impaired if any of our or our collaborators' manufacturing activities, or the activities of other third parties involved in our manufacture and supply chain, are found to infringe patents of others. • If sales of our marketed products do not meet the levels currently expected, or if the launch of any of our product candidates is delayed or unsuccessful, we may face costs related to excess inventory or unused capacity at our manufacturing facilities and at the facilities of third parties or our collaborators. • Third- party service or supply failures, failures at our manufacturing facilities in Rensselaer, New York and Limerick, Ireland, or failures at the facilities of any other party participating in the supply chain would adversely affect our ability to supply our products. • Our or our collaborators' failure to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates could result in incurring substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and / or in their commercial launch if regulatory approval is obtained, and a reduction in sales. Other Regulatory and Litigation Risks • If the testing or use of our products harms people, or is perceived to harm them even when such harm is unrelated to our products, we could be subject to costly and damaging product liability claims. • Our business

activities have been, and may in the future be, challenged under U. S. federal or state and foreign healthcare laws, which may subject us to civil or criminal proceedings, investigations, or penalties. • If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions, and fines. • We face risks from the improper conduct of our employees, agents, contractors, or collaborators, including those relating to potential non- compliance with relevant laws and regulations such as the Foreign Corrupt Practices Act and the U. K. Bribery Act. • Our operations are subject to environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. • Changes in laws ~~and ,~~ regulations **, and policies** affecting the healthcare industry could adversely affect our business. • Tax liabilities and risks associated with our operations outside the United States could adversely affect our business. • We face risks related to the personal data we collect, process, and share. Risks Related to Our Reliance on or Transactions with Third Parties • If our collaborations with Sanofi or Bayer or other third parties are terminated or breached, our ability to develop, manufacture, and commercialize certain of our products and product candidates in the time expected, or at all, may be materially harmed. • Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates and current and future products. • We have undertaken and may in the future undertake strategic acquisitions, and any difficulties from integrating such acquisitions or failure to realize the expected benefits from such acquisitions could adversely affect our business, operating results, and financial condition. Other Risks Related to Our Business and Our Common Stock • Our business is dependent on our key personnel and will be harmed if we cannot recruit and retain key members of our senior management team, including leaders in our research, development, manufacturing, and commercial organizations. • Significant disruptions of information technology systems or breaches of data security could adversely affect our business. • Public health outbreaks, epidemics, or pandemics (such as the COVID- 19 pandemic) have adversely affected and may in the future adversely affect our business. • Our indebtedness could adversely impact our business. • Our stock price is extremely volatile. • Our existing shareholders may be able to exert substantial influence over matters requiring shareholder approval and over our management. * * * Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products We are substantially dependent on the success of ~~our ophthalmology portfolio, which consists of~~ EYLEA and, since its August 2023 FDA approval, EYLEA HD. EYLEA net product sales have historically represented a substantial portion of our revenues, and we expect that there will continue to be a concentration of our net sales from the net product sales of EYLEA HD and EYLEA. For the years ended December 31, **2024 and** 2023 ~~and 2022~~ , our aggregate EYLEA HD and EYLEA net product sales in the United States represented **42 % and** 45 ~~% and 51~~ % of our total revenues, respectively. For the year ended December 31, ~~2023~~ **2024** , **EYLEA HD U. S. net product sales represented 20 % of our** aggregate EYLEA HD ~~U. S.~~ and EYLEA U. S. net product sales ~~decreased by 6 %, compared to the same period in 2022~~ . If we are successful in commercializing EYLEA HD, we expect that our dependence on EYLEA HD will grow relative to our historical dependence on EYLEA. If we ~~were to~~ experience difficulty with the commercialization of EYLEA HD or EYLEA in the United States or if Bayer ~~were to experience~~ **experiences** any difficulty with the commercialization of EYLEA HD or EYLEA outside the United States, if EYLEA net product sales experience a sustained decline in or outside the United States without an offset from EYLEA HD net product sales, or if we and Bayer are unable to maintain or obtain marketing approvals of these products (as applicable), we may experience a reduction in revenue and may not be able to stay profitable at the levels we previously achieved or at all, and our business, prospects, operating results, and financial condition may be materially harmed. ~~In~~ **Commercialization of EYLEA and EYLEA HD in** the United States **and elsewhere is subject to significant competition (as described further below under" The commercial success of our products and product candidates is subject to significant competition")** , **which we expect to continue to increase in** the **future. For the year ended December 31, 2024, EYLEA U. S. net product sales declined by 17 % compared to the same period in 2023. Following the expiration of the U. S.** regulatory exclusivity period for EYLEA (i. e., the period during which no biosimilar product can be approved by the FDA) **in** ~~will expire after~~ May ~~17,~~ 2024 ~~. See" Risks Related to Intellectual Property and Market Exclusivity- Loss or limitation of patent rights~~ , **several** ~~and regulatory pathways for~~ biosimilar **versions** ~~competition, could reduce the duration~~ of ~~market exclusivity for our products" below. As a result, we face the risk of lower~~ EYLEA **have been approved by the FDA, and one such product has launched in the United States. EYLEA and / or EYLEA HD** net product sales ~~due~~ **recorded by us are likely** to **be negatively impacted by** biosimilar competition ~~following such expiration~~ **in the United States** , which may have a material adverse impact on our results of operations. **In addition, we expect that competition for EYLEA outside the United States will increase in the future when biosimilar versions of EYLEA (including those already approved but not yet launched) are brought to market in additional countries, which may negatively impact the amount of collaboration revenue we earn from Bayer. While we anticipate several important 2025 milestones relevant to further commercialization of EYLEA HD as shown in the table under Part I, Item 1." Business- Programs in Clinical Development," there can be no assurance that any such milestones will be achieved or, if achieved, that they will enable us and Bayer to accelerate the ongoing launch and further commercialization of EYLEA HD.** The degree to which EYLEA HD net product sales may offset ~~any~~ **further** potential decrease in EYLEA net product sales, resulting from the factors discussed above or otherwise, is uncertain. **We also** ~~In addition, we~~ are substantially dependent on our share of profits from the commercialization of Dupixent under our Antibody Collaboration with Sanofi **. For the years ended December 31, 2024 and 2023, Sanofi collaboration revenue (most of which is attributable to our share of profits from the commercialization of Dupixent) represented 32 % and 29 % of our total revenues, respectively** . If we or Sanofi were to experience any difficulty with the commercialization of Dupixent or if we or Sanofi are unable to maintain current marketing approvals of Dupixent, we may experience a reduction in revenue and our business, prospects, operating results, and financial condition may be materially harmed. If we or our collaborators are unable to continue to successfully commercialize our products, our business, prospects, operating results, and financial condition will be materially harmed. We expect that the degree of commercial success of our

marketed products will continue to depend on many factors, including the following (as applicable): • effectiveness of the commercial strategy in and outside the United States for the marketing of our products, including pricing strategy; • sufficient coverage of, and reimbursement for, our marketed products by third- party payors, including Medicare and Medicaid in the United States and other government and private payors in the United States and foreign jurisdictions, as well as U. S. and foreign payor restrictions on eligible patient populations and the reimbursement process (including drug price control measures that have been or may be enacted or introduced in the United States by various federal and state authorities); • our ability and our collaborators' ability to maintain sales of our marketed products in the face of competitive products and to differentiate our marketed products from competitive products, including as applicable product candidates currently in clinical development; and, in the case of EYLEA and EYLEA HD, the existing and potential new branded and biosimilar competition (discussed further under" The commercial success of our products and product candidates is subject to significant competition- Marketed Products" below) and the willingness of retinal specialists and patients to start or continue treatment with such products or to switch from a competitive product to one of our products; • the safety and efficacy of our marketed products (particularly those launched recently, such as EYLEA HD) seen in a broader patient group (i. e., real- world use); • the effect of existing and new ~~health~~ **healthcare** ~~care~~ laws and regulations currently being considered or implemented in the United States and globally, including measures requiring the U. S. government in the future to negotiate the prices of certain drugs and price reporting and other disclosure requirements and the potential impact of such requirements on physician prescribing practices and payor coverage; • serious complications or side effects in connection with the use of our marketed products, as discussed under" Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products- Serious complications or side effects in connection with the use of our products and in clinical trials for our product candidates and new indications for our marketed products could cause our regulatory approvals to be revoked or limited or lead to delay or discontinuation of development of our product candidates or new indications for our marketed products, which could severely harm our business, prospects, operating results, and financial condition" below; • maintaining and successfully monitoring commercial manufacturing arrangements for our marketed products with third parties who perform fill / finish or other steps in the manufacture of such products to ensure that they meet our standards and those of regulatory authorities, including the FDA, which extensively regulate and monitor pharmaceutical manufacturing facilities; • our ability to meet the demand for commercial supplies of our marketed products; • the outcome of the pending proceedings relating to EYLEA ~~and REGEN- COV~~ (described further in Note 16 to our Consolidated Financial Statements included in this report), as well as other risks relating to our marketed products and product candidates associated with intellectual property of other parties and pending or future litigation relating thereto (as discussed under" Risks Related to Intellectual Property and Market Exclusivity" below); • the outcome of the pending government proceedings and investigations and other matters described in Note 16 to our Consolidated Financial Statements included in this report (including the civil **proceedings initiated or joined by** ~~complaint filed against us on June 24, 2020 in~~ the U. S. **Department** ~~District Court for the District~~ of ~~Massachusetts by~~ **Justice and** the U. S. Attorney' s Office for the District of Massachusetts); and • the results of post-approval studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and studies of other products that could implicate an entire class of products or are perceived to do so. More detailed information about the risks related to the commercialization of our marketed products is provided in the risk factors below. We and our collaborators are subject to significant ongoing regulatory obligations and oversight with respect to the products we or our collaborators commercialize. If we or our collaborators fail to maintain regulatory compliance for any of such products, the applicable marketing approval may be withdrawn, which would materially harm our business, prospects, operating results, and financial condition. We and our collaborators are subject to significant ongoing regulatory obligations and oversight with respect to the products we or they commercialize for the products' currently approved indications in the United States, EU, Japan, and other countries ~~where such products are approved~~. If we or our collaborators fail to maintain regulatory compliance or satisfy other obligations for such products' currently approved indications (including because the product does not meet the relevant endpoints of any required post- approval studies (such as those required under an accelerated approval by the FDA or other similar type of approval), or for any of the reasons discussed below under" Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products- Obtaining and maintaining regulatory approval for drug products is costly, time- consuming, and highly uncertain. If we or our collaborators do not maintain regulatory approval for our marketed products, and obtain regulatory approval for our product candidates or new indications for our marketed products, we will not be able to market or sell them, which would materially and negatively impact our business, prospects, operating results, and financial condition."), the applicable marketing approval may be withdrawn, which would materially harm our business, prospects, operating results, and financial condition. Failure to comply may also subject us to sanctions, product recalls, or withdrawals of previously approved marketing applications. See also" Risks Related to Manufacturing and Supply- Our or our collaborators' failure to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates could result in incurring substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and / or in their commercial launch if regulatory approval is obtained, and a reduction in sales" below. Sales of our marketed products are dependent on the availability and extent of coverage and reimbursement from third- party payors. Sales of our marketed products in the United States are dependent, in large part, on the availability and extent of reimbursement from third- party payors, including private payor healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies (" PBMs"), and government programs such as Medicare and Medicaid. Sales of our marketed products in other countries are also dependent, in large part, on complex coverage and reimbursement mechanisms and programs in those countries. Our future revenues and profitability will be adversely affected in a material manner if such third- party payors do not adequately defray or reimburse the cost of our marketed products. If these entities do not provide

coverage and reimbursement with respect to our marketed products or provide an insufficient level of coverage and reimbursement, such products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third- party payors cover only selected drugs, or may prefer selected drugs, making drugs that are not covered or preferred by such payors more expensive for patients. Third- party payors may also require prior authorization for reimbursement, or require failure on another type of treatment before covering a particular drug, particularly with respect to higher- priced drugs. As our currently marketed products and most of our product candidates are biologics, bringing them to market may cost more than bringing traditional, small- molecule drugs to market due to the complexity associated with the research, development, production, supply, and regulatory review of such products. Given cost sensitivities in many ~~health~~ **healthcare** ~~care~~ systems, our currently marketed products and product candidates are likely to be subject to continued pricing pressures, which may have an adverse impact on our business, prospects, operating results, and financial condition. In addition, in order for private insurance and governmental payors (such as Medicare and Medicaid in the United States) to reimburse the cost of our marketed products, we must maintain, among other things, our FDA registration and our National Drug Code, formulary approval by PBMs, and recognition by insurance companies and CMS. There is no certainty that we will be able to obtain or maintain the applicable requirements for reimbursement (including relevant formulary coverage, as discussed further below) of our current and future marketed products, which may have a material adverse effect on our business. In addition, PBMs and other managed- care organizations often develop formularies to reduce their cost for medications. The breadth of the products covered by formularies varies considerably from one PBM to another. Failure to be included in such formularies or to achieve favorable formulary status may negatively impact the utilization and market share of our marketed products. If our marketed products are not included within an adequate number of formularies, adequate reimbursement levels are not provided, the eligible insured patient population for our products is limited, or a key payor refuses to provide reimbursement for our products in a particular jurisdiction altogether, this could have a material adverse effect on our and our collaborators' ability to commercialize the applicable product. In many countries outside the United States, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we and our collaborators may be unable to obtain coverage, pricing, and / or reimbursement on terms that are favorable to us or necessary for us or our collaborators to successfully commercialize our marketed products in those countries. In some of these countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country, and may take into account the clinical effectiveness, cost, and service impact of existing, new, and emerging drugs and treatments. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. **In addition, in many countries outside the United States, we or our collaborators must participate in a tender process for public procurement of our products, and any failure to obtain acceptable pricing in the tender process could adversely affect our business.** Our results of operations may suffer if we or our collaborators are unable to market our products in countries outside the United States or if coverage and reimbursement for our marketed products in such countries is limited or delayed. As discussed below under" If we are unable to establish **sufficient** commercial capabilities outside the United States for ~~Libtayo, Dupixent, and any other~~ products we intend to commercialize or co- commercialize outside the United States, our business, prospects, operating results, and financial condition may be adversely affected," we will need to manage these and other commercialization- related risks in order for us to successfully **maintain and / or further** develop **sufficient** commercial capabilities outside the United States (including those necessary for our successful commercialization and co- commercialization of Libtayo and Dupixent, respectively). Changes to product reimbursement and coverage policies and practices may materially harm our business, prospects, operating results, and financial condition. Government and other third- party payors (including PBMs) are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs, such as by requiring outcomes- based or other pay- for- performance pricing arrangements. They are also imposing restrictions on eligible patient populations and the reimbursement process, including by means of required prior authorizations and utilization management criteria, such as step therapy (i. e., requiring the use of less costly medications before more costly medications are approved for coverage). Private payor healthcare and insurance providers, health maintenance organizations, and PBMs are increasingly requiring significant discounts and rebates from manufacturers as a condition to including products on formulary with favorable coverage and copayment / coinsurance. **In addition, many payors continue to adopt benefit plan changes that shift a greater portion of prescription costs to patients, including more limited benefit plan designs, higher patient co- pay or co- insurance obligations, and limitations on patients' use of commercial manufacturer co- pay payment assistance programs (including through co- pay accumulator adjustment or maximization programs).** Some states have also enacted or are considering legislation to control the prices and reimbursement of prescription drugs, **including by establishing Prescription Drug Affordability Boards (or similar entities) to review high- cost drugs, setting upper payment limits,** and **/ or implementing marketing cost disclosure and transparency measures. Additionally,** state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any prescription drug for which supplemental rebates are not being paid. It is likely that federal and state legislatures and health agencies will continue to focus on additional ~~health~~ **healthcare** ~~care~~ reform measures in the future that will impose additional constraints on prices and reimbursements for our marketed products. Further, there have been several recent U. S. Congressional inquiries and recently approved or proposed federal and state legislation, regulations, and policies (in addition to those already in effect) designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the out- of- pocket cost of prescription drugs, and reform government program reimbursement methodologies

for drugs. Notably, in 2022 the U. S. Congress passed the **Inflation Reduction Act ("** IRA **")** , which includes, among other items, provisions regarding the following: • Implementation of a Medicare Drug Price Negotiation Program (the" Medicare Drug Price Negotiation Program"). The Medicare Drug Price Negotiation Program requires the government to set prices for select high- expenditure drugs covered under Medicare Parts B and D. Starting in 2023 and 2026, the government is authorized to select Part D and Part B drugs, respectively, for inclusion in the Medicare Drug Price Negotiation Program, with established prices to go into effect for selected Part D drugs in 2026 and for selected Part B drugs in 2028, in each case absent certain disqualifying events. • Medicare Inflation Based Rebates. The IRA includes measures requiring manufacturers to pay rebates where **increases to** the average sales price or average manufacturer price of drugs covered under Medicare Parts B and D, respectively, ~~exceeds~~ **exceed** the rate of inflation. • Medicare Part D Program Redesign. The IRA implements changes to the Medicare Part D benefits to limit patient out- of- pocket drug costs and shift program liabilities from patients to other stakeholders, including health plans, manufacturers, and the government. **The** ~~While enacted into law, it is currently unclear the~~ extent to which the policy changes **described above** will ultimately impact reimbursement levels of our marketed products, including those covered under Medicare Part B (such as EYLEA and EYLEA HD) **,** or our product candidates that may be covered under Medicare Part B or Medicare Part D in the future **, is currently unclear** . At the state level, legislatures are becoming increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and price and marketing cost disclosure and transparency measures. In some cases, these measures are designed to encourage importation from other countries and bulk purchasing. A reduction in the availability or extent of reimbursement from U. S. government programs (including as a result of the legislation, proposals, initiatives, and developments described above) could have a material adverse effect on the sales of EYLEA, EYLEA HD, or our other marketed products. Economic pressure on state budgets may also have a similar impact. The commercial success of our products and product candidates is subject to significant competition. ~~There is~~ **We face** substantial competition ~~in the~~ **from pharmaceutical and** biotechnology ~~and pharmaceutical industries from biotechnology, pharmaceutical, and chemical~~ companies. Many of our competitors have substantially greater research, preclinical and clinical product development **,** and manufacturing capabilities, as well as financial, marketing, and human resources, than we do. Our competitors, regardless of their size, may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with other pharmaceutical or biotechnology companies. There is significant actual and potential future competition for each of our marketed products. EYLEA and EYLEA HD. EYLEA and EYLEA HD face significant competition in the marketplace. For example, each of EYLEA and EYLEA HD competes in one or more of its approved indications with other VEGF inhibitors. These include Genentech / Roche' s Vabysmo ® (faricimab- svoa) and Susvimo ® (ranibizumab ocular implant); Novartis and Genentech / Roche' s Lucentis ® (ranibizumab); Novartis' Beovu ® (brolucizumab); **and** biosimilar versions of Lucentis commercialized in the United States by Biogen Inc. and ~~Coherus BioSciences,~~ **Sandoz Group AG.** ~~Inc.~~ **In** ~~,~~ **addition, biosimilar versions of EYLEA have been approved both in** and ~~Biocon Biologics Ltd~~ **outside the United States. These include Amgen** ' s **Pavblu ™ (aflibercept- ayyh), which recently launched in the United States. We expect that** biosimilar ~~version of~~ **competition for** EYLEA ~~recently approved~~ **will increase** in **the future when additional biosimilar versions of EYLEA are launched in the United States and** ~~the~~ **other** ~~EU~~ **countries, the timing of which will depend on, among other factors, the outcome of the pending patent litigation proceedings described in Note 16 to our Consolidated Financial Statements and the expiration of the patents protecting EYLEA (including those set forth under Part I- Item 1." Business- Patents, Trademarks, and Trade Secrets")** . Ophthalmologists are also using off- label, third- party repackaged versions of Genentech / Roche' s approved VEGF antagonist, bevacizumab, for the treatment of certain of EYLEA' s and EYLEA HD' s respective indications, and we are aware of another company developing an ophthalmic formulation of such product **that has been approved in the EU** . In DME (and, in the case of EYLEA, also RVO), EYLEA and EYLEA HD also compete with intravitreal implants of corticosteroids. We are also aware of a number of companies working on the development of product candidates and extended delivery devices for the potential treatment of one or more of EYLEA' s and EYLEA HD' s respective indications, including those that act by blocking VEGF and VEGF receptors (including therapies designed to extend the treatment interval) and / or other targets. In addition, we are aware of several other companies developing biosimilar versions of EYLEA **, EYLEA HD,** and **/ or** other approved anti- VEGF treatments. Other potentially competitive products in development include products for use in combination with EYLEA and / or other anti- VEGF treatments, small- molecule tyrosine kinase inhibitors, gene therapies, and other eye- drop formulations, devices, and oral therapies. There also is a risk that third parties repackage ZALTRAP for off-label use and sale for the treatment of diseases of the eye, even though ZALTRAP has not been manufactured and formulated for use in intravitreal injections. We are aware of claims by third parties, including those based on published clinical data, alleging that ZALTRAP may be safely administered to the eye. EYLEA HD was approved by the FDA in August 2023 for the treatment of wAMD, DME, and DR **and** ~~. As a newly approved product, EYLEA HD has~~ entered the highly competitive environment described above. Our success in commercializing EYLEA HD will depend on a number of factors, including the degree of success and relative timing of our commercial launch and uptake efforts as compared to those of relevant competition, the extent to which we and our collaborators are able to differentiate EYLEA HD from competitive products **(such as on the basis of dosing frequency, the method of administration, or the breadth of indications in which the product is approved)** , the safety and efficacy of EYLEA HD seen in a broader patient group (i. e., real- world use), the extent of payor coverage and reimbursement, and the applicability of any restrictions imposed by payors, such as step therapy. Dupixent. The market for Dupixent' s current and potential future indications is also increasingly competitive. In atopic dermatitis, there are ~~topical and~~ systemic JAK inhibitors and antibodies against IL- 13 **and IL- 4Ra approved or in development for atopic dermatitis. There is also an antibody against IL- 31R** approved for atopic dermatitis **and prurigo nodularis** . In addition, a number of companies are developing antibodies against **other targets** ~~IL- 4Ra~~ , **including** ~~IL- 13Ra1,~~ OX40 (L), ~~and / or IL- 31R~~ that may

compete with Dupixent in atopic dermatitis and other indications (including asthma and / or prurigo nodularis) ~~, as applicable~~. In asthma, competitors to Dupixent include antibodies against the IL- 5 ligand or the IL- 5 receptor, immunoglobulin E, or thymic stromal lymphopoietin (" TSLP"); and some of these antibodies are either approved or in development for indications that also compete or may compete in the future with Dupixent in CRSwNP ~~and ,~~ EoE **, and COPD** . There are several other potentially competitive products in development that may compete with Dupixent in asthma, ~~as well as~~ **COPD, and** potential future indications, including antibodies against the IL- 33 ligand **or receptor** . Dupixent also faces competition from inhaled products in asthma **, COPD,** and potential future indications. Libtayo. Libtayo also faces significant competition. There are several competitors that are marketing and / or developing antibodies against PD- 1 and / or PDL- 1 (some of which were approved in the relevant indications and commercialized before Libtayo), including Merck' s Keytruda ® (pembrolizumab), Bristol- Myers Squibb' s Opdivo ® (nivolumab), Roche' s Tecentriq ® (atezolizumab), ~~and~~ AstraZeneca' s Imfinzi ® (durvalumab) **, and Checkpoint Therapeutics' UnloxcytTM (cosibelimab). While Libtayo is currently approved for intravenous administration only, certain of these products are also approved or in development for subcutaneous use** . Other marketed products. There is also significant actual and potential future competition for other products marketed or otherwise commercialized by us and / or our collaborators under our collaboration agreements with them. For example, there are several companies that are marketing and / or developing antibodies or other molecules (such as small interfering RNA molecules, or siRNAs) against PCSK9, ANGPTL3 and IL- 6 and / or IL- 6R, which currently (or, for product candidates in development, may in the future if approved) ~~compete with~~ **treat the same conditions as** Praluent, Evkeeza, and Kevzara, respectively. Our VelocImmune ® technology, other antibody generation technologies, and late- stage and earlier- stage clinical candidates face competition from many pharmaceutical and biotechnology companies using various technologies, including antibody generation technologies and other approaches such as RNAi, chimeric antigen receptor T cell (CAR- T cell), and gene therapy technologies. For example, we are aware of other pharmaceutical and biotechnology companies actively engaged in the research and development of antibody- based products against targets that are also the targets of our early- and late- stage product candidates. We are also aware of other companies developing or marketing small molecules or other treatments that may compete with our antibody- based product candidates in various indications, if such product candidates obtain regulatory approval in those indications. If any of these or other competitors announces a successful clinical study involving a product that may be competitive with one of our product candidates or the grant of marketing approval by a regulatory agency for a competitive product, such developments may have an adverse effect on our business or future prospects. In addition, the first product to reach the market in a therapeutic area is often at a significant competitive advantage relative to later entrants to the market. Accordingly, the relative speed with which we, or our collaborators, can develop our product candidates, complete the clinical trials and approval processes, and, if such product candidates are approved for marketing and sale, supply commercial quantities to the market is expected to continue to be an important competitive factor. Due to the uncertainties associated with developing biopharmaceutical products, we may not be the first to obtain marketing approval for a product against any particular target, which may have a material adverse effect on our business or future prospects. **While we evaluate market opportunities for our product candidates, there can be no assurance that our estimates will accurately reflect the market opportunity at the time of launch or that our product candidates will meet internal or external expectations and be successful commercially due to existing or potential future competition or otherwise.** We rely on our collaborations with Bayer and Sanofi for commercializing some of our marketed products. While we have established our own sales and marketing organization for EYLEA HD and EYLEA in the United States for its currently approved indications, we have no sales, marketing, commercial, or distribution capabilities for EYLEA HD or EYLEA outside the United States. Under the terms of our license and collaboration agreement with Bayer (which is terminable by Bayer at any time upon six or twelve months' advance notice, depending on the circumstances giving rise to termination), we rely on Bayer (and, in Japan, Santen pursuant to a Co- Promotion and Distribution Agreement with Bayer' s Japanese affiliate) for sales, marketing, and distribution of EYLEA HD and EYLEA outside the United States. In addition, under the terms of our Antibody Collaboration, we and Sanofi co- commercialize Dupixent in the United States and, as further discussed below, certain jurisdictions outside the United States. As a result, we rely in part on Sanofi' s sales and marketing organization for Dupixent. If we and Sanofi fail to coordinate our sales and marketing efforts effectively, sales of Dupixent may be materially **adversely** affected. Sanofi also maintains other important responsibilities relating to Dupixent. For example, Sanofi records product sales for Dupixent in the United States and leads negotiations with payors relating to this product. We also rely on Sanofi for sales, marketing, and distribution of Dupixent in many countries outside the United States. While we exercised our option under the Antibody Collaboration to co- commercialize Dupixent in certain jurisdictions outside the United States, we will continue to rely in considerable part on Sanofi' s sales and marketing organization in such jurisdictions. **As described in Note 16 to our Consolidated Financial Statements, we have sued Sanofi and certain of its affiliated entities (the" Antibody Collaboration Litigation") alleging that the defendants breached certain provisions of the agreement governing the Antibody Collaboration (the" Collaboration Agreement"). These provisions concern Sanofi' s obligation to provide Regeneron with full access to material information relating to the commercialization of Dupixent or other products commercialized pursuant to the Collaboration Agreement and Regeneron' s audit rights under the Collaboration Agreement. It is not possible to determine what impact (if any) the Antibody Collaboration Litigation may have on the Antibody Collaboration and our business relationship with Sanofi, or whether we will be successful in the Antibody Collaboration Litigation.** If we and our collaborators are unsuccessful in continuing to commercialize the marketed products subject to such collaborations, or if Bayer or Sanofi terminate their respective collaborations with us, our business, prospects, operating results, and financial condition would be materially impaired. While we have some commercial presence outside the United States, our commercial capabilities outside the United States are still limited and would need to be further developed or outsourced. Therefore, termination of the Bayer collaboration agreement or our Antibody Collaboration **with Sanofi** would create substantial new and

additional risks to the successful commercialization of the applicable products, particularly outside the United States. For additional information regarding our collaborations with Bayer and Sanofi, see" Risks Related to Our Reliance on or Transactions with Third Parties- If our collaboration with Bayer for EYLEA HD and EYLEA is terminated, or Bayer materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition, and our ability to continue to commercialize EYLEA HD and EYLEA outside the United States would be materially harmed" below and" Risks Related to Our Reliance on or Transactions with Third Parties- If our Antibody Collaboration with Sanofi is terminated, or Sanofi materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition, and our ability to develop, manufacture, and commercialize certain of our products and product candidates in the time expected, or at all, may be materially harmed" below. Sales of our marketed products recorded by us and our collaborators could be reduced by imports from countries where such products may be available at lower prices. Our sales of products we commercialize in the United States and our collaborators' sales of products they commercialize or co- commercialize with us under our collaboration agreements with them in the United States and other countries (which impact our share of any profits or losses from the commercialization of these products under the relevant collaboration agreements and, therefore, our results of operations) may be reduced if the applicable product is imported into those countries from lower priced markets, whether legally or illegally (a practice known as parallel trading or reimportation). Parallel traders (who may repackage or otherwise alter the original product or sell it through alternative channels such as mail order or the Internet) take advantage of the price differentials between markets arising from factors including sales costs, market conditions ~~(such as intermediate trading stages)~~ , tax rates, or national regulation of prices. Under our arrangement with Bayer, pricing and reimbursement for EYLEA HD and EYLEA outside the United States is the responsibility of Bayer. Similarly, under our Antibody Collaboration with Sanofi, pricing and reimbursement for the products commercialized or co- commercialized thereunder outside the United States are the responsibility of Sanofi. Prices for our marketed products in jurisdictions outside the United States are based on local market economics and competition and are likely to differ from country to country. In the United States, prices for pharmaceuticals are generally higher than in the bordering nations of Canada and Mexico and sales of our marketed products in the United States may be reduced if the applicable product marketed in those bordering nations is imported into the United States. In addition, there are proposals to legalize the import of pharmaceuticals from outside the United States into the United States. If such proposals were implemented, our future revenues derived from sales of our marketed products could be reduced. Parallel-trading practices also are of particular relevance to the EU, where they have been encouraged by the current regulatory framework. These types of imports may exert pressure on the pricing of our marketed products in a particular market or reduce sales recorded by us or our collaborators, thereby adversely affecting our results of operations. We may be unsuccessful in continuing the commercialization of our marketed products or in commercializing our product candidates or new indications for our marketed products, if approved, which would materially and adversely affect our business, profitability, and future prospects. Even if clinical trials demonstrate the safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates or new indications for our marketed products will depend upon, among other things, their acceptance by patients, the medical community, and third- party payors and on our and our collaborators' ability to successfully manufacture, market, and distribute those products in substantial commercial quantities or to establish and manage the required infrastructure to do so, including large- scale information technology systems and a large- scale distribution network. Establishing and maintaining sales, marketing, and distribution capabilities are expensive and time- consuming. Even if we obtain regulatory approval for our product candidates or new indications, if they are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business, prospects, operating results, and financial condition would be severely harmed. The commercial success of our products may also be adversely affected by guidelines or recommendations to healthcare providers, administrators, payors, and patient communities that result in decreased use of our products. Such guidelines or recommendations may be published not only by governmental agencies, but also professional societies, practice management groups, private foundations, and other interested parties. Our **marketed products and** product candidates are **typically** delivered either by intravenous infusion or by intravitreal or subcutaneous injections ~~, which~~ **. These methods of administration** are generally **disfavored** ~~less well received~~ by patients ~~than~~ **when compared to** tablet or capsule delivery ~~and this~~ **, which** could adversely affect the commercial success of ~~those~~ **such marketed** products **or,** if they receive marketing approval **, product candidates** . We are dependent upon a small number of customers for a significant portion of our revenue, and the loss of or significant reduction in sales to these customers would adversely affect our results of operations. We sell our marketed products for which we record net product sales in the United States to several distributors and specialty pharmacies, as applicable (collectively," distributor customers"), which generally sell the product directly to healthcare providers or other pharmacies (as applicable). For the years ended December 31, **2024 and** 2023 ~~and 2022~~ , our product sales to two distributor customers accounted on a combined basis for **74 % and** 76 ~~% and 83~~ % of our total gross product revenue, respectively. We expect significant distributor customer concentration to continue for the foreseeable future. Our ability to generate and grow sales of these products will depend, in part, on the extent to which our distributor customers are able to provide adequate distribution of these products to healthcare providers. Although we believe we can find additional distributors, if necessary, our revenue during any period of disruption could suffer and we might incur additional costs. In addition, these distributor customers are responsible for a significant portion of our net trade accounts receivable balances. The loss of any large distributor customer, a significant reduction in sales we make to them, any cancellation of orders they have made with us, or any failure to pay for the products we have shipped to them could adversely affect our results of operations. Commercialization of any of our marketed products may also be adversely impacted by vertical integration of private payor healthcare and insurance programs, health maintenance organizations, and PBMs, or further consolidation among the healthcare providers served **or operated** by our distributor customers if, for example, one or more consolidated groups of healthcare providers determines not

to use (or decides to switch from) such marketed product in favor of a competing product. See also" The commercial success of our products and product candidates is subject to significant competition- Marketed Products" above. If we are unable to establish **sufficient** commercial capabilities outside the United States for ~~Libtayo, Dupixent, and any other~~ products we intend to commercialize or co- commercialize outside the United States, our business, prospects, operating results, and financial condition may be adversely affected. ~~We~~ **While we** have ~~limited~~ **made progress with establishing** commercial capabilities **in certain jurisdictions** outside the United States ~~and have not yet fully established an organization for the sales, marketing, and distribution of marketed products outside the United States. We are in the process of establishing these capabilities outside the United States for Libtayo~~ in connection with **our acquisition of** the **exclusive** ~~2022 amendment to the IO Collaboration whereby all rights~~ **right** to develop, commercialize, and manufacture Libtayo ~~will be transferred exclusively to our Company, on a~~ worldwide **pursuant** ~~basis, over the course of a defined transition period. In addition~~ to ~~fully establishing these~~ **the 2022 Amended** ~~commercial capabilities by the end of the transition period, we will also need to obtain~~ and ~~/ or maintain regulatory approvals~~ **Restated Immuno- oncology License** and **Collaboration Agreement with Sanofi** ~~secure pricing and reimbursement for Libtayo in many jurisdictions outside the United States~~ (~~including Europe and Japan~~ **the" A & R IO LCA"**) **and** ~~. Further, following~~ the exercise of our option under the Antibody Collaboration to co- commercialize Dupixent in certain jurisdictions outside the United States, **our commercial** ~~we have established certain co- commercialization~~ capabilities **and experience with commercializing products outside the United States (as well as obtaining and / or maintaining regulatory approvals and securing pricing and reimbursement** for **our products outside** ~~Dupixent in some of these~~ **the** ~~jurisdictions and~~ **United States)** are **still somewhat limited** ~~in the process of establishing these capabilities in others~~ . There may be other circumstances in which we need to establish further commercial capabilities outside the United States, including because we decide to commercialize a particular product independently; we are unable to find an appropriate collaborator; or an existing collaborator decides to opt out or breaches its obligations to us with respect to a particular product. In order to commercialize or co- commercialize any products outside the United States beyond what we have done so far, we must build **or enhance** our sales, marketing, distribution, regulatory, managerial, and other capabilities in the relevant markets or make arrangements with third parties to perform these services, any of which will likely be expensive and time consuming and could delay product launch or the co- commercialization of a product in one or more markets outside the United States. We cannot be certain that we will be able to successfully develop **requisite** commercial capabilities outside the United States ~~(particularly as it relates to Libtayo, for which we plan to expand our global commercialization footprint as noted above)~~ within an acceptable time frame, without incurring substantial expenses, or at all. These and other difficulties relating to commercializing our products outside the United States may harm our business, prospects, operating results, and financial condition. We cannot sell or market products without regulatory approval or other authorization. If we or our collaborators do not maintain regulatory approval for our marketed products, and obtain regulatory approval for our product candidates or new indications of our marketed products (or are materially delayed in doing so), the value of our Company and our business, prospects, operating results, and financial condition may be materially harmed. In the United States, we (which, for purposes of this risk factor, includes our collaborators, unless otherwise stated or required by the context) must obtain and maintain approval from the FDA for each drug we intend to sell. We must obtain and maintain similar regulatory approvals from comparable foreign regulatory authorities in order to sell drugs outside the United States. Obtaining FDA or comparable foreign regulatory authority approval for a new drug or indication is typically a lengthy and expensive process, and approval is highly uncertain. We cannot predict with certainty if or when we might submit for regulatory approval for any of our product candidates currently under development. Any approvals we may obtain may not cover all of the clinical indications for which we are seeking approval. Also, an approval might contain significant limitations in the form of narrow indications, warnings, precautions, or contra- indications with respect to conditions of use. Additionally, in the United States, the FDA may determine that a REMS is necessary to ensure that the benefits of a new product outweigh its risks, and the product can therefore be approved. A REMS may include various elements, ranging from a medication guide or patient package insert to limitations on who may prescribe or dispense the drug, depending on what the FDA considers necessary for the safe use of the drug. The FDA has substantial discretion in the approval process (including with respect to setting specific conditions for submission) and may either refuse to accept an application for substantive review or may form the opinion after review of an application that the application is insufficient to allow approval of a product candidate. If the FDA does not accept our application for review or approve our application, it may require that we conduct additional clinical, preclinical, or manufacturing validation studies **or additional analyses of data from existing studies** and submit the data before it will reconsider our application. Depending on the extent of these or any other studies **or analyses** that might be required, approval of any applications that we submit may be delayed significantly, or we may be required to expend more resources. It is also possible that any such additional studies **or analyses** , if performed and completed, may not be considered sufficient by the FDA to make our applications approvable. If any of these outcomes occur, we may be forced to delay or abandon our applications for approval. For example, in October 2023, the FDA issued a CRL for the sBLA for Dupixent in CSU stating that additional efficacy data are required to support an approval. While ~~an ongoing~~ **we reported results from a confirmatory** Phase 3 clinical trial **of Dupixent in CSU** (in biologic- naïve patients) ~~continues to enroll patients and results are expected~~ in ~~late~~ **September** 2024, there can be no assurance that such data will ultimately result in FDA **or other regulatory** approval **. As another example of this type of risk, the FDA' s request for additional analyses regarding sub-populations from the BOREAS and NOTUS pivotal studies delayed by three months the FDA' s September 2024 approval of our sBLA for Dupixent as an add- on maintenance treatment of adults with inadequately controlled COPD and an eosinophilic phenotype** . In certain instances (such as when we use a biomarker- based test to identify and enroll specific patients in a clinical trial), regulatory approval of a companion diagnostic to our therapeutic product candidate may be required as a condition to regulatory approval of the therapeutic product candidate. We may need to rely on third parties to provide companion diagnostics for use with our product candidates. Such third parties may be unable or unwilling on terms

acceptable to us to provide such companion diagnostics or to obtain timely regulatory approval of or product labeling updates for such companion diagnostics, which could negatively impact regulatory approval of our product candidates or may result in increased development costs or delays. The FDA may also require us to conduct additional clinical trials after granting approval of a product. The FDA has the explicit authority to require post- marketing studies (also referred to as post- approval or Phase 4 studies), labeling changes based on new safety information, and compliance with FDA- approved risk evaluation and mitigation strategies. Post- approval studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other data about our marketed products (or data about products similar to our marketed products that implicate an entire class of products or are perceived to do so) may result in changes in product labeling, restrictions on use, product withdrawal or recall, loss of approval, or lower sales of our products. Obligations equivalent in scope, but which can vary widely in application, apply in countries outside the United States. According to the FDA policies under the Prescription Drug User Fee Act, the FDA system of review times for new drugs includes standard review and priority review. While the FDA has performance goals that provide for action on BLA submissions by certain deadlines, the FDA' s review goals are subject to change and the duration of the FDA' s review depends on a number of factors, including the number and types of other applications that are submitted to the FDA around the same time period or are pending. The FDA' s review **of our regulatory submissions has in the past been delayed, and** may be delayed ~~because~~ **in the future, due to** the FDA **' s** ~~requests~~ **request for** additional information or for other reasons, including those beyond our control ~~. For example, in 2022, an FDA travel complication related to scheduling a routine clinical trial site inspection in eastern Europe delayed by nearly two months the FDA' s approval of our sBLA for the combination treatment of Libtayo with chemotherapy in NSCLC~~ . If we believe we meet eligibility requirements, we may apply for various regulatory incentives in the United States, such as breakthrough therapy designation, fast track designation, accelerated approval, or priority review, where available, that serve to expedite drug development and / or review, and we may also seek similar designations elsewhere in the world. Often, regulatory agencies have broad discretion in determining whether or not product candidates qualify for such regulatory incentives and benefits, and we cannot guarantee we would be successful in obtaining beneficial regulatory designations by the FDA or other regulatory agencies. Even if obtained, such designations may not result in faster development processes, reviews, or approvals compared to drugs considered for approval under conventional FDA procedures. In addition, the FDA may later decide that any of our development programs no longer meets the conditions for a beneficial regulatory designation (including due to factors beyond our control, such as intervening competitive developments) or decide that the time period for FDA review or approval will not be shortened. ~~Recent~~ FDA ~~draft~~ guidance relating to accelerated approval of oncology therapeutics indicates that a confirmatory trial for a particular oncology product candidate should be underway when the related BLA is submitted to the FDA and also states that the FDA may require that a confirmatory trial for a particular oncology product candidate be well underway, if not fully enrolled, by the time of the accelerated approval action. Application of this guidance **and related rules** to our product candidates may result in a delay of the FDA review and approval process despite any earlier beneficial regulatory designation such product candidates may have received. **For example, in March 2024, the FDA issued CRLs concerning our BLA for odronextamab for the treatment of relapsed / refractory FL and DLBCL due to the enrollment status of confirmatory Phase 3 trials.** The FDA and comparable foreign regulatory authorities enforce GCPs and other regulations and legal requirements through periodic inspections of trial sponsors, clinical research organizations (" CROs"), principal investigators, and trial sites. If we or any of the third parties conducting our clinical studies are determined to have failed to fully comply with GCPs, the study protocol or applicable regulations, the clinical data generated in those studies may be deemed unreliable. This and similar instances of non- compliance with GCPs could result in non- approval of our product candidates by the FDA or foreign regulatory authorities such as the EC, or we or the FDA or such other regulatory authorities may decide to conduct additional inspections or require additional clinical studies, which would delay our development programs, require us to incur additional costs, and could substantially harm our business, prospects, operating results, and financial condition. Before approving a new drug or biologic product, the FDA and such comparable foreign regulatory authorities require that the facilities at which the product will be manufactured or advanced through the supply chain be in compliance with current Good Manufacturing Practices, or cGMP, requirements and regulations governing the manufacture, shipment, and storage of the product. Additionally, manufacturers of biological products and their facilities are subject to payment of substantial user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and adherence to any commitments made in the applicable BLA. These cGMP requirements and regulations are not prescriptive instructions on how to manufacture products, but rather a series of principles that must be observed during manufacturing; as a result, the manner in which such principles are implemented may not be specifically delineated, which can **be** ~~present a~~ challenging ~~environment~~ as the FDA and comparable foreign regulatory authorities increasingly scrutinize compliance with these requirements and regulations. As a result, manufacturing product candidates in compliance with these regulatory requirements is complex, time- consuming, and expensive. To be successful, our products must be manufactured in compliance with regulatory requirements, and at competitive costs. If we or any of our third- party manufacturers, product packagers, labelers, or other parties performing steps in the supply chain are unable to maintain regulatory compliance with cGMP, the FDA and comparable foreign regulatory authorities can impose monetary penalties or other civil or criminal sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre- existing approval. For example, in ~~June~~ **August** ~~2023~~ **2024** , the FDA issued a CRL concerning the Company' s BLA for **linvoseltamab in relapsed / refractory multiple myeloma** ~~EYLEA HD for the treatment of wAMD, DME, and DR~~ due to **findings** ~~unresolved observations resulting~~ from ~~an~~ **a pre- approval** inspection at **a third- party fill / finish provider for another company' s product candidate. While** the ~~contract manufacturing organization Catalent~~ **linvoseltamab BLA has recently been resubmitted to the FDA** , ~~which~~ **this has** resulted in a delay of ~~the~~ **any potential** FDA approval of **this product candidate** ~~EYLEA HD by nearly two months~~ . For additional information, see" Risks Related to

Manufacturing and Supply- Our or our collaborators' failure to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates could result in incurring substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and / or in their commercial launch if regulatory approval is obtained, and a reduction in sales." Our business, prospects, operating results, and financial condition may be materially harmed as a result of noncompliance with the requirements and regulations described in this paragraph. We are also subject to ongoing requirements imposed by the FDA and comparable foreign regulatory authorities governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record- keeping, and reporting of safety and other post- marketing information. The holder of an approved BLA or foreign equivalent is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA or foreign equivalent must also submit new or supplemental applications and obtain FDA **or other regulatory** approval for certain changes to the approved product, product labeling, or manufacturing process. Advertising and promotional materials must comply with FDA regulations and those of foreign regulatory authorities and may be subject to other potentially applicable federal and state laws. The applicable regulations in countries outside the U. S. grant similar powers to the competent authorities and impose similar obligations on companies. In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in countries outside the United States. The foreign regulatory approval process is similarly a lengthy and expensive process, the result of which is highly uncertain, and foreign regulatory requirements include all of the risks associated with FDA approval as well as country specific regulations. We and our collaborators must maintain regulatory compliance for the products we or they commercialize in countries outside the United States. From time to time, we may hold a product' s marketing approval in a jurisdiction outside the United States where we may have less experience and where our regulatory capabilities may be more limited; **for example,** this ~~will be~~ **is now** the case for Libtayo in many jurisdictions outside the United States (including Europe and Japan) **due to** ~~once we complete~~ the transition **under** ~~from Sanofi pursuant to~~ the ~~amendment to the~~ **A & R** IO ~~Collaboration~~ **LCA** discussed above. In addition, actions by a regulatory agency in a country or region with respect to a product candidate may have an impact on the approval process for that product candidate in another country or region. Foreign regulatory authorities may ask for additional data in order to begin a clinical study, including Phase 3 clinical trials required to submit a ~~Marketing Authorization Application (" MAA ")~~ in the EU. In addition, such authorities often have the authority to require post- approval studies, such as a PASS and / or PAES, which involve various risks similar to those described above. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval of the product by the comparable regulatory authorities in countries outside the United States before we can market that product or any other product in those countries. Furthermore, we are subject to extensive pharmacovigilance reporting and other pharmacovigilance requirements, which may differ in the numerous countries in which we conduct clinical trials or commercialize a product. Failure to comply with any such requirements may result in the premature closure of the clinical trials and other enforcement actions by the relevant regulatory authorities. For example, if we do not manage to retain a QPPV, to maintain a PSMF, or to comply with other pharmacovigilance obligations in the EEA, we may be at risk of our clinical trials being closed prematurely, our marketing authorization being suspended, and we may be subject to other enforcement actions by the national competent authorities of the EEA or the EC. Preclinical and clinical studies required for our product candidates and new indications of our marketed products are expensive and time- consuming, and their outcome is highly uncertain. If any such studies are delayed or yield unfavorable results, regulatory approval for our product candidates or new indications of our marketed products may be delayed or become unobtainable. As described above, we must conduct extensive testing of our product candidates and new indications of our marketed products before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting such studies is a lengthy, time- consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy ~~,~~**;** the development of serious or life- threatening adverse events (or side effects) caused by or connected with exposure to the product candidate (or prior or concurrent exposure to other products or product candidates) ~~,~~**;** difficulty in enrolling and maintaining subjects in a clinical trial ~~,~~**;** clinical trial design that may not make it possible to enroll or retain a sufficient number of patients to achieve a statistically significant result or the desired level of statistical significance for the endpoint in question ~~,~~**;** lack of sufficient supplies of the product candidate or comparator drug ~~,~~**;** and the failure of clinical investigators, trial monitors, contractors, consultants, or trial subjects to comply with the trial plan, protocol, or applicable regulations related to ~~the FDA' s~~ GLPs or GCPs. A clinical trial may also fail because the dose (s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting. Additionally, conducting clinical trials in countries outside the United States presents additional risks, including political and economic risks that are not present in the United States, such as armed conflict and economic embargoes or boycotts. For example, we and our collaborators are currently conducting and may in the future conduct or initiate clinical trials with sites in Russia, Ukraine, and / or Israel. While we currently do not expect the Russia- Ukraine or Hamas- Israel armed conflict or related developments to have a significant impact on our ability to obtain results from clinical trials conducted by us or our collaborators, further escalation (whether in these countries or surrounding areas) may adversely affect our ability to adequately conduct certain clinical trials and maintain compliance with relevant protocols due to, among other reasons, the prioritization of hospital resources away from clinical trials, reallocation or evacuation of site staff and subjects, or as a result of government- imposed curfews, warfare, violence, or other governmental action or other events that restrict movement. These developments may also result in our inability to access sites for monitoring or to obtain data from affected sites or patients going forward. We could also experience disruptions in our supply chain or limits to our ability to provide sufficient investigational materials in such countries and surrounding regions. Clinical trial sites may suspend or terminate the trials being conducted and patients could be forced to

evacuate or choose to relocate, making them unavailable for initial or further participation in such trials. Alternative sites in these areas may not be available and we may need to find other countries to conduct the relevant trials. Furthermore, military action may prevent the FDA or other regulatory agencies from inspecting clinical sites in these countries. Such interruptions may delay our plans for clinical development and approvals for our product candidates. We will need to reevaluate any drug candidate that does not test favorably and either conduct new studies, which are expensive and time consuming, or abandon that drug development program. If preclinical testing yields unfavorable results, product candidates may not advance to clinical trials. The failure of clinical trials to demonstrate the safety and effectiveness of our clinical candidates for the desired indication (s) would preclude the successful development of those candidates for such indication (s), in which event our business, prospects, operating results, and financial condition may be materially harmed. Furthermore, some of our products and product candidates (such as Libtayo) are studied in combination with agents and treatments developed by us or our collaborators. There may be additional risks and unforeseen safety issues resulting from such combined administration, any of which may materially adversely impact clinical development of these product candidates and our ability to obtain regulatory approval. In some jurisdictions such as the EU, initiating Phase 3 clinical trials and clinical trials in the pediatric population is subject to a requirement to obtain approval or a waiver from the competent authorities of the EU Member States and / or the EMA. If we do not obtain such approval, our ability to conduct clinical trials and obtain marketing authorizations or approvals may be severely impaired and our business may be adversely impacted. Certain of our research and development activities are conducted at our existing facilities primarily located in Tarrytown, New York. As we continue to expand, we may lease, operate, purchase, or construct additional facilities to expand our research and development capabilities in the future. Expanding our research and laboratory facilities may require significant time and resources. Further, we may be unable to pursue our research and development efforts if the relevant facility were to cease operations due to fire, climate change, natural disasters, acts of war or terrorism, or other disruptions. Any related delays may interfere with our research and development efforts and our business may be adversely impacted. Successful development of our current and future product candidates is uncertain. Only a small minority of all research and development programs ultimately result in commercially successful drugs. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates in these indications. Many companies in the biopharmaceutical industry, including our Company, have suffered significant setbacks in clinical trials, even after promising results had been obtained in earlier trials. In a number of instances, we have terminated the development of product candidates due to a lack of or only modest effectiveness and / or safety concerns, and clinical trials evaluating our product candidates have failed to meet the relevant endpoints. Moreover, even if we obtain positive results from preclinical testing or clinical trials, we may not achieve the same success in future trials, or the FDA and analogous foreign regulatory authorities may deem the results insufficient for an approval. If concerns arise about the safety of a product candidate or non- compliance with the protocol or applicable regulatory requirements, the FDA or other regulatory authorities can delay or suspend a clinical trial by placing it on a full or partial" clinical hold" pending receipt of additional data or the satisfaction of other conditions. A clinical hold may require us to spend significant resources to address the underlying causes of the clinical hold and may result in a delay in the clinical program, which may be significant. In addition, if we are not able to successfully address such underlying causes or our response is not deemed adequate to lift the clinical hold, the clinical program may have to be terminated. Any such clinical program delays or terminations may adversely affect our business. Many of our clinical trials are conducted under the oversight of **Independent Data Monitoring Committees ("** IDMCs **")** . These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial' s continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results ~~. For example, we previously discontinued actively treating patients with fasinumab following a recommendation from the responsible IDMC that the program be terminated based on available evidence at that time; and we later discontinued further clinical development of fasinumab~~ . The recommended termination or material modification of any of our ongoing late- stage clinical trials by an IDMC could negatively impact the future development of our product candidate (s), and our business, prospects, operating results, and financial condition may be materially harmed. We are studying our product candidates in a wide variety of indications in clinical trials. Many of these trials are exploratory studies designed to evaluate the safety profile of these compounds and to identify what diseases and uses, if any, are best suited for these product candidates. These product candidates may not demonstrate the requisite efficacy and / or safety profile to support continued development for some or all of the indications that are being, or are planned to be, studied, which would diminish our clinical" pipeline" and could negatively affect our future prospects and the value of our Company. Serious complications or side effects in connection with the use of our products and in clinical trials for our product candidates and new indications for our marketed products could cause our regulatory approvals to be revoked or limited or lead to delay or discontinuation of development of our product candidates or new indications for our marketed products, which could severely harm our business, prospects, operating results, and financial condition. During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time- to- time during clinical trials of our product candidates and new indications for our marketed products. It is possible that as we test our drug candidates or new indications in larger, longer, and more extensive **or complex** clinical programs **(including those evaluating combination therapies)** , or as use of these drugs becomes more widespread if they receive regulatory approval, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large- scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates or new

indications for our marketed products has many side effects or causes serious or life- threatening side effects, the development of the product candidate may be delayed or fail, or, if the product candidate has received regulatory approval, such approval may be revoked, which would severely harm our business, prospects, operating results, and financial condition. With respect to EYLEA and EYLEA HD, there are many potential safety concerns associated with significant blockade of VEGF that may limit our ability to further successfully commercialize EYLEA and to successfully commercialize EYLEA HD. These serious and potentially life- threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, congestive heart failure, heart attack, and stroke. Other VEGF blockers have reported side effects that became evident only after large- scale trials or after marketing approval when large numbers of patients were treated. There are risks inherent in the intravitreal administration of drugs like aflibercept (such as intraocular inflammation ~~(" IOI")~~ , sterile and culture positive endophthalmitis, corneal decomposition, retinal detachment, retinal tear, and retinal vasculitis), which can cause injury to the eye and other complications. The side effects previously reported for aflibercept include conjunctival hemorrhage, macular degeneration, eye pain, retinal hemorrhage, and vitreous floaters. While the safety of EYLEA HD was similar to EYLEA in clinical trials, it is possible that the use of EYLEA HD outside the clinical trial setting may yield different outcomes or patient experiences. In addition, commercialization of EYLEA and EYLEA HD or our other products and potential future commercialization of our product candidates may be impacted by actions of third parties on which we rely, such as manufacturers of syringes or other devices used in the administration of our products. These and other complications or issues or side effects could harm further development and / or commercialization of EYLEA and EYLEA HD. Dupixent and Libtayo are being studied in additional indications, as shown in the table under Part I, Item 1." Business- Programs in Clinical Development." There is no guarantee **that the safety data from these trials will be consistent with the known Dupixent and Libtayo safety profiles (as applicable) or** that regulatory approval of Dupixent or Libtayo (as applicable) in any of these indications will be successfully obtained. The side effects previously reported for Dupixent include hypersensitivity reactions, eye problems (including conjunctivitis and keratitis), injection- site reactions, eye and eyelid inflammation, cold sores, oropharyngeal pain, eosinophilia, insomnia, toothache, gastritis, joint pain (arthralgia), parasitic (helminth) infections, and facial rash or redness; and the side effects previously reported for Libtayo include certain immune- mediated adverse reactions that may occur in any organ system or tissue, including pneumonitis, colitis, hepatitis, endocrinopathies, nephritis, and dermatologic reactions, as well as infusion- related reactions, cellulitis, sepsis, pneumonia, urinary tract infection, fatigue, rash, and diarrhea. These and other complications or side effects could harm further development and / or commercialization of Dupixent and Libtayo (as applicable). There also are risks inherent in subcutaneous injections (which are used for administering most of our antibody- based products and product candidates), such as injection- site reactions (including redness, itching, swelling, pain, and tenderness) and other side effects. In addition, there are risks inherent in intravenous administration (which are used for some of our antibody- based products and product candidates), such as infusion- related reactions (including nausea, pyrexia, rash, and dyspnea). These and other complications or side effects could harm further development and / or commercialization of our antibody- based products and product candidates utilizing this method of administration. We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use, which would delay or prevent continued development of such candidates and / or receipt of regulatory approval or commercial sale, which could materially harm our business, prospects, operating results, and financial condition. If we are unable to continue to develop suitable product formulations or manufacturing processes to support large- scale clinical testing of our product candidates, including our antibody- based product candidates, we may be unable to supply necessary materials for our clinical trials, which would delay or prevent the development of our product candidates. Similarly, if we are unable, directly or through our collaborators or third parties, to supply sufficient quantities of our products or develop formulations of our product candidates suitable for commercial use, we will be unable to obtain regulatory approval for those product candidates. Many of our products are intended to be used and, if approved, our product candidates may be used in combination with drug- delivery devices, which may result in additional regulatory, commercialization, and other risks. Many of our products are used and some of our products and product candidates may be used, if approved, in combination with a drug- delivery device, including a pre- filled syringe, patch pump, auto-injector, or other delivery system. For example, in the United States and the EU, EYLEA is approved in the 2mg pre- filled syringe. **In addition, the 8mg pre- filled syringe for EYLEA HD is approved in the EU and is currently under regulatory review in the United States.** The success of our products and product candidates may depend to a significant extent on the performance of such devices, some of which may be novel or comprised of complex components. Given the increased complexity of the review process when approval of the product and device is sought under a single marketing application and the additional risks resulting from a product candidate' s designation as a combination product discussed below, our product candidates used with such drug- delivery devices may be substantially delayed in receiving regulatory approval or may not be approved at all. The FDA review process and criteria for such applications are not well established, which could also lead to delays in the approval process. In addition, some of these drug- delivery devices may be provided by single- source, third- party providers or our collaborators. In any such case, we may be dependent on the sustained cooperation of those third- party providers or collaborators to supply and manufacture the devices; to conduct the studies and prepare related documentation required for approval or clearance by the applicable regulatory agencies; and to continue to meet the applicable regulatory and other requirements to maintain approval or clearance once it has been received. In addition, other parties may allege that our drug- delivery devices infringe patents or other intellectual property rights. ~~For example, we are currently party to patent infringement and other proceedings relating to the EYLEA pre- filled syringe, as described in Note 16 to our Consolidated Financial Statements.~~ Failure to successfully develop or supply the devices, delays in or failure of the studies conducted by us, our collaborators, or third- party providers, or failure of our Company, our collaborators, or the third- party providers to obtain or maintain regulatory approval or clearance of the devices could result in increased development costs, delays in or failure to obtain regulatory approval, and associated delays in a product or product candidate reaching the market. Loss of regulatory

approval or clearance of a device that is used with our product may also result in the removal of our product from the market. Further, failure to successfully develop or supply and manufacture these devices, or to gain or maintain their approval, could adversely affect sales of the related products. In the United States, each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a drug, biologic, or device. The determination whether a product is a combination product or two separately regulated products is made by the FDA on a case- by- case basis. Although a single marketing application is generally sufficient for the approval, clearance, or licensure of a combination product, the FDA may determine that separate marketing applications are necessary. In addition, submitting separate marketing applications may be necessary to receive some benefit that accrues only from approval under a particular type of application. This could significantly increase the resources and time required to bring a particular combination product to market. For purposes of this subsection, references to our intellectual property (including patents, trademarks, copyrights, and trade secrets) include that of our collaborators and licensees, unless otherwise stated or required by the context. If we cannot protect the confidentiality of our trade secrets, or our patents or other means of defending our intellectual property are insufficient to protect our proprietary rights, our business and competitive position will be harmed. Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements and other means. If our trade secrets are improperly disclosed, by our current or former employees, our collaborators, or otherwise, it could help our competitors and adversely affect our business. Our ability to protect our trade secrets may be impaired by a number of risks and uncertainties, including those discussed under" Other Regulatory and Litigation Risks- Increasing use of social media and artificial intelligence- based platforms could give rise to liability, breaches of data security and privacy laws, or reputational damage" and" Other Risks Related to Our Business- Significant disruptions of information technology systems or breaches of data security could adversely affect our business" below. We will be able to protect our proprietary rights only to the extent that our proprietary technologies and other information are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies, including our Company, involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, held to be unenforceable, or circumvented. For example, certain of our U. S. patents (including those pertaining to our key products, such as EYLEA) have been and may in the future be challenged by parties who file a request for post- grant review or inter partes review under the America Invents Act of 2011 or ex parte reexamination, as **further** described in Note 16 to our Consolidated Financial Statements included in this report. Post-grant proceedings are increasingly common in the United States and are costly to defend. In addition, patent applications filed outside the United States may be challenged by other parties, for example, by filing pre- grant third- party observations that argue against patentability or a post- grant opposition. Such opposition proceedings are increasingly common in Europe and are costly to defend. For example, **certain of our** ~~in 2021, anonymous parties initiated opposition proceedings in the~~ European ~~Patent~~ **patents** ~~Office~~ **, including those pertaining to EYLEA** (~~" EPO") against our European Patent No. 2, 944, 306 (which concerns pre- filled syringes comprising ophthalmic formulations containing VEGF antagonists such~~ as **further** ~~aflibercept for intravitreal administration), as~~ described in Note 16 to our Consolidated Financial Statements included in this report **) and Dupixent, are subject to opposition proceedings before the EPO and / or patent offices of various European countries** . We have pending patent applications in the United States Patent and Trademark Office (the" USPTO"), the EPO, and the patent offices of other foreign jurisdictions, and it is likely that we will need to defend patents from challenges by others from time to time in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions or our ability to obtain, maintain, and enforce our intellectual property rights. Any such changes could also affect the value of our intellectual property or narrow the scope of our patents. We cannot be certain that our intellectual property rights related to any current or future product or product candidate or technology would not be eliminated, narrowed, or weakened by any such change or other rulemaking. Additionally, the United States and other government actions related to Russia' s invasion of Ukraine may limit or prevent filing, prosecution, and maintenance of patent applications in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. Further, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patent holders from the United States without consent or compensation. Consequently, we ~~would~~ **are** not ~~be~~ able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. We also currently hold issued trademark registrations and have trademark applications pending in the United States and other jurisdictions, any of which may be the subject of a governmental or third- party objection, which could prevent the maintenance or issuance of the trademark. As our products mature, our reliance on our trademarks to differentiate us from our competitors increases **;** and **;** as a result, if we are unable to prevent third parties from adopting, registering, or using trademarks that infringe, dilute or otherwise violate our trademark rights, our business could be adversely affected. We may be restricted in our development, manufacturing, and / or commercialization activities by patents or other proprietary rights of others, and could be subject to awards of damages if we are found to have infringed such patents or rights. Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of others (including those relating to trademarks, copyrights, and trade secrets). Other parties may allege that they own blocking patents to our products in clinical development or even to products that have received regulatory approval and are being or have been commercialized, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or the way it is used. Moreover, other parties may allege that they have blocking patents to antibody- based products made using our VelocImmune technology, or any other of our technologies, either because of the way the antibodies are discovered or produced or because of a proprietary composition

covering an antibody or the antibody' s target. We have been in the past, are currently, and may in the future be involved in patent litigation and other proceedings involving patents and other intellectual property. For example, we are currently party to patent infringement and other proceedings relating to EYLEA, as described in Note 16 to our Consolidated Financial Statements. We are aware of patents and pending patent applications owned by others that claim compositions and methods of treatment relating to targets and conditions that we are also pursuing with our products and / or product candidates. Although we do not believe that any of our products or our late- stage product candidates infringe any valid claim in these patents or patent applications, these other parties could initiate lawsuits for patent infringement and assert that their patents are valid and cover our products or our late- stage product candidates, similar to the patent infringement proceedings referred to above. Further, we are aware of a number of patent applications of others that, if granted with claims as currently drafted, may cover our current or planned activities. It could be determined that our products and / or actions in manufacturing or selling our products or product candidates infringe such patents. Patent holders could assert claims against us for damages and seek to prevent us from manufacturing, selling, or developing our products or product candidates, and a court may find that we are infringing validly issued patents of others. In the event that the manufacture, use, or sale of any of our products or product candidates infringes on the patents or violates other proprietary rights of others, we may be prevented from pursuing product development, manufacturing, and commercialization of those drugs and may be required to pay costly damages. In addition, in the event that we assert our patent rights against other parties that we believe are infringing our patent rights, such parties may challenge the validity of our patents and we may become the target of litigation, which may result in an outcome that is unfavorable to us. Any of these adverse developments may materially harm our business, prospects, operating results, and financial condition. In any event, legal disputes are likely to be costly and time consuming to defend. We seek to obtain licenses to patents when, in our judgment, such licenses are needed or advisable. For example, in 2018, we and Sanofi entered into a license agreement with Bristol- Myers Squibb, E. R. Squibb & Sons, and Ono Pharmaceutical to obtain a license under certain patents owned and / or exclusively licensed by one or more of these parties that includes the right to develop and sell Libtayo. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our products or product candidates, which could severely harm our business. In addition, other parties may have regulatory exclusivity in the United States or foreign jurisdictions for products relating to targets or conditions we are also pursuing, which could prevent or delay our ability to apply for or obtain regulatory approval for our product candidates in such jurisdictions. For example **, under the Orphan Drug Act in the United States, if a product candidate with an orphan drug designation subsequently receives FDA approval for indication (s) within the scope of such designation, the product will be entitled to orphan drug exclusivity for such indication (s), barring the FDA from approving for seven years in such approved indication (s) another sponsor' s application for a product candidate considered under the FDA regulations to be the same drug as the previously- approved drug with orphan drug exclusivity. This orphan drug exclusivity does not block approval of competing products intended for the orphan exclusivity- protected indication but containing a different active moiety or principal molecular structure, or containing the same active moiety or principal molecular structure but intended for a different indication. Similarly** , in the EU, a designated orphan drug is provided up to 10 years of market exclusivity in the orphan indication, during which time the EMA is generally precluded from accepting a MAA for a similar medicinal product ~~unless it~~ **. In both the United States and the EU, if a sponsor** can ~~be demonstrated~~ **demonstrate** that ~~it~~ **a new product** is safer, more effective, or otherwise clinically superior to the original orphan ~~medicinal~~ product ~~. Loss or limitation of patent rights~~ , **orphan** ~~and regulatory pathways for biosimilar competition, could reduce the duration of market~~ exclusivity ~~for our~~ **will not bar approval of the new** ~~products~~ **product** . In the pharmaceutical and biotechnology industries, the majority of an innovative product' s commercial value is usually realized during the period in which it has market exclusivity. In the United States and some other countries, when market exclusivity expires and generic versions of a product are approved and marketed, there usually are very substantial and rapid declines in the product' s sales. If our late- stage product candidates or other clinical candidates are approved for marketing in the United States or elsewhere, market exclusivity for those products will generally be based upon patent rights and / or certain regulatory forms of exclusivity. As described above under" If we cannot protect the confidentiality of our trade secrets, or our patents or other means of defending our intellectual property are insufficient to protect our proprietary rights, our business and competitive position will be harmed," the scope and enforceability of our patent rights may vary from country to country. The failure to obtain patent and other intellectual property rights, or limitations on the use, or the loss, of such rights could materially harm us. Absent patent protection or regulatory exclusivity for our products, it is possible, both in the United States and elsewhere, that generic, biosimilar, and / or interchangeable versions of those products may be approved and marketed, which would likely result in substantial and rapid reductions in revenues from sales of those products. Under the PPACA, there is an abbreviated path in the United States for regulatory approval of products that are demonstrated to be" biosimilar" or" interchangeable" with an FDA- approved biological product. The PPACA provides a regulatory mechanism that allows for FDA approval of biologic drugs that are similar to innovative drugs on the basis of less extensive data than is required by a full BLA. Under this regulation, an application for approval of a biosimilar may be filed four years after approval of the innovator product. However, qualified innovative biological products receive 12 years of regulatory exclusivity, meaning that the FDA may not approve a biosimilar version until 12 years after the innovative biological product was first approved by the FDA. However, the term of regulatory exclusivity may not remain at 12 years in the United States and could be shortened if, for example, the PPACA is amended. A number of jurisdictions outside the United States have also established abbreviated pathways for regulatory approval of biological products that are biosimilar to earlier versions of biological products. For example, the EU has had an established regulatory pathway for biosimilars since 2005. The increased likelihood of biosimilar competition has increased the risk of loss of innovators' market exclusivity. It is also not possible to predict changes in United States regulatory law that might reduce biological product regulatory exclusivity. Due to this risk, and

uncertainties regarding patent protection, it is not possible to predict the length of market exclusivity for any particular product we currently or may in the future commercialize with certainty based solely on the expiration of the relevant patent (s) or the current forms of regulatory exclusivity. ~~A biosimilar~~ **Biosimilar** ~~version~~ **versions** of EYLEA ~~was~~ **have been** recently approved in the **United States,** EU **,** and ~~we are aware of several~~ other ~~companies developing~~ **jurisdictions, with additional** biosimilar versions of EYLEA **and / or EYLEA HD in development** , as discussed further under" Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products- The commercial success of our products and product candidates is subject to significant competition- Marketed Products" above. ~~In~~ **As an EYLEA biosimilar has been launched in** the United States ~~,~~ **following** the **expiration of the U. S.** regulatory exclusivity period for EYLEA (i. e., the period during which no biosimilar product ~~can~~ **could** be approved by the FDA) **in** ~~extends through~~ May ~~17,~~ 2024 ~~following the pediatric~~ **, EYLEA no longer has U. S. market** exclusivity ~~granted by the FDA~~ . In addition, as EYLEA HD does not benefit from regulatory exclusivity in the United States, market exclusivity for EYLEA HD in the United States is based solely on our patent rights pertaining to this product (which are subject to the risks and uncertainties discussed above under" If we cannot protect the confidentiality of our trade secrets, or our patents or other means of defending our intellectual property are insufficient to protect our proprietary rights, our business and competitive position will be harmed."). ~~The~~ **Any future** loss of market exclusivity for a product ~~(such as EYLEA or EYLEA HD)~~ would likely negatively affect revenues from product sales of that product and thus our financial results and condition and could have a material negative impact on our business. We rely on limited internal and contracted manufacturing and supply chain capacity, which could adversely affect our ability to commercialize our marketed products and, if approved, our product candidates and to advance our clinical pipeline. We have large- scale manufacturing operations in Rensselaer, New York and Limerick, Ireland. Manufacturing facilities operated by us and by third- party contract manufacturers engaged by us would be inadequate to produce the active pharmaceutical ingredients of our current marketed products and our product candidates in sufficient clinical quantities if our clinical pipeline advances as planned or if there is greater demand than currently expected for our marketed products. In addition to expanding our internal capacity, we intend to continue to rely on our collaborators, and may also rely on contract manufacturers, to produce commercial quantities of drug material needed for commercialization of our products. As we increase our production in anticipation of potential regulatory approval for our product candidates, our current manufacturing capacity will likely not be sufficient, and our dependence on our collaborators and / or contract manufacturers may increase, to produce adequate quantities of drug material for both commercial and clinical purposes. The COVID- 19 pandemic has exacerbated **,** and **this or other public health outbreaks, epidemics, or pandemics** may in the future further exacerbate **,** certain of these risks. For example, the impact of **having to** ~~prioritizing~~ **prioritize** certain manufacturing- related resources for our COVID- 19 monoclonal antibodies ~~has~~ **in recent years** included and may in the future include, among other things, drawing down inventory safety stock levels for certain of our other products (including Dupixent and EYLEA). Depending on the demand for our products and other relevant factors, we may not be able to replenish our inventory safety stock to the levels we deem prudent or supply our products and product candidates in sufficient quantities to satisfy our commercial and development needs. We also **currently** rely entirely on other parties and our collaborators for filling and finishing services. Generally, in order for other parties to perform any step in the manufacturing and supply chain, we must transfer technology to the other party, which can be time consuming and may not be successfully accomplished without considerable cost and expense, or at all. We will have to depend on these other parties to perform effectively on a timely basis and to comply with regulatory requirements. If for any reason they are unable to do so, and as a result we are unable to directly or through other parties manufacture and supply sufficient commercial and clinical quantities of our products on acceptable terms, or if we should encounter delays or other difficulties with our collaborators, contract manufacturers, warehouses, shipping, testing laboratories, or other parties involved in our supply chain which adversely affect the timely manufacture and supply of our products or product candidates, our business, prospects, operating results, and financial condition may be materially harmed. Expanding our manufacturing capacity and establishing fill / finish capabilities **has been and** will **continue to** be costly and we may be unsuccessful in doing so in a timely manner, which could delay or prevent the launch and successful commercialization of our marketed products and product candidates or other indications for our marketed products if they are approved for marketing and could jeopardize our current and future clinical development programs. In addition to our existing manufacturing facilities in Rensselaer, New York and Limerick, Ireland, we may lease, operate, purchase, or construct additional facilities to conduct expanded manufacturing or other related activities in the future. Expanding our manufacturing capacity to supply commercial quantities of the active pharmaceutical ingredients for our marketed products and our product candidates if they are approved for marketing, and to supply clinical drug material to support the continued growth of our clinical programs, will require substantial additional expenditures, time, and various regulatory approvals and permits. This also holds true for establishing fill / finish capabilities in the future, for which we have constructed a fill / finish facility in Rensselaer, New York that is currently undergoing process validation as required by regulatory authorities (refer to Part II, Item 7." Management' s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources" for information about ~~expected~~ capital expenditures relating to this and other projects). In addition, we may need to develop or acquire additional manufacturing capabilities to the extent we or our collaborators pursue the development of drugs generated by means other than our existing" Trap" or VelociSuite ® technologies, such as siRNA gene silencing, genome editing, and targeted viral- based gene delivery and expression. Further, we will need to hire and train significant numbers of employees and managerial personnel to staff our expanding manufacturing and supply chain operations, as well as any future fill / finish activities. Start- up costs can be large, and scale- up entails significant risks related to process development and manufacturing yields. In addition, we may face difficulties or delays in developing or acquiring the necessary production equipment and technology to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable regulatory requirements. The FDA and analogous foreign regulatory authorities must determine that our existing and any expanded manufacturing facilities and any future fill / finish activities comply, or continue to comply, with

cGMP requirements for both clinical and commercial production and license them, or continue to license them, accordingly, and such facilities must also comply with applicable environmental, safety, and other governmental permitting requirements. We may not successfully expand or establish sufficient manufacturing or any future fill / finish capabilities or manufacture our products ~~economically~~ **in a cost- effective manner** or in compliance with cGMPs and other regulatory requirements, and we and our collaborators may not be able to build or procure additional capacity in the required timeframe to meet commercial demand for our product candidates if they receive regulatory approval, and to continue to meet the requirements of our clinical programs. This would interfere with our efforts to successfully commercialize our marketed products, and it could also delay or require us to discontinue one or more of our clinical development programs. As a result, our business, prospects, operating results, and financial condition could be materially harmed. Our ability to continue to manufacture products in our Rensselaer, New York and Limerick, Ireland facilities and at additional facilities (if any) in the future (including our ability to conduct any fill / finish activities in the future), the ability of our collaborators to manufacture products at their facilities, and our ability to utilize other third parties to produce our products, to supply raw materials or other products, or to perform fill / finish services or other steps in our manufacture and supply chain, depends on our and their ability to operate without infringing the patents or other intellectual property rights of others. Other parties may allege that our or our collaborators' manufacturing activities, or the activities of other third parties involved in our manufacture and supply chain (which may be located in jurisdictions outside the United States), infringe patents or other intellectual property rights ~~. For example, we are currently party to patent infringement and other proceedings relating to the EYLEA pre- filled syringe, as described in Note 16 to our Consolidated Financial Statements~~ . A judicial or regulatory decision in favor of one or more parties making such allegations could directly or indirectly preclude the manufacture of our products to which those intellectual property rights apply on a temporary or permanent basis, which could materially harm our business, prospects, operating results, and financial condition. We use our manufacturing facilities primarily to produce bulk product for commercial supply of our marketed products and clinical and preclinical candidates for ourselves and our collaborations. We also plan to use such facilities to produce bulk product for commercial supply of new indications of our marketed products and new product candidates if they are approved for marketing or otherwise authorized for use. If our clinical candidates are discontinued or their clinical development is delayed, if the launch of new indications for our marketed products or new product candidates is delayed or does not occur, or if such products are launched and the launch is unsuccessful or the product is subsequently recalled or marketing approval is rescinded, we may have to absorb ~~one hundred percent of~~ related overhead costs and inefficiencies, as well as similar costs of third- party contract manufacturers performing services for us. In addition, if we or our collaborators experience excess inventory, it may be necessary to write down or write off such excess inventory or incur an impairment charge with respect to the facility where such product is manufactured, which could adversely affect our operating results. For example, during each of the years ended December 31, 2022 and 2021, we recorded a charge to write down inventory related to REGEN- COV. Third- party service or supply failures, or other failures, business interruptions, or other disasters affecting our manufacturing facilities in Rensselaer, New York and Limerick, Ireland, the manufacturing facilities of our collaborators, or the facilities of any other party participating in the supply chain, would adversely affect our ability to supply our products. Bulk drug materials are currently manufactured at our manufacturing facilities in Rensselaer, New York and Limerick, Ireland, as well as at our collaborators' facilities. We and our collaborators would be unable to manufacture these materials if the relevant facility were to cease production due to regulatory requirements or actions, business interruptions, labor shortages or disputes, supply chain interruptions or constraints (including with respect to natural gas and other raw materials), contaminations, fire, climate change, natural disasters, acts of war or terrorism, or other problems. Many of our products and product candidates are very difficult to manufacture. As our products and most of our product candidates are biologics, they require processing steps that are more difficult than those required for many other chemical pharmaceuticals. Accordingly, multiple steps are needed to control the manufacturing processes. Problems with these manufacturing processes, even minor deviations from the normal process or from the materials used in the manufacturing process (which may not be detectable by us or our collaborators in a timely manner), **have led in the past and** could lead **in the future** to product defects or manufacturing failures, resulting in lot failures, product recalls, product liability claims, and **/ or** insufficient inventory. Also, the complexity of our manufacturing process may make it difficult, time- consuming, and expensive to transfer our technology to our collaborators or contract manufacturers. Certain raw materials or other products necessary for the manufacture and formulation of our marketed products and product candidates, some of which are difficult to source, are provided by single- source unaffiliated third- party suppliers. In addition, we rely on certain third parties or our collaborators to perform filling, finishing, distribution, laboratory testing, and other services related to the manufacture of our marketed products and product candidates, and to supply various raw materials and other products. We would be unable to obtain these raw materials, other products, or services for an indeterminate period of time if any of these third parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or actions (including recalls), adverse financial developments at or affecting the supplier, failure by the supplier to comply with cGMPs, contaminations, business interruptions, or labor shortages or disputes (in each case, including as a result of the ~~COVID- 19 pandemic and the~~ armed conflict between Russia and Ukraine ~~, which have exacerbated many of these issues,~~ or ~~other~~ public health outbreaks, epidemics, or pandemics or **other** geopolitical developments) **. Regional or single- source dependencies may in some cases accentuate these risks. For example, the pharmaceutical industry generally, and in some instances our Company or our collaborators or other third parties on which we rely, depend on China- based suppliers or service providers for certain raw materials, products and services, or other activities. Our ability or the ability of our collaborators or such other third parties to continue to engage these China- based suppliers or service providers for certain preclinical research programs and clinical development programs could be restricted due to geopolitical developments between the United States and China, including as a result of the escalation of tariffs or other trade restrictions or if the previously proposed federal legislation known as the**

BIOSECURE Act or a similar law were to be enacted . In any such circumstances, we may not be able to engage a backup or alternative supplier or service provider in a timely manner or at all. This, in turn, could materially and adversely affect our or our collaborators' ability to manufacture or supply marketed products and product candidates **or advance our or our collaborators' preclinical research or clinical development programs** , which could materially and adversely affect our business and future prospects. Certain of the raw materials required in the manufacture and testing of our products and product candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain regulatory restrictions on using these biological source materials. If we or our collaborators are required to substitute for these sources to comply with such regulatory requirements, our clinical development or commercial activities may be delayed or interrupted. We and our collaborators and other third- party providers are required to maintain compliance with cGMPs, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application (s) to the FDA or such comparable foreign agencies and acceptance of the change by the FDA or such comparable foreign agencies prior to release of product (s). Because we produce multiple products and product candidates at our facilities in Rensselaer, New York and Limerick, Ireland, there are increased risks associated with cGMP compliance. **Recently, the FDA issued CRLs to multiple companies (including us, as further discussed below) citing unresolved inspection findings at third- party manufacturers, which prevented the timely approval of such companies' marketing applications.** Our inability, or the inability of our collaborators and third- party fill / finish or other service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, **identify and onboard new service providers,** withdraw or recall product, halt or interrupt clinical trials, and / or interrupt commercial supply of any marketed products, and could also delay or prevent our obtaining regulatory approval for our product candidates or new indications for our marketed products. Any delay, interruption, or other issue that arises in the manufacture, fill / finish, packaging, or storage of any drug product or product candidate as a result of a failure of our facilities or the facilities or operations of our collaborators or other third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop, obtain approval for, and successfully commercialize our products, which would substantially harm our business, prospects, operating results, and financial condition. Any finding of non- compliance could also increase our costs, cause us to delay the development of our product candidates, result in delay in our obtaining, or our not obtaining, regulatory approval of product candidates or new indications for our marketed products, and cause us to lose revenue from any marketed products, which could be seriously detrimental to our business, prospects, operating results, and financial condition. For example, in ~~June~~ **August** ~~2023~~ **2024** , the FDA issued a CRL concerning the Company' s BLA for **linvoseltamab in relapsed / refractory multiple myeloma** ~~EYLEA HD for the treatment of wAMD, DME, and DR~~ due to **findings** ~~unresolved observations resulting~~ from ~~an~~ **a pre-approval** inspection at a third- party fill / finish provider ~~,~~ **for another company' s product candidate. While** the ~~contract manufacturing organization Catalent~~ **linvoseltamab BLA has recently been resubmitted to the FDA** , ~~which~~ **this has** resulted in a delay of ~~the~~ **any potential** FDA approval of ~~EYLEA HD by nearly~~ **this product candidate. Refer** ~~two~~ - **to** ~~months~~ **Part I, Item 1." Business- Programs in Clinical Development- Additional Information- Clinical Development Programs" for more information** . Significant noncompliance with the requirements discussed in this paragraph could also result in the imposition of monetary penalties or other civil or criminal sanctions and damage our reputation. The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who enroll in our clinical trials may not protect us from liability or the cost of litigation. We **have previously been subject to, and** may ~~also~~ **in the future** be subject to **,** claims by patients who use our approved products, or our product candidates if those product candidates receive regulatory approval and become commercially available, that they have been injured by a side effect associated with the drug. Even in a circumstance in which we do not believe that an adverse event is related to our products or product candidates, the related investigation may be time consuming or inconclusive and may have a negative impact on our reputation or business. We may face product liability claims and be found responsible even if injury arises from the acts or omissions of third parties who provide fill / finish or other services. To the extent we maintain product liability insurance in relevant periods, such insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, in the future we may not have access to liability insurance or be able to maintain our insurance on acceptable terms. The FDA regulates the marketing and promotion of our products, which must comply with the Food, Drug, and Cosmetic Act and applicable FDA implementing standards. The FDA' s review of promotional activities includes healthcare provider- directed and direct- to- consumer advertising, **certain** communications regarding unapproved uses, industry- sponsored scientific and educational activities, and sales representatives' communications. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse enforcement action by the FDA, the Department of Justice, or the Office of the Inspector General of the **U. S. Department of Health and Human Services ("** HHS **")** , as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes a drug. Any such failures could also cause significant reputational harm. The FDA may take enforcement action for promoting unapproved uses of a product or other violations of its advertising laws and regulations. The applicable regulations in countries outside the U. S. grant similar powers to the competent authorities and impose similar obligations on companies. In addition to FDA and related regulatory requirements, we are subject to ~~health~~ **healthcare** ~~care~~ " fraud and abuse" laws, such as the federal civil False Claims Act, the anti- kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. The U. S. federal healthcare program anti- kickback statute (the" AKS") prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving payments or other remuneration, directly or indirectly, to induce or reward someone to purchase, prescribe, endorse, arrange for, or recommend a product or service that is reimbursed under federal healthcare programs such as Medicare or Medicaid. If we provide payments or other

remuneration to a healthcare professional to induce the prescribing of our products, we could face liability under state and federal anti- kickback laws. The Bipartisan Budget Act of 2018 has increased the criminal and civil penalties that can be imposed for violating certain federal ~~health~~ **healthcare** ~~care~~ laws, including the federal anti- kickback statute. The federal civil False Claims Act prohibits any person from, among other things, knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. The False Claims Act also permits a private individual acting as a" whistleblower" to bring actions on behalf of the federal government alleging violations of the statute and to share in any monetary recovery. Pharmaceutical companies have been investigated and / or prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, known as off- label uses, that caused claims to be submitted to Medicaid for non- covered off- label uses; and submitting inflated best price information to the Medicaid Rebate program. Pharmaceutical and other healthcare companies also are subject to other federal false claims laws, including, among others, federal criminal fraud and false statement statutes that extend to non- government health benefit programs. The majority of states also have statutes or regulations similar to the federal anti- kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, **administrative fines and penalties,** damages, exclusion of a manufacturer' s products from reimbursement under government programs, criminal fines, and imprisonment for individuals and the curtailment or restructuring of operations. Even if it is determined that we have not violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would harm our business, prospects, operating results, and financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be challenged under one or more of such laws. As described further in Note 16 to our Consolidated Financial Statements included in this report, we are party to civil ~~litigation~~ **proceedings** initiated ~~in 2020~~ **or joined** by **the U. S. Department of Justice and** the U. S. Attorney' s Office for the District of Massachusetts concerning ~~our support of a 501 (c) (3) organization that provides financial assistance to patients; and we are cooperating with pending government investigations concerning~~ certain ~~other~~ business activities. Any adverse decision, finding, allegation, or exercise of enforcement or regulatory discretion in any such proceedings or investigations could harm our business, prospects, operating results, and financial condition. As part of the PPACA, the federal government requires that pharmaceutical manufacturers record any" transfers of value" made to U. S. licensed physicians and teaching hospitals as well as ownership and investment interests held by physicians and their immediate family members. Information provided by companies is aggregated and posted annually on an" Open Payments" website, which is managed by CMS, the agency responsible for implementing these disclosure requirements. Applicable manufacturers also are required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants, and certified nurse- midwives. We also have similar reporting obligations in other countries based on laws, regulations, and / or industry trade association requirements. We continue to dedicate significant resources to comply with these requirements ~~and need to be prepared to comply with additional reporting obligations outside the United States~~. In addition, ~~several~~ **a number of** states have legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities; restrict when pharmaceutical companies may provide meals or gifts to prescribers or engage in other marketing- related activities; require identification or licensing of sales representatives; and restrict the ability of manufacturers to offer co- pay support to patients for certain prescription drugs. Many of these requirements and standards are new or uncertain, and the penalties for failure to comply with these requirements may be unclear. If we are found not to be in full compliance with these laws, we could face enforcement actions, fines, and other penalties, and could receive adverse publicity, which would harm our business, prospects, operating results, and financial condition. Additionally, access to such data by fraud- and- abuse investigators and industry critics may draw scrutiny to our collaborations with reported entities. If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations, and future prospects. We participate in the Medicaid Drug Rebate program, the **Public Health Service' s** 340B program (which is administered by HRSA), the VA FSS pricing program, the Tricare Retail Pharmacy Program, and other federal and state government pricing programs. Such programs often require us to provide discounts and / or pay rebates to certain government payors and / or private purchasers. See Part I, Item 1," Business- Government Regulation- Pricing and Reimbursement" for additional information on these programs. Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies, and the courts. Such interpretation can change and evolve over time. For example, in the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program. Civil monetary penalties can be applied if we fail to pay the required rebate, if we are found to have knowingly submitted any false price or product information to the government, if we are found to have made a misrepresentation in the reporting of our average sales price, if we fail to submit the required price data on a timely basis, or if we are found to have knowingly and intentionally charged 340B covered entities more than the statutorily mandated ceiling price. CMS could also

decide to terminate our Medicaid drug rebate agreement, or HRSA could decide to terminate our 340B program participation agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. Our failure to comply with our reporting and payment obligations under the Medicaid Drug Rebate program and other governmental programs could negatively impact our ~~financial~~ **operating** results. ~~The final~~ **In September 2024, CMS modified the** ~~regulation~~ **regulations** governing the Medicaid Drug Rebate ~~program~~ **Program , which could further** ~~issued by CMS has increased and will continue to~~ increase our costs and the complexity of compliance, ~~has been~~ **impact rebate liabilities,** and ~~will continue to~~ be time- consuming to implement ~~, and could have a material adverse effect on our results of operations, particularly if CMS challenges the approach we have taken in our implementation of the final regulation~~ . Other regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program may have a similar impact. In addition, the final regulation issued by HRSA regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities has affected our obligations and potential liability under the 340B program. We are also required to report the 340B ceiling prices for our covered outpatient drugs to HRSA, which then publishes them to 340B covered entities. Any charge by HRSA that we have violated the requirements of the program or the regulation could negatively impact our ~~financial~~ **operating** results. Moreover, HRSA established an ADR process for claims by covered entities that a manufacturer has engaged in overcharging, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that could be appealed only in federal court. An ADR proceeding could subject us to onerous procedural requirements and could result in additional liability. ~~On November 30, 2022, HRSA issued a notice of proposed rulemaking that proposes several changes to the ADR process; and, following the solicitation of public comments, in October 2023 HRSA submitted a final version of the rule to the White House Office of Management and Budget for review.~~ Further, any ~~additional~~ future changes to the definition of average manufacturer price and the Medicaid rebate amount under the PPACA or otherwise could affect our 340B ceiling price calculations and negatively impact our results of operations. We have obligations to report the average sales price for certain of our drugs to the Medicare program. Statutory or regulatory changes or CMS guidance could affect the average sales price calculations for our products and the resulting Medicare payment rate, and could negatively impact our results of operations. ~~Manufacturers must pay refunds to Medicare for single- source drugs or biological products, or biosimilar biological products, reimbursed under Medicare Part B and packaged in single- dose containers or single- use packages for units of discarded drug reimbursed by Medicare Part B in excess of 10 percent of total allowed charges under Medicare Part B for that drug. Manufacturers that fail to pay refunds could be subject to civil monetary penalties of 125 percent of the refund amount.~~ Pursuant to applicable law, knowing provision of false information in connection with price reporting or contract - based requirements under the VA ~~/~~FSS and / or Tricare programs can subject a manufacturer to civil monetary penalties. These program and contract- based obligations also contain extensive disclosure and certification requirements. If we overcharge the government in connection with our arrangements with FSS or Tricare, we are required to refund the difference to the government. Failure to make necessary disclosures or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and / or response to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations, and future prospects. Risks from the improper conduct of employees, agents, contractors, or collaborators could adversely affect our reputation and our business, prospects, operating results, and financial condition. We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators that would violate the laws or regulations of the jurisdictions in which we operate, including, without limitation, healthcare, employment, foreign corrupt practices, trade restrictions and sanctions, environmental, competition, and privacy laws and regulations. Such improper actions could subject us to civil or criminal investigations, and monetary and injunctive penalties, and could adversely impact our ability to conduct business, operating results, and reputation. In particular, our business activities outside the United States (which have recently **expanded** ~~increased,~~ and ~~are expected to~~ continue to **expand** ~~increase,~~ due to, in part, our efforts to establish ~~our~~ **further** commercialization and co- commercialization capabilities in certain jurisdictions outside the United States) are subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti- bribery or anti- corruption laws, regulations or rules of other countries in which we operate, including the U. K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non- U. S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non- U. S. governments. Additionally, in many other countries, the ~~health~~ **healthcare** ~~care~~ providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. ~~Recently~~ **In recent years,** the SEC and Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. There is no certainty that all of our employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our ability to expand internationally, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition. Our operations are subject to environmental, health, and safety laws and regulations, including

those governing the use of hazardous materials. Compliance with these laws and regulations is costly, and we may incur substantial liability arising from our activities involving the use of hazardous materials. As a fully integrated biotechnology company with significant research and development and manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, infectious agents (such as viruses, bacteria, and fungi), radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions **(including the imposition of monetary penalties)** , which could exceed our resources or insurance coverage **. In addition, if we fail to obtain or maintain required permits and registrations, we may be subject to administrative fines and penalties or other regulatory actions, which could adversely affect our business** . All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, intellectual property rights, and the framework for dispute resolution and asserting our rights against others, are subject to extensive legislation and regulation. Changes in applicable U. S. federal, state, and foreign laws and agency regulations **and policies** could have a materially negative impact on our business. As described above, the PPACA and potential regulations thereunder easing the entry of competing follow- on biologics into the marketplace, other new legislation or implementation of existing statutory provisions on importation of lower- cost competing drugs from other jurisdictions, and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business. In addition, in April 2023, the European Commission published a proposal to replace the current pharmaceutical legislative framework in the EU. While it is uncertain whether such proposal will be adopted in its current form, there may ultimately be a number of changes to the current regulatory framework in the EU, including a reduction of the data protection and market exclusivity periods provided thereby. The U. S. federal or state governments could carry out other significant changes in legislation, regulation, or government policy, including with respect to government reimbursement changes or drug price control measures (such as those discussed above under" Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products- Changes to product reimbursement and coverage policies and practices may materially harm our business, prospects, operating results, and financial condition") or the PPACA or other healthcare reform laws. While it is not possible to predict whether and when any such changes will occur, changes in the laws, regulations, and policies governing the development and approval of our product candidates and the commercialization, importation, and reimbursement of our products could adversely affect our business. In addition, our development and commercialization activities could be harmed or delayed by a shutdown of the U. S. government, including the FDA. For example, a prolonged shutdown may significantly delay the FDA' s ability to timely review and process any submissions we have filed or may file or cause other regulatory delays, which could materially and adversely affect our business. Risks associated with our operations outside the United States could adversely affect our business. We have operations and conduct business in ~~several~~ **many** countries outside the United States and have been significantly expanding the scope of these activities in existing and / or additional countries, including EU countries and Japan. For example, as discussed above, we **now have** ~~are in the process of establishing~~ commercial **presence** ~~capabilities related to Libtayo~~ in ~~many~~ **certain** jurisdictions outside the United States ~~following~~ **in connection with our acquisition of** the ~~2022 amendment~~ **exclusive right** to **develop, commercialize, and manufacture Libtayo worldwide pursuant to** the **A & R** IO ~~Collaboration~~ **LCA** ; and we perform co- commercialization activities under the Antibody Collaboration related to Dupixent in certain jurisdictions outside the United States. Consequently, we are, and will continue to be, subject to risks related to operating in countries outside the United States, particularly those in which we have not previously established operations, and many of these risks will increase as we expand our activities in such jurisdictions. These risks include: • unfamiliar foreign laws or regulatory requirements or unexpected changes to those laws or requirements, including those with which we and / or our collaborators must comply in order to maintain our marketing authorizations outside the United States, and the cost of compliance with such foreign laws and regulatory requirements; • other laws and regulatory and industry trade association requirements to which our business activities abroad are subject, such as the FCPA and the U. K. Bribery Act (discussed in greater detail above under" Risks from the improper conduct of employees, agents, contractors, or collaborators could adversely affect our reputation and our business, prospects, operating results, and financial condition"), as well as labor and employment laws and regulations; • changes in the political or economic condition of a specific country or region, including as a result of the Russia- Ukraine or Hamas- Israel armed conflict; • fluctuations in the value of foreign currency versus the U. S. dollar; • tariffs **(including tariffs that have been or may in the future be imposed by the United States or other countries)** , trade protection measures, import or export licensing requirements, trade embargoes, ~~and~~ sanctions (including those administered by the Office of Foreign Assets Control of the U. S. Department of the Treasury), ~~and~~ other trade barriers **(including further legislation or actions taken by the United States or other countries that restrict trade), and protectionist or retaliatory measures taken by the United States or other countries** ; • difficulties in attracting and retaining qualified personnel; and • cultural differences in the conduct of business. We have large- scale manufacturing operations in Limerick, Ireland and have also established offices in the United Kingdom, Germany, Japan, and other countries outside the United States. Changes impacting our ability to conduct business in the those countries, or changes to the regulatory regime applicable to our operations in those countries (such as with respect to the approval of our product candidates), may materially and adversely impact our business, prospects, operating results, and financial condition. We may incur additional tax liabilities related to our operations. We are subject to income tax in the United States and foreign jurisdictions in which we operate. Significant judgment is required in determining our worldwide tax liabilities, and our effective tax rate is derived from the applicable statutory tax rates and relative earnings in each taxing jurisdiction. We record liabilities for uncertain tax positions that involve significant management judgment as to the application of law. Domestic or foreign taxing authorities have previously disagreed, and may in the future disagree, with our interpretation of tax law as applied to the operations of Regeneron

and its subsidiaries or with the positions we may take with respect to particular tax issues on our tax returns. Consequently, tax assessments or judgments in excess of accrued amounts that we have estimated in preparing our financial statements may materially and adversely affect our reported effective tax rate or our cash flows. Further, other factors may adversely affect our effective tax rate, including changes in the mix of our profitability from country to country, tax effects of stock- based compensation (which depend in part on the price of our stock and, therefore, are beyond our control), and changes in tax laws or regulations. For example, the ~~Organization for Economic Co- operation and Development (" OECD ") Global Anti- Base Erosion Model Rules (" Pillar Two~~ **framework has** ~~") have~~ influenced tax laws in countries in which we operate, including the implementation of minimum taxes. Changes to these or other laws and regulations or their interpretations could materially adversely impact our effective tax rate or cash flows. Our ability to conduct our business is significantly dependent on the data that we collect, process, and share in discovering, developing, and commercializing drug products. These data are often considered personal data and are therefore regulated by **privacy and data protection laws in and outside the United States, including health privacy laws, data breach notification laws, consumer protection laws, data localization laws, biometric privacy laws, and genetic privacy laws. Such laws may apply to our operations and / or those of our collaborators and business partners and may impose restrictions on our collection, use, and dissemination of individuals' health and other personal data, including data that we may receive throughout the clinical trial process, in the course of our research collaborations, from individuals who enroll in our patient assistance programs, from healthcare professionals that interact with us, or from our own employees. Laws and regulations in this area are constantly evolving and are often not interpreted consistently by regulatory authorities, institutional review boards / ethics committees, or clinical trial sites. In the United States, there are numerous federal and state laws and regulations governing** data privacy **of personal data and the collection, use, disclosure, and protection of health data, genetic data, consumer data, and children' s data. At the federal level, most U. S. healthcare providers, including research institutions from which we or our collaborators obtain clinical trial data, are subject to privacy and security regulations promulgated under HIPAA. While Regeneron is not directly subject to HIPAA, other than potentially with respect to providing certain employee benefits, we could be subject to criminal penalties if we, our affiliates, or our agents knowingly receive protected health information in a manner that is not permitted under HIPAA. The FTC also sets expectations for taking appropriate steps to safeguard consumers' personal information and for providing a level of privacy or security commensurate to promises made to individuals. Failure to meet these FTC standards may constitute unfair or deceptive acts or practices in violation of Section 5 of the FTC Act. The FTC also has the power to enforce the Health Breach Notification Rule, which imposes notification obligations on companies for breaches of certain health information contained in personal health records. Enforcement by the FTC under the FTC Act and Health Breach Notification Rule can result in civil penalties or enforcement actions. In addition, at the state level, many state consumer privacy** laws **recently went into effect and many other consumer privacy laws are expected to go into effect** in **the near future. These laws include certain transparency and other requirements to protect personal data and grant residents with certain rights regarding their personal data. These laws and regulations are constantly evolving and may impose limitations on our business activities. Outside** the United States **, we** ~~and abroad. We~~ have operations and conduct business in several countries ~~outside the United States~~ and ~~plan to~~ **have been** significantly ~~expand~~ **expanding** the scope of these activities in those and / or additional countries, as discussed above under" Risks associated with our operations outside the United States could adversely affect our business." **We also conduct clinical trials in these and many other countries around the world.** These activities subject us to additional data protection authority oversight and require us to comply with stringent local and regional data privacy laws ~~,~~**. Such laws** ~~including~~ **include** the ~~EU' s General Data Protection Regulations (" GDPR~~ **, which** ~~"). The GDPR~~ has a wide range of compliance obligations ~~, including increased consent~~ **relating to the processing** and ~~transparency requirements and~~ **protection of personal** data ~~subject rights~~. Violations of the GDPR carry significant financial penalties for noncompliance ~~(including possible fines~~ **. The GDPR also confers a private right** of ~~up~~ **action on data subjects and consumer associations** to ~~4 % of global annual turnover~~ **file complaints with data protection authorities, seek judicial remedies, and obtain compensation** for **damages resulting from violations of** ~~the preceding financial year or € 20 million (whichever is higher)). In addition to~~ the GDPR ~~, certain EU Member~~ **. Many other jurisdictions outside the United** States have **adopted** ~~issued or will be issuing their own implementation legislation. In June 2021, the EC introduced new standard contractual clauses required to be incorporated into certain new~~ and ~~existing agreements within prescribed timeframes in order to~~ continue to **adopt varying** ~~lawfully transfer personal data outside the EU. Many of the countries that have comprehensive data privacy laws have modeled their requirements after the GDPR. Compliance with these requirements has been and is expected to continue to be costly and time consuming. We conduct clinical trials in many countries around the world, which have new or evolving data privacy laws that are often not interpreted consistently by regulatory authorities, institutional review boards / ethics committees, or clinical trial sites. This complexity has resulted in increased liability in the management of clinical trial data, as well as additional compliance, contractual, and due- diligence obligations that could lead to a delay in clinical trial site start- up. There also has been an increase of enforcement activities in various EU countries that require evidence of compliance with local data privacy requirements. While we continue to monitor these developments, there remains some uncertainty surrounding the legal and regulatory environment for these evolving~~ privacy and data protection ~~laws. Complying with varying jurisdictional requirements could~~ **legislation, the continued emergence of which has** ~~increase~~ **increased** the costs and complexity of compliance **. If we** ~~, including the risk of substantial financial penalties for~~ - **or any** ~~insufficient notice and consent, failure to respond to data subject rights requests, lack~~ of ~~a legal basis for the transfer of personal information out of the EU or other countries with localization laws (i. e., laws mandating that personal data collected in a foreign country be processed and stored within that country), or improper processing of personal data. Failure by~~ our collaborators **fail** to comply with **applicable federal** ~~the strict rules on the transfer of personal data into the U. S. could result in the imposition of criminal and administrative sanctions on such~~

~~collaborators or impact the flow of personal data~~ , ~~which could adversely affect~~ **state, local,** ~~our~~ **or foreign** ~~business. Most U. S. health care providers, including research institutions from which we or our collaborators obtain clinical trial data, are subject to privacy and security regulations~~ **regulatory** ~~promulgated under HIPAA. For example, as part of our human genetics initiative, our wholly- owned subsidiary, Regeneron Genetics Center LLC, has entered into collaborations with many research institutions, which are subject to HIPAA. Regeneron is not a covered entity or business associate under HIPAA and thus is not subject to its~~ requirements ~~. However~~ , we could be subject to ~~criminal penalties if we, our affiliates, or our agents knowingly receive PHI in a manner that is not permitted under HIPAA. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive PHI from a health care provider or research institution that has not satisfied HIPAA' s requirements for its disclosure. There are instances where we collect and maintain personal data, which may include health information that is outside the scope of HIPAA but within the scope of state health privacy laws or similar state level privacy legislation. This information may be received throughout the clinical trial process, in the course of our research collaborations, directly from individuals who enroll in our patient assistance programs, and from our own employees in a pandemic response process (such as in connection with the COVID- 19 pandemic). Consumer protection laws impact the manner in which we develop and maintain processes to support our patient assistance programs, product marketing activities, and the sharing of employee and clinical data for internal and third- party commercial activities. Several U. S. states have proposed and passed consumer privacy laws, which were modeled after the CCPA and influenced by the GDPR. The CCPA is a consumer protection law that establishes requirements for data use and sharing transparency and provides California residents with personal data privacy rights regarding the use, disclosure, and retention of their personal data. Amendments to the CCPA have, among other things, imposed new obligations to provide notice where personal data will be de- identified. Failure to comply with the CCPA may result in, among other things, significant civil penalties and injunctive relief, or statutory or actual damages. In addition, California residents have the right to bring a private right of action in connection with data privacy incidents involving certain elements of personal data. These claims may result in significant liability and damages. These laws and regulations are constantly evolving and may impose limitations on our business activities. Several additional state consumer privacy laws went into effect in 2023 and many other consumer privacy laws are expected to go into effect in the near future. Notably, these state laws provide more restrictions on the use of sensitive personal data, including health information. These states require robust consent and authorizations prior to any collection or use of this data, which may have a large impact on our ability to market to individuals in these jurisdictions based on their health conditions. At the federal level, Section 5 of the FTC Act is a consumer protection law that bars unfair and deceptive acts and practices and requires, among other things, companies to notify individuals that they will safeguard their personal data and that they will fulfil the commitments made in their privacy notices. The FTC has brought legal actions against organizations that have violated consumers' privacy rights or have misled them by failing to maintain appropriate security. For example, in 2023 the FTC issued several enforcement actions related to privacy in the healthcare space, under both Section 5 of the FTC Act and the Health Breach Notification Rule, involving companies allegedly using consumer health data for marketing purposes in violation of their own policies and assurances. Furthermore, health privacy laws, data breach notification laws, consumer protection laws, data localization laws, biometric privacy laws, and genetic privacy laws may apply directly to our operations and / or those of our collaborators and business partners and may impose restrictions on our collection, use, and dissemination of individuals' health and other personal data. Individuals about whom we or our collaborators obtain health or other personal data, as well as the providers and third parties who share this data with us, may have statutory or contractual limits that impact our ability to further use and disclose the data. Many of these laws differ from each other in significant ways and have different effects. Many of the state laws enable a state attorney general to bring actions and provide private rights of action to consumers as enforcement mechanisms. Compliance with these laws requires a flexible privacy framework as they are constantly evolving. Federal regulators, state attorneys general, and plaintiffs' attorneys have been active in this space. If we or any collaborators fail to comply with applicable federal, state, local, or foreign regulatory requirements, we could be subject to~~ a range of regulatory actions that could **result in fines or other penalties or otherwise** affect our or any **such** collaborators' ability to commercialize our products. Any threatened or actual government enforcement action could also generate adverse publicity and could result in additional regulatory oversight. Increasing use of social media and artificial intelligence- based platforms could give rise to liability, breaches of data security and privacy laws, or reputational damage. We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally. Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is a risk that the use of social media by us or our employees to communicate about our products or business may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal data of our employees, clinical trial participants, customers, and others. Furthermore, negative posts or comments about us or our products in social media could seriously damage our reputation, brand image, and goodwill. Additionally, artificial intelligence (" AI")- based solutions, including generative AI, are increasingly being used in the biopharmaceutical industry (including by us). The use of AI solutions by our employees or third parties on which we rely may continue to increase and may lead to the **impermissible use or** public disclosure of confidential information (including personal data and proprietary information) in contravention of our internal policies, data protection laws, other applicable laws, or contractual requirements **. In the United States and in many jurisdictions outside the United States, new regulations have recently passed or have been proposed to ensure the ethical use, privacy, and security of AI solutions and the data processed thereby** . The misuse of AI solutions may give rise to liability, lead to the loss of trade secrets or other intellectual property, result in reputational harm, or lead to outcomes with unintended biases or other consequences. The misuse of AI solutions could also result in unauthorized access and use of personal data of our employees, clinical trial participants,

collaborators, or other third parties. Any of these events could have a material adverse effect on our business, prospects, operating results, and financial condition and could adversely affect the price of our Common Stock. If our Antibody Collaboration with Sanofi is terminated, or Sanofi materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition, and our ability to develop, manufacture, and commercialize certain of our products and product candidates in the time expected, or at all, may be materially harmed. We rely on support from Sanofi to develop, manufacture, and commercialize certain of our products and product candidates. With respect to the products and product candidates that we are co- developing with Sanofi under our Antibody Collaboration (currently consisting of Dupixent, Kevzara, and itepekimab), Sanofi initially funds a significant portion of development expenses incurred in connection with the development of these products and product candidates. In addition, we rely on Sanofi to lead much of the clinical development efforts, assist with or lead efforts to obtain and maintain regulatory approvals, and lead the commercialization efforts for these products and product candidates. If Sanofi terminates the Antibody Collaboration or fails to comply with its obligations thereunder, our business, prospects, operating results, and financial condition may be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our development efforts or cut back on such activities. If Sanofi does not perform its obligations with respect to the products and product candidates it is co- developing and / or co- commercializing with us, our ability to develop, manufacture, and commercialize these products and product candidates may be adversely affected. **As described in Note 16 to our Consolidated Financial Statements, we have commenced the Antibody Collaboration Ligation against Sanofi and certain of its affiliated entities. It is not possible to determine what impact (if any) the Antibody Collaboration Litigation may have on the Antibody Collaboration and our business relationship with Sanofi, or whether we will be successful in the Antibody Collaboration Litigation.** While we have some commercial presence outside the United States, our commercial capabilities outside the United States are still limited and would need to be further developed or outsourced for products commercialized under our Antibody Collaboration (see also" Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products- If we are unable to establish **sufficient** commercial capabilities outside the United States for ~~Libtayo, Dupixent, and any other~~ products we intend to commercialize or co- commercialize outside the United States, our business, prospects, operating results, and financial condition may be adversely affected" above). Termination of the Antibody Collaboration may create substantial new and additional risks to the successful development and commercialization of the products and product candidates subject to such collaborations, particularly outside the United States. If our collaboration with Bayer for EYLEA HD and EYLEA is terminated, or Bayer materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition, and our ability to continue to commercialize EYLEA HD and EYLEA outside the United States would be materially harmed. We rely heavily on Bayer with respect to the commercialization of EYLEA HD and EYLEA outside the United States. Bayer is responsible for obtaining and maintaining regulatory approval outside the United States, as well as providing all sales, marketing, and commercial support for the product outside the United States. In particular, Bayer has responsibility for selling EYLEA HD and EYLEA outside the United States using its sales force and, in Japan, in cooperation with Santen pursuant to a Co- Promotion and Distribution Agreement with Bayer' s Japanese affiliate. If Bayer and, in Japan, Santen do not perform their obligations in a timely manner, or at all, our ability to commercialize EYLEA HD and EYLEA outside the United States will be significantly adversely affected. Bayer has the right to terminate its collaboration agreement with us at any time upon six or twelve months' advance notice, depending on the circumstances giving rise to termination. If Bayer were to terminate its collaboration agreement with us, we may not have the resources or skills to replace those of our collaborator, which could require us to seek another collaboration that might not be available on favorable terms or at all, and could cause significant issues for the commercialization of EYLEA HD and EYLEA outside the United States and result in substantial additional costs and / or lower revenues to us. We have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities (see also" Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products- If we are unable to establish **sufficient** commercial capabilities outside the United States for ~~Libtayo, Dupixent, and any other~~ products we intend to commercialize or co- commercialize outside the United States, our business, prospects, operating results, and financial condition may be adversely affected" above). Termination of the Bayer collaboration agreement would create substantial new and additional risks to the successful commercialization of EYLEA HD and EYLEA. We depend upon third- party collaborators, including Sanofi and Bayer, and service providers such as CROs, outside testing laboratories, clinical investigator sites, third- party manufacturers, fill / finish providers, and product packagers and labelers, to assist us in the manufacture and preclinical and clinical development of our product candidates. We also depend, or will depend, on some of these or other third parties in connection with the commercialization of our marketed products and our product candidates and new indications for our marketed products if they are approved for marketing. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner (including as a result of its inability to perform due to financial or other relevant constraints, such as due to the armed conflict between Russia and Ukraine) or in compliance with applicable GMPs, GLPs, or GCP standards, we could experience additional costs, delays, and difficulties in the manufacture or development of, or in obtaining approval by regulatory authorities for, or successfully commercializing our product candidates. See also" Risks Related to Manufacturing and Supply- Our or our collaborators' failure to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates could result in incurring substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and / or in their commercial launch if regulatory approval is obtained, and a reduction in sales." We and our collaborators rely on third-party service providers to support the distribution of our marketed products and for many other related activities in connection with the commercialization of these marketed products. Despite our or our collaborators' arrangements with them, these third parties may not perform adequately. If these service providers do not perform their services adequately, sales of our marketed

products will suffer. We have undertaken and may in the future undertake strategic acquisitions, and any difficulties from integrating such acquisitions could adversely affect our business, operating results, and financial condition. We may acquire companies, businesses, products, or product candidates that complement or augment our existing business. For example, in May 2022 and September 2023, we completed our acquisition of Checkmate Pharmaceuticals, Inc. and Decibel Therapeutics, Inc., respectively **; and in April 2024, we acquired full development and commercialization rights to 2seventy bio, Inc.' s oncology and autoimmune preclinical and clinical stage cell therapy pipeline** . The process of proposing, negotiating, completing, and integrating any such acquisition is lengthy and complex. Other companies may compete with us for such acquisitions. In addition, we may not be able to integrate any acquired business successfully or operate any acquired business profitably. Integrating any newly acquired business could be expensive and time consuming. Integration efforts often take a significant amount of time, place a significant strain on managerial, operational, and financial resources, result in a loss of key personnel of the acquired business, and could prove to be more difficult or expensive than we predict. The diversion of our management' s attention and any delay or difficulties encountered in connection with any acquisitions we may consummate could result in the disruption of our ongoing business or inconsistencies in standards ~~and~~ **,** controls **, systems, practices, policies, and procedures of our Company and the acquired business** that could negatively affect our ability to maintain third- party relationships. Moreover, we may need to raise additional funds through public or private debt or equity financing to acquire any businesses, products, or product candidates, which may result in dilution for shareholders or the incurrence of indebtedness. As part of our efforts to acquire companies, businesses, products, or product candidates or to enter into other significant transactions, we will conduct business, legal **, research and development, regulatory** , and financial due diligence with the goal of identifying and evaluating material risks involved in the transaction. Despite our efforts, we ultimately may be unsuccessful in ascertaining or evaluating all such risks and, as a result, might not realize the intended advantages of the transaction. If we fail to realize the expected benefits from acquisitions we have consummated or may consummate in the future, whether as a result of unidentified risks or liabilities, integration difficulties, **product development or** regulatory setbacks **(including those relating to issues that may have arisen before we completed the transaction in question)** , litigation with current or former employees and other events, our business, operating results, and financial condition could be adversely affected. For any acquired product candidates, we will also need to make certain assumptions about, among other things, development costs, the likelihood of receiving regulatory approval, and the market for any such product candidates. Our assumptions may prove to be incorrect, which could cause us to fail to realize the anticipated benefits of these transactions. In addition, we may experience significant charges to earnings in connection with our efforts ~~, if any,~~ to consummate acquisitions. For transactions that are ultimately not consummated, these charges may include fees and expenses for investment bankers, attorneys, accountants, and other advisors in connection with our efforts. Even if our efforts to consummate a particular transaction are successful, we may incur substantial charges for closure costs associated with elimination of duplicate operations and facilities, acquired in- process research and development charges, or intangible asset impairment charges. In either case, the incurrence of these charges could adversely affect our operating results for particular periods. We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed. We are highly dependent on certain of our executive officers and other key members of our senior management team. If we are not able to retain (or for any other reason lose the services of) any of these persons, our business may suffer. In particular, we depend on the services of Leonard S. Schleifer, M. D., Ph. D., our **Board co- Chair,** President and Chief Executive Officer, and George D. Yancopoulos, M. D., Ph. D., our **Board co- Chair,** President and Chief Scientific Officer. We are also highly dependent on the expertise and services of other senior management members leading our research, development, manufacturing, and commercialization efforts. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the research, development, ~~manufacture~~ **manufacturing** , and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary to continue to advance our business and achieve our strategic objectives. Our business is increasingly dependent on critical, complex, and interdependent information technology systems, including Internet- based systems, to support business processes as well as internal and external communications. ~~These systems are also critical to enable remote working arrangements, which have been growing in importance.~~ The size and complexity of our computer systems make us potentially vulnerable to IT system breakdowns, internal and external malicious intrusion, and computer viruses and ransomware, which may impact product production and key business processes. We also have outsourced significant elements of our information technology infrastructure and operations to third parties, which may allow them to access our confidential information and may also make our systems vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by such third parties or others. In addition, our systems are potentially vulnerable to data security breaches ~~-~~ – whether by employees or others ~~-~~ – which may expose sensitive data to unauthorized persons. Data security breaches could lead to the loss of trade secrets or other intellectual property, result in demands for ransom or other forms of blackmail, or lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers, and others. Such attacks are of ever- increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including industrial espionage or extortion) and expertise, including by organized criminal groups," hacktivists," nation states, and others. As a company with an increasingly global presence, our systems are subject to frequent attacks **and incidents. For example, in the past we have experienced, and expect to continue to experience, various types of cybersecurity incidents, including unauthorized access to our IT systems, data security breaches, malware incursions, denial- of- service attacks, phishing campaigns, and other similar disruptions. Similar incidents have been experienced and may in the future be experienced by certain third parties on which we rely. Although we believe, based on an assessment of the relevant facts available to us, that none of these incidents has had a material adverse impact on our operations, there can be no assurance that a future incident would not result in material harm to our business, prospects, operating results, and**

financial condition . There is **also** the potential that our systems may be directly or indirectly affected as nation- states conduct global cyberwarfare, including in connection with the current Russia- Ukraine or Hamas- Israel armed conflict. Due to the nature of some of these attacks, there is a risk that an attack may remain undetected for a period of time. While we continue to make investments to improve the protection of data and information technology, and to oversee and monitor the security measures of our suppliers and / or service providers, there can be no assurance that our efforts will prevent service interruptions or security breaches. In addition, we depend in part on third- party security measures over which we do not have full control to protect against data security breaches. If we or our suppliers and / or service providers fail to maintain or protect our information technology systems and data security effectively and in compliance with U. S. and foreign laws, or fail to anticipate, plan for, or manage significant disruptions to these systems, we or our suppliers and / or service providers could have difficulty preventing, detecting, or controlling such disruptions or security breaches, which could result in legal proceedings, liability under U. S. and foreign laws that protect the privacy of personal information, disruptions to our operations, government investigations, breach of contract claims, and damage to our reputation (in each case in the U. S. or globally), which could have a material adverse effect on our business, prospects, operating results, and financial condition. The COVID- 19 pandemic previously adversely affected, and ~~the COVID- 19 pandemic or other~~ actual or threatened public health outbreaks, epidemics, or pandemics may in the future adversely affect, among other things, the economic and financial markets and labor resources of the countries in which we operate; our manufacturing and supply chain operations, research and development efforts, commercial operations and sales force, administrative personnel, third- party service providers, and business partners and customers; and the demand for our marketed products. Such disruptions in our operations could materially adversely impact our business, prospects, operating results, and financial condition. To the extent a public health outbreak, epidemic, or pandemic adversely affects our business, prospects, operating results, or financial condition, it may also have the effect of heightening many of the other risks described in this" Risk Factors" section. We have certain indebtedness and contingent liabilities, including milestone and royalty payment obligations. As of December 31, ~~2023~~ **2024** , we had an aggregate of $ 2. ~~703~~ **704** billion of outstanding indebtedness under our senior unsecured notes and the lease financing facility. We may also incur additional debt in the future. Any such indebtedness could: • limit our ability to access capital markets and incur additional debt in the future; • require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, thereby reducing the availability of our cash flow for other purposes, including business development efforts, research and development, and mergers and acquisitions; and • limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate, thereby placing us at a competitive disadvantage compared to competitors that have less debt. Changes in foreign currency exchange rates could have a material adverse effect on our operating results. Our revenue from outside the United States will increase as our products, whether marketed or otherwise commercialized by us or our collaborators, gain marketing approval in such jurisdictions. Our primary foreign currency exposure relates to movements in the Japanese yen, euro, British pound sterling, Canadian dollar, Chinese yuan, and Australian dollar. If the U. S. dollar weakens against a specific foreign currency, **assuming all other variables remained constant,** our revenues will increase, having a positive impact on net income, but our overall expenses will increase, having a negative impact. Conversely, if the U. S. dollar strengthens against a specific foreign currency, **assuming all other variables remained constant,** our revenues will decrease, having a negative impact on net income, but our overall expenses will decrease, having a positive impact. Therefore, significant changes in foreign exchange rates can impact our operating results and the financial condition of our Company. For example, as previously reported, the amount of our share of profits we earned in connection with commercialization of antibodies outside the United States was adversely impacted in 2022 by the U. S. dollar strengthening against foreign currencies, including the Japanese yen and the euro. Our investments are subject to risks and other external factors that may result in losses or affect the liquidity of these investments. As of December 31, ~~2023~~ **2024** , we had $ 2. ~~730~~ **488** billion in cash and cash equivalents and $ ~~13~~ **15** . ~~511~~ **424** billion in marketable securities (including $ ~~977~~ **1** . ~~4~~ **095** ~~million~~ **billion** in equity securities). Our investments consist primarily of debt securities, including investment- grade corporate bonds. These fixed- income investments are subject to external factors that may adversely affect their market value or liquidity, such as interest rate, liquidity, market, and issuer credit risks, including actual or anticipated changes in credit ratings. The equity securities we hold may experience significant volatility and may decline in value or become worthless if the issuer experiences an adverse development. Furthermore, our equity investments could be subject to dilution (and decline in value) as a result of the issuance of additional equity interests by the applicable issuer. If any of our investments suffer market price declines, such declines may have an adverse effect on our financial condition and operating results. Risks Related to Our Common Stock There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our Common Stock. These factors include, by way of example: • net product sales of our marketed products (as recorded by us or our collaborators), in particular EYLEA HD, EYLEA, Dupixent, and Libtayo, ~~as well as~~ **our ability and our collaborators' ability to maintain sales of our marketed products in the face of competitive products and to differentiate our marketed products from competitive products, and** our overall operating results; • if any of our product candidates or our new indications for our marketed products receive regulatory approval, net product sales of, and profits from, these product candidates and new indications; • market acceptance of, and the market share for, our marketed products, especially EYLEA HD, EYLEA, Dupixent, and Libtayo; • whether our net product sales and net profits underperform, meet, or exceed the expectations of investors or analysts **; • U. S. or other major market launch of a biosimilar version of one of our key marketed products (such as EYLEA or EYLEA HD)** ; • announcement of actions by the FDA or foreign regulatory authorities or their respective advisory committees regarding our, or our collaborators', or our competitors', currently pending or future application (s) for regulatory approval of product candidate (s) or new indications for marketed products; • announcement of submission of an application for regulatory approval of one or more of our, or our competitors', product candidates or new indications for marketed products; • progress, delays, or results in clinical trials of our or our competitors' product candidates or

new indications for marketed products; • announcement of technological innovations or product candidates by us or competitors; • claims by others that our products or technologies infringe their patents; • challenges by others to our patents in the EPO and in the USPTO **and developments relating to patent litigation and other proceedings and government investigations relating to our Company and operations** ; • public concern as to the safety or effectiveness of any of our marketed products or product candidates or new indications for our marketed products; • pricing or reimbursement actions, decisions, or recommendations by government authorities, insurers, or other organizations (such as health maintenance organizations and PBMs) affecting the coverage, reimbursement, or use of any of our marketed products or competitors' products; • ~~our ability to raise additional capital as needed on favorable terms; •~~ developments in our relationships with collaborators or key customers; • developments in the biotechnology industry or in government regulation of healthcare, including those relating to compounding (i. e., a practice in which a pharmacist, a physician, or, in the case of an outsourcing facility, a person under the supervision of a pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient); • large sales of our Common Stock by our executive officers or other employees, directors, or significant shareholders (or the expectation of any such sales); • changes in tax rates, laws, or interpretation of tax laws; • arrivals and departures of key personnel; • general market conditions **, including as a result of changes in trade, economic, and other policies of the United States or other countries** ; • impact of public health outbreaks, epidemics, or pandemics (such as the COVID- 19 pandemic) on our business; • our ability to repurchase our Common Stock under any share repurchase program on favorable terms or at all **and our ability to continue to declare cash dividends on our Common Stock and Class A Stock** ; • trading activity that results from the rebalancing of stock indices in which our Common Stock is included, or the inclusion or exclusion of our Common Stock from such indices; • other factors identified in these" Risk Factors"; and • the perception by the investment community or our shareholders of any of the foregoing factors. The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. As discussed in greater detail under" Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings" below, a large percentage of our Common Stock is owned by a small number of our principal shareholders. As a result, the public float of our Common Stock (i. e., the portion of our Common Stock held by public investors, as opposed to the Common Stock held by our directors, officers, and principal shareholders) may be lower than the public float of other large public companies with broader public ownership. Therefore, the trading price of our Common Stock may fluctuate significantly more than the stock market as a whole. These factors may exacerbate the volatility in the trading price of our Common Stock and may negatively impact your ability to liquidate your investment in Regeneron at the time you wish at a price you consider satisfactory. Broad market fluctuations may also adversely affect the market price of our Common Stock. ~~In the past, securities~~ **Securities** class action litigation ~~has~~ **is** often ~~been~~ initiated against companies following periods of volatility in their stock price **. For example, a putative class action civil complaint was recently filed against the Company and certain current and former executive officers of the Company asserting violations of federal securities laws, as further described in Note 16 to our Consolidated Financial Statements** . This type of litigation could result in substantial costs and divert our management' s attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation, which may harm our business, prospects, operating results, and financial condition. Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings. A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of December 31, ~~2023~~ **2024** , our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 39. ~~3~~ **0** % of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of December 31, ~~2023~~ **2024** . If our significant shareholders or we sell substantial amounts of our Common Stock in the public market, or there is a perception that such sales may occur, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders also might make it more difficult for us to raise funds by selling equity or equity- related securities in the future at a time and price that we deem appropriate. There can be no assurance that we will **continue to** repurchase shares of our Common Stock or **continue to declare cash dividends** ~~that we will repurchase shares at favorable prices~~ . In ~~January~~ **April** ~~2023~~ **2024** , our board of directors authorized a share repurchase program to repurchase up to $ 3. 0 billion of our Common Stock (of which $ 1. ~~531~~ **917** billion remained available as of December 31, ~~2023~~ **2024**) ~~. There~~ **; and, in February 2025, authorized** ~~can~~ **an** ~~be no assurance~~ **additional $ 3. 0 billion for share repurchases. In February 2025, our board** of ~~any~~ **directors also initiated a quarterly cash dividend program and declared a first quarter 2025 cash dividend on our Common Stock and Class A Stock. Any** future share repurchases ~~or~~ **,** share repurchase program authorizations ~~. Any share repurchases~~ **, or dividend declarations** will depend upon, among other factors, our cash balances and potential future capital requirements, our results of operations and financial condition, the price of our Common Stock on the NASDAQ Global Select Market, and other factors that we may deem relevant. ~~We~~ **Our share repurchases and dividend payments may change from time to time, and we** can provide no assurance that we will repurchase shares of our Common Stock at favorable prices, ~~if~~ **in particular amounts, or** at all **, or that we will maintain or increase our quarterly cash dividend payments or declare future cash dividends. A reduction in our share repurchases or reduction in, or elimination of, our quarterly cash dividend payments could have an adverse effect on our stock price** . Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of December 31, ~~2023~~ **2024** , holders of Class A Stock held 14. ~~5~~ **4** % of the combined voting power of all shares of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to substantially influence the election of our directors and the vote on certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our

taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of December 31, ~~2023~~ **2024** : • our current executive officers and directors beneficially owned ~~6~~ **5** . ~~1~~ **4** % of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options **and release of all restricted stock units** held by such persons which are exercisable **or releasable** within 60 days of December 31, ~~2023~~ **2024** , and 17. ~~7~~ **2** % of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options **and release of all restricted stock units** held by such persons which are exercisable **or releasable** within 60 days of December 31, ~~2023~~ **2024** ; and • our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 39. ~~3~~ **0** % of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days **of** December 31, ~~2023~~ **2024** . In addition, these five shareholders plus our Chief Executive Officer held approximately 46. ~~5~~ **2** % of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of December 31, ~~2023~~ **2024** . The anti- takeover effects of provisions of our charter, by- laws, and of New York corporate law, as well as the contractual provisions in our investor and collaboration agreements and certain provisions of our compensation plans and agreements, could deter, delay, or prevent an acquisition or other" change of control" of us and could adversely affect the price of our Common Stock. Our certificate of incorporation, our by- laws, and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our Company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions include: • authorization to issue" blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our Common Stock and Class A Stock; • a staggered board of directors, so that it would take three successive annual shareholder meetings to replace all of our directors; • a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80 %) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors; • a provision whereby any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting; • a requirement that any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and • under the New York Business Corporation Law, in addition to certain restrictions which may apply to" business combinations" involving our Company and an" interested shareholder," a plan of merger or consolidation of our Company must be approved by two- thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor above captioned" Our existing shareholders may be able to exert substantial influence over matters requiring shareholder approval and over our management." Further, certain of our current or former collaborators are currently bound by" standstill" provisions under their respective agreements with us. These include the January 2014 amended and restated investor agreement between us and Sanofi, as amended, which contractually prohibits Sanofi from seeking to directly or indirectly exert control of our Company or acquiring more than 30 % of our Class A Stock and Common Stock, taken together. In addition, our Change in Control Severance Plan and the employment agreement with our Chief Executive Officer, each as amended and restated, provide for severance benefits in the event of termination as a result of a change in control of our Company. Also, equity awards issued under our long- term incentive plans may become fully vested in connection with a" change in control" of our Company, as defined in the plans. These contractual provisions may also have the effect of deterring, delaying, or preventing an acquisition or other change in control.