BAXTER INTERNATIONAL INC
Form 10-K
February 21, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission file number 1-4448

Baxter International Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	36-0781620
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
One Baxter Parkway, Deerfield, Illinois	60015
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code 224.948.2000

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common stock, $1.00 par value	New York Stock Exchange Chicago Stock Exchange
1.3% Senior Notes due 2025	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether registrant has submitted electronically every Interactive Data File required to be submitted and pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files) Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
Emerging growth company	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the

Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The aggregate market value of the voting common equity held by non-affiliates of the registrant as of June 29, 2018 (the last business day of the registrant's most recently completed second fiscal quarter), based on the per share closing sale price of $73.84 on that date and the assumption for the purpose of this computation only that all of the registrant's directors and executive officers are affiliates, was approximately $40 billion. The number of shares of the registrant's common stock, $1.00 par value, outstanding as of January 31, 2019 was 512,538,202.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive 2019 proxy statement for use in connection with its Annual Meeting of Stockholders to be held on May 7, 2019 are incorporated by reference into Part III of this report.

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PART I

Item 1. Business.

Company Overview

Baxter International Inc., through its subsidiaries, provides a broad portfolio of essential healthcare products, including acute and chronic dialysis therapies; sterile intravenous (IV) solutions; infusion systems and devices; parenteral nutrition therapies; inhaled anesthetics; generic injectable pharmaceuticals; and surgical hemostat and sealant products. In 2017, Baxter added capabilities in the production of essential generic injectable medicines with the acquisition of Claris Injectables Limited (Claris). The company's global footprint and critical nature of its products and services play a key role in expanding access to healthcare in emerging and developed countries. These products are used by hospitals, kidney dialysis centers, nursing homes, rehabilitation centers, doctors' offices and by patients at home under physician supervision. As of December 31, 2018, Baxter manufactured products in over 20 countries and sold them in over 100 countries.

Baxter International Inc. was incorporated under Delaware law in 1931. As used in this report, "Baxter International" means Baxter International Inc. and "Baxter," the "company" or the "Company" means Baxter International and its consolidated subsidiaries (after giving effect to the separation and distribution of Baxalta Incorporated (Baxalta), as further described below), unless the context otherwise requires.

Business Segments and Products

The company manages its business based on three geographic segments: Americas (North and South America), EMEA (Europe, Middle East and Africa) and APAC (Asia-Pacific).

Each of the company's segments provide a broad portfolio of essential healthcare products, including acute and chronic dialysis therapies; sterile IV solutions; infusion systems and devices; parenteral nutrition therapies; inhaled anesthetics; generic injectable pharmaceuticals; and surgical hemostat and sealant products.

For financial information about Baxter's segments, see Note 18 in Item 8 of this Annual Report on Form 10-K.

Sales and Distribution

The company has its own direct sales force and also makes sales to and through independent distributors, drug wholesalers acting as sales agents and specialty pharmacy or other alternate site providers. In the United States, third parties such as Cardinal Health, Inc. warehouse and ship a significant portion of the company's products through their distribution centers. These centers are generally stocked with adequate inventories to facilitate prompt customer service. Sales and distribution methods include frequent contact by sales and customer service representatives, automated communications via various electronic purchasing systems, circulation of catalogs and merchandising bulletins, direct-mail campaigns, trade publication presence and advertising.

Sales are made and products are distributed on a direct basis or through independent distributors or sales agents in more than 100 countries as of December 31, 2018.

International Operations

The majority of the company's revenues are generated outside of the United States and geographic expansion remains a component of the company's strategy. Baxter's international presence includes operations in Europe (including Eastern and Central Europe), the Middle East, Africa, Asia-Pacific, Latin America and Canada. The company is subject to certain risks inherent in conducting business outside the United States. For more information on these risks, see the information under the captions "Risks Related to Baxter's Business —We are subject to risks associated with doing business globally" and "— Changes in foreign currency exchange rates and interest rates could have a material adverse effect on our operating results and liquidity" in Item 1A of this Annual Report on Form 10-K.

For financial information about foreign and domestic operations and geographic information, see Note 18 in Item 8 of this Annual Report on Form 10-K. For more information regarding foreign currency exchange risk, refer to the discussion under the caption entitled "Financial Instrument Market Risk" in Item 7 of this Annual Report on Form 10-K.

Contractual Arrangements

The company's products are sold through contracts with customers, both within and outside the United States. Some of these contracts have terms of more than one year and place limits on the company's ability to increase prices. In the case of hospitals, governments and other facilities, these contracts may specify minimum quantities of a particular product or categories of products to be purchased by the customer.

In keeping with the increased emphasis on cost-effectiveness in healthcare delivery, many hospitals and other customers of medical products in the United States have joined group purchasing organizations (GPOs), or formed integrated delivery networks (IDNs), to enhance purchasing power. GPOs and IDNs negotiate pricing arrangements with manufacturers and distributors and the negotiated prices are made available to members. Baxter has purchasing agreements with several of the major GPOs in the United States. GPOs may have agreements with more than one supplier for certain products. Accordingly, in these cases, Baxter faces competition from other suppliers even where a customer is a member of a GPO under contract with Baxter. Purchasing power is similarly consolidated in many other countries. For example, public contracting authorities act as the purchasing entities for the hospitals and other customers of medical products in their region and many hospitals and other customers have joined joint procurement entities and buying consortia. The result is that demand for healthcare products is increasingly concentrated across the company's markets globally.

Raw Materials

Raw materials essential to Baxter's business are purchased from numerous suppliers worldwide in the ordinary course of business. Although most of these materials are generally available, Baxter at times may experience shortages of supply. In an effort to manage risk associated with raw materials supply, Baxter works closely with its suppliers to help ensure availability and continuity of supply while maintaining high quality and reliability. The company also seeks to develop new and alternative sources of supply where beneficial to its overall raw materials procurement strategy.

The company also utilizes long-term supply contracts with some suppliers to help maintain continuity of supply and manage the risk of price increases. Baxter is not always able to recover cost increases for raw materials through customer pricing due to contractual limits and market forces.

In connection with the separation and distribution of Baxalta, Baxter entered into a long-term manufacturing and supply agreement with Baxalta. Baxalta manufactures and supplies Baxter with ARTISS, TISSEEL, FLOSEAL and stand-alone thrombin under the manufacturing and supply agreement, on a cost-plus basis.

Competition and Healthcare Cost Containment

Baxter's businesses benefit from a number of competitive advantages, including the breadth and depth of their product offerings, as well as strong relationships with customers, including hospitals and clinics, GPOs, physicians, and patients, many who self-administer the home-based therapies supplied by Baxter. Baxter as a whole benefits from efficiencies and cost advantages resulting from shared manufacturing facilities and the technological advantages of its products.

Although no single company competes with Baxter in all of its businesses, Baxter faces substantial competition in each of its segments from international and domestic healthcare and pharmaceutical companies and providers of all sizes, and these competitors often differ across our businesses. In addition, global and regional competitors continue to expand their manufacturing capacity and sales and marketing channels. Competition is primarily focused on cost-effectiveness, price, service, product performance, and technological innovation. There has been increasing

consolidation in the company's customer base and by its competitors, which continues to result in pricing and market pressures.

Global efforts toward healthcare cost containment continue to exert pressure on product pricing. Governments around the world use various mechanisms to control healthcare expenditures, such as price controls, the formation of public contracting authorities, product formularies (lists of recommended or approved products), and competitive tenders which require the submission of a bid to sell products. Sales of Baxter's products are dependent, in part, on the availability of reimbursement by government agencies and healthcare programs, as well as insurance companies and other private payers. In the United States, the federal and many state governments have adopted or proposed initiatives relating to Medicaid and other health programs that may limit reimbursement or increase rebates that Baxter and other providers are required to pay to the state. In addition to government regulation, managed care organizations in the United States, which include medical insurance companies, medical plan administrators, health-maintenance organizations, hospital and physician alliances and pharmacy benefit managers, continue to put pressure on the price and usage of healthcare products. Managed care organizations seek to contain healthcare expenditures, and their purchasing strength has been increasing due to their consolidation into fewer, larger organizations and a growing number of enrolled patients. Baxter faces similar issues outside of the United States. In Europe and Latin America, for example, the government provides healthcare at low cost to

patients, and controls its expenditures by purchasing products through public tenders, collective purchasing, regulating prices, setting reference prices in public tenders or limiting reimbursement or patient access to certain products.

Intellectual Property

Patents and other proprietary rights are essential to Baxter's business. Baxter relies on patents, trademarks, copyrights, trade secrets, know-how and confidentiality agreements to develop, maintain and strengthen its competitive position. Baxter owns a number of patents and trademarks throughout the world and has entered into license arrangements relating to various third-party patents and technologies. Products manufactured by Baxter are sold primarily under its own trademarks and trade names. Some products distributed by the company are sold under the company's trade names, while others are sold under trade names owned by its suppliers or partners. Trade secret protection of unpatented confidential and proprietary information is also important to Baxter. The company maintains certain details about its processes, products and technology as trade secrets and generally requires employees, consultants, and business partners to enter into confidentiality agreements. These agreements may be breached and Baxter may not have adequate remedies for any breach. In addition, Baxter's trade secrets may otherwise become known or be independently discovered by competitors. To the extent that Baxter's employees, consultants, and business partners use intellectual property owned by others in their work for the company, disputes may arise as to the rights in related or resulting know-how and inventions.

Baxter's policy is to protect its products and technology through patents and trademarks on a worldwide basis. This protection is sought in a manner that balances the cost of such protection against obtaining the greatest value for the company. Baxter also recognizes the need to promote the enforcement of its patents and trademarks and takes commercially reasonable steps to enforce its patents and trademarks around the world against potential infringers, including judicial or administrative action where appropriate.

Baxter operates in an industry susceptible to significant patent litigation. At any given time, the company is involved as either a plaintiff or defendant in a number of patent infringement and other intellectual property-related actions. Such litigation can result in significant royalty or other payments or result in injunctions that can prevent the sale of products. For more information on patent and other litigation, see Note 17 in Item 8 of this Annual Report on Form 10-K.

Research and Development

Baxter's investment in research and development (R&D), consistent with the company's portfolio optimization and capital allocation strategies, helps fuel its future growth and its ability to remain competitive in each of its product categories. Accordingly, Baxter continues to focus its investment on select R&D programs to enhance future growth through clinical differentiation. Expenditures for Baxter's R&D activities were $655 million in 2018, $613 million in 2017, and $646 million in 2016. These expenditures include costs associated with R&D activities performed at the company's R&D centers located around the world, which include facilities in Belgium, Sweden, India, Italy, Germany, China, Japan and the United States, as well as in-licensing, milestone and reimbursement payments made to partners for R&D work performed at non-Baxter locations.

For more information on the company's R&D activities, refer to the discussion under the caption entitled "Strategic Objectives" in Item 7 of this Annual Report on Form 10-K.

Quality Management

Baxter's continued success depends upon the quality of its products. Quality management plays an essential role in determining and meeting customer requirements, preventing defects, facilitating continuous improvement of the

company's processes, products and services, and assuring the safety and efficacy of the company's products. Baxter's quality system enables the design, development, manufacturing, packaging, sterilization, handling, distribution and labeling of the company's products to ensure they conform to customer requirements. In order to continually improve the effectiveness and efficiency of the quality system, various measurements, monitoring and analysis methods such as management reviews and internal, external and vendor audits are employed at local and central levels.

Each product that Baxter markets is required to meet specific quality standards, both in packaging and in product integrity and quality. If any of those is determined to be compromised at any time, Baxter endeavors to take corrective and preventive actions designed to ensure compliance with regulatory requirements and to meet customer expectations. For more information on corrective actions taken by Baxter, refer to the discussion under the caption entitled "Certain Regulatory Matters" in Item 7 of this Annual Report on Form 10-K.

Government Regulation

The operations of Baxter and many of the products manufactured or sold by the company are subject to extensive regulation by numerous government agencies, both within and outside the United States. The Food and Drug Administration (FDA) in the United States, the European Medicines Agency (EMA) in Europe, the China Food and Drug Administration (CFDA) in China and other government agencies inside and outside of the United States, administer requirements covering the testing, safety, effectiveness, manufacturing, labeling, promotion and advertising, distribution and post-market surveillance of Baxter's products. The company must obtain specific approval from FDA and non-U.S. regulatory authorities before it can market and sell most of its products in a particular country. Even after the company obtains regulatory approval to market a product, the product and the company's manufacturing processes and quality systems are subject to continued review by FDA and other regulatory authorities globally. State agencies in the United States also regulate the facilities, operations, employees, products and services of the company within their respective states. The company and its facilities are subject to periodic inspections and possible administrative and legal actions by FDA and other regulatory agencies inside and outside the United States. Such actions may include warning letters, product recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, refusal of a government to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses. As situations require, the company takes steps to ensure safety and efficacy of its products, such as removing products found not to meet applicable requirements from the market and improving the effectiveness of quality systems. For more information on compliance actions taken by the company, refer to the discussion under the caption entitled "Certain Regulatory Matters" in Item 7 of this Annual Report on Form 10-K.

The company is also subject to various laws inside and outside the United States concerning its relationships with healthcare professionals and government officials, price reporting and regulation, the promotion, sales and marketing of its products and services, the importation and exportation of products, the operation of its facilities and distribution of products. In the United States, the company is subject to the oversight of FDA, Office of the Inspector General within the Department of Health and Human Services (OIG), the Center for Medicare/Medicaid Services (CMS), the Department of Justice (DOJ), Environmental Protection Agency, Department of Defense and Customs and Border Protection in addition to others. The company supplies products and services to healthcare providers that are reimbursed by federally funded programs such as Medicare. As a result, the company's activities are subject to regulation by CMS and enforcement by OIG and DOJ. In each jurisdiction outside the United States, the company's activities are subject to regulation by government agencies including the EMA in Europe, CFDA in China and other agencies in other jurisdictions. Many of the agencies enforcing these laws have increased their enforcement activities with respect to healthcare companies in recent years. These actions appear to be part of a general trend toward increased enforcement activity globally.

Environmental policies of the company require compliance with all applicable environmental regulations and contemplate, among other things, appropriate capital expenditures for environmental protection.

Separation of Baxalta

On July 1, 2015, Baxter completed the distribution of approximately 80.5% of the outstanding common stock of Baxalta to Baxter stockholders (the Distribution). The Distribution was made to Baxter's stockholders of record as of the close of business on June 17, 2015 (the Record Date), who received one share of Baxalta common stock for each Baxter common share held as of the Record Date. As a result of the distribution, Baxalta became an independent public company.

In 2016, Baxter disposed of its remaining 19.5% interest in Baxalta through a series of transactions including debt-for-equity exchanges, an equity-for-equity exchange and a contribution to its U.S. pension plan. As a result of

these transactions, the company extinguished approximately $3.65 billion in company indebtedness, repurchased 11,526,638 Baxter shares and contributed 17,145,570 Baxalta shares to its U.S. pension plan. On June 3, 2016, Baxalta became a wholly-owned subsidiary of Shire plc (Shire). In January 2019, Takeda Pharmaceutical Company Limited (Takeda) acquired Shire.

As a result of the separation, the consolidated statements of income, consolidated balance sheets, consolidated statements of cash flow, and related financial information reflect Baxalta's operations, assets and liabilities, and cash flows as discontinued operations for all periods presented.

Refer to Note 2 in Item 8 of this Annual Report on Form 10-K for additional information regarding the separation of Baxalta.

Employees

As of December 31, 2018, Baxter employed approximately 50,000 people.

Available Information

Baxter makes available free of charge on its website at www.baxter.com its Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (Exchange Act), as soon as reasonably practicable after electronically filing or furnishing such material with the Securities and Exchange Commission. These reports are also available free of charge via EDGAR through the Securities and Exchange Commission website (www.sec.gov). In addition, Baxter's Corporate Governance Guidelines, Code of Conduct, and the charters for the committees of Baxter's Board of Directors are available on Baxter's website at www.baxter.com under "About Baxter—About us — Governance." All the foregoing materials will be made available to stockholders in print upon request by writing to: Corporate Secretary, Baxter International Inc., One Baxter Parkway, Deerfield, Illinois 60015. Information contained on Baxter's website shall not be deemed incorporated into, or to be a part of, this Annual Report on Form 10-K.

Item 1A.Risk Factors.

In addition to the other information in this Annual Report on Form 10-K, stockholders or prospective investors should carefully consider the following risk factors. If any of the events described below occurs, our business, financial condition, results of operations, future growth prospects and stock price could suffer.

We may not achieve our long-term financial improvement goals.

We have been implementing plans to enhance profitability and returns for our stockholders. These plans include the achievement of certain financial goals in 2019 and beyond. While we are continuing to refine these goals, our plan contemplates significant margin expansion over our long-range plan, which runs through 2023. We have identified certain key strategies to help achieve these targets. These strategies include optimizing our core product portfolio globally, driving operational excellence through the realignment of our cost structure and various restructuring activities and maximizing the value derived from the allocation of our capital.

As part of these strategies, we continue to evaluate the performance of all of our businesses and may sell or acquire a business or product line or exit a particular market. We are also evaluating our corporate and commercial infrastructure in the interest of streamlining costs while maintaining our commitment to quality and safety. Future divestitures may result in significant write-offs, including those related to goodwill and other intangible assets. Future acquisitions may fail to achieve the desired financial results (including return on investment) and synergies and may not provide the desired market access. The restructuring of our operations may not generate targeted savings or may cause unexpected disruptions to our business. As a result, we may not achieve our targeted financial results, which could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to successfully introduce new products or fail to keep pace with advances in technology, our business, financial condition and results of operations could be adversely affected.

We need to successfully introduce new products to achieve our strategic business objectives. Product development requires substantial investment and there is inherent risk in the R&D process. A successful product development process depends on many factors, including our ability to properly anticipate and satisfy customer needs, adapt to new technologies, obtain regulatory approvals on a timely basis, demonstrate satisfactory clinical results, manufacture products in an economical and timely manner and differentiate our products from those of our competitors. If we cannot successfully introduce new products or adapt to changing technologies, our products may become obsolete and

our revenue and profitability could suffer.

Issues with product supply or quality could have an adverse effect on our business, subject us to regulatory actions, or cause a loss of customer confidence in us or our products, among other negative consequences.

Our success depends upon the availability and quality of our products. The pharmaceutical and medical products industries are competitive and subject to complex market dynamics and varying demand levels. These levels vary in response to macro-economic conditions, regulatory requirements (including the availability of private or public reimbursement), seasonality, natural disasters, epidemics and other matters. Additionally, the development of new or enhanced products involves a lengthy regulatory process and is capital intensive. As a result, our ability to match our production levels and capacity to market demand is imprecise and may result in a failure to meet market demand or satisfy customer requirements for our products or, alternatively, an oversupply of inventory. Failure to meet market demand may result in customers transitioning to available competitive products, loss of market share, negative publicity, reputational damage, loss of customer confidence or other negative consequences (including a decline in stock price). In the event of an oversupply, we may be forced to lower our prices, record asset impairment charges or take other actions, which may adversely affect our business, financial condition and results of operations.

Additionally, quality management plays an essential role in determining and meeting customer requirements, preventing defects, improving our products and services and assuring the safety and efficacy of our products. Our future success depends on our ability to maintain and continuously improve our quality management program. While we have a quality system that covers the lifecycle of our

products, quality and safety issues may occur with respect to any of our products. A quality or safety issue may result in adverse inspection reports, voluntary or official action indicated, warning letters, import bans, product recalls (either voluntary or required by FDA or similar governmental authorities in other countries) or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, costly litigation, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses. An inability to address a quality or safety issue in an effective and timely manner may also cause negative publicity, a loss of customer confidence in us or our current or future products, which may result in the loss of sales and difficulty in successfully launching new products. Additionally, Baxter has made and continues to make significant investments in assets, including inventory and property, plant and equipment, which relate to potential new products or modifications to existing products. Product quality or safety issues may restrict us from being able to realize the expected returns from these investments, potentially resulting in asset impairments in the future.

Unaffiliated third party suppliers provide a number of goods and services to our R&D, clinical and manufacturing organizations. Third party suppliers are required to comply with our quality standards. Failure of a third party supplier to provide compliant raw materials or supplies could result in delays, service interruptions or other quality related issues that may negatively impact our business results.

For more information on regulatory matters currently affecting us, refer to the discussion under the caption entitled “Certain Regulatory Matters” in Item 7 of this Annual Report on Form 10-K.

If we are unable to obtain sufficient components or raw materials on a timely basis or for a cost-effective price or if we experience other manufacturing or supply difficulties, our business and results of operations may be adversely affected.

The manufacture of our products requires, among other things, the timely supply or delivery of sufficient amounts of quality components and materials. We manufacture our products in approximately 50 manufacturing facilities around the world. We acquire our components, materials and other requirements for manufacturing from many suppliers and vendors in various countries, including sometimes from ourselves for self-supplied requirements. We endeavor, either alone or working closely with our suppliers, to ensure the continuity of our inputs and supplies but we cannot guarantee these efforts will always be successful. Further, while efforts are made to diversify certain of our sources of components and materials, in certain instances there is only a sole source or supplier with no alternatives yet identified. For most of our components and materials for which a single source or supplier is used, alternative sources or suppliers may exist, but we have made a strategic determination to use the single source or supplier. Although we do carry strategic inventory and maintain insurance to help mitigate the potential risk related to any related supply disruption, there can be no assurance that such measures will be sufficient or effective. A reduction or interruption in supply and an inability to quickly develop acceptable alternative sources for such supply, could adversely affect our ability to manufacture and distribute our products in a timely or cost-effective manner, and our ability to make product sales. Additionally, volatility in our costs of energy, transportation/freight, components, raw materials and other supply, manufacturing and distribution costs could adversely affect our results of operations. Climate change (including laws or regulations passed in response thereto) could increase our costs, in particular our costs of supply, energy and transportation/freight. Material or sustained increases in the price of oil could have an adverse impact on the cost of many of the plastic materials we use to make and package our products, as well as our transportation/freight costs. These outcomes may in turn result in customers transitioning to available competitive products, loss of market share, negative publicity, reputational damage, loss of customer confidence or other negative consequences (including a decline in stock price).

Many of our products are difficult to manufacture. This is due to the complex nature of manufacturing pharmaceuticals, including biologics, and devices, as well as the strict regulatory regime governing our manufacturing operations. Variations in the manufacturing process may result in production failures which could lead to launch

delays, product shortage, unanticipated costs, lost revenues and damage to our reputation. A failure to identify and address manufacturing problems prior to the release of products to our customers may also result in a quality or safety issue of the type discussed above.

Some of our products are manufactured at a single manufacturing facility or stored at a single storage site. Loss or damage to a manufacturing facility or storage site due to a natural disaster, such as we experienced as a result of Hurricane Maria, or otherwise could adversely affect our ability to manufacture sufficient quantities of key products or otherwise deliver products to meet customer demand or contractual requirements which may result in a loss of revenue and other adverse business consequences (including those identified in the paragraph above). Because of the time required to approve and license a manufacturing facility, a third party manufacturer may not be available on a timely basis (if at all) to replace production capacity in the event we lose manufacturing capacity or products are otherwise unavailable due to natural disaster, regulatory action or otherwise.

We are increasingly dependent on information technology systems and subject to privacy and security laws, and our systems and infrastructure face certain risks, including from cyber security breaches and data leakage.

We increasingly rely upon technology systems and infrastructure, including support provided by our partners and third parties, to support our business, our products and our customers. For example, we routinely rely on our technology systems and infrastructure to aid us in the collection, use, storage and transfer, disclosure and other processing of voluminous amounts of data including confidential, business, financial, personal and other sensitive information (collectively, Confidential Information). We also rely on systems for manufacturing, customer orders, shipping, regulatory compliance and various other matters. Certain of our products and systems collect data regarding patients and their therapy and some connect to our systems for maintenance and other purposes.

Additionally, the legal and regulatory environment surrounding information security and privacy is increasingly demanding, with the imposition of new and changing requirements across businesses. We are required to comply with increasingly complex and changing legal and regulatory requirements that govern the collection, use, storage, security, transfer, disclosure and other processing of personal data, including, but not limited to, The Health Insurance Portability and Accountability Act, The Health Information Technology for Economic and Clinical Health Act, the California Consumer Privacy Act of 2018 and the European Union's General Data Protection Regulation (GDPR). In May 2018, the GDPR superseded current European Union data protection legislation, imposed more stringent European Union data protection requirements, and provided for greater penalties for noncompliance. We or our third-party providers and business partners may also be subjected to audits or investigations by one or more domestic or foreign government agencies relating to compliance with information security and privacy laws and regulations, and noncompliance with the laws and regulations could result in substantial and material fines or class action litigation.

The increasing use and evolution of technology, including cloud-based computing, and reliance on third parties creates additional opportunities for the unintentional, intentional and/or unauthorized exposure,