

Risk Factors Comparison 2024-02-23 to 2023-02-22 Form: 10-K

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

In evaluating our business, you should carefully consider the following discussion of material risks, events and uncertainties that make an investment in us speculative or risky in addition to the other information in this Annual Report on Form 10-K. A manifestation of any of the following risks and uncertainties could, in circumstances we may or may not be able to accurately predict, materially and adversely affect our business and operations, growth, reputation (including the commercial or scientific reputation of our products), prospects, product pipeline and sales, operating and financial results, financial condition, cash flows, liquidity and stock price. We note these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. It is not possible to predict or identify all such factors; our operations could also be affected by factors, events or uncertainties that are not presently known to us or that we currently do not consider to present significant risks to our operations. Therefore, you should not consider the following risks to be a complete statement of all the potential risks or uncertainties that we face.

Product and Commercialization Risks Certain of our products subject us to additional or heightened risks. HIV We receive a substantial portion of our revenue from sales of our products for the treatment and prevention of HIV infection. During the year ended December 31, ~~2022~~ **2023**, sales of our HIV products accounted for approximately ~~64~~ **67**% of our total product sales. We may be unable to sustain or increase sales of our HIV products for any number of reasons, including market share gains by competitive products, including generics, or the inability to introduce new HIV medications necessary to remain competitive. In such case, we may need to scale back our operations, including our future drug development and spending on research and development (“ R & D ”) efforts. For example, many of our HIV products contain tenofovir alafenamide (“ TAF ”), which belongs to the nucleoside class of antiviral therapeutics. If there are any changes to the treatment or prevention paradigm for HIV ~~that cause~~, **and** nucleoside- based therapeutics ~~to fall out of favor~~ **do not remain the preferred regimen**, our HIV product sales would be adversely impacted.

Veklury We face risks related to our supply and ~~distribution~~ **sale** of Veklury, which was approved by U. S. Food and Drug Administration (“ FDA ”) ~~in October 2020~~ as a treatment for patients ~~hospitalized~~ with coronavirus disease 2019 (“ COVID- 19 ”), ~~in January 2022~~ as a treatment for ~~non- hospitalized adult and adolescent patients who are at high risk of progression to severe COVID- 19, including hospitalization or death, and in April 2022~~ as a treatment for ~~pediatric patients who are 28 days of age (and older), weighing at least 3 kg, and are either hospitalized with COVID- 19 or have mild- to- moderate COVID- 19 and are considered at high risk for progression to severe COVID- 19, including hospitalization or death.~~ While Veklury sales generally reflect COVID- 19 related rates and severity of infections and hospitalizations, as well as the availability, uptake and effectiveness of vaccines and alternative treatments for COVID- 19. **In May 2023**, we are ~~unable to accurately predict our revenues or supply needs over~~ **the World Health Organization declared the end of COVID- 19 as a public health emergency of international concern. Future sales of Veklury in** the short- and long- term **remain uncertain** due to the dynamic nature of the COVID- 19 pandemic. If we do not accurately forecast demand or manufacture Veklury at levels to align with actual demand, then we may experience product shortages or build excess inventory that may need to be written off. ~~We also remain subject to significant public attention and scrutiny over the complex decisions made regarding clinical data, supply, allocation, distribution and pricing of Veklury, all of which affects our corporate reputation.~~ Cell Therapy Advancing a novel and personalized therapy such as Yescarta or Tecartus, which are chimeric antigen receptor (“ CAR ”) T- cell therapies, creates significant challenges, including: • educating and certifying medical personnel regarding the procedures and the potential side effects, such as cytokine release syndrome and neurologic toxicities, in compliance with the Risk Evaluation and Mitigation Strategy program required by FDA; • securing sufficient supply of other medications to manage side effects, such as tocilizumab and corticosteroids, which may not be available in sufficient quantities, may not adequately control the side effects and / or may have detrimental impacts on the efficacy of cell therapy; • developing and maintaining a robust and reliable process for engineering a patient’ s T cells in our facilities and infusing them back into the patient; and • conditioning patients with chemotherapy in advance of administering our therapy, which may increase the risk of adverse side effects. The use of engineered T cells as a potential cancer treatment is a recent development and may not be broadly accepted by physicians, patients, hospitals, cancer treatment centers, payers and others in the medical community. While FDA has approved some cell therapies, including Yescarta and Tecartus, we must continue to demonstrate to the medical community the potential advantages of cell therapy compared to existing and future therapeutics. **In November 2023, FDA announced that it is investigating the risk of T- cell malignancies in patients who received treatment with CAR T- cell therapy, noting that the overall benefits of CAR T- cell therapy products continue to outweigh their potential risks for their approved uses. In January 2024, FDA determined that safety labeling issues were needed for approved CAR T- cell therapies, including a “ boxed warning ” about the possible risk of T- cell malignancies in patients treated with CAR T- cell therapy. Additionally, FDA requested continued monitoring and reporting of cases of secondary cancers.** For challenges related to the reimbursement of Yescarta and Tecartus, see also “ Our existing products are subject to reimbursement pressures from government agencies and other third parties, required rebates and ~~other discounts~~, **on our products** and other pricing pressures. ” We rely on third- party sites to collect patients’ white blood cells, known as apheresis centers, as well as shippers, couriers, and hospitals for the logistical collection of patients’ white blood cells and ultimate delivery of Yescarta and Tecartus to patients. These vendors may encounter disruptions or difficulties that could result in product loss and regulatory action. Apheresis centers may also choose not to participate in our quality certification process, or we may be unable to complete such certification in a timely manner or at all, which could delay or constrain our manufacturing and commercialization efforts. We ~~operate a new automated~~ **also face risks related to our in- house** CAR T- cell therapy manufacturing ~~facility~~ **facilities** in Frederick

California, Maryland, which received FDA approval for commercial production in April 2022. We have not previously manufactured our products in an **and the Netherlands automated facility on a commercial scale, spanning process development** and as a result, we may require additional time and resources in order to effectively increase manufacturing capacity. We also operate a new retroviral vector manufacturing facility in Oceanside, **clinical trial production and** California, which received FDA approval for commercial production ~~--- product~~ in October 2022. We also have not previously manufactured viral vectors on a commercial scale, and as a result, we may require additional time and resources in order to effectively increase manufacturing capacity. **Quality, reliability and speed are critical in cell therapy manufacturing to quickly and safely deliver our cell therapies to patients. Any delays or quality issues with our manufacturing operations could adversely affect our business and damage our reputation**. In addition, we may not be able to produce or otherwise obtain an amount of viral vector supply sufficient **sufficiently increase manufacturing network capacity** to satisfy ~~meet~~ **growing** demand for our finished products. If we are unable to meet product demand, we will have difficulty meeting sales forecasts for our finished products. Our success depends on developing and commercializing new products or expanding the indications for existing products. If we are unable to launch commercially successful new products or new indications for existing products, our business will be adversely impacted. The launch of commercially successful products is necessary to grow our business, cover our substantial R & D expenses, and offset revenue losses when existing products lose market share due to factors such as competition and loss of patent exclusivity. There are many difficulties and uncertainties inherent in drug development and the introduction of new products. The product development cycle is characterized by significant investments of resources, long lead times and unpredictable outcomes due to the nature of developing medicines for human use. We expend significant time and resources on our product pipeline without any assurance that we will recoup our investments or that our efforts will be commercially successful. A high rate of failure is inherent in the discovery and development of new products, and failure can occur at any point in the process, including late in the process after substantial investment. We face challenges in accurately forecasting sales because of the difficulties in predicting demand for our products and fluctuations in purchasing patterns or wholesaler inventories. We may be unable to accurately predict demand for our products, including the uptake of new products, as demand depends on a number of factors. For example, product demand may be adversely affected if physicians do not see the benefit of our products. Additionally, the non-retail sector in the U. S., which includes government institutions, including state AIDS Drug Assistance Programs, the U. S. Department of Veterans Affairs, correctional facilities and large health maintenance organizations, tends to be less consistent in terms of buying patterns and often causes quarter-over-quarter fluctuations that do not mirror actual patient demand for our products. Federal and state budget pressures, as well as the annual grant cycles for federal and state funds, may cause purchasing patterns to not reflect patient demand for our products. We expect to continue to experience fluctuations in the purchasing patterns of our non-retail customers. In light of the budget crises faced by many European countries, we have observed variations in purchasing patterns induced by cost containment measures in Europe. We believe these measures have caused some government agencies and other purchasers to reduce inventory of our products in the distribution channels, and we may continue to see this trend in the future. We sell and distribute most of our products in the U. S. exclusively through the wholesale channel. For the year ended December 31, ~~2022~~ **2023**, approximately ~~89-91~~ % of our product sales in the U. S. were to three wholesalers, **Cencora, Inc. (formerly known as AmerisourceBergen Corporation)**, Cardinal Health, Inc. and McKesson Corporation. The U. S. wholesalers with whom we have entered into inventory management agreements make estimates to determine end-user demand and may not be accurate in matching their inventory levels to actual end-user demand. As a result, changes in inventory levels held by those wholesalers can cause our operating results to fluctuate unexpectedly if our sales to these wholesalers do not match end-user demand. In addition, inventory is held at retail pharmacies and other non-wholesaler locations with whom we have no inventory management agreements and no control over buying patterns. Adverse changes in economic conditions, increased competition or other factors may cause retail pharmacies to reduce their inventories of our products, which would reduce their orders from wholesalers and, consequently, the wholesalers' orders from us, even if end-user demand has not changed. In addition, we have observed that strong wholesaler and sub-wholesaler purchases of our products in the ~~fourth quarter~~ **second half of the year** typically results in inventory draw-down by wholesalers and sub-wholesalers in the subsequent first quarter. As inventory in the distribution channel fluctuates from quarter to quarter, we may continue to see fluctuations in our earnings and a mismatch between prescription demand for our products and our revenues. We face significant competition from global pharmaceutical and biotechnology companies, specialized pharmaceutical firms and generic drug manufacturers. New branded or generic products entering major markets affects our ability to maintain pricing and market share. Our products compete with other available products based primarily on efficacy, safety, tolerability, acceptance by doctors, ease of patient compliance, ease of use, price, insurance and other reimbursement coverage, distribution and marketing. A number of companies are pursuing the development of products and technologies that may be competitive with our existing products or research programs. These competing companies include large pharmaceutical and biotechnology companies and specialized pharmaceutical firms acting either independently or together with other such companies. Furthermore, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection or may establish collaborative arrangements for competitive products or programs. We may be adversely impacted if any of these competitors gain market share as a result of new technologies, commercialization strategies or otherwise. Product Reimbursements Successful commercialization of our products depends, in part, on the availability and amount of third-party payer reimbursement for our products and related treatments and medical services in the markets where we sell our products. As our products mature, pricing pressures from private insurers and government payers often result in a reduction of the net product prices. Legislative and regulatory actions affecting government prescription drug procurement and reimbursement programs occur relatively frequently. For example, in September 2020, FDA issued a final rule implementing a pathway for the importation of certain prescription drugs from Canada. This rule is subject **In January 2024, FDA authorized Florida's proposed program** to ongoing litigation **import**

prescription drugs from Canada, although Florida must meet certain additional requirements before it can begin shipments of prescription drugs into the U. S. from Canada. The list of the specific prescription drugs that Florida intends to import has not been made public. We may be adversely impacted by any such legislative and regulatory actions, though it is difficult to predict the impact, if any, on the use and reimbursement of our products. Product Pricing, Discounts and Rebates In the U. S., the European Union (“ EU ”) and other significant or potentially significant markets for our products and product candidates, government authorities and third- party payers are increasingly attempting to limit or regulate the price of medical products and services. The volume of drug pricing- related legislation has dramatically increased in recent years, including: • U. S. Congress has enacted laws requiring manufacturer refunds on certain amounts of discarded drug from single-use vials ~~beginning in 2023~~ and eliminating the existing cap on Medicaid rebate amounts beginning in 2024. • U. S. Congress has enacted the Inflation Reduction Act of 2022 (the “ Act ”), which, among other changes, (1) requires the Department of Health and Human Services to “ negotiate ” Medicare prices for certain drugs (starting with 10 drugs in 2026, adding 15 drugs in 2027 and 2028, and adding 20 drugs in 2029 and subsequent years), (2) imposes an inflation- based rebate on Medicare Part B utilization starting in 2023 and Part D utilization beginning October 1, 2022, and (3) restructures the Medicare Part D benefit to cap out- of- pocket expenses for Part D beneficiaries beginning in 2024 and, effective January 1, 2025, increases Part D plans’ contributions in the catastrophic coverage phase and ~~increase~~ **increases** manufacturers’ discount contributions across coverage phases such that manufacturers must pay a 10 % discount in the initial coverage phase and a 20 % discount in the catastrophic phase on drugs utilized by all Part D beneficiaries, including low income subsidy patients. We continue to evaluate the **potential** impact of the Act on our business. **Centers for Medicare & Medicaid Services (“ CMS ”) has issued a number of guidance documents,** but ~~expect it remains unclear how certain provisions will be implemented.~~ **Additional guidance, legislation or rulemaking may be issued that could reflect the government’s evolving views. In addition, multiple manufacturers and trade organizations have challenged the Medicare “ negotiation ” provisions of the Act, and additional legal challenges may be filed in the future. While the full impact of the Act on our business and the pharmaceutical industry remains uncertain at this time, we anticipate that** the Act will increase our payment obligations under the redesigned Part D discount program, limit the prices we can charge **for our products**, and increase the rebates we must provide government programs for our products, thereby reducing our profitability and negatively impacting our financial results. ~~In addition, it is unclear how certain provisions of the Act will be implemented, there may be additional legislation or rulemaking related to the Act and select provisions may become subject to legal challenges in the future. Therefore, the full impact of the Act on the profitability of our business and the pharmaceutical industry as a whole remains uncertain at this time.~~ Many state legislatures are considering, or have already passed into law, legislation that seeks to indirectly or directly regulate pharmaceutical drug pricing, such as requiring manufacturers to publicly report proprietary pricing information, creating review boards for prices, **establishing drug payment limits,** and encouraging the use of generic drugs. **For example, in August 2023, the Colorado Prescription Drug Affordability Review Board selected Genvoya for an affordability review, and it is possible the board may designate an upper limit on the amount certain purchasers and payors can pay for Genvoya.** These initiatives and such other legislation may cause added pricing pressures on our products, and the resulting impact on our business is uncertain **at this time**. • Many countries outside the U. S., including the EU member states, have established complex and lengthy procedures to obtain price approvals and coverage reimbursement and periodically review their pricing and reimbursement decisions. The outcome of these reviews cannot be predicted and could have an adverse effect on the pricing and reimbursement of our medical products in the EU member states. Reductions in the pricing of our medical products in one member state could affect the price in other member states and have a negative impact on our financial results. A substantial portion of our product sales is subject to significant discounts from list price, including rebates that we may be required to pay state Medicaid agencies and discounts provided to covered entities under Section 340B of the Public Health Service Act (“ 340B ”). Changes to the 340B program or the Medicaid program at the federal or state level could have a material adverse effect on our business. For example, the continued growth of the 340B program limits the prices we may charge on an increasing percentage of sales. Changes to the calculation of rebates under the Medicaid program could substantially increase our Medicaid rebate obligations and decrease the prices we charge 340B- covered entities. ~~We recently~~ **In March 2022, we** implemented a contract pharmacy integrity initiative for our branded hepatitis C virus (“ HCV ”) products. This integrity initiative ~~will~~ **does** not involve any products from Asegua Therapeutics LLC. Our integrity initiative requires covered entities that enter into 340B bill to / ship to arrangements with contract pharmacies for our branded HCV products to provide claims level data for units dispensed from such contract pharmacies; covered entities without an in- house pharmacy that choose not to participate in the initiative can designate a single contract pharmacy for shipment. Certain manufacturers that have implemented other contract pharmacy integrity programs have received enforcement letters from the U. S. Department of Health and Human Services (“ HHS ”) asserting that those programs violate the 340B statute, have been referred to the HHS Office of Inspector General for assessment of civil monetary penalties, and have been subject to administrative dispute resolution proceedings brought on behalf of covered entities. These manufacturers are currently challenging HHS’ position in ongoing litigation. **Certain states have also enacted laws requiring manufacturers to provide 340B pricing** ~~Although~~ **through contract pharmacy arrangements;** ~~we believe these laws, which are being challenged in ongoing litigation, are invalid.~~ **We also** believe that our integrity initiative complies with the requirements of the 340B statute. **However,** additional legal or legislative developments with respect to the 340B program, including potential litigation with HHS **or other stakeholders,** may negatively impact our ability to implement or continue our integrity initiative. In addition, standard reimbursement structures may not adequately reimburse for innovative therapies. For example, beginning in fiscal year 2021, CMS established a new severity- adjusted diagnosis- related group (“ DRG ”) 018 for Medicare inpatient reimbursement of CAR T- cell products such as Yescarta and Tecartus. While the new DRG has a significantly higher base payment amount than the prior DRG 016, the payment available may not be sufficient to reimburse some hospitals for their cost of care for patients receiving Yescarta and Tecartus. When reimbursement is not aligned

well to account for treatment costs, Medicare beneficiaries may be denied access as this misalignment could impact the willingness of some hospitals to offer the therapy and of doctors to recommend the therapy. Additionally, in the EU, there are barriers to reimbursement in individual countries that could limit the uptake of Yescarta and Tecartus. Moreover, we estimate the rebates we will be required to pay in connection with sales during a particular quarter based on claims data from prior quarters. In the U. S., actual rebate claims are typically made by payers one to three quarters in arrears. Actual claims and payments may vary significantly from our estimates. We may experience adverse impacts resulting from the importation of our products from lower price markets or the distribution of illegally diverted or counterfeit versions of our products. Prices for our products are based on local market economics and competition and sometimes differ from country to country. Our sales in countries with relatively higher prices may be reduced if products can be imported and resold into those countries from lower price markets. For example, U. S. sales could also be affected if FDA permits importation of drugs from Canada. We have entered into agreements with generic drug manufacturers as well as licensing agreements with the Medicines Patent Pool, a United Nations- backed public health organization, which allow generic drug manufacturers to manufacture generic versions of certain of our products for distribution in certain low- and middle- income countries. We may be adversely affected if any generic versions of our products, whether or not produced and / or distributed under these agreements, are exported to the U. S., the EU or markets with higher prices. In the EU, we are required to permit products purchased in one EU member state to be sold in another member state. Purchases of our products in member states where our selling prices are relatively low for resale in member states in which our selling prices are relatively high can affect the inventory level held by our wholesalers and can cause the relative sales levels in the various countries to fluctuate from quarter to quarter and not reflect the actual consumer demand in any given quarter. Additionally, diverted products may be used in countries where they have not been approved and patients may source the diverted products outside the legitimate supply chain. These diverted products may be handled, shipped and stored inappropriately, which may affect the **quality and / or** efficacy of the products and could harm patients and adversely impact us. We are also aware of the existence of various suppliers around the world that, without Gilead’ s authorization, purport to source our products and generic versions of our products and sell them for use in countries where those products have not been approved. As a result, patients may be at risk of taking unapproved medications that may not be what they purport to be, may not have the potency they claim to have or may contain harmful substances, which could harm patients and adversely impact us. Further, third parties have illegally distributed and sold, and may continue to illegally distribute and sell, illegally diverted and counterfeit versions of our medicines, which do not meet the rigorous quality standards of our manufacturing and supply chain. For example, as part of a U. S. civil enforcement lawsuit in coordination with law enforcement, and pursuant to court order, we seized thousands of bottles of Gilead- labeled medication with counterfeit supply chain documentation. Our investigation revealed that pharmaceutical distributors that are not authorized by Gilead to sell Gilead medicine sold purportedly genuine Gilead medicine sourced from an illegal counterfeiting scheme to independent pharmacies nationwide. Illegally diverted and counterfeit versions of Gilead- branded medicines exist and may pose a serious risk to patient health and safety. Our actions to stop or prevent the distribution and sale of illegally diverted and counterfeit versions of our medicines around the world may be costly and unsuccessful, which may adversely affect patients and our reputation and business, including our product revenues and financial results.

Product Development and Supply Chain Risks We face risks in our clinical trials, including the potential for unfavorable results, delays in anticipated timelines and disruption. We are required to demonstrate the safety and efficacy of product candidates that we develop for each intended use through extensive preclinical studies and clinical trials. The results from these studies do not always accurately predict results in later, large- scale clinical trials. Even successfully completed large- scale clinical trials may not result in marketable products. We face numerous risks and uncertainties with our clinical trials that could result in delays or prevent completion of the development and approval of our product candidates, including challenges in clinical trial protocol design, our ability to enroll patients in clinical trials, the possibility of unfavorable or inadequate trial results to support further development of our product candidates, including failure to meet a trial’ s primary endpoint, safety issues arising from our clinical trials, and the need to modify or delay our clinical trials or to perform additional trials. For example, in October 2022, we announced that FDA issued a complete response letter for our Biologics License Application for bulevirtide for the treatment of adults with hepatitis delta virus infection. In **addition January 2024**, see Note 8. Goodwill and Intangible Assets **we announced that our Phase 3 EVOKE- 01 study evaluating sacituzumab govitecan- hziy did not meet its primary endpoint of overall survival** the Notes to Consolidated Financial Statements included in Part II, Item 8 of **previously treated metastatic non- small cell lung cancer (“ NSCLC ”)**. We believe **that this represents Annual Report on Form 10- K for a discussion of the partial in- process research and- an development indicator of potential impairment in the first quarter of 2024, which could result in us being required to record an impairment charge that we recognized during the three months ended March 31, 2022-2024 related to assets**. Any such **impairment charge, which we acquired from Immunomedics are unable to reasonably estimate at this time**, **we could have a material impact on our results of operations (for more information, see Item 7. Management’ s Discussion and Analysis of Financial Condition and Results of Operations “ Immunomedics Results of Operations- In- Process Research and Development Impairments ”)**. **In addition, in February 2020-2024**, we announced a full clinical hold placed by FDA on all magrolimab studies in myelodysplastic syndromes and acute myeloid leukemia, and that we will not pursue further development of magrolimab in hematologic cancers. As a result, we may be unable to successfully complete our clinical trials on our anticipated timelines, or at all. Based on trial results, it is possible that FDA and other regulatory authorities do not approve our product candidates, or that any market approvals include significant limitations on the products’ use. In addition, clinical trials involving our commercial products can raise new safety issues for our existing products, which could adversely impact our business. Further, we **have in the past and we may in the future** make a strategic decision to discontinue development of our product candidates **if, for example, including but not limited to situations where** we believe commercialization will be difficult relative to other opportunities in our pipeline. **For example, in February 2024, we**

announced a full clinical hold placed by FDA on all magrolimab studies in myelodysplastic syndromes and acute myeloid leukemia, and based on these results and data from other clinical studies, we will not pursue further development of magrolimab in hematologic cancers. In addition, in January 2024, we announced with our partner Arcus Biosciences, Inc. (“ Arcus ”) the discontinuation of further enrollment in the Phase 3 ARC- 10 study evaluating domvanalimab plus zimberelimab in first- line locally advanced or metastatic, PD- L1- high NSCLC based on strategic prioritization to advance and potentially accelerate other Phase 3 studies in our collaboration with Arcus. Therefore, our product candidates may never be successfully commercialized, and we may be unable to recoup the significant R & D and clinical trial expenses incurred. We expect to ~~expend~~ **spend** significant time and resources on our clinical trial activities without any assurance that we will recoup our investments or that our efforts will be commercially successful. There are also risks associated with the use of third parties in our clinical trial activities. We extensively outsource our clinical trial activities and usually perform only a small portion of the start- up activities in- house. We rely on independent third- party contract research organizations (“ CROs ”) to perform most of our clinical studies, including document preparation, site identification, screening and preparation, pre- study visits, training, program management, patient enrollment, ongoing monitoring, site management and ~~bioanalytical analysis~~ **bioanalysis**. Many important aspects of the services performed for us by the CROs are out of our direct control. If there is any dispute or disruption in our relationship with our CROs, our clinical trials may be delayed. Moreover, in our regulatory submissions, we rely on the quality and validity of the clinical work performed by third- party CROs. If any of our CROs’ processes, methodologies or results were determined to be invalid or inadequate, our own clinical data and results and related regulatory approvals may be adversely affected. We may face manufacturing difficulties, delays or interruptions, including at our third- party manufacturers and corporate partners. Our products, which are manufactured at our own facilities or by third- party manufacturers and corporate partners, are the result of complex, highly regulated manufacturing processes. We depend on third- party manufacturers and corporate partners to perform manufacturing activities effectively and on a timely basis for the majority of our active pharmaceutical ingredients and drug products. These third parties are independent entities subject to their own unique operational and financial risks that are out of our control. We and our third- party manufacturers and corporate partners are subject to Good Manufacturing Practices (“ GMP ”), which are extensive regulations governing manufacturing processes, stability testing, record keeping and quality standards as defined by FDA and European Medicines Agency (“ EMA ”), as well as comparable regulations in other jurisdictions. Manufacturing operations are also subject to routine inspections by regulatory agencies. Any adverse developments affecting or resulting from our manufacturing operations or the operations of our third- party manufacturers and corporate partners may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the commercial supply of our products. We have incurred, and will continue to incur, inventory write- off charges and other expenses for products that fail to meet specifications and quality standards **as well as changes we may adopt in our manufacturing strategy** , and we may need to undertake costly remediation efforts or seek more costly manufacturing alternatives . **For example, see Note 10. Other Financial Information of the Notes to Consolidated Financial Statements included in Part II, Item 8 of this Annual Report on Form 10- K for a discussion of certain charges we incurred related to changes in our manufacturing strategy** . Such developments could increase our manufacturing costs, cause us to lose revenues or market share and damage our reputation. In addition, manufacturing issues may cause delays in our clinical trials and applications for regulatory approval. For example, if we are unable to remedy any deficiencies cited by FDA or other regulatory agencies in their inspections, our existing products and the timing of regulatory approval of product candidates in development could be adversely affected. Further, there is risk that regulatory agencies in other countries where marketing applications are pending will undertake similar additional reviews or apply a heightened standard of review, which could delay the regulatory approvals for products in those countries. Our business may be adversely affected if approval of any of our product candidates were delayed or if production of our products were interrupted. We may not be able to obtain materials or supplies necessary to conduct clinical trials or to manufacture and sell our products, which could limit our ability to generate revenues. We need access to certain supplies and products to conduct our clinical trials and to manufacture and sell our products. If we are unable to purchase enough of these materials or find suitable alternative materials in a timely manner, our development efforts for our product candidates may be delayed or our ability to manufacture and sell our products could be limited . **For example, in the U. S., there has been a shortage of certain cancer drugs that are the backbone of standard- of- care treatments, such as carboplatin and cisplatin, which are also used in R & D and clinical trials. While we have observed minimal impacts to our oncology clinical trials to date, if these shortages continue or increase in magnitude, our ongoing and future oncology clinical trials may be delayed, halted or adversely impacted** . Suppliers of key components and materials must be named in the new drug application or marketing authorization application filed with the regulatory authority for any product candidate for which we are seeking marketing approval, and significant delays can occur if the qualification of a new supplier is required. Even after a manufacturer is qualified by the regulatory authority, the manufacturer must continue to expend time, money and effort in the area of production and quality control to maintain full compliance with GMP. Manufacturers are subject to regular periodic inspections by regulatory authorities following initial approval. If, as a result of these inspections, a regulatory authority determines that the equipment, facilities, laboratories or processes do not comply with applicable regulations and conditions of product approval, the regulatory authority may suspend the manufacturing operations. If the manufacturing operations of any of the single suppliers for our products are suspended, we may be unable to generate sufficient quantities of commercial or clinical supplies of product to meet market demand. In addition, if deliveries of materials from our suppliers are interrupted for any reason, **including as a result of natural disasters or extreme weather conditions**, we may be unable to ship certain of our products for commercial supply or to supply our product candidates in development for clinical trials. Also, some of our products and the materials that we utilize in our operations are manufactured by only one supplier or at only one facility, which we may not be able to replace in a timely manner and on commercially reasonable terms, or at all. Problems with any of the single suppliers or facilities we depend on,

including in the event of a disaster, such as an earthquake, flood or fire, equipment failure or other difficulty, may negatively impact our development and commercialization efforts. A significant portion of the raw materials and intermediates used to manufacture our antiviral products are supplied by third- party manufacturers and corporate partners outside of the U. S. As a result, any political or economic factors in a specific country or region, including any changes in or interpretations of trade regulations, compliance requirements or tax legislation, that would limit or prevent third parties outside of the U. S. from supplying these materials could adversely affect our ability to manufacture and supply our antiviral products to meet market needs and have a material and adverse effect on our operating results. If we were to encounter any of these difficulties, our ability to conduct clinical trials on product candidates and to manufacture and sell our products could be impaired.

Regulatory and Other Legal Risks Our operations depend on compliance with complex FDA and comparable international regulations. Failure to obtain broad approvals on a timely basis or to maintain compliance could delay or halt commercialization of our products. The products we develop must be approved for marketing and sale by regulatory authorities and, once approved, are subject to extensive regulation by FDA, EMA and comparable regulatory agencies in other countries. We have filed, and anticipate that we will continue to file, for marketing approval in additional countries and for additional indications and products. These and any future marketing applications we file may not be approved by the regulatory authorities on a timely basis, or at all. Even if marketing approval is granted for these products, there may be significant limitations on their use. We cannot state with certainty when or whether any of our product candidates under development will be approved or launched; whether we will be able to develop, license or acquire additional product candidates or products; or whether any products, once launched, will be commercially successful. Further, how we manufacture and sell our products is subject to extensive regulation and review. For example, under FDA rules, we are often required to conduct post- approval clinical studies to assess a known serious risk, signals of serious risk or to identify an unexpected serious risk. In certain circumstances, we may be required to implement a Risk Evaluation and Mitigation Strategy program for our products, which could include a medication guide, patient package insert, a communication plan to healthcare providers, restrictions on distribution or use of a product and other elements FDA deems necessary to assure safe use of the drug. Discovery of previously unknown problems with our marketed products or product candidates, including serious safety, resistance or drug interaction issues, or problems with our manufacturing, safety reporting or promotional activities, may result in regulatory approvals being delayed, denied or granted with significant restrictions on our products, including limitations on or the withdrawal of the products from the market. Failure to comply with these or other requirements imposed by FDA could result in significant civil monetary penalties, fines, suspensions of regulatory approvals, product recalls, seizure of products and criminal prosecutions. We are impacted by evolving laws, regulations and legislative or regulatory actions applicable to the healthcare industry. The healthcare industry is subject to various federal, state and international laws and regulations pertaining to drug approval, reimbursement, rebates, price reporting, healthcare fraud and abuse, and data privacy and security. In the U. S., these laws include anti- kickback and false claims laws, Federal Food, Drug, and Cosmetic Act, laws and regulations relating to the Medicare and Medicaid programs and other federal and state programs, such as the Medicaid Rebate Statute and the 340B statute, laws that regulate written and verbal communications about our products, individual state laws relating to pricing and sales and marketing practices, the Health Insurance Portability and Accountability Act and other federal and state laws relating to the privacy and security of health information. Actual or alleged violations of these laws or any related regulations may be punishable by criminal and / or civil sanctions, including, in some instances, substantial fines, civil monetary penalties, exclusion from participation in federal and state healthcare programs, including Medicare, Medicaid and U. S. Department of Veterans Affairs and U. S. Department of Defense health programs, actions against executives overseeing our business and significant remediation measures, negative publicity or other consequences. These laws and regulations are broad in scope and subject to changing and evolving interpretations, which could require us to incur substantial costs associated with compliance, or to alter one or more of our sales or marketing practices, or impact our ability to obtain or maintain regulatory approvals. The resulting impact on our business is uncertain and could be material. In addition, government price reporting and payment regulations are complex, and we are continually assessing the methods by which we calculate and report pricing in accordance with these obligations. Our methodologies for calculations are inherently subjective and may be subject to review and challenge by various government agencies, which may disagree with our interpretation. If the government disagrees with our reported calculations, we may need to restate previously reported data and could be subject to additional financial and legal liability. There also continues to be enhanced scrutiny of company- sponsored patient assistance programs, including co- pay assistance programs and manufacturer donations to third- party charities that provide such assistance. There has also been enhanced scrutiny by governments on reimbursement and other patient support offerings, clinical education programs and promotional speaker programs. If we, or our agents and vendors, are deemed to have failed to comply with laws, regulations or government guidance in any of these areas, we could be subject to criminal or civil sanctions. Any similar violations by our competitors could also negatively impact our industry reputation and increase scrutiny over our business and our products. For a description of our government investigations and related litigation, see Note 13.

Commitments and Contingencies of the Notes to Consolidated Financial Statements included in Part II, Item 8 of this Annual Report on Form 10- K. We are subject to risks if significant safety issues arise for our marketed products or our product candidates. As additional studies are conducted after obtaining marketing approval for our products, and as our products are used over longer periods of time by many patients, including patients with underlying health problems or those taking other medicines, we expect to continue finding new issues related to safety, resistance or drug interactions. Any such issues may require changes to our product labels, such as additional warnings, contraindications or even narrowed indications, or to the halt of product sales of a product. Regulatory authorities have been moving towards more active and transparent pharmacovigilance and are making greater amounts of stand- alone safety information and clinical trial data directly available to the public through websites and other means, such as periodic safety update report summaries, risk management plan summaries and various adverse event data. Safety information, without the appropriate context and expertise, may be misinterpreted and lead to

misperception or legal action. Our success depends to a significant degree on our ability to obtain and defend our patents and other intellectual property rights both domestically and internationally, and to operate without infringing upon the patents or other proprietary rights of third parties. Patents and other proprietary rights are very important to our business. As part of our business strategy, we actively seek patent protection both in the U. S. and internationally and file additional patent applications, when appropriate, to cover improvements in our compounds, products and technology. Our success depends to a significant degree on our ability to:

- obtain patents and licenses to patent rights;
- preserve trade secrets and internal know-how;
- defend against infringement of our patents and efforts to invalidate them; and
- operate without infringing on the intellectual property of others.

Because patent applications are confidential for a period of time after filing, we may not know if our competitors have filed applications for technology covered by our pending applications or if we were the first to invent or first to file an application directed toward the technology that is the subject of our patent applications. If competitors file patent applications covering our technology, we may have to participate in litigation, post-grant proceedings before the U. S. Patent and Trademark Office or other proceedings to determine the right to a patent or validity of any patent granted. Such litigation and proceedings are unpredictable and expensive, and could divert management attention from other operations, such that, even if we are ultimately successful, we may be adversely impacted. Patents covering our existing compounds, products and processes, and those that we will likely file in the future, may not provide complete or adequate protection. Filing patent applications is a fact-intensive and complex process. We may file patent applications that ultimately do not result in patents or have patents that do not provide adequate protection for the related product. Future litigation or other proceedings regarding the enforcement or validity of our existing patents or any future patents could result in the invalidation of our patents or substantially reduce their protection. In addition, we may face criticism as a result of our legitimate use of the patent systems to protect our investments in new and useful innovations in medicine. Generic manufacturers have sought, and may continue to seek, FDA approval to market generic versions of our products through an abbreviated new drug application (“ANDA”), the application process typically used by manufacturers seeking approval of a generic drug. For a description of our ANDA litigation, see Note 13. Commitments and Contingencies of the Notes to Consolidated Financial Statements included in Part II, Item 8 of this Annual Report on Form 10-K. ANDA litigation and related settlement and license agreements, in some cases, may result in a loss of exclusivity for our patents sooner than we would otherwise expect. In addition, loss of exclusivity may be earlier than expected under these settlement and license agreements under certain circumstances. For example, settlement and license agreements with generic manufacturers typically include acceleration clauses that permit generic entry before the agreed-upon entry date in certain circumstances, and generic manufacturers may continue to challenge the patents protecting our products. The entry of generic versions of our products has, and may in the future, lead to market share and price erosion. If we are found to infringe the valid patents of third parties, we may be required to pay significant monetary damages or we may be prevented from commercializing products or may be required to obtain licenses from these third parties. We may not be able to obtain alternative technologies or any required license on commercially reasonable terms or at all. If we fail to obtain these licenses or alternative technologies, we may be unable to develop or commercialize some or all of our products. For example, we are aware of patents and patent applications owned by other parties that such parties may claim to cover the use of our products and research activities. For a description of our pending patent litigation, see Note 13. Commitments and Contingencies of the Notes to Consolidated Financial Statements included in Part II, Item 8 of this Annual Report on Form 10-K. Furthermore, we also rely on unpatented trade secrets and improvements, unpatented internal know-how and technological innovation. We protect these rights mainly through confidentiality agreements with our corporate partners, employees, consultants and vendors. We cannot be certain that these parties will comply with these confidentiality agreements, that we have adequate remedies for any breach or that our trade secrets, internal know-how or technological innovation will not otherwise become known or be independently discovered by our competitors. Under some of our R & D agreements, inventions become jointly owned by us and our corporate partner and in other cases become the exclusive property of one party. In certain circumstances, it can be difficult to determine who owns a particular invention and disputes could arise regarding those inventions. We could be adversely affected if our trade secrets, internal know-how, technological innovation or confidential information become known or independently discovered by competitors or if we enter into disputes over ownership of inventions. We face potentially significant liability and increased expenses from litigation and government investigations relating to our products and operations. We are involved in a number of litigation, investigation and other dispute-related matters that require us to expend substantial internal and financial resources.

From time to time, these these matters could require us to pay significant monetary amounts, including royalty payments for past and future sales. For example, on February 1, 2022, we reached an agreement with ViiV Healthcare Company and related parties (collectively, “ViiV”) for a global resolution of all claims related to our sales of Biktarvy, pursuant to which (1) Gilead agreed to make a one-time payment of \$ 1.25 billion and an ongoing royalty at a rate of 3% on future sales of Biktarvy and the bictegravir component of bictegravir-containing products in the U. S. until October 5, 2027, and (2) ViiV granted Gilead a broad worldwide license and covenant not to sue relating to any past, present or future development or commercialization of bictegravir. We expect these matters will continue to require a high level of internal and financial resources for the foreseeable future. These matters have reduced, and are expected to continue to reduce, our earnings and require significant management attention. In addition, the testing, manufacturing, marketing and use of our commercial products, as well as product candidates in development, involve substantial risk of product liability claims. These claims may be made directly by consumers, healthcare providers, pharmaceutical companies or others. We have limited insurance for product liabilities that may arise and claims may exceed our coverage. For a description of our litigation, investigation and other dispute-related matters, see Note 13. Commitments and Contingencies of the Notes to Consolidated Financial Statements included in Part II, Item 8 of this Annual Report on Form 10-K. The outcome of such legal proceedings or any other legal proceedings that may be brought against us, the investigations or any other investigations that may be initiated and any other dispute-related matters, are inherently uncertain, and adverse developments or outcomes can result in significant expenses, monetary damages, penalties or injunctive

relief against us. Operational Risks Our business has been, and may in the future be, adversely affected by outbreaks of epidemic, pandemic or contagious diseases, ~~including the ongoing COVID-19 pandemic~~. Actual or threatened outbreaks of epidemic, pandemic or contagious diseases, or other public health emergencies, may significantly disrupt our global operations and adversely affect our business, financial condition and results of operations. As we have seen with the COVID-19 pandemic, outbreaks can result in global supply chain and logistics disruptions and distribution constraints. The impact of an outbreak or other public health crisis on our results of operations and financial condition would depend on numerous evolving factors, but could involve higher operating expenses, lower demand for our products as a result of governmental, business and individuals' actions taken in response to such an event (including quarantines, travel restrictions and interruptions to healthcare services, which can impact enrollment in or operation of our clinical trials or limit patients' ability or willingness to access and seek care), challenges associated with the safety of our employees and safe occupancy of our job sites, and financial market volatility and significant macroeconomic uncertainty in global markets. An outbreak or public health emergency also could amplify many of the other risks described throughout the "Risk Factors" section of this Annual Report on Form 10-K. We face risks associated with our global operations. Our global operations are accompanied by certain financial, political, economic and other risks, including those listed below:

- **Foreign Currency Exchange:** For the year ended December 31, ~~2022~~ **2023**, approximately ~~31~~ **26** % of our product sales were **denominated in foreign currencies outside the U.S.** Because a significant percentage of our product sales is denominated in foreign currencies, primarily the Euro, we face exposure to adverse movements in foreign currency exchange rates. Overall, we are a net receiver of foreign currencies, and therefore, we benefit from a weaker U.S. dollar and are adversely affected by a stronger U.S. dollar. Our hedging program does not eliminate our exposure to currency fluctuations. We may be adversely impacted if the U.S. dollar appreciates significantly against certain currencies and our hedging program does not sufficiently offset the effects of such appreciation. For example, see **"Foreign Currency Exchange Impact" in Part II, Item 7** of this Annual Report on Form 10-K for a discussion of our exposure to movements in foreign currency exchange rates, primarily in the Euro, and the impacts from foreign currency exchange, net of hedges, for the year ended December 31, ~~2022~~ **2023**.
- **Interest Rates and Inflation:** We hold interest-generating assets and interest-bearing liabilities, including our available-for-sale debt securities and our senior unsecured notes and credit facilities. Fluctuations in interest rates, including the U.S. Federal Reserve's recent increases in interest rates **and anticipated decreases in 2024**, could expose us to increased financial risk. In addition, high inflation, such as what we are seeing in the current economic environment, has adversely impacted and may continue to adversely impact our business and financial results.
- **Anti-Bribery:** We are subject to the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws that govern our international operations with respect to payments to government officials. Our international operations are heavily regulated and require significant interaction with foreign officials. We operate in parts of the world that have experienced governmental corruption to some degree. In certain circumstances, strict compliance with anti-bribery laws may conflict with local customs and practices or may require us to interact with doctors and hospitals, some of which may be state-controlled, in a manner that is different than local custom. It is possible that certain of our practices may be challenged under these laws. In addition, our internal control policies and procedures may not protect us from reckless or criminal acts committed by our employees and agents. Enforcement activities under anti-bribery laws could subject us to administrative and legal proceedings and actions, which could result in civil and criminal sanctions, including monetary penalties and exclusion from healthcare programs. Other risks inherent in conducting a global business include:
- **Restrictive government actions against our intellectual property and other foreign assets** such as nationalization, expropriation, the imposition of compulsory licenses or similar actions, including waiver of intellectual property protections.
- **Protective economic policies taken by foreign governments**, such as trade protection measures and import and export licensing requirements, which may result in the imposition of trade sanctions or similar restrictions by the U.S. or other governments.
- **Political instability or disruption in a geographic region where we operate, regardless of cause, including war, terrorism, social unrest and political changes, including in China, Russia, Ukraine, Israel and surrounding areas.**
- **Increasing use of social media platforms and modern technologies present new risks and challenges, and inappropriate or unauthorized use of these platforms can result in exposure of sensitive data or information and damage our brand and reputation.**
- **Climate change and related natural disasters, as well as legal, regulatory, or market measures to address climate change, can negatively affect our Business-business interruptions stemming from and operations. Many of our operations and facilities, including those essential to our manufacturing, R & D and commercialization / distribution activities, are located in regions subject to natural or man-made disasters, such as climate change, earthquakes, hurricanes, rising sea levels and flooding, fires, extreme heat, drought or other extreme weather conditions actual or threatened public health emergencies, or efforts taken by third parties to prevent or mitigate such disasters, such as public safety power shutoffs and facility shutdowns. The severity and frequency of weather-related events has been amplified, and is expected to continue to be amplified, by climate change. Such natural disasters have caused, and in the future may cause, damage to and / for- or disrupt our operations, which we may not have sufficient insurance result in a material adverse effect on our business and financial results. For example, our facility in Cork, Ireland, where we conduct commercial manufacturing, packaging and labeling and perform quality control testing and final release of many of our products, temporarily suspended on-site operations as a result of the flooding caused by Storm Babet in October 2023. Additionally, our corporate headquarters in Foster City and certain R & D and manufacturing facilities are located in California, a seismically active region. In the event Although we have business continuity plans and contingencies in place and conduct periodic assessments of our natural disaster risk as part of our overall enterprise risk management program, a major earthquake or other natural disaster can result in, we may not carry sufficient earthquake insurance, and significant recovery time could and a prolonged interruption to our operational and business activities. We may be required to incur significant costs to remedy the effects of such natural disasters and to resume or restore our operations, which could adversely impact us.**
- **Political instability or Our suppliers and third-party manufacturers and corporate partners**

face similar risks, and any disruption in a geographic region where we operate to their operations could have an adverse effect on our manufacturing and supply chain. Also, regardless of cause see risks under the headings “ We may face manufacturing difficulties, delays or interruptions , including war, terrorism, social unrest at our third- party manufacturers and political corporate partners ” and “ We may not be able to obtain materials or supplies necessary to conduct clinical trials or to manufacture and sell our products, which could limit our ability to generate revenues. ” In addition, growing concern regarding climate changes— change has resulted in an evolving legal and regulatory landscape, with new requirements enacted to prevent, mitigate or adapt to the implications of climate change. These regulations, which can differ across jurisdictions, subject Gilead to many transitional risks , including in China, Russia for example, new or expanded carbon pricing or taxes, increased compliance costs, restrictions on greenhouse gas emissions, investment in new technologies, increased carbon disclosure and Ukraine transparency, investments in data gathering and reporting systems, upgrades of facilities to meet new building codes and the redesign of utility systems, which could increase the company’ s operating costs, including the cost of electricity and energy. Our suppliers and third- party manufacturers and corporate partners face similar transition risks and may pass along any increased costs to the company .

Our aspirations, goals and disclosures related to environmental, social and governance (“ ESG ”) matters expose us to numerous risks, including risks to our reputation and stock price. Institutional and individual investors are increasingly using ESG screening criteria to determine whether Gilead qualifies for inclusion in their investment portfolios. We are frequently asked by investors and other stakeholders to set ambitious ESG goals and provide new and more robust disclosure on goals, progress toward goals and other matters of interest to ESG stakeholders. In response, we have adapted the tracking and reporting of our corporate responsibility program to various evolving ESG frameworks, and we have established and announced goals and other objectives related to ESG matters. These goal statements reflect our current plans and aspirations and are not guarantees that we will be able to achieve them. Our efforts to accomplish and accurately report on these goals and objectives present numerous operational, reputational, financial, legal and other risks, any of which could have a material negative impact, including on our reputation and stock price. Our ability to achieve any goal or objective, including with respect to environmental and diversity initiatives, is subject to numerous risks, many of which are outside of our control. Examples of such risks include: (1) the availability and cost of low- or non- carbon- based energy sources and technologies, (2) evolving regulatory requirements affecting ESG standards or disclosures, (3) the availability of suppliers that can meet our sustainability, diversity and other standards, (4) our ability to recruit, develop and retain diverse talent in our labor markets and (5) the impact of our organic growth and acquisitions or dispositions of businesses or operations. The standards for tracking and reporting on ESG matters are relatively new, have not been harmonized and continue to evolve. Our selection of disclosure frameworks that seek to align with various reporting standards may change from time to time and may result in a lack of consistent or meaningful comparative data from period to period. In addition, regulatory authorities may impose mandatory disclosure requirements with respect to ESG matters. For example, in March 2022, U. S. Securities and Exchange Commission (“ SEC ”) proposed rule changes that would require companies to make certain climate- related disclosures, including information about climate- related risks, greenhouse gas emissions and certain climate- related financial statement metrics. **Also, in October 2023, the California Governor signed the Climate- Related Financial Risk Act and the Climate Corporate Data Accountability Act into law, which impose significant and mandatory climate- related reporting requirements for large companies doing business in the state.** Our processes and controls may not reflect evolving standards for identifying, measuring and reporting ESG matters, immediately or at all, our interpretation of reporting standards may differ from those of others, and such standards may change over time, any of which could result in significant revisions to our goals or reported progress in achieving such goals. In addition, enhancements to our processes and controls to reflect evolving reporting standards may be costly and require additional resources. If our ESG practices do not meet evolving investor or other stakeholder expectations and standards, then our reputation, our ability to attract or retain employees and our attractiveness as an investment, business partner or acquirer could be negatively impacted. Similarly, our failure or perceived failure to pursue or fulfill our goals, targets and objectives or to satisfy various reporting standards within the timelines we announce, or at all, could also have similar negative impacts and expose us to government enforcement actions and private litigation. We depend on relationships with third parties for sales and marketing performance, technology, development, logistics and commercialization of products. Failure to maintain these relationships, poor performance by these companies or disputes with these third parties could negatively impact our business. We rely on a number of collaborative relationships with third parties for our sales and marketing performance in certain territories. In some countries, we rely on international distributors for sales of certain of our products. Some of these relationships also involve the clinical development of these products by our partners. Reliance on collaborative relationships poses a number of risks, including the risk that: • we are unable to control the resources our corporate partners devote to our programs or products; • disputes may arise with respect to the ownership of rights to technology developed with our corporate partners; • disagreements with our corporate partners could cause delays in, or termination of, the research, development or commercialization of product candidates or result in litigation or arbitration; • contracts with our corporate partners may fail to provide significant protection or may fail to be effectively enforced if one of these partners fails to perform; • our corporate partners have considerable discretion in electing whether to pursue the development of any additional products and may pursue alternative technologies or products either on their own or in collaboration with our competitors; • our corporate partners with marketing rights may choose to pursue competing technologies or to devote fewer resources to the marketing of our products than they do to products of their own development; and • our distributors and our corporate partners may be unable to pay us. Given these risks, there is a great deal of uncertainty regarding the success of our current and future collaborative efforts. If these efforts fail, our product development or commercialization of new products could be delayed or revenues from products could decline. Due to the specialized and technical nature of our business, the failure to attract, develop and retain highly qualified personnel could adversely impact us. Our future success will depend in large part on our continued ability to attract,

develop and retain highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical testing, governmental regulation and commercialization. Our ability to do so also depends in part on how well we maintain a strong workplace culture that is attractive to employees. In addition, competition for qualified personnel in the biopharmaceutical field is intense, and there is a limited pool of qualified potential employees to recruit. We face competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations. ~~Additionally~~ **Furthermore**, changes to ~~U.S.~~ immigration and work authorization laws and regulations could make it more difficult for employees to work in or transfer to one of the jurisdictions in which we operate. **Additionally, we periodically make adjustments to reflect our personnel needs in response to changing macroeconomic conditions, market opportunities, management changes, acquisitions, cost levels and other internal and external considerations, which may adversely impact our workplace culture and ability to retain and incentivize employees. The failure to successfully implement or upgrade enterprise resource planning and other information systems could adversely impact our business and results of operations. We periodically implement or upgrade new or enhanced enterprise resource planning (“ERP”) and other information systems in order to better manage our business operations, align our global organizations and enable future growth. Implementation or upgrade of new business processes and information systems requires the commitment of Significant significant personnel, training and financial resources, and entails risks to our business operations. If we do not successfully implement ERP and other information systems improvements, or if there are delays or difficulties in implementing these systems, we may not realize anticipated productivity improvements or cost efficiencies, and we may experience operational difficulties and challenges in effectively managing our business, all of which could result in quality issues, reputational harm, lost market and revenue opportunities, and otherwise adversely affect our business, financial condition and results of operations. For example, we are currently in the process of implementing new ERP and other information systems to help us manage our operations and financial reporting. Costs and risks inherent in this transition may include disruptions to business continuity, administrative and technical problems, interruptions or delays in sales, manufacturing or R & D processes, expenditure overruns, delays in paying our suppliers and employees, and data migration issues. If we do not properly address or mitigate these issues, this could result in increased costs and diversion of resources, negatively impacting our operating results and ability to effectively manage our business. Additionally, if we do not effectively implement the ERP system as planned, or the ERP system does not operate as intended, the effectiveness of our internal control over financial reporting could be negatively affected. Information system service interruptions or breaches, including significant cybersecurity incidents,** could give rise to legal liability and regulatory action under data protection and privacy laws and adversely affect our business and operations. We are dependent upon information technology systems, infrastructure and data, including our Kite Konnect platform, which is critical to maintain chain of identity and chain of custody of Yescarta and Tecartus. The multitude and complexity of our computer systems make them inherently vulnerable to service interruption or destruction, **including those caused by failures during system upgrades or implementations, user error, network or hardware failure,** malicious intrusion and ransomware attack. Likewise, data privacy or cybersecurity incidents or breaches by employees or others can result in the exposure of sensitive data, including our intellectual property or trade secrets or the personal information of our employees, patients, customers or other business partners to unauthorized persons or to the public. **If our information systems or third-party information systems on which we rely suffer severe damage, disruption or shutdown, including during upgrades or new implementations, and our business continuity plans do not effectively resolve the issues in a timely manner, we could experience delays in reporting our financial results, and we may lose revenue and profits as a result of our inability to timely manufacture, distribute, invoice and collect payments.** Cybersecurity attacks and incidents are increasing in their frequency, sophistication and intensity. Malicious actors seek to steal money, gain unauthorized access to, destroy or manipulate data, and disrupt operations, and some of their attacks may not be recognized or discovered until ~~launched~~ **or after a significant period of time well** after initial entry into the environment, such as novel or zero-day attacks that are launched before patches are available and defenses can be readied. Malicious actors are also increasingly developing methods to avoid prevention, detection and alerting capabilities, including employing counter-forensic tactics making response activities more difficult. Such attacks and incidents include, for example, the deployment of harmful malware, **exploitation of vulnerabilities, computer viruses, key loggers,** ransomware, denial-of-service, social engineering and other means to affect service reliability and operations and threaten data confidentiality, integrity and availability. Our business and technology partners face similar risks and any security breach of their systems could adversely affect our security posture. Like many companies, we have experienced **and expect to continue to be the target of** cybersecurity incidents, including data breaches and **temporary** service interruptions. When cybersecurity incidents occur, our policy is to respond and address them in accordance with applicable governmental regulations and other legal requirements, including our cybersecurity protocols. There can be no assurance that our efforts in response to cybersecurity incidents, as well as our investments to protect our information technology infrastructure and data, will shield us from significant losses, brand and reputational harm and potential liability or prevent any future interruption or breach of our systems. Such cybersecurity incidents can cause the loss of critical or sensitive information, including personal information, and could give rise to legal liability and regulatory action under data protection and privacy laws. **Financial, legal, business, or reputational losses may result from a cybersecurity incident or breach of our information technology systems.** Regulators globally are also imposing new data privacy and security requirements, including new and greater monetary fines for privacy violations. For example, the **EU’s** General Data Protection Regulation (“GDPR”) established regulations regarding the handling of personal data, and non-compliance with the GDPR may result in monetary penalties of up to four percent of worldwide revenue. In addition, ~~new~~ domestic data privacy and security laws, such as the California Consumer Privacy Act and the California Privacy Rights Act and other laws that have been or may be passed, similarly introduce requirements with respect to personal information, and non-compliance with such laws may result in

liability through private actions (subject to statutorily defined damages in the event of certain data breaches) and enforcement. Other changes or new laws or regulations associated with the enhanced protection of personal information, could greatly increase our cost of providing our products and services or even prevent us from offering certain services in jurisdictions in which we operate.

Strategic and Financial Risks We are subject to risks associated with engaging in business acquisitions, licensing arrangements, collaborations, options, equity investments, asset divestitures and other strategic transactions. We have engaged in, and may in the future engage in, such transactions as part of our business strategy. We may not identify suitable transactions in the future and, if we do, we may not complete such transactions in a timely manner, on a cost-effective basis, or at all, including the possibility that a governmental entity or regulatory body may delay or refuse to grant approval for the consummation of the transaction. If we are successful in making an acquisition or closing a licensing arrangement or collaboration, the products, intellectual property and technologies that are acquired or licensed may not be successful or may require significantly greater resources and investments than anticipated. As part of our annual impairment testing of our goodwill and other indefinite-lived intangible assets in the fourth quarter, and earlier if impairment indicators exist, as required under U. S. generally accepted accounting principles, we **have in the past and may in the future** need to recognize impairment charges related to the products, intellectual property and technologies that are acquired or licensed. For example, as a result of an impairment analysis we conducted following our receipt of data in March 2022 from the Phase 3 TROPiCS- 02 study evaluating Trodelvy in patients with hormone receptor- positive, human epidermal growth receptor 2- negative metastatic breast cancer, we recognized a partial in- process research and development impairment charge on our **Condensed** Consolidated Statements of Income during 2022 . **Similarly, we are evaluating whether we could be required to record an impairment charge during the three months ended March 31, 2024 in connection with our Phase 3 EVOKE- 01 study evaluating sacituzumab govitecan- hziy. Any such impairment charge, which we are unable to reasonably estimate at this time, could have a material impact on our results of operations (for more information, see Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations “ Results of Operations- In- Process Research and Development Impairments ”).** For option structured deals, there is no assurance that we will elect to exercise our option right, and it is possible that disagreements, uncertainties or other circumstances may arise, including with respect to whether our option rights have been appropriately triggered, which may hinder our ability to realize the expected benefits. For **example, in March 2023, we waived our exclusive option to acquire Pionyr Immunotherapeutics, and in September 2023, we waived our exclusive option to acquire Tizona Therapeutics, Inc. For** equity investments in our strategic partners, such as in connection with our collaborations with Arcus Biosciences, Inc. and Galapagos NV, the value of our equity investments may fluctuate and decline in value. If we are not successful in the execution or implementation of these transactions, our financial condition, cash flows and results of operations may be adversely affected, and our stock price could decline. We have paid substantial amounts of cash and incurred additional debt to finance our strategic transactions. Additional indebtedness and a lower cash balance could result in a downgrade of our credit ratings, limit our ability to borrow additional funds or refinance existing debt on favorable terms, increase our vulnerability to adverse economic or industry conditions, and reduce our financial flexibility to continue with our capital investments, stock repurchases and dividend payments. For example, as a result of the cash used and the debt issued in connection with our acquisition of Immunomedics , **Inc.** in 2020, S & P Global Ratings downgraded our credit rating. We may be adversely impacted by any failure to overcome these additional risks. Changes in our effective income tax rate could reduce our earnings. We are subject to income taxes in the U. S. and various foreign jurisdictions. Due to economic and political conditions, various countries are actively considering and have made changes to existing tax laws, and we cannot predict the form or timing of such changes. Our effective tax rates are affected by changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities, the introduction of new taxes, and changes in tax laws, regulations, administrative practices and interpretations, including in the U. S., Germany and Ireland. We are also subject to the examination of our tax returns and other tax matters by the U. S. Internal Revenue Service and tax authorities in various foreign jurisdictions. There are differing interpretations of tax laws and regulations and, as a result, significant disputes may arise with these tax authorities involving issues of the timing and amount of deductions and allocations of income among various tax jurisdictions. We may be adversely affected by the resolution of one or more of these exposures in any reporting period.