

## Risk Factors Comparison 2023-11-29 to 2022-12-22 Form: 10-K

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You should carefully consider the following risks and other information in this Annual Report on Form 10-K in evaluating Embecta and Embecta common stock. The summary below provides an overview of many of the risks and uncertainties we encounter that are described in this Annual Report on Form 10-K that could materially and adversely affect Embecta's business, financial condition or results of operations. An investment in our common stock involves a variety of risks and uncertainties. Additional risks that we currently do not know about or that we currently believe to be immaterial may also impair our business, financial condition, operating results, liquidity, and future prospects. The risks we face include, but are not limited to, the following:

- Risks Related to Embecta's Business
- The medical technology industry is very competitive.
- Embecta generates a significant amount of its profits and cash flows from a few key products, and any events that adversely affect the sale or profitability of these products could have an adverse impact on Embecta's sales, results of operations and cash flows.
- Technological breakthroughs in diabetes treatment or prevention may reduce demand for Embecta's products.
- Embecta obtains components and raw materials for its products from third parties, including BD. These third parties may fail to perform under their agreements with Embecta, or there may be a reduction or interruption in the manufacturing and supply of these components and raw materials. Any such failure to perform or a reduction or interruption in supply could have a material adverse effect on Embecta's business and operations.
- Embecta may experience difficulties and delays in the manufacturing of its products or sterilization operations, and any such difficulties and delays could adversely affect Embecta's business.
- A substantial portion of Embecta's revenue is derived from sales to a few customers. If these customers reduce the amount of product that they purchase from Embecta, reduce the amount that they are willing to pay for such products or increase charges to distribute such products, Embecta's business, financial condition and results of operations could be adversely affected.
- Embecta's products are subject to continuous reimbursement, coverage and access scrutiny by both private and government payers, including the scope of products covered, access and coverage among product brands and manufacturers, reimbursement limitations and price adjustment restrictions. A change in any of these factors could have an adverse impact on Embecta's financial condition and results of operations.
- Embecta may enter into strategic collaborations, in-licensing arrangements or alliances with third parties that may not result in the development of commercially viable products or the generation of revenue.
- Embecta's sales and marketing efforts rely upon independent distributors that are free to market products that compete with Embecta's products, and if Embecta is unable to maintain or expand its network of independent distributors, its business could be materially adversely affected.
- Embecta's future growth is dependent in part upon the development of new products, and there can be no assurance that such products will be developed or be successful.
- If the third parties on which Embecta relies to conduct its clinical trials and to assist it with pre-clinical development do not perform as contractually required or expected, or if market or clinical studies are unfavorable to its products in development, Embecta may not be able to obtain regulatory clearance or approval or commercialize its products.
- Embecta may be unable to maintain strong relationships with physicians and other healthcare professionals which could adversely affect its business.
- Embecta may not be able to successfully execute its acquisition strategy, which could adversely affect its financial condition and results of operations.
- Embecta's international operations subject it to certain business risks.
- Embecta's business and operations are subject to risks related to climate change.
- Embecta's may be exposed to environmental, social and governance risks.
- Embecta's intellectual property and proprietary technology are material to its business operations and are subject to infringement and other risks.
- Breaches of Embecta's information systems or cyberattacks could adversely affect our business.
- A disruption at one of our facilities could adversely affect our business and operating results.
- Insurance coverage may be inadequate or unavailable to cover any product liability losses we incur.
- Embecta is subject to a number of restrictive covenants under its indebtedness, including customary operating restrictions and financial covenants, which could restrict Embecta's ability to pay dividends or adversely affect its financing options and liquidity position.
- Embecta is subject to risks associated with public health threats, including such as the ongoing COVID-19 pandemic, which could have a material adverse effect on Embecta's financial condition and results of operations.
- Risks Related to the Separation and Distribution from BD
- Embecta has a limited history of operating as an independent company, and its historical financial information may not be a reliable indicator of its future results.
- Since the Separation, Embecta's financial profile has changed, and it is a smaller, less diversified company than BD prior to the Separation.
- Embecta may not achieve some or all of the expected benefits of the Separation.
- In order to conduct its operations and meet its financial reporting and other obligations, Embecta may be relies on certain services provided by BD pursuant to the transaction documents entered into with BD in connection with the Separation, including the TSA and the LSA. If Embecta is unable to extend the services on the terms contemplated by the Extension or replace the services that BD currently provides to it on terms that are at least as favorable to Embecta as the terms on which BD is providing such these services, which could have or if BD otherwise terminates an any adverse effect on of the services, Embecta's business, financial condition and results of operations may be materially adversely affected.
- Following the end of the transition period, Embecta will be required to rebrand its products to remove the BD name, transfer or obtain new manufacturing, supply chain, regulatory and product licenses and registrations in the name of Embecta, which could adversely affect its ability to attract and maintain end users or which could result in delays or interruptions of Embecta's commercialization and distribution operations or the loss of customers or revenue, all of which could adversely affect its financial condition and results of operations.
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Embecta has incurred indebtedness, which debt obligations that could adversely affect its business and profitability and its ability to meet other obligations.

- Embecta may be affected by significant restrictions under the tax matters agreement, including on its ability to engage in certain corporate transactions for a two- year period after the Separation Date, in order to avoid triggering significant tax- related liabilities.
- Embecta may be held liable to BD if it fails to perform under its agreements with BD.
- There could be significant income tax liability if the Separation or certain related transactions are determined to be taxable for United States federal income tax purposes.
- The transfer to Embecta of certain contracts, permits and other assets and rights may require the consents, approvals of, or provide other rights to, third parties and governmental authorities. If such consents or approvals are not obtained, Embecta may not be entitled to the full benefit of such contracts, permits and other assets and rights, which could increase its expenses or otherwise harm its business and financial performance.
- The closing of the Separation was deferred in certain jurisdictions, and may not occur at all in such jurisdictions, due to local regulatory requirements, which may adversely affect Embecta's manufacturing, business, financial condition and results of operations.
- Satisfaction of indemnification obligations following the distribution could have a material adverse effect on Embecta's financial condition, results of operations and cash flows.

**Risks Related to Embecta's Common Stock**

- The price and trading volume of Embecta's common stock may be volatile, and stockholders could lose all or part of their investment in Embecta.
- Embecta cannot guarantee the timing, amount or payment of any dividends on its common stock.
- Anti- takeover provisions could enable Embecta's Board of Directors to resist a takeover attempt by a third- party and limit the power of its stockholders.
- Embecta's amended and restated certificate of incorporation designates the state courts within the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by Embecta stockholders, which could discourage lawsuits against Embecta and its directors and officers. The risks described below may not be the only risks we face but are risks we believe may be material at this time. Other risks of which we are not yet aware, or that we currently believe are not material, may also materially adversely impact our business, financial condition or results of operations. If any of the events or circumstances described below occurs, our business, financial condition or results of operations could be adversely impacted and the value of an investment in our securities could decline. Investors and prospective investors should consider the risks described below and the information contained under the caption " Cautionary Statements Regarding Forward- Looking Statements " and elsewhere in this Annual Report on Form 10- K before deciding whether to invest in our securities. We may update these risk factors in our future periodic reports.

Embecta faces significant competition from a wide range of companies in each market in which its products are sold. These include large companies with multiple product lines and non- traditional entrants such as technology companies, some of which may have greater financial and marketing resources than Embecta in the United States or other markets, as well as smaller, more specialized companies. Embecta's ability to compete will also be affected by changing preferences and requirements of people with diabetes, as well as changes in the ways healthcare services are delivered. Efforts to contain healthcare costs by governments and the private sector are also resulting in increased emphasis on products that reduce costs, improve clinical results and expand access. Embecta's ability to remain competitive will depend on how well it will meet these changing market demands in terms of its product offerings and marketing approaches. The medical technology industry is subject to rapid technological change and frequent introduction of new products. The development of new or improved products, processes or technologies by other companies (such as new technologies to administer insulin) that provide better features, pricing, clinical outcomes or economic value may make Embecta's existing or new products less competitive. In some instances, competitors, including pharmaceutical companies, also offer, or are attempting to develop, alternative therapies, including oral anti- diabetic drugs, GLP- 1s and GLP- 1 combination products, for disease states (including diabetes) that may be delivered without a medical device, such as pen needles. Lower cost producers have also created pricing pressure, particularly in emerging markets. There can be no assurance that Embecta's products will be commercially successful, and it is possible that its business will be adversely affected from time to time as a result of products developed by its competitors. Consolidation among payers, retailers, wholesalers, healthcare systems, and other providers is resulting in greater purchasing power for these companies. Group purchasing organizations and integrated health delivery networks have also served to concentrate purchasing decisions for some customers, which has led to downward pricing pressure for medical device suppliers. Further consolidation in the industry could intensify competition among medical device suppliers and exert additional pressure on the demand for, and prices of, Embecta's products. Embecta's ability to generate profits and operating cash flow depends largely upon the continued profitability of its key products, such as its pen needles and syringes. For example, for the fiscal year ended September 30, 2022-2023, sales of pen needles (including both conventional and safety pen needles) accounted for \$ 912 million, or 81 %, of total net revenues. Any event that adversely affects the sale or profitability of this product could adversely affect Embecta's sales, results of operations and cash flows. These adverse events could include a decrease in the demand for such products, the pressure to decrease the price of such products, any increase in costs of manufacturing such products or other supply chain disruptions, increased availability of competitive products, increased competition from the introduction of new products related to the treatment of diabetes or removal from the market of these products for any reason. The diabetes treatment industry is subject to technological change and product innovation. A number of companies and medical researchers are pursuing new ways to deliver insulin to patients, including insulin administration technologies that do not require the use of a needle, or to treat diabetes without the use of insulin or by delaying the use of insulin, such as oral anti- diabetic drugs, GLP- 1s and GLP- 1 combination products. If they are successful in developing and commercializing these technologies or treatment therapies, the demand for Embecta's products could decline. Furthermore, the National Institutes of Health and other supporters of diabetes research are continually seeking ways to prevent diabetes. Any technological breakthroughs in diabetes prevention or treatment could decrease demand

for Embecta's products and have a material adverse effect on its business or results of operations. Embecta obtains components, services and raw materials for its products from third parties, including BD. These third parties may fail to perform under their agreements with Embecta, or there may be a reduction or interruption in the manufacturing and supply of these components and raw materials. Any such failure to perform or a reduction or interruption in supply could have a material adverse effect on Embecta's business and operations. Embecta relies on a number of third parties to supply and manufacture the components, services and raw materials for its products. For example, in connection with the Separation and prior to the distribution, Embecta and BD entered into a cannula supply agreement, whereby BD sells to Embecta cannulas for incorporation into Embecta's products for sale within the diabetes care sector. Cannulas are a component part of a wide variety of medical devices that use needles to deliver fluid into, or through which blood is drawn from, the body. BD retains ownership of all cannula production activities and all intellectual property rights of BD and its subsidiaries relating to cannula, the manufacture thereof and other critical cannula-related technology. Pricing under the cannula supply agreement is determined by BD based on several factors, including Embecta's yearly forecast, the cost of raw materials and other cost methodologies. The cannula supply agreement is terminable by BD without cause by providing at least 36 months' written notice; however, such termination can be effective no earlier than ten years from the Separation spin-off. In the event of a change of control of Embecta, BD also has the right to terminate the cannula supply agreement. The cannula supply agreement will also terminate automatically, subject to a 36-month wind-down period, if Embecta's yearly forecast is below the required minimum purchase amount, and the parties will have other customary termination rights for material breach or bankruptcy of the other party. Embecta is also limited to a maximum number of cannulas that it can purchase under the cannula supply agreement. If BD fails to perform under this agreement or BD terminates this agreement in accordance with its terms and, in either case, Embecta cannot find a way to purchase cannula from another party or manufacture cannula, or if Embecta needs to purchase more cannula than it is permitted under cannula supply agreement, Embecta may have insufficient cannulas for its products, which could materially adversely affect Embecta's business, financial condition or results of operations. In addition, in connection with the Separation, Embecta and BD entered into a lease agreement for a manufacturing facility location in Holdrege, Nebraska that Embecta leases from BD and several contract manufacturing agreements where BD provides certain manufacturing services to Embecta. If BD is unable to perform under these arrangements, terminates certain services or modifies its operations and Embecta cannot find substantially similar alternatives to perform these services or is forced to change its operations as a result, Embecta may incur additional costs, delays or other deficiencies in its operations, which could materially adversely affect Embecta's business, financial condition or results of operations.

Embecta also obtains other component parts and raw materials from other third parties. In many cases, Embecta does not have long-term supply agreements with suppliers of these component parts and raw materials, and its arrangements with these suppliers are on a purchase-order basis. Certain raw materials that we obtain from suppliers are subject to fluctuations in price and availability attributable to a number of factors, including general economic conditions, commodity price fluctuations, the demand by other companies for the same raw materials and the availability of complementary and substitute materials. In some cases, Embecta's agreements with suppliers can be terminated by either party by convenience upon short notice. Certain raw materials and components used in the manufacture of pen needles and syringes, including cannulas, certain oil-based resins and rubber stoppers, are not always available from multiple sources. New laws or regulations adopted in response to climate change could also increase energy and transportation costs, as well as the costs of certain raw materials and components. In addition, for quality assurance, cost-effectiveness and other reasons, Embecta purchases certain raw materials and components from a single supplier. The price and supply of these materials and components may be affected or disrupted for reasons beyond Embecta's control. While Embecta works with suppliers to ensure continuity of supply, no assurance can be given that these efforts will be successful. In the event that any of its existing supply arrangements are terminated or there is a reduction or interruption of supply under these existing arrangements, Embecta expects that it will be able to enter into new arrangements with alternative suppliers, but these new arrangements may be on terms that are less favorable, including with respect to price and volume, and it may be costly or cause delays in Embecta's manufacturing process to transition to a new supplier, particularly in cases in which Embecta must comply with regulatory requirements relating to qualification of new suppliers. The termination, reduction or interruption in supply of these raw materials and components could adversely impact Embecta's ability to manufacture and sell certain of its products. Third-party suppliers may encounter problems during manufacturing for a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction, component part supply constraints, and environmental factors, any of which could delay or impede their ability to supply the components and raw materials for Embecta's products. Any such failure to perform or a reduction or interruption in supply could have a material adverse effect on Embecta's business and operations. Embecta may experience difficulties and delays inherent in manufacturing its products, such as failure of Embecta or its suppliers to comply with applicable regulations and quality assurance guidelines, which failures may lead to: manufacturing shutdowns or manufacturing delays; delays related to the construction of new facilities or the expansion of existing facilities; and other manufacturing or distribution problems, including changes in manufacturing production sites and limits to manufacturing capacity resulting from regulatory requirements, changes in types of products produced and physical limitations that could affect supply. In addition, Embecta could experience difficulties or delays in manufacturing its products caused by natural disasters. Manufacturing difficulties can also result in product shortages, leading to lost sales and reputational harm. In addition, many of Embecta's products require sterilization prior to sale. In some instances, only a few facilities are qualified under applicable regulations to conduct this sterilization. To the extent Embecta or third parties (including BD) are unable to sterilize Embecta's products, whether due to lack of capacity, increased demand, regulatory requirements or changes or otherwise, Embecta may be unable to transition sterilization to other sites or modalities in a timely or cost effective manner, or at all, which could have an adverse impact on Embecta's business. A substantial portion of Embecta's revenue is derived from sales to a few customers. For example, for the

fiscal year ended September 30, ~~2022~~ **2023**, gross sales to McKesson Corporation, Cardinal Health and **Cencora** ~~AmerisourceBergen Drug Corporation~~, Embecta's three largest distributors, together represented approximately 40 % of Embecta's worldwide gross sales. The costs charged by these and other distributors to distribute Embecta's products is also subject to negotiation, and such distributors may propose increases in such charges from time to time. In addition, for the fiscal year ended September 30, ~~2022~~ **2023**, direct gross sales to the five largest retail pharmacies for Embecta's products together represented approximately 14 % of Embecta's worldwide gross sales. If any of Embecta's largest customers reduce the amount of product that they purchase from Embecta, negotiate a reduced price for such products or increase the charges to distribute such products, each could have a material adverse effect on Embecta's business, financial condition and results of operations. In the United States, both public and private payers continue to take aggressive steps to control their expenditures for medical devices by placing restrictions on how many and which brands of devices they will provide coverage for across the spectrum of available products. Important competitive factors include quality, price, price guarantees and demonstrated ability to supply markets. Any failure by Embecta to differentiate its products with existing payers based on these and other factors or establish new payer relationships may adversely affect its financial condition and results of operations. In addition, consolidation and integration among healthcare institutions and providers significantly affects the competitive landscape for medical devices. Health plans, pharmacy benefit managers, wholesalers, and other supply chain stakeholders have been consolidating into fewer, larger entities, thus enhancing their purchasing strength and importance. Specifically, private third- party insurers and governments typically maintain formularies that specify coverage (the conditions under which drugs and medical devices are included on a plan's formulary) and reimbursement (including both the associated out- of- pocket cost to the consumer and payment to the distributor) to control costs by negotiating discounted prices, inflation guarantees and other terms in exchange for formulary inclusion. Adverse formulary placement can lead to reduced usage of a medical device for the relevant patient population due to coverage restrictions, such as prior authorizations and formulary exclusions, or due to reimbursement limitations that result in higher consumer out- of- pocket cost, such as nonpreferred co- pay tiers, increased co- insurance levels, and higher deductibles. Consequently, medical device companies compete for formulary placement not only on the basis of product attributes but also by providing rebates. Price to the end customer is an increasingly important factor in formulary decisions, particularly in treatment areas in which the payer has taken the position that multiple branded products are therapeutically comparable (like that of diabetes). These downward pricing pressures could continue to negatively affect Embecta's business. In addition to formulary placement, changes in insurance designs continue to drive greater consumer cost-sharing through high deductible plans and higher co- insurance or co- pays, increasing consumer sensitivity to product choice. Embecta is consistently managing the burden of continued pressures associated with payers' discount requirements to maintain positive formulary positions. If Embecta fails to maintain these formulary positions or reduces prices on its products to maintain these formulary positions, it could adversely affect Embecta's results of operations. In addition to the evolving payer market that continues to put price pressure on Embecta's products, new competitors have emerged. Competitors that are new to the pen needle and insulin syringe categories, along with some that have emerged to begin engaging with payers, have accelerated the focus on these product categories, providing payers more choices for formulary partners within these medical device categories. In addition to the ongoing challenges faced across the United States, Embecta faces similar access, pricing and reimbursement trends outside of the United States. Although payers' preferences for particular devices varies regionally, key foundational considerations for choice include: product specifications, clinical evidence demonstrating efficacy ~~and,~~ positive clinical outcomes **, investment in proper injection technique training for customers and patients,** and pricing. Embecta is challenged to deliver new, innovative and differentiated products, along with price concessions, in markets outside of the United States, and price guarantees in these regions are critical to maintain access to key distributors and end users. For example, in EMEA (which includes Europe, the Middle East and Africa), the demand for medical devices that are paid out of pocket by the end user is limited. Access to these products is largely defined by the availability and size of government reimbursement, or, in a limited number of countries, the ability of manufacturers to negotiate reimbursement directly with insurance companies. In China, the most notable threat continues to be access through volume- based procurement and Group Purchasing Organizations (" GPOs"), with potential significant price ~~erosions-~~ **erosion** and cost containment within the healthcare landscape. These continued pricing pressures could adversely affect Embecta's financial condition and results of operations. In the ordinary course of its business, Embecta may enter into strategic collaborations, in- licensing arrangements or alliances to develop product candidates. Other companies, including those with substantially greater financial, marketing, sales, technology or other resources, may compete with us for these arrangements. These arrangements are subject to a variety of risks, including: • Embecta may not identify or secure these collaborations in a timely manner, on a cost- effective basis, on acceptable terms or at all; • these collaborations may not result in the development of products that achieve commercial success or result in any revenue to Embecta; • Embecta may not exercise sole decision making authority with respect to material **development, regulatory submission, or** commercial decisions under these collaborations, resulting in gridlock with its partners, and its collaborators may have economic or business interests or goals that are, or that may become, inconsistent with its business interests or goals; • Embecta may have limited control over the amount and timing of resources that its current collaborators or any future collaborators devote to its collaborators' or its future products; • disputes between Embecta and its collaborators may result in litigation or arbitration that would increase Embecta's expenses and divert the attention of its management; and • these collaborations may be terminated or dissolved in accordance with their terms prior to the development of any Embecta products or any realization by Embecta of any other benefits. Embecta believes that a significant portion of its sales will continue to be **to from** independent distributors for the foreseeable future, and it is possible that the percentage of its sales **to from** independent distributors could increase. None of Embecta's independent distributors in the United States has been required to sell Embecta's products exclusively, and each of them may freely sell the products of Embecta's competitors. If Embecta is unable to maintain or expand its network of independent distributors, its sales may be negatively affected. For the fiscal year ended

September 30, 2022-2023, McKesson Corporation, Cardinal Health and **Cencora** AmerisourceBergen Drug Corporation, Embecta's three largest distributors, together represented approximately 40% of Embecta's worldwide gross sales. If any of **its Embecta's** key independent distributors were to cease to distribute Embecta's products or reduce their promotion of such products as compared to the products of Embecta's competitors, Embecta may need to seek alternative independent distributors or increase its reliance on other independent distributors or its direct sales representatives, which alternative arrangements may not be sufficient to prevent a material reduction in sales of its products. A significant element of Embecta's strategy is to increase revenue growth by focusing on innovation and new product development. For example, Embecta is currently working on developing an insulin patch pump focused on serving the needs of people with Type 2 diabetes. ~~Embecta is also currently working on a new finer gauge pen needle.~~ However, potential products are still in the product development phase, and Embecta has not yet submitted an application to the FDA seeking clearance for these products. In addition, even if Embecta submits an application to the FDA for clearance, there is no assurance that such clearance will be obtained or that Embecta will be able to market and sell such products successfully. New product development requires significant investment in research and development. The results of Embecta's product development efforts may be affected by a number of factors, including Embecta's ability to anticipate the needs of people with diabetes, successfully complete clinical trials, obtain regulatory clearance and approvals for its products, manufacture such products in a cost-effective manner, obtain appropriate intellectual property protection for such products, gain and maintain market acceptance of such products, **secure distribution channels**, and obtain **access, coverage and reimbursement** for such products. There can be no assurance that Embecta will be able to successfully develop or commercialize any products now in development or that Embecta may seek to develop or commercialize in the future. Embecta relies on third parties, such as contract research organizations, medical institutions, clinical investigators, contract laboratories and other third parties, to conduct some of its clinical trials, **human factors studies** and pre-clinical investigations. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, or if the quality or accuracy of the data they obtain is compromised due to failure to adhere to **the Embecta's** clinical protocols or regulatory requirements or for other reasons, Embecta's pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and Embecta may not be able to obtain regulatory clearance or approval for, or successfully commercialize, its products on a timely basis, or at all, and Embecta's business and operating results may be adversely affected. Furthermore, **such Embecta's third parties** ~~party clinical trial investigators~~ may be **experience delayed delays** in conducting such **clinical studies and** trials for reasons outside of their control. **In addition, Embecta faces the risk of potential unauthorized disclosure or misappropriation of its intellectual property by contract research organizations, which may reduce Embecta's trade secret protection and allow its potential competitors to access and exploit its proprietary technology.** In addition, if future clinical trials fail to support the efficacy or safety of Embecta's current or future products **or if the data obtained from such studies are unfavorable or inadequate to support satisfactory conclusions about Embecta's current or future products**, Embecta's sales may be adversely affected and may have a material adverse effect on its business, financial condition and results of operations. In addition, future clinical studies or other articles regarding Embecta's existing products or any competing products may be published that either support a claim, or are perceived to support a claim, that a competitor's product is clinically more effective or easier to use than Embecta's **existing products** ~~insulin patch pump and/or products finer gauged pen needle~~ in development or that any such product is not as effective as Embecta claims. Any of these events may negatively affect Embecta's sales efforts and result in decreased revenue. Embecta's failure to maintain strong relationships with physicians and other healthcare professionals could adversely affect its business. Embecta depends on its ability to maintain strong working relationships with physicians and other healthcare professionals in connection with research and development for some of its products. Embecta relies on these professionals to provide it with considerable knowledge and advice regarding the development and use of these products. If Embecta fails to maintain its working relationships with physicians and, as a result, no longer has the benefit of their knowledge and advice, Embecta's products may not be developed in a manner that is responsive to the needs and expectations of the professionals who use and support such products, which could have a material adverse effect on Embecta's business. Embecta intends to explore strategic partnerships and acquisition opportunities that enable it to accelerate its growth. There is no assurance that future acquisitions will be available on attractive terms and Embecta's ability to consummate any acquisition will be subject to various risks and uncertainties, including the negotiation of agreements on satisfactory terms, obtaining applicable regulatory clearances and approvals and, after consummation, achieving anticipated synergies and other benefits. If Embecta does not successfully execute on its acquisition strategy, it could adversely affect its financial condition and results of operations. A substantial amount of Embecta's sales come from its operations outside the United States, and Embecta intends to continue to pursue growth opportunities outside of the United States, especially in emerging markets. Embecta's international operations subject it to certain risks relating to, among other things, fluctuations in foreign currency exchange, local economic and political conditions, competition from local companies, increases in trade protectionism, United States relations with the governments of the foreign countries in which Embecta operates, foreign regulatory requirements or changes in such requirements, changes in local healthcare payment systems and healthcare delivery systems, local product preferences and requirements, longer payment terms for account receivables than we experience in the United States, difficulty in establishing, staffing and managing foreign operations, changes to international trade agreements and treaties, changes in tax laws, weakening or loss of the protection of intellectual property rights in some countries and import or export licensing requirements. The success of Embecta's international operations also depends, in part, on its ability to make necessary infrastructure enhancements to, among other things, its production facilities and sales and distribution networks. These and other factors may adversely impact its ability to pursue its growth strategy in these regions. In addition to the risks discussed elsewhere, other risks associated with doing business internationally, include, but are not limited to: • political instability and actual or anticipated military or political conflicts; • trade protection measures **and barriers**, such as tariffs, and import and export licensing and control requirements; •

negative consequences from changes in or interpretations of tax laws; • difficulty in establishing, staffing and managing international operations; • difficulties associated with foreign legal systems, including increased costs associated with enforcing contractual obligations in foreign jurisdictions; • changes in regulatory requirements; • adapting to the differing laws and regulations, business and clinical practices, and consumer preferences in foreign markets; • difficulties in managing foreign relationships and operations, including any relationships that we establish with foreign partners, distributors or sales or marketing agents; and • difficulty in collecting accounts receivable and longer collection periods. In addition, **Embeceta's international operations are governed by the United States U. S. Foreign Corrupt Practices Acts (FCPA), the U. K. Bribery Act, and similar anti- corruption and anti- bribery laws enacted outside the United States generally prohibit companies and their intermediaries from making improper payments to foreign officials for the purpose of obtaining or retaining business**. Global enforcement of anti- corruption laws has increased substantially in recent years, with more enforcement proceedings by United States and foreign governmental agencies and the imposition of significant fines and penalties. Embecta's international operations, which often involve customer relationships with foreign governments **or government- sponsored healthcare systems**, create the risk that there may be unauthorized payments or offers of payments made by employees, consultants, sales agents or distributors. **Because Embecta does business in the U. K., the U. K. Bribery Act also extends to its interaction with public and private sector entities and persons outside the U. K., including in the United States. Embecta's policies mandate compliance with these laws. Embecta operates in parts of the world that have experienced governmental corruption to some degree, and in certain circumstances strict compliance with anti- bribery laws may conflict with local customs and practices. Despite Embecta's training and compliance programs, its internal control policies and procedures may not always protect Embecta from reckless or criminal acts committed by its employees or agents.** Any alleged or actual violations of these laws may subject Embecta to government investigations and significant criminal or civil sanctions and other liabilities, **and including exclusion from government contracting, which could negatively affect its our reputation, could disrupt Embecta's business and have a material adverse effect on its results of operations, financial condition, and cash flow**. Changes in United States policy regarding international trade, including import and export regulation and international trade agreements, could also negatively impact Embecta's business. The United States has imposed tariffs and export controls on certain goods and products imported from China and certain other countries, which has resulted in retaliatory tariffs by China and other countries. Additional tariffs imposed by the United States on a broader range of imports, or further retaliatory trade measures taken by China or other countries in response, could result in an increase in supply chain costs that Embecta may not be able to offset or that otherwise adversely impact its results of operations. In addition, political tensions between the United States and China have escalated in recent years. Rising political tensions could reduce trade, investment and other economic activities between the two major economies. Any of these factors could have a material adverse effect on Embecta's business, prospects, financial condition and results of operations. The departure of the United Kingdom from the European Union (" EU ") (commonly known as " Brexit ") on January 31, 2020 ~~has~~ created uncertainties affecting business operations in the United Kingdom, the EU and a number of other countries, including with respect to compliance with the regulatory regimes regarding the labeling and registration of the products Embecta sells in these markets. Embecta could face increased costs, volatility in exchange rates, market instability and other risks as a result of Brexit. The military conflict between Russia and Ukraine has resulted in the implementation of sanctions by the United States and other governments against Russia and has caused significant volatility and disruptions to the global markets. It is not possible to predict the short- and long- term implications of this conflict, which could include but are not limited to further sanctions, uncertainty about economic and political stability, increases in inflation rate and energy prices, supply chain challenges and adverse effects on currency exchange rates and financial markets. In addition, the United States government reported that United States sanctions against Russia in response to the conflict could lead to an increased threat of cyberattacks against United States companies. These increased threats could pose risks to the security of **our Embecta's** Information Technology systems, networks and product offerings, as well as the confidentiality, availability and integrity of **our Embecta's** data. **In addition, the recent hostilities in Israel could develop to have a more widespread economic and geopolitical affect in the Middle East and Europe, and / or economic sanctions between or among countries, as well as general geopolitical issues in the Middle East. This may impact oil production capacity, oil prices, and disruptions in supply chain and shipping routes in the Middle East. These impacts may Further further cause increases in resin costs, if as well as energy costs. If the these conflict conflicts develops- develop beyond Ukraine these areas or further intensifies intensify, it they** could have an adverse impact on **our Embecta's** business operations in the ~~European Union~~ **EU, the Middle East** or other affected areas. ~~We are~~ **Embeceta is** continuing to monitor the ~~situation~~ **situations** in Ukraine, **Israel** and globally as well as assess ~~its their~~ potential impact on **our Embecta's** business, **including impacts to suppliers and customers**. Although operations in Russia ~~and~~, Ukraine ~~and Israel~~ do not **currently** constitute a material portion of **our Embecta's** business, a significant escalation or further expansion of the **conflict conflicts**' s current scope or related disruptions to the global markets could have a material adverse effect on **Embeceta's** results of operations. **The U. S. Department of the Treasury's Office of Foreign Assets Control, and the Bureau of Industry and Security at the U. S. Department of Commerce, administer certain laws and regulations that restrict U. S. persons and, in some instances, non- U. S. persons, in conducting activities, and transacting business with our- or making investments in certain countries, governments, entities and individuals subject to U. S. economic sanctions. Due to Embecta's international operations, it is subject to such laws and regulations, which are complex, restrict its business dealings with certain countries and individuals, and are constantly changing. Further restrictions may be enacted, amended, enforced or interpreted in a manner that materially impacts Embecta's operations. Violations of these regulations are punishable by civil penalties, including fines, denial of export privileges, injunctions, asset seizures, debarment from government contracts and revocations or restrictions of licenses, as well as criminal fines and imprisonment. Embecta has established procedures designed to assist with its compliance with such laws and regulations.**

However, Embecta has only limited experience dealing with these laws and regulations and it cannot guarantee that its procedures will effectively prevent it from violating these regulations in every transaction in which Embecta may engage. Any such violation could adversely affect Embecta's reputation, business, financial condition and results of operations. The long-term effects of global climate change present risks to our Embecta's business and operations. Extreme weather, natural disasters or other conditions caused by climate change could adversely impact our its supply chain and the availability and cost of raw materials and components, energy supply, transportation or other inputs required for the operation of our its business. Such conditions could also result in physical damage to products, plants and distribution centers, or our suppliers' facilities, as well as the infrastructure and facilities of hospitals, medical care facilities and other customers. Additionally, increased environmental regulation, including to address climate change, may result in increases in the costs to operate its business or restrict certain aspects of its activities. These events could adversely affect our Embecta's operations and our financial performance. Embecta's business could be negatively impacted by evolving regulations, policies and expectations relating to environmental, social and governance (ESG) initiatives, setting related goals, collecting data and disclosing related information. There is an increasing focus from certain investors, customers, consumers, employees and other stakeholders concerning ESG matters. Additionally, public interest and legislative pressure related to public companies' ESG practices continue to grow. These changing rules, regulations and stakeholder expectations have resulted in, and are likely to continue to result in, increased general and administrative expenses and increased management time and attention spent complying with or meeting such regulations and expectations. A number of participants in the medical device industry are also joining voluntary ESG groups or organizations, such as the Responsible Business Alliance. These ESG provisions and initiatives are subject to change, can be unpredictable, and may be difficult and expensive for us to comply with, given the complexity of our supply chain and operations. If our ESG practices fail to meet regulatory requirements or investor, customer, consumer, employee or other stakeholders' evolving expectations and standards in areas including environmental stewardship, support for local communities, Board of Directors and employee diversity, human capital management, employee health and safety practices, product quality, supply chain management, corporate governance and transparency, our reputation, brand and employee retention may be negatively impacted, and our customers and suppliers may be unwilling to continue to do business with us. Further, statements about our ESG-related initiatives and goals, and progress against those goals, may be based on standards for measuring progress that are still developing, internal controls and processes that continue to evolve, and assumptions that are subject to change in the future. In addition, we could be criticized for the scope or nature of such initiatives or goals, or for any revisions to these goals. If we do not adapt to or comply with new regulations, or fail to meet evolving investor, industry or stakeholder expectations and concerns regarding ESG issues, investors may reconsider their capital investment in our Company, and customers may choose to stop purchasing our products, which could have a material adverse effect on our reputation, business or financial condition. Foreign currency exchange rate, inflation, commodity price, energy and oil prices and supply, and interest rate fluctuations may adversely affect Embecta's financial condition and results of operations. Embecta is exposed to a variety of market risks, including the effects of changes in foreign currency exchange rates, commodity prices, energy resource prices and uninterrupted energy supply, and interest rates. Products manufactured in, and sold into, regions outside of the United States represent a significant portion of Embecta's operations. The Consolidated Financial Statements in Item 8 of this Annual Report on Form 10-K reflect translation of financial statements denominated in non-United States currencies to United States dollars as well as the foreign currency exchange gains and losses resulting from the re-measurement of assets and liabilities. A strengthening or weakening of the United States dollar in relation to the foreign currencies of the countries in which Embecta sells or manufacture its products, such as the euro, will affect its United States dollar-reported revenue and income. Changes in the relative values of currencies may, in some instances, have a significant effect on its results of operations. Many of Embecta's products have significant resin content. Embecta also uses quantities of other commodities, such as rubber, corrugate and steel. Increases in the prices of these commodities, including due to inflation in the United States or in other markets, could increase the production and other input costs of Embecta's products. Embecta may not be able to pass on these costs to its customers, which could have a material adverse effect on its results of operations and cash flows. The Russia and Ukraine conflict, the Israel-Hamas war and the growing geopolitical tensions between China and Taiwan, coupled with possible related supply chain shortages may affect the energy power and oil sector's networks and ability to supply their customers, including Embecta. These disruptions may lead to manufacturing shutdowns, raw material and component shortages, supply chain and logistics constraints, project delays, loss of productivity, divergent product standards and regulations, trade policies, labor shortages, commodity shortages, and price increases, among others. Embecta relies on uninterrupted energy to power its manufacturing facilities and any disruption could adversely affect its operations. In addition, increases in energy and oil prices could increase the production, raw materials and other costs of Embecta's operations and products. Increases in interest rates may adversely affect the financial condition of Embecta's distributors and suppliers, thereby adversely affecting their ability to buy Embecta's products and supply the components or raw materials needed by Embecta, in each case adversely affecting Embecta's financial condition or results of operations. If the United States Federal Reserve continues to raise the benchmark interest rate, then we Embecta would expect the interest expense on our its variable rate debt to increase in fiscal 2023-2024. To the extent we Embecta borrow borrows on our under its revolving credit facility, we it will also be subject to risks related to changes in interest rates. Fluctuations in Embecta's effective tax rate and changes to tax laws may adversely affect it. As a global company, Embecta is subject to taxation in numerous countries, states and other jurisdictions. Embecta's effective tax rate is derived from a combination of applicable tax rates in the various countries, states and other jurisdictions in which it operates. In preparing its financial statements, Embecta estimates the amount of tax that will become payable in each of these jurisdictions and significant judgement is required in determining our worldwide provision for income taxes. Embecta's effective tax rate may, however,

differ from the estimated amount due to numerous factors, including a change in overall profitability, geographical mix of earnings before income taxes, tax discrete items that are not recurring in nature, and changes in tax laws, including potential proposed tax legislation. **The Organization for Economic Cooperation and Development (" OECD") has developed major reform of the international tax system with respect to a global minimum 15 % tax rate. In December 2022, European Union member states agreed to adopt the OECD' s minimum tax rules, which are expected to begin going into effect in tax years beginning on January 1, 2024 or later. Certain other countries have enacted the law changes and other countries are considering changes to their tax laws; the impact of the changes will go into effect for the Company beginning in fiscal year 2025. The Company is evaluating the impact of these proposed and enacted changes.** If any potential legislative proposals are ultimately enacted, they could materially impact Embecta' s tax provision, cash tax liability and effective tax rate. Any of these factors could cause Embecta to experience an effective tax rate significantly different from previous periods or its current expectations, which could have an adverse effect on its business, financial condition, results of operations and cash flows. If Embecta fails to protect its intellectual property or proprietary technology, such failure could adversely affect its business and results of operations. Embecta relies primarily on patent, trademark and trade secret laws, as well as confidentiality and non- disclosure agreements covering its know- how and confidential information, to protect its proprietary technologies. Third parties, including its competitors, may contest or oppose its patents and trademarks and future patent and trademark applications, and if such patents or trademarks are successfully challenged, it may be easier for its competitors to offer the same or similar products or technologies or require Embecta to rebrand its products. Embecta can also lose the protection afforded by these intellectual property assets through patent expirations, legal challenges or governmental action. Patents attained by competitors may also adversely affect Embecta' s competitive position. In addition, competitors may seek to invalidate patents on its products or claim that its products infringe upon their intellectual property, which could result in a loss of competitive advantage or the payment of significant legal fees, damage awards and past or future royalties, as well as injunctions against future sales of its products. Embecta has entered into confidentiality agreements and intellectual property assignment agreements with its officers, certain employees, consultants and potential collaborators regarding its intellectual property and proprietary technology. In the event of unauthorized use or disclosure or other breaches of those agreements, Embecta may not be provided with meaningful protection for its trade secrets, know- how or other proprietary information. Embecta also operates in countries that do not protect intellectual property rights to the same extent as in the United States, which could make it easier for competitors to compete with Embecta in those countries. The loss of a significant portion of its portfolio of intellectual property assets may have an adverse effect on its business and results of operations. Embecta' s products or processes may infringe the intellectual property rights of others, which may cause Embecta to pay unexpected litigation costs, damages, or settlement fees (including royalties) or prevent Embecta from selling its products. Embecta cannot be certain that its products, **both existing and in development,** do not and will not infringe issued patents or other intellectual property rights of third parties. Embecta may be subject to legal proceedings and claims in the ordinary course of its business, including claims of alleged infringement of the intellectual property rights of third parties. **Patentability, invalidity, freedom- to- operate or other opinions may be required to determine the scope and validity of third- party proprietary rights. The nature of claims contained in unpublished patent filings around the world is unknown to Embecta and it is not possible to know which countries patent holders may choose for an extension of their filings under the Patent Cooperation Treaty or other mechanisms. Embecta may also be subject to claims based on the actions of employees and consultants with respect to the usage or disclosure of intellectual property learned at other employers.** Any such claims, whether or not meritorious, could result in litigation and divert the time and attention of its management team. **Consequently, Embecta is unable to guarantee that it will be able to manufacture, use, offer for sale, sell or import any of its commercial products or products in development in the event of an infringement action.** If Embecta is found liable for infringement, it may be required to enter into licensing agreements (which may not be available on acceptable terms or at all) or to pay damages or cease developing, making or selling certain products. **Even if Embecta were able to obtain a license, the rights may be non- exclusive, which could potentially limit its competitive advantage. Ultimately, Embecta could be prevented from commercializing any products that it may commercialize or promote or be forced to cease some aspects of its business operations, if, as a result of actual or threatened patent infringement or other claims, it is unable to enter into licenses on acceptable terms. This inability to enter into licenses or the ability to exclude others from using proprietary rights could have a material adverse effect on Embecta' s reputation, business, financial condition or results of operations.** Embecta may also need to redesign some of Embecta' s products or processes to avoid future infringement liability. Breaches of Embecta' s information systems **and cyberattacks aimed at accessing Embecta' s devices, products and services or related devices, products and services** could have a material adverse effect on its operations. Embecta faces various security threats on a regular basis, including ongoing cyber security threats to and attacks on our information technology infrastructure. Some of Embecta' s products, **and products in development may,** include information systems that collect data, **including sensitive medical information,** regarding patients and patient therapy on behalf of Embecta' s customers and some connect to Embecta' s systems for maintenance and management purposes. **We Embecta uses its and certain third party, including BD' s, information technology systems to manage or support a variety of business processes and activities, including sales, shipping, billing, customer service, procurement, supply chain, manufacturing, and accounts payable. In addition, Embecta uses enterprise information technology systems to record, process, and summarize transactions and other financial information and results of operations for internal reporting purposes and to comply with financial reporting, legal, and tax regulatory requirements. Embecta deploys** defenses against such threats and attacks and **work works** to secure the integrity of **our-its** data systems using techniques, hardware, and software typical of companies of **our-its** size and scope. Despite **our Embecta' s** security measures, however, **our-its** information technology and infrastructure may be vulnerable to attacks by increasingly sophisticated intruders or others who try to cause harm to or interfere with **our-its** normal use of **our-its**



systems. They are also susceptible to breach due to employee error, malfeasance, or other disruptions. Our Embecta's suppliers, distributors, contractors, service providers, and other third parties with whom we do it does business also could be subject to cyber threats and attacks that are similar in frequency and sophistication. In many cases, we have Embecta has to rely on the controls and safeguards put in place by these suppliers, distributors, contractors, service providers, including BD, and other third parties to defend against, respond to, and report these attacks. Many of Embecta's information systems are cloud-hosted and managed by these third-party vendors, some of which may have access to confidential business, employee, healthcare professional, and / or customer information. Embecta's information technology systems may also be susceptible to damage, disruptions, or shutdowns due to computer viruses, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, user errors, or catastrophic events. Any failure by Embecta to maintain or protect its information technology systems and data integrity, including from cyberattacks, intrusions, disruptions, or shutdowns, could result in the unauthorized access to customer data and personally identifiable information, theft of intellectual property or other misappropriation of assets or the loss of key data and information, or otherwise compromise Embecta's confidential or proprietary information and disrupt its operations. The potential impact of future cyber incidents can vary widely in severity and scale. This could also impact our Embecta's compliance with privacy and other laws and regulations and could result in actions by regulatory bodies or civil litigation. There can be no assurance that the various procedures and controls we Embecta utilize utilizes to mitigate these threats will be sufficient to prevent disruptions to our-its systems, in part because (i) cyberattack cyber-attack techniques change frequently and, at times, new techniques are not recognized until launched, and (ii) cyberattacks cyber-attacks can originate from a wide variety of sources. We Embecta will continue to evaluate organization risk priorities and dedicate resources to protect against unauthorized access, and work to align to industry-leading cybersecurity frameworks to incorporate cybersecurity into our-its enterprise systems, manufacturing processes and products. Our Embecta's results of operations could be adversely affected if these systems are interrupted or damaged or fail for any extended period. In addition, medical devices are increasingly connected to the internet, healthcare networks, and other medical devices to provide features that improve healthcare and increase the ability of healthcare providers to treat patients and patients to manage their conditions. For example, Embecta is pursuing collaborations to enable the connectivity and interoperability of its insulin patch pump in development with third-party patient monitoring products, which may in turn be connected with the internet, healthcare networks and other medical devices. These same features may also increase cybersecurity risks and the risks of unauthorized access and use by third parties, as noted by the FDA's warning that insulin pumps may have cybersecurity vulnerabilities and could be manipulated by hackers, causing danger to people with diabetes. As such, a cyberattack which intrudes, disrupts, or corrupts Embecta's devices, products, and services, or related devices, products, and services could impact the quality- of- care patients receive or the confidentiality of patient information. Additionally, modifying or using any such devices, products, or services in a way inconsistent with Embecta's FDA clearances and approvals may create risks to users and potential exposure to the company. Embecta needs to attract and retain key employees to be competitive. Embecta's ability to compete effectively depends upon its ability to attract and retain executives and other key employees. Competition for experienced employees, particularly for persons with specialized skills, can be intense. Embecta's ability to recruit such talent will depend on a number of factors, including compensation and benefits, work location and work environment. If Embecta cannot effectively recruit and retain qualified executives and employees, its business could be adversely affected. Embecta's business may be adversely affected by work stoppages, union negotiations and labor disputes. As of September 30, 2022-2023, only certain employees, all outside of the United States and representing approximately 27-35% of our headcount (approximately 30-17% if of those employees are in deferred closing countries are included—China, Mexico, Italy), are represented by various unions, works council and other collective bargaining groups. As of September 30, 2023, approximately 48% of those employees within these groups have collective bargaining power. In addition, on January 1, 2023, the BD Shanghai, China employees transferred from the BD local legal entity to the Embecta local legal entity. Embecta Shanghai, China employees participate in unions, as required by China regulations, and as was established by BD prior to the transfer. As of September 30, 2023, these unions do not have collective bargaining agreements. Historically, the effects of collective bargaining and other similar labor agreements have not been significant. However, if a larger number of Embecta's employees were to unionize, including in the wake of any future legislation or administrative regulation that makes it easier for employees to unionize, the effect could be significant. A significant portion of Embecta's unionized employees have collective bargaining agreements. Any inability to negotiate acceptable new contracts and new terms and conditions under these collective bargaining arrangements could cause strikes or other work stoppages, including at our Ireland manufacturing facility, and new contracts could result in increased operating costs for Embecta. If any strikes or other work stoppages occur, or if additional employees become represented by a union, a disruption of Embecta's operations and higher labor costs could result. Labor relations matters affecting Embecta's suppliers of products and services could also adversely affect Embecta's business from time to time. Embecta is subject to extensive regulation. Embecta's operations are global and are affected by complex state, federal and international laws relating to healthcare, environmental protection, antitrust, anti- corruption, marketing, fraud and abuse (including anti- kickback and false claims laws), import and export control, product safety and efficacy, employment, privacy, financial transparency, conflict minerals and other areas. Violations of these laws can result in criminal or civil sanctions, including substantial fines and, in some cases, exclusion from participation in healthcare programs such as Medicare and Medicaid. Environmental laws, particularly with respect to the emission of greenhouse gases, such as taxes on fuel and energy, to mitigate the impacts of climate change, are becoming more stringent throughout the world, which may increase Embecta's costs of operations or necessitate closures of or changes to its manufacturing plants or processes or those of its suppliers, or result in liability to Embecta. Embecta is also subject to various laws and regulations relating to the safety and effectiveness of

medical devices, including relating to design, development and manufacturing, **product traceability and record keeping procedures, product complaints, complaint reporting, recalls and field safety corrective actions**, advertising and promotion and clinical trials and post-market studies with respect to its products. Failure to comply with these laws may result in enforcement actions by the FDA or other similar regulatory agencies and other liability to Embecta. The enactment of additional laws or changes in existing laws may increase compliance costs or otherwise adversely impact Embecta's operations. **Embeccta is also subject to numerous post-marketing regulatory requirements, which include quality system regulations related to the manufacture of its devices, labeling regulations, and medical device reporting regulations. The last of these regulations requires Embecta to report to the FDA if its devices cause or contribute to a death or serious injury, or malfunction in a way that would likely cause or contribute to a death or serious injury if the malfunction recurred. If Embecta fails to comply with present or future regulatory requirements that are applicable to it, it may be subject to enforcement action by the FDA, which may include any of the following sanctions: • untitled letters, warning letters, fines, injunctions, consent decrees, and civil penalties; • customer notification, or orders for repair, replacement, or refunds; • voluntary or mandatory recall or seizure of our current or future products; • administrative detention by the FDA of medical devices believed to be adulterated or misbranded; • operating restrictions, suspension or shutdown of production; • refusing our requests for 510 (k) clearance of new products, new intended uses or modifications to Embecta's current products; • rescinding 510 (k) clearance or suspending that have already been granted; or • criminal prosecution.** In addition, the European Union ("EU") has adopted the EU Medical Device Regulation (the "EU MDR"), which imposes stricter requirements for the marketing and sale of medical devices, including in the area of labeling requirements, clinical evidence requirements, quality systems and post-market surveillance. The EU MDR has been fully operational for previously approved self-certified medical devices (class I) since May 2021, and companies have until May 2024 to meet the requirements for medical devices with a valid conformity assessment certificate (class II and III). Complying with and maintaining devices under these regulations requires ~~us~~ **Embeccta** to incur significant expenditures. Additionally, the availability of EU notified body services certified to **assist Embecta with validation of, and compliance with,** the new requirements is limited, which may delay the marketing approval for some of ~~our~~ **Embeccta's** products under the EU MDR. Any such delays, or any failure to meet these requirements could adversely impact our business in the EU and other non-EU regions that tie their product registrations to EU conformity requirements. Healthcare reform may have a material adverse effect on Embecta's financial condition and results of operations. Political, economic and regulatory developments have effected fundamental changes in the healthcare industry. **In response to perceived increases in health care costs in recent years, there have been, and continue to be, proposals by the federal government, state governments, regulators, and third-party payors to control these costs and, more generally, to reform the U. S. health care system. Certain of these proposals could limit the prices Embecta is able to charge for its products or the amounts of reimbursement available for its products and could limit the acceptance and availability of its products.** The Patient Protection and Affordable Care Act (the "Affordable Care Act") substantially changed the way healthcare is financed by both government and private insurers. It also encourages improvements in the quality of healthcare products and services and significantly impacts the United States pharmaceutical and medical device industries ~~by~~. **Among among** other things, **imposing certain stringent compliance, recordkeeping, and reporting requirements on companies in various sectors of** the Affordable Care Act: ~~• established a new Patient life sciences industry, and enhanced penalties for non-~~ **compliance**. ~~Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research; • implemented payment system reforms, including a national pilot program to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and • created an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.~~ ~~We~~ **Embeccta** cannot predict at this time the full impact of the Affordable Care Act or other **new legislation, agency priorities, rulemaking and** healthcare reform measures **from U. S. federal or state governments, foreign governments, or third-party payors** that may be adopted **or implemented** in the future on Embecta's financial condition, results of operations and cash flows. ~~Although~~ ~~In this regard,~~ several legislative initiatives to repeal and replace the Affordable Care Act have been proposed, and legal challenges to the constitutionality of the Affordable Care Act or its component parts have been made ~~The~~, ~~the~~ nature and effect of any modification or repeal of, or legislative substitution for, the Affordable Care Act, or any court decision regarding the Affordable Care Act's validity, is uncertain, and ~~we~~ **Embeccta** cannot predict the effect that any of these events would have on the longer-term viability of the act, or on Embecta's financial condition, results of operations or cash flows. **However, any changes that create stricter and more costly compliance obligations or lower reimbursement for Embecta's products could materially and adversely affect its business, financial condition and results of operations. Future significant changes in the healthcare systems in the United States or elsewhere could also have a negative impact on the demand for Embecta's current and future products. These include changes that may reduce reimbursement rates for its products and changes that may be proposed or implemented by the current or future laws or regulations.** Certain modifications to Embecta's products may require new 510 (k) clearances or other marketing authorizations and may require Embecta to recall or cease marketing its products. Once a medical device is permitted to be legally marketed in the United States pursuant to a 510 (k) clearance, a manufacturer may be required to notify the FDA of certain modifications to the device. Manufacturers determine in the first instance whether a change to a product requires a new 510 (k) clearance or premarket submission, but the FDA may review any manufacturer's decision. The FDA may not agree with Embecta's decisions regarding whether new clearances are necessary. Embecta has made modifications to its products in the past and has determined based on its review of the applicable FDA regulations and guidance that in certain instances new 510 (k) clearances or other premarket submissions were not required. Embecta may make similar modifications or add additional features in the future that it believes does not require a new 510 (k) clearance. If the FDA disagrees with Embecta's

determinations and requires it to submit new 510 (k) notifications, Embecta may be required to cease marketing or to recall the modified product until it obtains clearance, and it may be subject to significant regulatory fines or penalties. Embecta may be subject to enforcement actions if it engages in improper marketing or promotion of its products. Embecta's promotional materials and training methods must comply with applicable laws, regulations and regulatory authority's rules and guidelines, including the FDA and the Federal Trade Commission (the "FTC"). If the FDA, the FTC or another regulatory agency determines that Embecta's promotional or training material constitutes off-label, false or misleading, unfair or deceptive promotion of its products, it could request that Embecta modify its training or promotional materials or subject Embecta to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider Embecta's promotional, **educational** or training materials to constitute off-label, false or misleading, unfair or deceptive promotion of its products, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement, and reputational harm. Embecta is subject to complex and evolving laws and regulations regarding privacy and data protection, many of which are subject to change and uncertain interpretation, which could result in claims, changes to its business practices, penalties, increased cost of operations or declines in user growth or engagement, or otherwise adversely affect its business. Embecta is subject to complex and frequently changing laws in the United States and elsewhere regarding privacy and the **processing**, collection, use, storage and protection of personal information, and noncompliance with these laws could result in substantial fines or litigation. For instance, the EU has also adopted the General Data Protection Regulation ("GDPR"), which applies to personal data involved in Embecta's operations in the EU or products and services that Embecta offers to EU users involving personal data. The GDPR contains a range of compliance obligations that could require Embecta to change its existing business practices policies, and significantly increases financial penalties for noncompliance. In the state of California, the California Consumer Privacy Act ("CCPA"), which provides certain privacy rights and consumer protection for residents of the state became effective in 2020, and the California Privacy Rights Act, which amends and expands the CCPA, **will take effect on January 1, 2023**. These consumer rights include the right to know what personal information is collected, the right to know whether the data is sold or disclosed and to whom, the right to request a company to delete the personal information it has collected, the right to opt-out of the sale of personal information and the right to non-discrimination in terms of price or service when a consumer exercises a privacy right. California's and other states' laws apply more broadly and now or in the future may reach data we hold that relates to employees and healthcare providers, not just customers. In addition, data security protection laws passed by the federal government and many states require notification to data subjects, including customers and others, when there is a security breach of personal data. **The CCPA also created a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. The effects of state data protection laws are significant and may cause Embecta to incur substantial costs and expenses to ensure ongoing compliance.** If we **fail** to comply with these regulations, **we** could be subject to civil sanctions, including fines and penalties for noncompliance. In addition, foreign data protection, privacy, and other laws and regulations can be more restrictive than those in the United States. Data localization laws in some countries generally mandate that certain types of data collected in a particular country be stored and / or processed within that country. Embecta could be subject to audits in Europe and around the world, particularly in the areas of consumer and data protection, as Embecta continues to grow and expand its operations. Legislators and regulators may make legal and regulatory changes, or interpret and apply existing laws, in ways that make Embecta's products less useful to users, require us to incur substantial costs, expose us to unanticipated civil or criminal liability, or cause us to change Embecta's business practices. These changes or increased costs could affect Embecta's business and results of operations. **A disruption at one of Embecta's facilities could adversely affect our business and operating results.** Although **we** **operate** in multiple locations, **our** manufacturing of **our** pen needles and syringes is conducted, and **our** **its** components for such products are **primarily** stored, at **our** **its** facilities in the United States, Ireland and China. Political or financial instability, currency fluctuations, the outbreak of pandemics such as COVID- 19, labor unrest, transport capacity and costs, port security, supply chain disruptions, wars, weather conditions, natural disasters, or other events that could slow or disrupt port activities and affect foreign trade are beyond **our** **Embecta's** control and could materially disrupt **our** **its** supply of product from any of these locations, increase **our** **its** costs, and / or adversely affect **our** **its** results of operations. Further, following the COVID- 19 pandemic there may be increased pressure for **United States U.S.** medical device companies to reduce dependency on China for their supply chain **and reevaluating nearshoring strategies**. **We** **Embecta** **take** **takes** precautions to ensure that **our** **its** third- party contractors and logistics entities safeguard **our** **Embecta's** assets, including insurance, health and safety protocols, and off- site storage of computer data. However, a natural or other disaster, such as a fire or flood, could cause substantial delays in **our** **Embecta's** operations, damage or destroy **our** **its** manufacturing equipment and / or inventory and cause **us** **it** to incur additional expenses. The insurance **we** **Embecta** **maintain** **maintains** may not be adequate to cover **our** **its** losses in any particular case. With or without insurance, damage to **our** **Embecta's** facility, manufacturing equipment, inventory or other property or to any of **our** **its** suppliers, may have a material adverse effect on **our** **Embecta's** business, financial condition and results of operations. **The majority** **A significant amount** of **our** **Embecta's** inventories of finished goods is stored in distribution centers around the world, but primarily in various distribution centers in the United States and Europe. **We** **Embecta** **take** **takes** precautions to safeguard **our** **its** facilities and data infrastructure. However, vandalism, terrorism, unplanned power outages, cyberattacks or a natural disaster, such as an earthquake, fire or flood, or other catastrophic event, could damage or destroy **our** **Embecta's** inventories of component supplies and finished goods, cause substantial delays in **our** **its** operations, result in the loss of key information, result in reduced sales, and cause **us** **Embecta** to incur additional expenses. **Our** **Embecta's** insurance coverage may not be sufficient to provide coverage with respect to the damages incurred in any particular case, and **our** **its** insurance carrier may deny coverage with respect to all or a portion of **our** **its** claims. Regardless

of the level of insurance coverage or other precautions taken, damage to **our Embecta's** facilities may have a material adverse effect on **our is** business, financial condition and **operating results of operations**. **Our Insurance coverage may be inadequate or unavailable to cover any product liability losses Embecta incurs. Embecta's** business exposes **us it** to potential product liability claims that are inherent in the design, manufacture, testing, inspection, and sale of medical devices. **We are Embecta is** subject to product liability lawsuits alleging that component failures, manufacturing flaws, manufacturing defects, negligence in manufacturing, design defects, negligence in design, or inadequate disclosure of product-related risks, warnings, or product-related information resulted in an unsafe condition, injury or death to customers. The risk of one or more product liability claims or lawsuits may be even greater after **we Embecta launch launches** new products with new features or **enter enters** new markets where **we have it has** no prior experience selling **our its** products and **rely relies** on newly-hired staff or new independent distributors or contractors to provide new customer training and customer support. In addition, the misuse of **our Embecta's** products or the failure of customers to adhere to operating guidelines could cause significant harm to customers, including death, which could result in product liability claims. Product liability lawsuits and claims, safety alerts or product recalls, with or without merit, regardless of any available insurance coverage, could cause **us Embecta** to incur substantial costs, and could place a significant strain on **our its** financial resources, divert the attention of management from **our Embecta's** core business, harm **our Embecta's** reputation and adversely affect **our its** ability to attract and retain customers, any of which could have a material adverse effect on **our Embecta's** business, financial condition and **operating results of operations**. Embecta is subject to a number of restrictive covenants under its indebtedness, including customary operating restrictions and financial covenants, which could restrict Embecta's ability to pay dividends or adversely affect its financing options and liquidity position. Embecta's current indebtedness contains, and any future indebtedness may contain, customary operating restrictions and financial covenants. This indebtedness may adversely affect Embecta's ability to operate or grow its business or could have other material adverse consequences, including by: • limiting Embecta's ability to obtain additional financing in the future for working capital, capital expenditures and acquisitions; • limiting Embecta's ability to refinance its indebtedness on terms acceptable to Embecta or at all; • restricting Embecta's operations or development plans; • requiring Embecta to dedicate a significant portion of its cash flows from operations to paying amounts due under its indebtedness, thereby reducing funds available for other corporate purposes; • impeding Embecta's ability to pay dividends; • making Embecta more vulnerable to economic downturns; or • limiting Embecta's ability to withstand competitive pressures. Any of these restrictions on Embecta's ability to operate its business in its discretion could adversely affect its business by, among other things, limiting Embecta's ability to adapt to changing economic, financial or industry conditions and to take advantage of corporate opportunities, including opportunities to obtain debt financing, repurchase stock, refinance or pay principal on Embecta's outstanding debt, dispose of property, complete acquisitions for cash or debt, or make other investments. In addition, events beyond Embecta's control, including prevailing economic, financial, and industry conditions, could affect Embecta's ability to satisfy applicable financial covenants, and Embecta cannot assure you that it will satisfy them. Any failure to comply with the restrictions of Embecta's current indebtedness, or any future financing agreements, including as a result of events beyond Embecta's control, may result in an event of default under these agreements, which in turn may result in defaults or acceleration of obligations under these agreements and other agreements, giving Embecta's lenders and other debt holders the right to terminate any commitments they may have made to provide Embecta with further funds and to require Embecta to repay all amounts then outstanding. Embecta is subject to risks associated with public health threats, **including such as** the ongoing COVID-19 pandemic, which could have a material adverse effect on Embecta's financial condition and results of operation. Embecta is subject to risks associated with public health threats, **including such as** the COVID-19 pandemic. **Public health threats have** ~~The COVID-19 pandemic has~~ the potential to significantly impact Embecta's supply chain if the manufacturing plants that produce its products, raw materials or product components, the distribution centers where Embecta manages its inventory or the operations of its logistics and other service providers, including third parties that sterilize its products, are disrupted, temporarily closed or experience worker shortages for a sustained period of time. Embecta's manufacturing sites in China, Ireland and the United States, where Embecta manufactures a significant amount of products, largely avoided any significant disruption due to the COVID-19 pandemic. However, notwithstanding that each of these communities has experienced a relative recovery in COVID-19 transmission and a lessening of restrictions related to COVID-19, a future outbreak of **a public health threat, including** COVID-19, at any of Embecta's manufacturing sites in China, Ireland and / or the United States or in the surrounding communities, could lead to delays in the manufacturing of Embecta's products, which could have a material adverse effect on Embecta's business and results of operations. Moreover, any resurgence in COVID-19 infections, including due to new variants of the virus for which current vaccines may not be effective, **and public health measures** could result in the imposition of new governmental lockdowns, quarantine requirements or other restrictions to slow the spread of the virus. **The extent to which fear of exposure to or actual effects of COVID-19, new variants, disease outbreak, epidemic or a similar widespread health concern impacts our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the speed and extent of geographic spread of the disease, the duration of the outbreak, travel restrictions, the efficacy of vaccination and treatment; impact on the U. S. and international healthcare systems, the U. S. economy and worldwide economy, the timing, scope and effectiveness of U. S. and international governmental response, and the impact on the health, well-being and productivity of our employee. These** could result in closures or other restrictions that significantly disrupt Embecta's operations or those of distributors or suppliers in Embecta's supply chain, which could adversely affect Embecta's financial condition. Risks Related to the Separation **from BD Certain** and Distribution A significant amount of the historical information about Embecta in this Annual Report on Form 10-K refers to the diabetes care business as operated by and integrated with BD. **The Certain** historical financial information of Embecta **'s fiscal year 2022** included in this Annual Report on Form 10-K is derived from the **Consolidated Financial Statements in Item 8 of this Annual Report on Form 10-K** and accounting records of BD. Accordingly, the **certain** historical

financial information included in this Annual Report on Form 10- K does not necessarily reflect the financial condition, results of operations or cash flows that we would have achieved **in previous fiscal years** as a separate, publicly traded company during ~~those such~~ periods ~~presented~~ or those that Embecta will achieve in the future primarily as a result of the factors described below:

- Generally, **prior to the Separation**, Embecta’s working capital requirements and capital for its general corporate purposes, including capital expenditures and acquisitions, were historically satisfied as part of the corporate- wide cash management policies of BD. On a going forward basis, Embecta’s results of operations and cash flows may be more volatile, and it may need to obtain additional financing from banks, through public offerings or private placements of debt or equity securities, strategic relationships or other arrangements, which may or may not be available and may be more costly.
- Prior to the Separation, Embecta’s business was operated by BD as part of its broader corporate organization, rather than as an independent company. BD or one of its affiliates performed various corporate functions for us, such as legal, treasury, accounting, auditing, human resources, investor relations, and finance. The historical financial results for the periods **prior from October 1, 2021 to the Separation March 31, 2022** reflect allocations of corporate expenses from BD for such functions, which are likely to be less than the expenses we would have incurred had we operated as a separate publicly traded company.
- Embecta’s business shared economies of scope and scale in costs, employees, vendor relationships and customer relationships with BD. While we have sought to minimize the impact on Embecta when separating these arrangements, there is no guarantee these arrangements will continue to capture these benefits in the future. **While Embecta has entered into transition agreements that govern certain commercial and other relationships between it and BD, those arrangements may not capture the benefits to Embecta’s business that resulted from being integrated with the other affiliates of BD.**
- **Prior From October 1, 2021 to the Separation March 31, 2022**, Embecta’s business utilized the advantage of BD’s overall size and scope to procure more advantageous arrangements. ~~As After the Separation, as~~ a standalone company, Embecta may be unable to obtain similar arrangements to the same extent as BD did, or on terms as favorable as those BD obtained, prior to completion of the Separation.
- The cost of capital for Embecta’s business may be higher than when Embecta was integrated with BD and leveraged BD’s cost of capital.
- Other significant changes may occur in Embecta’s cost structure, management, **effective tax rate**, financing and business operations as a result of operating as a company separate from BD. For additional information about the past financial performance of its business and the basis of presentation of the historical combined financial statements, see Item 7 : ~~“Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the Consolidated Financial Statements in~~ Item 8 of this Annual Report on Form 10- K. The Separation has resulted in Embecta being a smaller, less diversified company than BD. As a result, Embecta may be more vulnerable to changing market conditions, which could have a material adverse effect on its business, financial condition and results of operations. In addition, the diversification of Embecta’s revenues, costs, and cash flows ~~will has diminish~~ **diminished** as a standalone company, such that its results of operations, cash flows, working capital and financing requirements may be subject to increased volatility and its ability to fund capital expenditures and investments, pay dividends and service debt may be diminished. We ~~may also lose~~ **have less** capital allocation efficiency and flexibility, as Embecta no longer has access to cash flows from BD to fund Embecta’s business. Embecta may not be able to achieve the full strategic and financial benefits expected to result from the Separation, or such benefits may be delayed or not occur at all. The Separation is expected to provide the following benefits, among others: (1) enabling management of Embecta to more effectively pursue the distinct operating priorities and strategies of its business; (2) permitting Embecta to allocate financial resources to meet the unique needs of its business, which will allow us to intensify our focus on distinct strategic priorities and to more effectively pursue our own distinct capital structures and capital allocation strategies; (3) allowing Embecta to more effectively articulate a clear investment thesis to attract a long- term investor base suited to our business and providing investors with a distinct and targeted investment opportunity; (4) creating an independent equity security tracking Embecta’s underlying business, affording Embecta with direct access to the capital markets and facilitating its ability to consummate future acquisitions or other transactions using its common stock; and (5) permitting Embecta to more effectively recruit, retain and motivate employees through the use of stock- based compensation that more closely aligns management and employee incentives with specific business goals and objectives related to Embecta’s business. Embecta may not achieve these and other anticipated benefits for a variety of reasons, including, among others: (1) the ongoing transition and separation activities may demand significant management resources and require significant amounts of management’s time and effort, which may divert management’s attention from operating and growing Embecta’s business; (2) Embecta may be more susceptible to market fluctuations, and other adverse events than if it were still a part of BD because Embecta’s business is less diversified than BD’s businesses prior to the completion of the Separation; (3) as a standalone company, Embecta may be unable to obtain certain goods, services and technologies at prices or on terms as favorable as those BD obtained prior to completion of the Separation; (4) the Separation may require Embecta to pay costs that could be substantial and material to its financial resources, including accounting, tax, legal and other professional services costs, recruiting and relocation costs associated with hiring key senior management and personnel new to Embecta, tax costs and costs to separate information systems, including its enterprise resource planning systems; (5) under the terms of the tax matters agreement that Embecta entered into with BD, it is restricted from taking certain actions that could cause the distribution or certain related transactions to fail to qualify as tax- free to BD and BD shareholders, or could result in certain other taxes to BD, and these restrictions may limit us for a period of time from pursuing certain strategic transactions and equity issuances or engaging in other transactions that might increase the value of its business; and (6) the contractual arrangements between Embecta and BD are on less favorable terms than the prior existing intercompany arrangements from which Embecta benefited, and such arrangements may be inadequate to provide for the ongoing operation and growth of Embecta’s business. If Embecta fails to achieve some or all of the benefits expected to result from the Separation, or if such benefits are delayed, it could have a material adverse effect on its competitive position, business, financial condition, results of operations and cash flows. ~~If~~ **In connection with the Separation**, Embecta **and BD entered into various agreements, including a Separation and**

Distribution Agreement, a TSA, an LSA, a tax matters agreement, an employee matters agreement, a cannula supply agreement, contract manufacturing agreements, an intellectual property matters agreement, distribution agreements and other transaction agreements. See “ Agreements Related to the Separation ” in Item 1. Certain of these agreements provide for the performance of services by each company for the benefit of the other for a period of time after the Separation. Embecta relies on certain services provided by BD pursuant to the TSA, the LSA, and other transaction agreements entered into with BD in connection with the Separation, including with respect to information technology, procurement, quality and regulatory affairs, medical affairs, tax and treasury services, distribution logistics, shared services infrastructure support and enterprise resource planning, accounting and reporting and other systems, in order to conduct its operations and meet its financial reporting and other obligations. Embecta and BD have agreed to extend certain services under the TSA, the LSA and other transaction agreements in a limited set of markets, subject to the condition described below, to support the Interim Business Continuity Processes. The Extension is unable being entered into to replace the reduce potential operational disruptions related to certain services that BD currently provides to it on terms that are at least as favorable to Embecta as pursuant to the TSA, the LSA, and the other terms on transaction agreements, which BD is providing. Embecta has determined will likely not be fully replaced prior to April 1, 2024, the date by which several such services were to terminate prior to the Extension. The Extension is conditioned upon BD obtaining the Supplemental PLR. Although Embecta believes that BD will be able to obtain the Supplemental PLR, such process may be delayed, the Supplemental PLR may not be obtained, and there can be no assurance that the Supplemental PLR will be obtained by March 31, 2024, or at all. If the Extension does not occur, Embecta’s business, financial condition and results of operations could would be adversely affected. Embecta’s ability to effectively manage and operate its business depends significantly on the systems provided by BD. For example, Embecta currently relies upon BD to perform certain activities in markets in which it is unable to independently import, distribute, buy or sell certain products pending its receipt of required licenses, permits, and regulatory registrations. Embecta also relies on the services provided by BD to meet its financial reporting and other obligations. This includes relying on certain services from BD for material financial consolidation and reporting design and operation disclosure controls and procedures. Once the TSA, the LSA, and other transaction agreements, or any extension thereto, expire or terminate, if Embecta is unable to extend or replace the services that BD currently provides to it under the TSA, the LSA and other transaction agreements, until it is able to extend such services, complete the steps necessary to perform these services itself or otherwise materially replace these services on substantially similar terms and conditions, Embecta may not be able to effectively operate its business or maintain effective financial and management controls and reporting systems. This could impair Embecta’s ability to effectively sell, distribute and commercialize its products, generate revenue, comply with local regulatory regulations, meet SEC reporting obligations and internal control over financial reporting, maintain its stock exchange listing, service its existing indebtedness and comply with the debt covenants under its existing indebtedness. Any such occurrence may have a material adverse effect on Embecta’s business, financial condition and results of operations. In addition, Embecta may not be successful in timely, effectively or efficiently implementing these systems and services or in transitioning from BD’s systems to Embecta’s systems. Embecta will continue to engage in the process of creating its own, or engaging third parties separate from BD to provide, systems and services to replace many of the systems and services that BD currently provides to Embecta once the TSA, the LSA and other transaction agreements, or any extension thereto, expires or is terminated including, for example, information technology infrastructure, enterprise resource planning and other systems, logistics, employee, customer, vendor and accounting support services, distribution and regulatory support and services and accounting and reporting systems. Embecta expects this process to be complex, time- consuming and costly. Embecta may incur temporary interruptions in business operations if it cannot transition effectively from BD’s existing operating systems, logistics, distribution and regulatory support, databases and programming languages that support these functions to its own systems. The failure to implement the new systems and transition data successfully and cost- effectively could disrupt Embecta’s business operations, including preventing Embecta from paying suppliers and have a material adverse effect employees, receiving revenue from its customers, entering into new agreements, selling or delivering products in certain jurisdictions, complying with financial reporting and other obligations and performing administrative or other services on its profitability a timely basis, which could adversely affect Embecta’s financial condition and results of operations. In addition, Embecta’s costs for the operation of these systems may be higher than the amounts reflected in its historical combined financial statements. Following the end of the transition period, Embecta will be required to rebrand its products to remove the BD name, transfer or obtain new manufacturing, supply chain, regulatory and product licenses and registrations in the name of Embecta, which could adversely affect its ability to attract and maintain customers and end users or which could result in delays or interruptions of Embecta’s commercialization and distribution operations or the loss of customers and revenue, all of which could adversely affect its financial conditions and results of operations. Embecta has historically marketed its products using the “ BD ” name and logo, which is a globally recognized brand with a strong reputation for high- quality products among people with diabetes and Embecta’s distributors. Under the terms of the agreements entered into with BD in connection with the Separation and Distribution, Embecta received a temporary license to use the “ BD ” and “ Becton Dickinson ” name and logo on its products and marketing, certain legal entities and relevant regulatory registrations. Following the expiration of this license, Embecta will be required to rebrand and update, as applicable, its products and marketing, manufacturing, supply chain, and regulatory registrations and licenses using the “ Embecta ” name or other names and marks and remove the “ BD ” name and logo on its products and marketing, registrations and licenses. These new names and brands may not benefit from the same recognition and association with product quality as the BD name, which could adversely affect Embecta’s ability to attract and maintain its customers and end users, who may prefer to use products with a stronger brand identity. The failure to timely transfer, or in certain instances obtain new,

registrations and licenses in the “ Embecta ” name could result in delays or interruptions in Embecta’ s ability to continuously commercialize, import, export, market, promote, sell and otherwise distribute its products to its customers. This could result in customer dissatisfaction and turnover to our competitors, which could further result in loss of revenue for Embecta. In addition, Embecta will be required to closely collaborate with its customers, and ensure the proper changes, modifications, system inputs, supply chain logistics, administration, and adjudication operations are properly transitioned within the customer’ s internal infrastructure, processes and systems, in order to successfully achieve the transition. Embecta’ s or its customer’ s inability to properly achieve these transitions could result in disruptions to Embecta’ s product end- to- end product flow management and end- user access to products, which could adversely affect Embecta’ s financial condition and results of operations. Embecta ~~has incurred debt obligations that could adversely affect its business and profitability and its ability to meet other obligations.~~

Embecta currently has approximately \$ 1, ~~645-636~~ million in aggregate principal amount of indebtedness outstanding as of September 30, ~~2022-2023~~ (not including undrawn commitments of \$ 500 million under its revolving credit facility). Embecta may also incur additional indebtedness in the future. This significant amount of debt could potentially have important consequences to Embecta and its debt and equity investors, including: • requiring a substantial portion of its cash flow from operations to make interest payments; • making it more difficult to satisfy debt service and other obligations; • increasing the risk of a future credit ratings downgrade of its debt, which could increase future debt costs and limit the future availability of debt financing; • increasing its vulnerability to general adverse economic and industry conditions; • reducing the cash flow available to fund capital expenditures and other corporate purposes and to grow its business; • limiting Embecta’ s flexibility in planning for, or reacting to, changes in its business and the industry; • placing Embecta at a competitive disadvantage relative to its competitors that may not be as highly leveraged with debt; and • limiting Embecta’ s ability to borrow additional funds as needed or take advantage of business opportunities as they arise, pay cash dividends or repurchase ordinary shares. To the extent that Embecta incurs additional indebtedness, the foregoing risks could increase. In addition, Embecta’ s actual cash requirements in the future may be greater than expected. Its cash flow from operations may not be sufficient to repay all of the outstanding debt as it becomes due, and Embecta may not be able to borrow money, sell assets or otherwise raise funds on acceptable terms, or at all, to refinance its debt. Embecta may be affected by significant restrictions under the tax matters agreement, including on its ability to engage in certain corporate transactions for a two- year period after the distribution, in order to avoid triggering significant tax- related liabilities. Under current United States federal income tax law, a spin- off that otherwise qualifies for tax- free treatment can be rendered taxable to the parent corporation and its stockholders as a result of certain post- spin- off transactions, including certain acquisitions of shares or assets of the spun- off corporation. Under the tax matters agreement that Embecta entered into with BD, Embecta is restricted from taking certain actions that could prevent the distribution and certain related transactions from being tax- free for United States federal income tax purposes, or could result in certain other taxes to BD. In particular, under the tax matters agreement, for the two- year period following the Separation Date, as described in the section entitled “ Agreements Related to the Separation, ” in Item 1 ~~of this Annual Report on Form 10- K~~, Embecta is subject to specific restrictions on its ability to pursue or enter into acquisition, merger, sale and redemption transactions with respect to Embecta stock. These restrictions may limit Embecta’ s ability to pursue certain strategic transactions or other transactions that it may believe to be in the best interests of its stockholders or that might increase the value of its business. In addition, under the tax matters agreement, Embecta may be required to indemnify BD and its affiliates against any tax- related liabilities incurred by them as a result of the acquisition of Embecta’ s stock or assets, even if Embecta does not participate in or otherwise facilitate the acquisition, or as a result of certain other actions taken by Embecta. Furthermore, Embecta will be subject to specific restrictions on discontinuing the active conduct of its trade or business, the issuance or sale of stock or other securities (including securities convertible into Embecta stock but excluding certain compensatory arrangements), and sales of assets outside the ordinary course of business. Such restrictions may reduce Embecta’ s strategic and operating flexibility. For more information, see the section entitled “ Agreements Related to the Separation ” in Item 1 ~~of this Annual Report on Form 10- K~~. Embecta may be held liable to BD if it fails to perform under its agreements with BD, and the performance of such services may negatively affect Embecta’ s business and operations. In connection with the Separation, Embecta and BD entered into various ~~agreements, including a separation Separation and distribution agreement, a transition services agreement, a tax matters agreement, an employee matters agreement, a cannula supply agreement, contract manufacturing agreements, an intellectual property matters agreement, a logistics services agreement, distribution agreements and other transaction agreements. See “ Agreements that Related to the Separation ” in Item 1. These agreements will~~ provide for the performance of certain services by each company for the benefit of the other for a period of time after the Separation. If Embecta does not satisfactorily perform its obligations under these agreements, it may be held liable for any resulting losses suffered by BD, subject to certain limits. In addition, during the transition services periods under the transition services agreement, Embecta’ s management and employees may be required to divert their attention away from its business in order to provide services to BD, which could adversely affect Embecta’ s business. Embecta’ s agreements with BD may be on terms that are less beneficial to Embecta than the terms may have otherwise been from unaffiliated third parties. ~~The agreements that Embecta entered into with BD in connection with the Separation include the separation and distribution agreement, a transition services agreement, a tax matters agreement, an employee matters agreement, a cannula supply agreement, contract manufacturing agreements, an intellectual property matters agreement, a logistics services agreement, distribution agreements and other transaction agreements. See “ Agreements Related to the Separation ” in Item 1. These agreements~~ were prepared in the context of the Separation while Embecta was still a wholly owned subsidiary of BD. Accordingly, during the period in which the terms of those agreements were prepared, Embecta did not have an independent Board of Directors or a management team that was independent of BD. As a result, the terms of those agreements may not reflect terms that would have resulted from arm’ s- length negotiations between unaffiliated third parties. If there is a determination that the distribution or certain related transactions are taxable for United States federal income tax purposes, BD and its stockholders could incur significant tax liabilities, and Embecta could incur significant liabilities pursuant

to its indemnification obligations under the tax matters agreement. BD received a private letter ruling from the Internal Revenue Service (“IRS”) to the effect that, among other things, the Separation and the Distribution will qualify as a transaction that is tax-free for United States federal income tax purposes under Sections 368 (a) (1) (D), 355, and 361 of the Internal Revenue Code of 1986, as amended (the “Code”). It was a condition to the distribution that BD receive (i) a private letter ruling from the IRS, satisfactory to the BD Board of Directors, regarding certain United States federal income tax matters relating to the Separation and Distribution and (ii) an opinion of its outside tax counsel, satisfactory to the BD Board of Directors, regarding the qualification of the contribution of assets from BD to Embecta and the distribution, taken together, as a “reorganization” within the meaning of Sections 368 (a) (1) (D) and 355 of the Code and such opinion has not been withdrawn or rescinded. The opinion of its outside tax counsel and the private letter ruling are based upon and rely on, among other things, various facts and assumptions, as well as certain representations, statements and undertakings of BD and Embecta, including facts, assumptions, representations, statements and undertakings relating to the past and future conduct of the companies’ respective businesses and other matters. If any of these facts, assumptions, representations and statements are or become inaccurate or incomplete, or if any such undertaking is not complied with, BD may not be able to rely on the opinion of its outside tax counsel or the private letter ruling, and the conclusions reached therein could be jeopardized. **Further, the Extension is conditioned upon BD obtaining the Supplemental PLR.** Notwithstanding BD’s receipt of a private letter ruling from the IRS and the opinion of its outside tax counsel, the IRS could determine on audit that the distribution or certain related transactions are taxable for United States federal income tax purposes if it determines that any of the facts, assumptions, representations, statements and undertakings upon which the private letter ruling or the opinion was based are incorrect or have been violated, or if it disagrees with any of the conclusions in the opinion. **Additionally, although Embecta believes that BD will be able to obtain the Supplemental PLR, such process may be delayed, the Supplemental PLR may not be obtained, and there can be no assurance that the Supplemental PLR will be obtained by March 31, 2024, or at all.** Accordingly, notwithstanding BD’s receipt of a private letter ruling from the IRS and the opinion of its outside tax counsel, there can be no assurance that the IRS will not assert that the distribution or certain related transactions do not qualify for tax-free treatment for United States federal income tax purposes, or that a court would not sustain such a challenge. In the event the IRS were to prevail in such a challenge, BD and BD’s shareholders could incur significant tax liabilities. Under the tax matters agreement that Embecta entered into with BD, Embecta generally is required to indemnify BD for any taxes incurred by BD that arise as a result of any representations made by Embecta being inaccurate or Embecta taking or failing to take, as the case may be, certain actions, including in each case those provided in connection with the private letter ruling from the IRS or the opinion of its outside tax counsel that result in the distribution and certain related transactions failing to qualify as tax-free for United States federal income tax purposes or result in certain other taxes to BD, **which indemnity is also applicable in connection with the Extension.** Any such indemnification could materially adversely affect Embecta’s financial condition, results of operations and cash flows. For a more detailed discussion, see “Agreements Related to the Separation” in Item 1 **of this Annual Report on Form 10-K**. The separation and distribution agreement provides that certain contracts, permits and other assets and rights are to be transferred from BD or its subsidiaries to Embecta or its subsidiaries in connection with the Separation. The transfer of certain of these contracts, permits and other assets and rights may require consents or approvals of third parties or governmental authorities or provide other rights to third parties. In addition, in some circumstances, Embecta and BD are joint beneficiaries of contracts, and Embecta and BD may need the consents of third parties in order to split or separate the existing contracts or the relevant portion of the existing contracts to Embecta or BD. Some parties may use consent requirements or other rights to seek to terminate contracts or obtain more favorable contractual terms from us, which, for example, could take the form of unfavorable price increases. This could require us to expend additional resources in order to obtain the services or assets previously provided under the contract, or require us to seek arrangements with new third parties or obtain letters of credit or other forms of credit support. If Embecta is unable to obtain required consents or approvals, it may be unable to obtain the benefits, permits, assets and contractual commitments that are intended to be allocated to Embecta as part of its Separation from BD, and Embecta may be required to seek alternative arrangements to obtain services and assets that may be more costly and / or of lower quality. The termination or modification of these contracts or permits or the failure to timely complete the transfer or separation of these contracts or permits could negatively affect Embecta’s business, financial condition, results of operations and cash flows. The closing of the transfer of certain assets related to the Diabetes Care Business in certain jurisdictions, including China, Mexico, and Italy, as contemplated by the Separation and Distribution Agreement did not occur at the Separation and may not occur due to local regulatory requirements. If Embecta is unable to obtain required approval of local regulators or otherwise comply with such local regulatory requirements to effect the Separation in these jurisdictions, it may be unable to obtain the assets that are intended to be allocated to Embecta as part of its separation from BD. A temporary suspension of manufacturing operations associated with the regulatory approvals and transitions, including for inspections, may be required. **This includes A temporary suspension of manufacturing operations has already been initiated in China. These temporary suspensions, and any unforeseen delays in the termination of any suspension,** may ultimately impact Embecta’s ability to continuously supply its products to such jurisdictions and any other markets that receive such products. The failure to timely complete the transfer of these local assets or interruptions resulting from these foreign transfers could negatively affect Embecta’s business, financial condition, results of operations and cash flows. Satisfaction of indemnification obligations could have a material adverse effect on Embecta’s financial condition, results of operations and cash flows. Pursuant to the Separation and Distribution Agreement and certain other agreements Embecta entered into with BD in connection with the separation and distribution, BD agreed to indemnify Embecta for certain liabilities, and Embecta will agree to indemnify BD for certain liabilities as discussed further in “Agreements Related to the Separation” in Item 1 **of this Annual Report on Form 10-K**. Indemnities that Embecta will be required to provide BD could negatively affect Embecta’s business, particularly with respect to indemnities provided in the tax matters agreement. The indemnity from BD may not be sufficient to protect Embecta against the full amount of such liabilities



if, for example, BD is not able to fully satisfy its indemnification obligations. Moreover, even if Embecta ultimately succeeds in recovering from BD any amounts for which it is held liable, Embecta may be temporarily required to bear these losses itself, requiring Embecta to divert cash that would otherwise have been used in furtherance of its operating business. In addition, third parties could also seek to hold Embecta responsible for any of the liabilities that BD has agreed to retain. Each of these risks could have a material adverse effect on Embecta's financial condition, results of operations and cash flows.

**Risks Related to Embecta Common Stock** The price of Embecta common stock may fluctuate significantly, and stockholders could lose all or part of their investment in Embecta. We cannot predict the prices at which shares of Embecta common stock may trade. Given the competitiveness of the life sciences and medical device industry, the prices at which shares of Embecta common stock trade may fluctuate more significantly than might otherwise be typical, even with other market conditions, including general volatility, held constant. This volatility could negatively impact Embecta's ability to raise additional capital or utilize equity as consideration in any acquisition transactions Embecta may pursue, and could make it more difficult for existing stockholders to sell their shares of the common stock at a price they consider acceptable or at all. The market price of Embecta common stock may fluctuate significantly due to a number of factors, some of which may be beyond our control, including:

- actual or anticipated fluctuations in Embecta's operating results, **including those associated with the Interim Business Continuity Processes**;
- Embecta's liquidity and ability to obtain additional capital, including the market's reaction to any capital-raising transaction Embecta may pursue;
- changes in earnings estimated by securities analysts or Embecta's ability to meet those estimates;
- the operating and stock price performance of comparable companies;
- sales of substantial amounts of Embecta's common stock, or the perception that substantial amounts of Embecta's common stock may be sold, by stockholders in the public market;
- changes to the regulatory and legal environment under which Embecta operates;
- any negative decisions by the FDA or similar regulatory bodies inside and outside of the United States regarding Embecta's products and product candidates;
- actual or anticipated fluctuations in commodities prices;
- analyst research reports, recommendation and changes in recommendations, price targets, and withdrawals of coverage;
- **changes in the diabetes care landscape, including changes to consumer habits and market dynamics for means and methods of insulin delivery or alternative means of diabetes management without the use of insulin or by delaying the use of insulin**;
- and
- domestic and worldwide economic conditions.

In addition, the stock market in general, and the market for stock of companies in the life sciences and medical device industries in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of comparable companies. In the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against a company. This type of litigation, if instituted against Embecta, could result in substantial costs and a diversion of its management's attention and resources. Your percentage of ownership in Embecta may be diluted in the future. In the future, your percentage ownership in Embecta may be diluted because of equity issuances for acquisitions, capital market transactions or otherwise, including any equity awards that Embecta will grant to its directors, officers and employees. Embecta employees will have stock-based awards granted from time to time based on various employee benefit plans. Such awards will have a dilutive effect on Embecta's earnings per share, which could adversely affect the market price of Embecta common stock. Embecta cannot guarantee the timing, amount or payment of dividends on its common stock. Embecta currently expects that it will pay a regular cash dividend. However, the timing, declaration, amount and payment of any dividends will be within the discretion of Embecta's Board of Directors, and will depend upon many factors, including Embecta's financial condition, earnings, capital requirements of its operating subsidiaries, covenants associated with certain of Embecta's debt service obligations, legal requirements, regulatory constraints, industry practice, ability to access capital markets, and other factors deemed relevant by Embecta's Board of Directors. Moreover, Embecta cannot guarantee that it will continue to pay any dividends in the future and cannot guarantee the amount of any such dividends. Embecta's amended and restated certificate of incorporation and amended and restated bylaws contain, and Delaware law contains, provisions that are intended to deter coercive takeover practices and inadequate takeover bids by making such practices or bids unacceptably expensive to the bidder and to encourage prospective acquirers to negotiate with Embecta's Board of Directors rather than to attempt a hostile takeover. These provisions include, among others:

- until the annual stockholder meeting in 2026, Embecta's Board of Directors will be divided into three classes, with each class consisting, as nearly as may be possible, of one-third of the total number of directors, which could have the effect of making the replacement of incumbent directors more time consuming and difficult;
- as long as the Board of Directors is classified, Embecta directors can be removed by stockholders only for cause;
- vacancies occurring on the Board of Directors can only be filled by a majority of the remaining members of Embecta's Board of Directors or by a sole remaining director;
- stockholders do not have the right to call a special meeting or act by written consent;
- Embecta's Board of Directors has the power to designate and issue, without any further vote or action by the Embecta stockholders, shares of preferred stock from time to time in one or more series; and
- stockholders have to follow certain procedures and notice requirements in order to present certain proposals or nominate directors for election at stockholder meetings.

In addition, Embecta will be subject to Section 203 of the Delaware General Corporate Law, which could have the effect of delaying or preventing a change of control that you may favor. Section 203 provides that, subject to limited exceptions, persons that acquire, or are affiliated with persons that acquire, more than 15 % of the outstanding voting stock of a Delaware corporation may not engage in a business combination with that corporation, including by merger, consolidation or acquisitions of additional shares, for a three-year period following the date on which that person or any of its affiliates becomes the holder of more than 15 % of the corporation's outstanding voting stock. We believe these provisions will protect Embecta stockholders from coercive or otherwise unfair takeover tactics by requiring potential acquirers to negotiate with Embecta's Board of Directors and by providing the Board with more time to assess any acquisition proposal. These provisions are not intended to make Embecta immune from takeovers; however, these provisions will apply even if the offer may be considered beneficial by some stockholders and could delay or prevent an acquisition that Embecta's Board of Directors determines is not in the best interests

of Embecta and its stockholders. These provisions may also prevent or discourage attempts to remove and replace incumbent directors. In addition, an acquisition or further issuance of Embecta common stock could trigger the application of Section 355 (e) of the Code, causing the distribution to be taxable to BD. Under the tax matters agreement, Embecta would be required to indemnify BD for the resulting tax, and this indemnity obligation might discourage, delay or prevent a change of control that Embecta stockholders may consider favorable. Embecta's amended and restated certificate of incorporation provides that, unless Embecta (through approval of the Board of Directors) consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (1) any derivative action brought on behalf of Embecta, (2) any action asserting a claim of breach of a fiduciary duty owed by any director or officer or other employee of Embecta to Embecta or Embecta's stockholders, (3) any action asserting a claim against Embecta or any director or officer or other employee of Embecta arising pursuant to, or seeking to enforce any right, obligation or remedy under, any provision of the Delaware General Corporation Law ("DGCL") or Embecta's amended and restated certificate of incorporation or amended and restated bylaws (as either may be amended from time to time), (4) any action asserting a claim against Embecta or any director or officer or other employee of Embecta governed by the internal affairs doctrine, which is a conflict of laws principle which recognizes that only one state should have the authority to regulate a corporation's internal affairs or (5) any action as to which the DGCL (as it may be amended from time to time) confers jurisdiction on the Court of Chancery of the State of Delaware. If and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state court sitting in the State of Delaware (or, if no state court located within the State of Delaware has jurisdiction, the federal district court for the District of Delaware). These exclusive forum provisions will apply to all covered actions, including any covered action in which the plaintiff chooses to assert a claim or claims under federal law in addition to a claim or claims under Delaware law. These exclusive forum provisions will not apply to actions asserting only federal law claims under the Securities Act of 1933, as amended, (the "Securities Act") or the Securities Exchange Act of 1934, as amended (the "Exchange Act") regardless of whether the state courts in the State of Delaware have jurisdiction over those claims. Although Embecta believes the exclusive forum provision benefits it by providing increased consistency in the application of law in the types of lawsuits to which it applies, the provision may limit the ability of Embecta stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with Embecta or its directors or officers, and it may be costlier for Embecta stockholders to bring a claim in the Court of Chancery of the State of Delaware than other judicial forums, each of which may discourage such lawsuits against Embecta and its directors and officers. Although Embecta's amended and restated certificate of incorporation includes this exclusive forum provision, it is possible that a court could rule that this provision is inapplicable or unenforceable. Alternatively, if a court were to find this exclusive forum provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings described above, Embecta may incur additional costs associated with resolving such matters in other jurisdictions, which could negatively affect its business, results of operations and financial condition.