

Risk Factors Comparison 2025-03-14 to 2024-02-22 Form: 10-K

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If any of the events described in the following risk factors occur, our business, financial condition or results of operations could be materially harmed. In that case, the trading price of our common stock could decline and investors may lose all or part of their investment. Additional risks and uncertainties that we are unaware of or that we currently deem immaterial may also become important factors that affect Repligen. This Annual Report on Form 10- K (“ Form 10- K ”) contains forward looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks faced by us described below and elsewhere in this Form 10-K. **Risks Related to Our Business** We compete with life sciences, pharmaceutical and biotechnology companies ~~who~~ **that** are capable of developing new approaches that could make our products and technology obsolete. The bioprocessing market is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. We compete with several medium and small companies in each of our product categories as well as several large companies, including Danaher Corporation (Pall Corporation and Cytiva), Thermo Fisher Scientific Inc., MilliporeSigma and Sartorius. Many of our competitors are large, well- capitalized companies that may have greater financial, manufacturing, marketing, research and development (“ R & D ”) resources than we have, as well as stronger name recognition, longer operating histories and benefits derived from greater economies of scale. As a consequence, they are able to spend more aggressively on product development, marketing, sales and other product initiatives than we can, and may have additional lines of products and the ability to bundle products. These factors, among others, may enable our competitors to market their products at lower prices or on terms more advantageous to customers than what we can offer. Competition may result in price reduction, reduced gross margins and loss of market share, any of which could have a material adverse effect on our business, financial condition and results of operations. Our current and future competitors, including certain of our customers, may at any time develop additional products that compete with our products. If any company develops products that compete with or are superior to our products, our revenue may decline. Additionally, new approaches by these competitors may make our products and technologies obsolete or noncompetitive. If we are unable to continue to hire and retain skilled personnel, then we will have trouble developing and marketing our products. Our success depends largely upon the continued service of our management and scientific staff and our ability to attract, retain and motivate highly skilled technical, scientific, management and marketing personnel. We also face significant competition in the hiring and retention of such personnel from other companies, research and academic institutions, government and other organizations ~~who~~ **that** have superior funding and resources. The loss of key personnel or our inability to hire and retain skilled personnel could materially **and** adversely affect our product development efforts and our business. Despite our increasingly diversified client base, we have historically depended on a limited number of customers for a high percentage of our revenues. The loss of, or a significant reduction in orders from, any of our large customers, including following any termination or failure to renew a long- term supply contract, would significantly reduce our revenues and harm our results of operations. If a large customer purchases fewer of our products, defers orders or fails to place additional orders with us for any reason, including for business continuity purposes, our revenue could decline, and our operating results may not meet market expectations. In addition, if our customers order our products, but fail to pay on time or at all, our liquidity and operating results could be materially and adversely affected. Furthermore, if any of our current or future products compete with those of any of our largest customers, these customers may place fewer orders with us or cease placing orders with us, which would negatively affect our revenues and operating results. Certain of our products are used by customers in the production of gene therapies, which represent a relatively new and still- developing mode of treatment. Unforeseen adverse events, negative clinical outcomes, or increased regulatory scrutiny of cell and gene therapy (“ C & GT ”) and its financial cost may damage public perception of the safety, utility, or efficacy of gene therapies and may harm our customers’ ability to conduct their business. Such events may negatively impact our revenues and have an adverse effect on our performance. C & GT remains a relatively new and developing treatment method, with only a limited number of gene therapies approved to date by regulatory authorities. Public perception may be influenced by claims that C & GT is unsafe or ineffective, and C & GT may not gain the acceptance of the public or the medical community. In addition, ethical, social, legal, and financial concerns about C & GT and genetic testing could result in additional regulations, limitations or even prohibitions on certain C & GTs or C & GT- related products. More restrictive regulations or negative public perception could reduce certain of our customers’ use of our products, which could negatively affect our revenue and performance. **Risks Related to Product Development and Acquisitions** If we are unable to expand our product portfolio, our ability to generate revenue could be adversely affected. We are increasingly seeking to develop and commercialize our portfolio of products. Our future financial performance will depend, in part, on our ability to successfully develop and acquire additional bioprocessing products. There is no guarantee that we will be able to successfully acquire or develop additional bioprocessing products, and our financial performance will likely suffer if we are unable to do so. Our acquisitions expose us to risks that could adversely affect our business, and we may not achieve the anticipated benefits of acquisitions of businesses or technologies. As a part of our growth strategy, we may make selected acquisitions of complementary products and / or businesses, such as our most recent acquisitions of **Tantti Laboratory Inc.**, Metenova Holding AB and FlexBiosys, Inc. Any acquisition involves numerous risks and operational, financial, and managerial challenges, including the following, any of which could adversely affect our business, financial condition, or results of operations: • difficulties in integrating new operations, technologies, products, and personnel; • problems maintaining uniform procedures, controls and policies with respect to our financial accounting systems; • lack of

synergies or the inability to realize expected synergies and cost- savings; • difficulties in managing geographically dispersed operations, including risks associated with entering foreign markets in which we have no or limited prior experience; • underperformance of any acquired technology, product, or business relative to our expectations and the price we paid; • negative near- term impacts on financial results after an acquisition, including acquisition- related earnings charges; • the potential loss of key employees, customers, and strategic partners of acquired companies; • claims by terminated employees and shareholders of acquired companies or other third parties related to the transaction; • the assumption or incurrence of additional debt obligations or expenses, or use of substantial portions of our cash; • the issuance of equity securities to finance or **to use** as consideration for any acquisitions that dilute the ownership of our stockholders; • the issuance of equity securities to finance or **to use** as consideration for any acquisitions may not be an option if the price of our common stock is low or volatile which could preclude us from completing any such acquisitions; • any collaboration, strategic alliance and licensing arrangement may require us to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us; • diversion of management' s attention and company resources from existing operations of the business; • inconsistencies in standards, controls, procedures, and policies; • assumption of, or exposure to, historical liabilities of the acquired business, including unknown contingent or similar liabilities that are difficult to identify or accurately quantify; and • risks associated with acquiring intellectual property, including potential disputes regarding acquired companies' intellectual property. In addition, the successful integration of acquired businesses requires significant efforts and expense across all operational areas, including sales and marketing, R & D, manufacturing, finance, legal, and information technologies. There can be no assurance that any of the acquisitions we may make will be successful or will be, or will remain, profitable. Our failure to successfully address the foregoing risks may prevent us from achieving the anticipated benefits from any acquisition in a reasonable time frame, or at all. If intangible assets and goodwill that we recorded in connection with our acquisitions become impaired, we may have to take significant charges against earnings. In connection with the accounting for our completed acquisitions, we recorded a significant amount of intangible assets, including developed technology and customer relationships relating to the acquired product lines, and goodwill. Under accounting principles generally accepted in the United States, we must assess, at least annually and potentially more frequently, whether the value of intangible assets and goodwill has been impaired. Intangible assets and goodwill will be assessed for impairment in the event of an impairment indicator. Any reduction or impairment of the value of intangible assets and goodwill will result in a charge against earnings, which could materially adversely affect our results of operations and shareholders' equity in future periods.

Risks Related to Manufacturing and Supply If we are unable to manufacture our products in sufficient quantities and in a timely manner, our operating results will be harmed, our ability to generate revenue could be diminished and our gross margin may be negatively impacted. Our revenues and other operating results will depend in large part on our ability to manufacture and assemble our products in sufficient quantities and in a timely manner. Any interruptions we experience in the manufacturing or shipping of our products could delay our ability to recognize revenues in a particular quarter. Manufacturing problems can and do arise, and as demand for our products increases, any such problems could have an increasingly significant impact on our operating results. While we have not generally experienced problems with, or delays in, our production capabilities that resulted in delays in our ability to ship finished products, there can be no assurance that we will not encounter such problems in the future. We may not be able to quickly ship products and recognize anticipated revenues for a given period if we experience significant delays in the manufacturing process. In addition, we must maintain sufficient production capacity in order to meet anticipated customer demand, which carries fixed costs that we may not be able to offset if orders were to slow, which would adversely affect our operating margins. If we are unable to manufacture our products consistently, in sufficient quantities, and on a timely basis, our bioprocessing revenue, gross margins and our other operating results will be materially and adversely affected. We rely on a limited number of suppliers or, for certain of our products, one supplier, and we may not be able to find replacements or immediately transition to alternative suppliers, which could have a material adverse effect on our financial condition, results of operations and reputation. There are only a limited number of suppliers of materials for certain of our products. An interruption in operations of the business related to these products could occur if we encounter delays or difficulties in securing the required materials, or if we cannot then obtain an acceptable substitute. Any such interruption could significantly affect the business related to these products and our financial condition, results of operations and reputation. For example, we believe that only a small number of suppliers are currently qualified to supply materials for the XCell ATF ® systems. The use of materials furnished by these replacement suppliers would require us to alter our operations related to the XCell ATF systems. Transitioning to a new supplier for our products would be time- consuming and expensive, may result in interruptions in our operations, could affect the performance specifications of our product lines or could require that we revalidate the materials. There can be no assurance that we will be able to secure alternative materials and bring such materials online and revalidate them without experiencing interruptions in our workflow. If we should encounter delays or difficulties in securing, reconfiguring or revalidating the materials required for our products, our business related to these products and our financial condition, results of operations and reputation could be adversely affected.

Risks Related to Our Financial Position and Need for Additional Capital Servicing our debt will require a significant amount of cash, and we may not have sufficient cash flow from our business to make payments on our debt and we may not have the ability to raise the funds necessary to settle for cash conversions of our Notes or to repurchase the Notes for cash upon a fundamental change, which could adversely affect our business and results of operations. In December 2023, we incurred significant indebtedness with the issuance of \$ 600. 0 million in aggregate principal amount of 1. 00 % Convertible Senior Notes due 2028 (the “ 2023 Notes ”) where \$ 309. 9 million principal amount of the 2023 Notes were issued in exchange for \$ 217. 7 million principal amount of our 0. 375 % Convertible Senior Notes due 2024 (the “ 2019 Notes ”, and together with the 2023 Notes, the “ Notes ”) and \$ 290. 1 million principal amount of the 2023 Notes were issued for \$ 290. 1 million in cash. As of December 31, **2023-2024**, \$ **69-600. 7-0** million in aggregate principal amount of the **2019-2023** Notes remain outstanding. Our ability to make scheduled payments of the principal of, to pay interest on, or to refinance our indebtedness, including the Notes,

depends on our future performance, which is subject to economic, financial, competitive and other factors that may be beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations, including the Notes. In addition, holders of the Notes have the right, subject to certain conditions, to require us to repurchase all or any portion of their Notes upon the occurrence of a “ fundamental change ” (as defined in the indentures governing the Notes) at a fundamental change repurchase price equal to 100 % of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest, if any, but excluding the fundamental change repurchase date. Upon any conversion of Notes, we will also be required to make cash payments for each \$ 1, 000 principal amount of 2023 Notes converted of at least the lesser of \$ 1, 000 and the sum of the “ daily conversion values ” (as defined in the indenture governing the 2023 Notes). However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of Notes surrendered therefor or pay cash with respect to Notes being converted. In addition, our ability to repurchase the Notes or to pay cash upon conversions of the Notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase Notes at a time when the repurchase is required by the applicable indenture or to pay any cash payable on future conversions of the Notes as required by the applicable indenture would constitute a default under such indenture. A default under either indenture governing the Notes or the fundamental change itself could also lead to a default under agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Notes or make cash payments upon conversions thereof. In addition, our significant indebtedness, combined with our other financial obligations and contractual commitments, could have other important consequences. For example, it could: • make us more vulnerable to adverse changes in general U. S. and worldwide economic, industry and competitive conditions and adverse changes in government regulation; • limit our flexibility in planning for, or reacting to, changes in our business and our industry; • place us at a disadvantage compared to our competitors who have less debt; and • limit our ability to borrow additional amounts for working capital and other general corporate purposes, including to fund possible acquisitions of, or investments in, complementary businesses, products, services and technologies. Any of these factors could materially and adversely affect our business, financial condition and results of operations. In addition, if we incur additional indebtedness, the risks related to our business and our ability to service or repay our indebtedness would increase. The conditional conversion feature of the Notes, if triggered, may adversely affect our financial condition and liquidity. In the event the conditional conversion feature of the Notes is triggered, holders of Notes will be entitled to convert the Notes at any time during specified periods at their option, as described in the indentures governing the Notes. If one or more holders elect to convert their Notes, we would be required to settle any converted principal through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the notes as a current rather than long- term liability, which would result in a material reduction of our net working capital. ~~As a result of the satisfaction of one of the conversion triggers, the 2019 Notes are convertible at the option of the holders thereof during the calendar quarter ending March 31, 2024. Because the 2019 Notes mature within one year of the report date, the Company classifies the carrying value of the 2019 Notes of \$ 69.5 million as current liabilities on the Company's consolidated balance sheets at December 31, 2023.~~ Future strategic transactions or acquisitions may require us to seek additional financing, which we may not be able to secure on favorable terms, if at all. We plan to continue a strategy of growth and development for our bioprocessing business, and we actively evaluate various strategic transactions on an ongoing basis, including licensing or acquiring complementary products, technologies or businesses that would complement our existing portfolio of development programs. In order to complete such strategic transactions, we may need to seek additional financing to fund these investments and acquisitions. Should we need to do so, we may not be able to secure such financing, or obtain such financing on favorable terms because of the volatile nature of the biotechnology marketplace. In addition, future acquisitions may require the issuance or sale of additional equity or debt securities, which may result in additional dilution to our stockholders. Our corporate restructuring and the associated headcount reduction may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business. In July 2023, our Board of Directors (“ Board ”) authorized the Company' s management team to undertake restructuring activities to simplify and streamline our organization and strengthen the overall effectiveness of our operations (the “ Restructuring Plan ”). As part of the Restructuring Plan, we consolidated a portion of our manufacturing business between certain U. S. locations and reduced our headcount. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, ~~our~~ **Restructuring Plan**, our operating results and financial condition could be adversely affected. Furthermore, the Restructuring Plan may be disruptive to our operations. ~~For example, our headcount reductions~~ **Further restructuring and cost- cutting activities may be required and could yield unanticipated unintended consequences and costs**, such as **a reduction in morale among our remaining employees, adverse effects to our reputation as both an employer and with respect to customers, the loss of institutional knowledge and expertise, and increased difficulties in likelihood of turnover of key members of management and employees, all of which can impede our ability to successfully implementing** ~~our business strategy, including retention of and consequently, our remaining employees~~ **business, financial condition, and results of operations could be materially and adversely affected**. Our exposure to political, economic and other risks that arise from operating a multinational business has and may continue to increase. We operate on a global basis with offices or activities in Japan, South

Korea, China, India, **Taiwan**, Europe and North America. Our operations and sales outside of the United States have increased as a result of our strategic acquisitions and the continued expansion of our commercial organization. Risks related to these increased foreign operations include:

- fluctuations in foreign currency exchange rates, which may affect the costs incurred in international operations and foreign acquisitions and could harm our results of operations and financial condition;
- changes in general economic and political conditions in countries where we operate, particularly as a result of ongoing economic instability within foreign jurisdictions;
- the occurrence of a trade war, or other governmental action related to tariffs or trade agreements;
- differing protection of intellectual property, technology and data in foreign jurisdictions;
- difficulty in staffing and managing widespread operations;
- being subject to complex and restrictive employment and labor laws and regulations, as well as union and works council restrictions;
- changes in tax laws or rulings in the United States or other foreign jurisdictions that may have an adverse impact on our effective tax rate;
- being subject to burdensome foreign laws and regulations, including regulations that may place an increased tax burden on our operations;
- being subject to longer payment cycles from customers and experiencing greater difficulties in timely accounts receivable collections; and
- required compliance with a variety of foreign laws and regulations, such as data privacy requirements, real estate and property laws, anti-competition regulations, import and trade restrictions, export requirements, U. S. laws such as the Foreign Corrupt Practices Act of 1977 (the “FCPA”) and the U. S. Department of Commerce’s Export Administration Regulations, and other U. S. federal laws and regulations established by the Office of Foreign Assets Control, local laws such as the U. K. Bribery Act of 2010 or other local laws that prohibit corrupt payments to governmental officials or certain payments or remunerations to customers.

Our business success depends in part on our ability to anticipate and effectively manage these and other related factors. We cannot assure you that these and other related factors will not materially adversely affect our international operations or business as a whole. In addition, a deterioration in diplomatic relations between the United States and any country where we conduct business could adversely affect our future operations and lead to a decline in profitability. We may be unable to efficiently manage our growth as a larger and more geographically **diverse-expansive** organization. Our strategic acquisitions, the continued expansion of our commercial sales operations, and our organic growth have increased the scope and complexity of our business. As a result, we will face challenges inherent in efficiently managing a more complex business with an increased number of employees over large geographic distances, including the need to implement appropriate systems, policies, benefits and compliance programs. Our inability to manage successfully the geographically and culturally **diverse-expansive**, and substantially larger combined organization could materially adversely affect our operating results and, as a result, the market price of our common stock. Our results of operations could be negatively affected by potential fluctuations in foreign currency exchange rates. We conduct a large portion of our business in international markets. For the fiscal year ended December 31, **2023-2024**, **38-37.5-0**% of our revenues were denominated in foreign currencies with the primary foreign currency exposures being the Swedish krona, Euro and Chinese yuan. We are exposed to the risk of an increase or decrease in the value of the foreign currencies relative to the U. S. dollar, which could decrease the value of our revenue and increase the value of our expenses and costs when measured in U. S. dollars. These fluctuations could also adversely affect the demand for products and services provided by us. As a result, our results of operation may be influenced by the effects of future exchange rate fluctuations and such effects may have an adverse impact on our common stock price. Natural disasters, geopolitical unrest, war, terrorism, public health issues or other catastrophic events could disrupt the supply, delivery or demand of products, which could negatively affect our operations and performance. We are subject to the risk of disruption by earthquakes, floods and other natural disasters, fire, power shortages, geopolitical unrest, war, terrorist attacks and other hostile acts, public health issues, epidemics or pandemics and other events beyond our control and the control of the third parties on which we depend. Any of these catastrophic events may have a strong negative impact on our employees, facilities, partners, suppliers, distributors or customers, and could decrease demand for our products, create delays and inefficiencies in our supply chain and make it difficult or impossible for us to deliver products to our customers. In addition, a catastrophic event that results in the destruction or disruption of our data centers or our critical business or information technology systems would severely affect our ability to conduct normal business operations and, as a result, our operating results would be adversely affected. Our business, financial condition and results from operations could be adversely affected by disruptions in the global economy caused by geopolitical events, such as the ongoing conflicts between Russia and Ukraine and Israel and Palestine. Global conflicts could increase costs and limit availability of fuel, energy, and other resources we depend upon for our business operations. For example, while we do not operate in Russia or Ukraine, the increasing tensions between the United States and Russia and the other effects of the ongoing conflict of Ukraine, have resulted in many broader economic impacts such as the United States and European Union imposing sanctions and bans against Russia and Russian products imported into the United States and Europe, respectively. Such sanctions and bans have impacted and may continue to impact commodity pricing such as fuel and energy costs, making it more expensive for us and our partners to deliver products to our customers. Further sanctions, bans or other economic actions in response to the ongoing conflict between Russia and Ukraine or in response to any other global conflict such as the ongoing conflict between Israel and Palestine, could result in, among other things, cyber- attacks, supply disruptions, lower consumer demand, and changes to foreign exchange rates and financial markets, any of which may adversely affect our business and supply chain. In addition, the effects of the ongoing conflict could heighten many of our known risks described in this section. Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non- performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and our financial condition and results of operations. Actual events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (“SVB”) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (“FDIC”) as

receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. If any of our lenders or counterparties to any such instruments were to be placed into receivership, we may be unable to access such funds. We have a banking relationship with SVB and hold cash, cash equivalents and marketable securities of \$ 0. ~~1~~**3** million as of December 31, ~~2023~~**2024** in SVB depository accounts to cover short-term operational payments. While we have not experienced any losses in such accounts, the recent failure of SVB caused us to utilize our accounts at other financial institutions in order to mitigate potential operational risks stemming from the temporary inability to access funds in our SVB operating accounts. In addition, if any of our customers, suppliers or other parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U. S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to \$ 25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. Additionally, there is no guarantee that the U. S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion. Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the Company, the financial institutions with which the Company has credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which the Company has financial or business relationships, but could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. In addition, investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and / or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and / or projected business operations and financial condition and results of operations. In addition, any further deterioration in the **macroeconomic global economy or financial services industry, including but not limited to the change in the U. S. presidential administration, or increased U. S. trade tariffs and trade disputes with other countries** could lead to losses or defaults by our suppliers, which in turn, could have a material adverse effect on our current and / or projected business operations and results of operations and financial condition **. For example, increased tariffs on essential materials could raise production costs and reduce profitability if we are unable to pass these costs on to customers. Additionally, retaliatory trade measures by other countries could limit our access to key international markets, restricting revenue growth. Any delays or disruptions in our supply chain due to geopolitical tensions, regulatory changes, or trade disputes could adversely affect our ability to manufacture and deliver products, potentially impacting our financial performance and customer relationships**. Risks Related to Ownership of Our Common Stock Risks Related to Investment in Our Securities Our operating results may fluctuate significantly, our customers' future purchases are difficult to predict and any failure to meet financial expectations may result in a decline in our stock price. Our quarterly operating results may fluctuate in the future due to many factors, such as the impact of seasonal spending patterns, changes in overall spending levels in the life sciences industry, the inability of some of our customers to consummate anticipated purchases of our products due to changes in end- user demand, and other unpredictable factors that may affect ordering patterns. Because our revenue and operating results are difficult to predict, we believe that our past results of operations are not necessarily a good indicator of our future performance. Additionally, if revenue declines in a quarter, whether due to a delay in recognizing expected revenue, adverse economic conditions or otherwise, our results of operations will be harmed because many of our expenses are relatively fixed. In particular, a large portion of our manufacturing costs, our R & D, sales and marketing and general and administrative expenses are not significantly affected by variations in revenue. Further, our gross margins are dependent on product mix. A shift in sales away from our higher- margin products to lower margin products will adversely affect our gross margins. If our quarterly operating results fail to meet investor expectations, the price of our common stock may decline. Securities or industry analysts may not publish favorable research or reports about our business or may publish no information, which could cause our stock price or trading volume to decline. The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us and our business. We do not have any control over these analysts, and we cannot provide any assurance that analysts will cover us or provide favorable coverage. If any of the analysts who cover us issue an adverse opinion regarding our stock price, our business or stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports covering us, we could lose visibility in the market, which in turn could cause our stock price or trading

volume to decline. Our stock price could be volatile, which could cause shareholders to lose part or all of their investment. The market price of our common stock, like that of the common stock of many other companies with similar market capitalizations, is highly volatile. The stock market in general, and the market for life sciences, biotechnology and pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of specific companies, the conflict in Ukraine and Israel, and rising inflation and interest rates in the United States, which have resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including potentially worsening economic conditions, may adversely affect the market price of our common stock, regardless of our actual operating performance. **We have** ~~If we fail to maintain an effective system of internal controls, we may not be able to accurately report financial results or prevent fraud. If we identify~~ **identified** ~~a material weakness~~ **weaknesses** ~~in our internal control over financial reporting, and may identify additional material weaknesses in the future~~ ~~our~~ ~~or ability otherwise fail to maintain effective internal control over financial reporting, which may result in a material misstatement of our consolidated financial statements or cause us to fail~~ ~~to meet our~~ **periodic** ~~reporting obligations and the trading price of our stock could be negatively affected.~~ Effective internal controls are necessary to provide reliable financial reports and to assist in the effective prevention of fraud. Any inability to provide reliable financial reports or prevent fraud could harm our business. We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under the Sarbanes- Oxley Act of 2002 to report annually on our internal control over financial reporting. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met, including objectives that may involve our reliance on third- party advisors and professionals. ~~If we, or our independent registered public accounting firm, determine that our internal control over financial reporting are not effective, discover areas that need improvement in the future or discover a material weakness, these shortcomings could have an adverse effect on our business and financial results, and the price of our common stock could be negatively affected. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Accordingly, a material weakness increases the risk that the financial information we report contains material errors. If we cannot conclude that we have effective internal control over our financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified opinion regarding the effectiveness of our internal control over financial reporting, investors could lose confidence in the reliability of our financial statements, which could lead to a decline in our stock price. Failure to comply with reporting requirements could also subject us to sanctions and /or investigations by the Securities and Exchange Commission, the Nasdaq Global Select Market or other regulatory authorities. We have previously implemented several significant enterprise resource planning (“ ERP ”) modules and expect to implement additional ERP modules in the future. The implementation of the ERP system represents a change in our internal control over financial reporting. Although we continue to monitor and assess our internal controls in the new ERP system environment as changes are made and new modules are implemented, and we have taken additional steps to modify and enhance the design and effectiveness of our internal control over financial reporting, there is a risk that deficiencies may occur that could aggregate to a material weakness.~~ As discussed below in Part II, Item 9A, “ Controls and Procedures, ” of this report, we **have** ~~identified a material weakness~~ **weaknesses** ~~in our internal control over financial reporting related to~~ **(i) controls related to revenue recognition specific to the evaluation of accounting for deferred income taxes on contract terms,** **(ii) information technology (“ IT ”) general controls for information systems that are relevant to the preparation** ~~December 2023 exchange of~~ **our financial statements, and (iii) business process- level controls related to inventory valuation and the financial statement close process either in a portion of timely manner** ~~our~~ ~~or with 2019 Notes and an appropriate precision threshold~~ ~~issuance of our 2023 Notes.~~ As a result of ~~this~~ **these** ~~material weakness~~ **weaknesses**, our management concluded that our internal control over financial reporting was not effective as of December 31, **2023-2024**. We have designed **Following identification of these material weaknesses, and as part of our commitment to strengthen our internal control over financial reporting, we** are implementing **remedial actions under the oversight of the Audit Committee of our Board to address these deficiencies. Our remediation activities will include the following: Our remediation activities include the following with respect to revenue recognition: • Designing and implementing new internal controls to validate there is a complete listing of revenue contracts that have non- standard terms, which require incremental accounting analysis under ASC 606. • Designing and implementing new internal controls evaluating the accounting for contract amendments, including amendments accounted for as contract modifications. • Enhancing and expanding our existing revenue recognition control procedures and attributes when evaluating the accounting impact of non- standard contract terms and contract modifications. • Increased education for internal resources on accounting for contracts within the scope of ASC 606 and deploying enablers to facilitate documentation of accounting analyses and conclusions. Our remediation activities will include the following with respect to IT general controls: • Reassessing the operating effectiveness of internal controls related to the program and data change management and user access processes; and • Expanding the management and governance over IT system controls. Our remediation activities will include the following with respect to certain business process- level controls: • Reassessing the operating effectiveness of these controls, including precision thresholds, timely execution, and documentation requirements for control owners; • Assessing the frequency of our control monitoring activities to ensure that they are conducted in a timely manner; and • Hiring additional staff, including external experts, to enhance the performance, documentation, and monitoring of such controls. This includes providing training for control owners setting out expectations as it relates to the control risk and design, execution and monitoring of such controls, including enhancements to the documentation to evidence the execution of the control. We will continue to monitor the design and operating effectiveness of these and other processes,**

procedures and controls and make any further changes management determines appropriate. While we are undertaking efforts to remediate these material weaknesses, the material weaknesses will not be considered remediated until our remediation plan has been fully implemented, the applicable controls operate for a sufficient period of time, and we have concluded, through testing, that the newly implemented and enhanced controls are operating effectively. At this time, we cannot predict the success of such efforts or the outcome of our assessment of the remediation efforts. We can give no assurance that our efforts will remediate these material weaknesses. However, in our internal control over financial reporting, we may or that additional material weaknesses will not be successfully identified in remediating this material weakness in the near-term, future. The effectiveness of our internal control over financial reporting is subject to various inherent limitations, particularly including cost limitations, judgments used in light of decision making, assumptions about the infrequency with which likelihood of future events, the possibility of human error and the risk of fraud. If we are likely to undertake the types of transactions that could test our remediation efforts, or be able to identify and remediate any additional control deficiency, including any material weaknesses, that may arise in the future. If we fail to remediate the material weakness or our ability to maintain the adequacy of our internal controls, we process and report financial information accurately, and to prepare the consolidated financial statements within the time periods specified by the rules and regulations of the SEC, could be adversely affected which subject to regulatory scrutiny, civil, in turn, may adversely affect or our criminal penalties, reputation and business and the trading price of or our shareholder litigation common stock. Any In addition, failure to maintain adequate internal controls, or difficulties encountered in their implementation, could result in errors in our consolidated financial statements that could do not accurately reflect our operating results result in a restatement of or our financial statements and could cause us to fail to meet our reporting obligations, any of which could diminish investor confidence in us and cause a decline in the price of our common stock. In addition, any such failures could result in litigation or regulatory actions by the SEC or other regulatory authorities, loss of investor confidence, delisting of our securities and harm to our reputation and financial condition, or diversion of financial and management resources could prevent us from preparing and filing the operation of our business. The restatement of our previously issued financial statements may affect stockholder and investor confidence in us or harm our reputation, and may subject us to additional risks and uncertainties, including increased costs and the increased possibility of legal proceedings and regulatory inquiries, sanctions or investigations Upon identifying the revenue recognition material weakness described above, we amended and restated certain items in our Quarterly Reports on Form 10- Q for the fiscal quarters ended March 31, 2023 through June 30, 2024, as well as certain items in our Annual Report on Form 10- K for the fiscal year ended December 31, 2023. As a result of this restatement, we have incurred, and may continue to incur, unanticipated costs for accounting and legal fees in connection with required time periods, or related to, such restatement. In addition, such restatements could subject us to a number of additional risks and uncertainties, including the increased possibility of legal proceedings and inquiries, sanctions or investigations by the SEC or other regulatory authorities. Any of the foregoing may adversely affect our reputation, the accuracy and timing of our financial reporting, or our business, results of operations, liquidity and financial condition, or cause stockholders, investors, members and customers to lose confidence in the accuracy and completeness of our financial reports or cause the market price of our common stock to decline. As of the date of this Form 10- K, we have no knowledge of any such legal proceedings and regulatory inquiries, sanctions or investigation. However, we can provide no assurance that such legal proceedings and regulatory inquiries, sanctions or investigation will not arise in the future. Any such legal proceedings and regulatory inquiries, sanctions or investigation, whether successful or not, could adversely affect our business, financial condition and results of operations.

Risks Related to Our Charter and Bylaws Anti- takeover provisions in our charter documents, certain of our contracts with third parties, and under Delaware law could make an acquisition of us, even one that may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our certificate of incorporation and by- laws may delay or prevent an acquisition of us or a change in our management. These provisions include the ability of our Board to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15 % of our outstanding voting stock to merge or combine with us. Although we believe these provisions collectively provide for an opportunity to obtain greater value for stockholders by requiring potential acquirers to negotiate with the Board, they would apply even if an offer rejected by our board was considered beneficial by some stockholders. Additionally, certain of our contracts with third parties allow for termination upon specified change of control transactions. Anti- takeover provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of the Board, which is responsible for appointing the members of our management, and anti- takeover or change of control contract termination rights may frustrate or prevent any attempts by a third- party to acquire or attempt to acquire us. Risks Related to Tax Matters The enactment of legislation implementing changes in taxation of international business activities, the adoption of other corporate tax reform policies, or changes in tax legislation or policies, or interpretations thereof, could materially impact our financial position and results of operations. Corporate tax reform, base- erosion efforts and tax transparency continue to be high priorities in many tax jurisdictions where we have business operations. As a result, policies regarding corporate income and other taxes in numerous jurisdictions are under heightened scrutiny and tax reform legislation is being proposed or enacted in a number of jurisdictions. There is no assurance that our actual income tax liability will not be materially different than what is reflected in our income tax (benefit) provisions and accruals as a result of changes in tax laws. In addition, many countries are beginning to implement legislation and other guidance to align their international tax rules with the Organisation for Economic Co- operation and Development' s Base Erosion and Profit Shifting recommendations and action plan that aim to standardize and modernize

global corporate tax policy, including changes to cross-border tax, transfer pricing documentation rules, and nexus-based tax incentive practices. Because of the heightened scrutiny of corporate taxation policies, prior decisions by tax authorities regarding treatments and positions of corporate income taxes could be subject to enforcement activities, and legislative investigation and inquiry, which could also result in changes in tax policies or prior tax rulings. Any such changes in policies or rulings may also result in the taxes we previously paid being subject to change. Due to the large scale of our international business activities, any substantial changes in international corporate tax policies, enforcement activities or legislative initiatives may materially adversely affect our business, the amount of taxes we are required to pay and our financial condition and results of operations generally. Our ability to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments is limited by provisions of the Internal Revenue Code, and it is possible that certain transactions or a combination of certain transactions may result in material additional limitations on our ability to use our net operating loss and tax credit carryforwards. Section 382 and 383 of the Internal Revenue Code of 1986, as amended, contain rules that limit the ability of a company that undergoes an ownership change, which is generally any change in ownership of more than 50 percentage points of its stock over a three-year period, to utilize its net operating loss and tax credit carryforwards and certain built-in losses recognized in years after the ownership change. These rules generally operate by focusing on ownership changes involving stockholders owning directly or indirectly 5% or more of the stock of a company and any change in ownership arising from a new issuance of stock by the company. Generally, if an ownership change occurs, the yearly taxable income limitation on the use of net operating loss and tax credit carryforwards and certain built-in losses is equal to the product of the applicable long-term, tax-exempt rate and the value of the company's stock immediately before the ownership change. We may be unable to offset our taxable income with losses, or our tax liability with credits, before such losses and credits expire and therefore would incur larger federal income tax liability. Federal net operating losses generated after December 31, 2017, are not subject to expiration and generally may not be carried back to prior taxable years except that, under the Coronavirus Aid, Relief, and Economic Security Act, net operating losses generated in 2018, 2019 and 2020 may be carried back five taxable years. Additionally, for taxable years beginning after December 31, 2020, the deductibility of such deferral net operating losses is limited to 80% of our taxable income in any future taxable year.

Risks Related to Government Regulation

Risks Related to Regulations and Compliance

We are subject to export and import control laws and regulations that could impair our ability to compete in international markets or subject us to liability if we violate such laws and regulations. We are subject to U. S. export controls and sanctions regulations that restrict the shipment or provision of certain products and services to certain countries, governments, and persons. While we take precautions to prevent our products and services from being exported in violation of these laws, we cannot guarantee that the precautions we take will prevent violations of export control and sanctions laws. We believe that, in the past, we and our subsidiaries may have exported certain products without a required export license in apparent violation of U. S. export control laws. As a result, we have submitted to the U. S. Department of Commerce's Bureau of Industry and Security various notices of voluntary self-disclosure concerning potential violations. If we are found to be in violation of U. S. sanctions or export control laws, it could result in substantial fines and penalties for us and for the individuals working for us. We may also be adversely affected through other penalties, reputational harm, loss of access to certain markets, or otherwise. Complying with export control and ~~sanctions~~ **sanction** regulations may be time-consuming and may result in the delay or loss of sales opportunities or impose other costs. Any change in export or import regulations, economic sanctions or related legislation, or change in the countries, governments, persons or technologies targeted by such regulations, could result in our decreased ability to export or sell certain products to existing or potential customers in affected jurisdictions. Our business is subject to a number of environmental risks. Our manufacturing business involves the controlled use of hazardous materials and chemicals and is therefore subject to numerous environmental and safety laws and regulations and periodic inspections for possible violations of these laws and regulations. In addition to these hazardous materials and chemicals, our facility in Sweden also uses *Staphylococcus aureus* and toxins produced by *Staphylococcus aureus* in some of its manufacturing processes. *Staphylococcus aureus* and the toxins it produces, particularly enterotoxins, can cause severe illness in humans. The costs of compliance with environmental and safety laws and regulations are significant. Any violations, even if inadvertent or accidental, of current or future environmental and safety laws or regulations and the cost of compliance with any resulting order or fine could adversely affect our operations. Climate change, climate change-related regulation and sustainability concerns could adversely affect our businesses and the operations of our subsidiaries, and any actions we take or fail to take in response to such matters could damage our reputation. Investor advocacy groups, certain institutional investors, investment funds, other market participants and other stakeholders have focused increasingly on the Environmental, Social and Governance ("ESG") practices of companies, including those associated with climate change. These parties have placed increased importance on the importance on the implications of the social cost of their investments. If our ESG practices do not meet investor or other industry stakeholder expectations and standards, which continue to evolve, our reputation and associate retention may be negatively impacted based on an assessment of our ESG practices. Any sustainability disclosures we make may include our policies and practices on a variety of social and ethical matters, including corporate governance, environmental compliance, employee health and safety practices, human capital management, product quality, supply chain management, and workforce inclusion ~~and diversity~~. It is possible that stakeholders may not be satisfied with our ESG practices or the speed of their adoption, or that we may not sufficiently communicate our ESG practices sufficiently to stakeholders. We could also incur additional costs and require additional resources to monitor, report, and comply with various ESG practices. In addition, investors may decide to refrain from investing in us as a result of their assessment of our approach to and consideration of the ESG factors. In addition, we face physical risks associated with climate change. These physical risks include risks to our manufacturing and supply chain from flooding, severe storms, wildfires, droughts or extreme temperatures, all of which could increase costs and impair our ability to meet customer demands in a timely manner. To date, we have not experienced material losses or disruptions to our operations related to climate change, and we do not anticipate that these risks will have a material

impact to our Company in the near term. Health care reform measures could adversely affect our business. The efforts of governmental and third- party payors to contain or reduce the costs of health care may adversely affect the business and financial condition of pharmaceutical and biotechnology companies, including ours. Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. For the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (together, the “ ACA ”), substantially changed the way health care is financed by both governmental and private insurers. The ACA and other federal and state proposals and health care reforms could limit the prices that can be charged for the products we develop and may limit our commercial opportunity. In August 2022, the Inflation Reduction Act of 2022 (the “ IRA ”) was signed into law. The IRA includes several provisions that will impact our business to varying degrees, including provisions that create a \$ 2, 000 out- of- pocket cap for Medicare Part D beneficiaries, impose new manufacturer financial liability on all drugs in Medicare Part D, allow the U. S. government to negotiate Medicare Part B and Part D pricing for certain high- cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delay the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA' s Medicare drug price negotiation program. The effect of IRA on our business and the healthcare industry in general is not yet known. Additionally, the federal government and individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through the U. S. Food and Drug Administration' s (“ FDA' s ”) accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislation measures to control drug costs. Legally mandated price controls on payment amounts by third- party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our products or put pressure on drug pricing, which could negatively affect our business, financial condition, results of operations and prospects. We expect that additional state and federal healthcare reform measures will be adopted in the future. We may be exposed to liabilities under the Foreign Corrupt Practices Act, and any determination that we violated the Foreign Corrupt Practices Act could have a material adverse effect on our business. We are subject to the FCPA and other laws that prohibit improper payments or offers of payments to foreign governments and their officials and political parties by U. S. persons and issuers as defined by the statute for the purpose of obtaining or retaining business. We have operations and agreements with third parties and make sales in jurisdictions outside of the United States, which may experience corruption. Our activities in jurisdictions outside of the United States create the risk of unauthorized payments or offers of payments by one of our employees, consultants, sales agents or distributors, because these parties are not always subject to our control. These risks have increased following our recent acquisitions of overseas operations and facilities. It is our policy to implement safeguards to discourage these practices by our employees. However, our existing safeguards and any future improvements may prove to be less than effective, and the employees, consultants, sales agents or distributors of Repligen may engage in conduct for which we might be held responsible. Violations of the FCPA may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could negatively affect our business, operating results and financial condition. In addition, the government may seek to hold us liable for successor liability FCPA violations committed by any companies in which we invest or that we acquire. Changes in accounting standards and subjective assumptions, estimates, and judgments by management related to complex accounting matters could significantly affect our financial results or financial condition. Generally accepted accounting principles and related accounting pronouncements, implementation guidelines, and interpretations with regard to a wide range of matters that are relevant to our business, such as revenue recognition, asset impairment and fair value determinations, inventories, business combinations and intangible asset valuations, leases, and litigation, are highly complex and involve many subjective assumptions, estimates, and judgments. Changes in these rules or their interpretation or changes in underlying assumptions, estimates, or judgments could significantly change our reported or expected financial performance or financial condition. Risks Related to Data and Privacy Our internal computer systems, or those of our customers, collaborators or other contractors, may be subject to cyber- attacks or security **breaches incidents or compromises**, which could result in a material disruption of our product development programs. Despite the implementation of security measures, our internal computer systems and those of our customers, collaborators cloud- based platform service providers, and other contractors are vulnerable to damage from unauthorized access and from cyber- attacks, such as computer viruses, malware, ransomware, phishing denial- of- service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. **We have in the past experienced threats and security incidents related to our data and systems, and we may in the future experience other threats, compromises, breaches, or incidents.** A material cyber- attack or security **breach-incident or compromise** could cause interruptions in our operations and could result in a material disruption of our business operations, damage to our reputation or a loss of revenues. In the ordinary course of our business, we collect and store sensitive data, including, among other things, personally identifiable

information about our employees, intellectual property, and proprietary business information. In addition, we could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees, and company and vendor confidential data. Like other companies, we have on occasion experienced, and believe we will continue to experience, data security incidents involving access to company data threats to our data and systems. **As previously disclosed, recent cybersecurity incidents and compromises affecting similarly situated companies, including an incident that affected us in 2024, suggest that the risk of such events is significant, even if privacy protection and security measures are implemented and enforced.** If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to respond to these threats or breaches, and to repair or replace information systems or networks and could suffer financial loss or the loss of valuable confidential information. In addition, we could be subject to regulatory actions and / or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely and there can be no assurance that any measures we take will prevent cyber- attacks or security ~~breaches~~ **incidents or compromises** that could adversely affect our business. Changes in laws and regulations governing the privacy and protection of data and personal information could adversely affect our business. We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of proprietary information and personally- identifying information, which among other things, imposes certain requirements relating to the privacy, security and transmission of certain individually identifiable information. In addition, numerous other federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure and security of personal information. These laws continue to change and evolve and are increasing in breadth and impact. For example, **with respect to the collection and processing of personal data relating to** the European Union ~~'s~~ **(“ EU ”), European Economic Area (“ EEA ”) and United Kingdom ~~kingdom~~ ^{kingdom} ~~'s~~ (“ UK ”), we are subject to the EU General Data Protection Regulations – Regulation (EU GDPR), the UK General Data Protection Regulation (UK GDPR), as well as applicable data protection laws in effect in the Member States of the EEA and in the UK (including the UK Data Protection Act 2018) which govern the processing of personal data in connection with (a) the offering of goods or services to / the monitoring of the behavior of individuals in the UK and EEA; or (b) the activities of our establishments in the UK and any EEA Member State. The UK’ s data protection regime is independent from but aligned to the EU’ s data protection regime. In this Form 10- K, “ GDPR ” refers to both the EU GDPR and the UK GDPR, unless specified otherwise. The GDPR is wide- ranging in scope and ~~impose~~ **imposes significant numerous requirements on companies that how we collect, process personal data, including imposing special requirements in respect of the processing of health and other sensitive data, requiring that consent of individuals to whom the personal data relates is obtained in certain circumstances, requiring additional disclosures to individuals regarding data processing activities, requiring that safeguards are implemented to protect the security and confidentiality of personal data, limiting retention periods for personal data, creating mandatory data breach notification requirements in certain circumstances, and requiring that certain measures (including contractual requirements) are put in place when engaging third- party service providers. The GDPR also imposes strict rules on the transfer of personal data to countries outside of the UK and EEA that do not ensure ~~and~~ an adequate level of protection, including the United States in certain circumstances, unless derogation exists or a valid GDPR transfer mechanism (for example, the European Commission approved Standard Contractual Clauses (SCCs) and the UK International Data Transfer Agreement or Addendum (UK IDTA) have been put in place, and transfer impact assessments conducted. Any inability to transfer personal data from the UK or EEA to the United States in compliance with data protection laws may impede our operations and may adversely affect our business and financial position. Following the UK’ s exit from the EU, or Brexit, there will be increasing scope for divergence in application, interpretation and enforcement of the data protection laws between these territories. For example, the UK ~~as has well as significant~~ introduced the Data Reform Bill into the UK legislative process with the intention for this bill to reform the UK’ s data protection regime following Brexit. If passed, the final version of the Data Reform Bill may have the effect of further altering the similarities between the UK and EEA data protection regimes and threaten the UK adequacy decision from the EU Commission allowing the free flow of personal data from the UK to the EEA, which may lead to additional compliance costs and could increase our overall risk. This lack of clarity on future UK laws and ~~regulatory- regulations~~ **penalties and their interaction with those of the EEA could add legal liability risk, uncertainty, complexity, and cost to our handling of European personal data and our privacy and security compliance programs, and could require us to implement different compliance measures for the UK and EEA. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA Member States and the UK may result in fines up to € 20 million (17. 5 million for the UK GDPR) or 4 % of a company’ s global annual revenues for the preceding financial year, whichever is higher. The GDPR also confers a private right of action ~~non- on~~ ~~on~~ ~~compliance~~ data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR.** Complying with these **European data protection** laws may impose significant costs or otherwise require us to divert resources or implement changes to our business processes, and any actual or perceived non- compliance could result in significant penalties, claims and reputational damage. Additionally, we face risks from evolving and uncertain privacy standards in our industry. For example, the California **Privacy Rights Act imposes additional obligations on companies covered by the legislation and will significantly modify the California Consumer Privacy Act by expanding (“ CCPA ”) is a comprehensive******

privacy law that creates individual privacy rights and increased privacy and security obligations on businesses handling the personal data of California residents. The CCPA requires covered businesses to provide certain disclosures to consumers — rights with respect about data collection, use and sharing practices, to allow California residents to opt out of certain sales and disclosures of personal information, and to opt out of certain uses of sensitive personal information, including health information. The law also created a new regulatory agency in California and that agency's finalized and proposed regulations are continuing to change the standard of privacy protection we are required to meet. Numerous More than a dozen other states, including Virginia, Colorado and Connecticut, have passed similar consumer privacy laws that are or will be implemented and enforced by various state regulators. Like the CCPA, these laws grant consumers rights in relation to their personal information and impose new obligations on regulated businesses, including, in some instances, broader data security requirements. In addition, federal and state legislators and regulators are imposing new and heightened protections for health and other sensitive information that could impact our business. For example, the Federal Trade Commission ("FTC") has imposed stringent requirements on the collection and disclosure of sensitive categories of personal information, including health information, and has expanded the application of its Health Breach Notification Rule. Through executive and legislative action, the federal government has also taken steps to restrict data transactions involving certain sensitive data categories — including health data, genetic data, and biospecimens — with persons affiliated with China, Russia, and other countries of concern. Washington's My Health My Data Act, which went into effect in March 2024, requires regulated entities to obtain consent to collect health information, grants consumers certain rights, including to request deletion, and provides for robust enforcement mechanisms, including enforcement by the state attorney-general and by litigants through a private right of action for consumer claims. These current and future data privacy laws and regulations may require us to modify our data collection or processing practices and policies, incur substantial costs and expenses in an effort to comply and increase our potential exposure to regulatory enforcement, reputational damage, and / or litigation. Also, our customers may be subject to different privacy laws, rules and legislation, which may mean that they require us to be bound by varying contractual requirements applicable to certain other jurisdictions. Adherence to such contractual requirements may impact our collection, use, processing, storage, sharing and disclosure of information. As we expand our customer base, these requirements may vary from customer to customer, further increasing the cost of compliance and doing business. The use of new and evolving technologies, such as artificial intelligence ("AI"), in our offerings may present risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data. We may build and integrate AI into our business practices, and the evolving nature of AI technologies and the surrounding legal and regulatory environment presents risks and uncertainties that could affect our business. The use of AI technology can give rise to intellectual property risks, including compromises to proprietary intellectual property and intellectual property infringement. Additionally, we expect to see increasing government regulation related to artificial intelligence use and ethics, which may also significantly increase the burden and cost of research, development and compliance in this area. For example, in the U. S., a number of states have proposed and passed laws regulating various uses of AI, and federal regulators have issued guidance affecting the use of AI in regulated sectors. In Europe, the EU's Artificial Intelligence Act ("AI Act") — which entered into force on August 1, 2024 and, with some exceptions, will begin to apply as of August 2, 2026 — imposes significant obligations on providers and deployers of high-risk artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. If we develop or deploy AI systems that are governed by these laws and regulations, we may be required to adopt higher standards of data quality, transparency, and human oversight, and adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. Even in the absence of dedicate AI laws and regulations, we may be subject to novel legal and business risks relating to our adoption of these new technologies. Our vendors may in turn incorporate AI tools into their own offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business. Risks Related to Our Products and Technology Risks Related to Our Intellectual Property If we are unable to obtain or maintain our intellectual property, we may not be able to succeed commercially. We endeavor to obtain and maintain trade secrets and pursue strategic patent protection in order to protect our products and processes from unauthorized use, and to produce a financial return consistent with the significant time and expense required to bring our products to market and continue to be competitive in our technical fields. Our success depends, in part, on our ability to: • preserve our trade secrets, know-how and confidential information; • operate without infringing the proprietary rights of third parties; • obtain and maintain patent protection for our products and processes; and • secure any necessary licenses from others on acceptable terms. We consider trade secrets, know-how and other forms of market protection to be among the most important elements of our proprietary position, in particular, as it relates to many of the products that currently account for a majority of our revenue. We also own or have exclusive rights to U. S. patents and U. S. pending patent applications as well as corresponding foreign patents and patent applications. We continue to actively and selectively pursue patent protection and seek to expand our patent estate, particularly for our products currently in development, and we cannot be sure that any patent applications that we will file in the future or that any currently pending applications will issue on a timely basis, if ever. We cannot be certain that we were the first to conceive the invention (s) described by each of our pending patent applications or that we were the first to file patent applications for such invention (s). Even if patents are issued, the degree of protection afforded by such patents will depend upon the: • scope of the patent claims; • validity and enforceability of the claims obtained in such patents; and • our willingness and financial ability to enforce and / or defend them. Patents that

may be granted to us in certain foreign countries may be subject to opposition proceedings brought by third parties or result in suits by us, which may be costly and result in adverse consequences for us. In some cases, litigation or other proceedings may be necessary to assert claims of infringement, to enforce patents issued to us or our licensors, to protect trade secrets, know-how or other intellectual property rights we own or to determine the scope and validity of the proprietary rights of third parties. Such litigation could result in substantial costs to us and diversion of our resources. An adverse outcome in any such litigation or proceeding could have a material adverse effect on our business, financial condition and results of operations. If our competitors prepare and file patent applications that claim technology also claimed by us, we may be required to participate in interference proceedings declared by Patent Offices to determine priority of invention, which would result in substantial costs to us. While we continue to obtain patent grants directed towards Protein A, other patent grants directed towards Protein A have expired, and as a result, we may face increased competition, which could harm our results of operations, financial condition, cash flow and future prospects. Other companies could begin manufacturing and selling native or some of the commercial forms of recombinant Protein A in the United States and may directly compete with us on certain Protein A products. This may induce us to sell Protein A at lower prices and may erode our market share, which could adversely affect our results of operations, financial condition, cash flow and future prospects. Our freedom to develop our products may be challenged by others, and we may have to engage in litigation to determine the scope and validity of competitors' patents and proprietary rights, which, if we do not prevail, could harm our business, results of operations, financial condition, cash flow and future prospects. There has been substantial litigation and other proceedings regarding the complex patent and other intellectual property rights in the life sciences industry. We have been a party to, and in the future may become a party to, patent litigation or other proceedings regarding intellectual property rights. We may become involved in patent litigation or other intellectual property proceedings, including the following situations:

- We may initiate litigation or other proceedings against third parties to seek to invalidate the patents held by such third parties or to obtain a judgment that our products or services do not infringe on such third parties' patents.
- We may initiate litigation or other proceedings against third parties to seek to enforce our patents against infringers.
- If our competitors file patent applications that claim technology also claimed by us, we may participate in interference or opposition proceedings to determine the priority of invention.
- If third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we will need to defend against such claims. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. If a patent litigation or other intellectual property proceeding is resolved in a way that is unfavorable to us, we or our collaborative or strategic partners may be enjoined from manufacturing or selling our products and services without a license from the other party and be held liable for significant damages. The failure to obtain any required license on commercially acceptable terms or at all may harm our business, results of operations, financial condition, cash flow and future prospects. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time, attention and resources.

~~The market may not be receptive to our new bioprocessing products upon their introduction. We expect a portion of our future revenue growth to come from introducing new bioprocessing products, including line extensions and new features for our OPUS® disposable chromatography columns, our XCell ATF system, our SIUS® tangential flow filtration ("TFF") cassettes, our Spectrum® hollow fiber modules TFF line of cassettes, our process analytics products and our growth factors. The commercial success of all of our products will depend upon their acceptance by the life science and biopharmaceutical industries. Many of the bioprocessing products that we are developing are based upon new technologies or approaches. As a result, there can be no assurance that these new products, even if successfully developed and introduced, will be accepted by customers. If customers do not adopt our new products and technologies, our results of operations may suffer and, as a result, the market price of our common stock may decline. Our products are subject to quality control requirements. Whether a product is produced by us or purchased from outside suppliers, it is subjected to quality control procedures, including the verification of porosity and with certain products, the complete validation for good manufacturing practices, FDA, CE and ISO® compliance, prior to final packaging. Quality control is performed by a staff of technicians utilizing calibrated equipment. In the event we, or our manufacturers, produce products that fail to comply with required quality standards, it may incur delays in fulfilling orders, write-downs, damage to our reputation and damages resulting from product liability claims. If our products do not perform as expected or the reliability of the technology on which our products are based is questioned, we could experience lost revenue, delayed or reduced market acceptance of our products, increased costs and damage to our reputation. Our success depends on the market's confidence that we can provide reliable, high-quality bioprocessing products. We believe that customers in our target markets are likely to be particularly sensitive to product defects and errors. Our reputation and the public image of our products and technologies may be impaired if our products fail to perform as expected. Although our products are tested prior to shipment, defects or errors could nonetheless occur in our products. Furthermore, the Protein A that we manufacture is subsequently incorporated into products that are sold by other life sciences companies and we have no control over the manufacture and production of those products. In the future, if our products experience, or are perceived to experience, a material defect or error, this could result in loss or delay of revenues, delayed market acceptance, damaged reputation, diversion of development resources, legal claims, increased insurance costs or increased service and warranty costs, any of which could harm our business. Such defects or errors could also narrow the scope of the use of our products, which could hinder our success in the market. Even after any underlying concerns or problems are resolved, any lingering concerns in our target market regarding our technology or any manufacturing defects or performance errors in our products could continue to result in lost revenue, delayed market acceptance, damaged reputation, increased service and warranty costs and claims against us. Risks Related to Litigation We may become involved in litigation or other proceedings with collaborative partners, which may be time consuming, costly and could result in delays in our development and~~

commercialization efforts. In connection with our decision to focus efforts on the growth of our core bioprocessing business, we sought development and commercialization partnerships for our remaining portfolio of clinical stage assets. Any disputes with such partners that lead to litigation or similar proceedings may result in us incurring legal expenses, as well as facing potential legal liability. Such disputes, litigation or other proceedings are also time-consuming and may cause delays in our development and commercialization efforts. If we fail to resolve these disputes quickly and with terms that are no less favorable to us than the current terms of the arrangements, our business, results of operations, financial condition, cash flow and future prospects may be harmed. We may become subject to litigation, which could result in substantial costs and divert management's attention and resources from our business. From time to time, we may become involved in litigation or other legal proceedings relating to claims arising from the ordinary course of business. Litigation is subject to inherent risks and uncertainties that may cause actual results to differ materially from our expectations. If we receive an adverse judgment in any litigation, we could be required to pay substantial damages. With or without merit, litigation can be complex, can extend for a protracted period of time, can be very expensive and the expense can be unpredictable. Litigation initiated by us could also result in counterclaims against us, which could increase the costs associated with the litigation and result in our payment of damages or other judgments against us. In addition, litigation, and any related publicity, may divert the efforts and attention of some of our management and key personnel, which could adversely affect our business.