BECTON DICKINSON & CO Form 10-K November 23, 2011

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#### As filed with the Securities and Exchange Commission on November 23, 2011

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

### Form 10-K ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

#### FOR THE FISCAL YEAR ENDED SEPTEMBER 30, 2011

#### **COMMISSION FILE NUMBER 1-4802**

#### BECTON, DICKINSON AND COMPANY

(Exact name of registrant as specified in its charter)

**New Jersey** 

(State or other jurisdiction of incorporation or organization)

1 Becton Drive Franklin Lakes, New Jersey (Address of principal executive offices) 22-0760120

(I.R.S. Employer Identification No.)

**07417-1880** (*Zip code*)

(201) 847-6800

(Registrant s telephone number, including area code)

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

**Title of Each Class**Common Stock, par value \$1.00

Name of Each Exchange on Which Registered 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 b No o

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

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 b No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes b No o

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, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer b Accelerated filer o Non-accelerated filer o (Do not check if a smaller reporting company)
Smaller reporting company o

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

As of March 31, 2011, the aggregate market value of the registrant s outstanding common stock held by non-affiliates of the registrant was approximately \$17,370,014,569.

As of October 31, 2011, 214,890,631 shares of the registrant s common stock were outstanding.

# **Documents Incorporated by Reference**

Portions of the registrant s Proxy Statement for the Annual Meeting of Shareholders to be held January 31, 2012 are incorporated by reference into Part III hereof.

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#### PART I

#### Item 1. Business.

#### General

Becton, Dickinson and Company (also known as BD) was incorporated under the laws of the State of New Jersey in November 1906, as successor to a New York business started in 1897. BD s executive offices are located at 1 Becton Drive, Franklin Lakes, New Jersey 07417-1880, and its telephone number is (201) 847-6800. All references in this Form 10-K to BD refer to Becton, Dickinson and Company and its domestic and foreign subsidiaries, unless otherwise indicated by the context.

BD is a global medical technology company engaged principally in the development, manufacture and sale of medical devices, instrument systems and reagents used by healthcare institutions, life science researchers, clinical laboratories, the pharmaceutical industry and the general public.

#### **Business Segments**

BD s operations consist of three worldwide business segments: BD Medical, BD Diagnostics and BD Biosciences. Information with respect to BD s business segments is included in Note 6 to the consolidated financial statements contained in Item 8, Financial Statements and Supplementary Data, and is incorporated herein by reference.

#### **BD** Medical

BD Medical produces a broad array of medical devices that are used in a wide range of healthcare settings. BD Medical s principal product lines include needles, syringes and intravenous catheters for medication delivery (including safety-engineered and auto-disable devices); prefilled IV flush syringes; syringes and pen needles for the self-injection of insulin and other drugs used in the treatment of diabetes; prefillable drug delivery systems provided to pharmaceutical companies and sold to end-users as drug/device combinations; regional anesthesia needles and trays; sharps disposal containers; and closed-system transfer devices. The primary customers served by BD Medical are hospitals and clinics; physicians office practices; consumers and retail pharmacies; governmental and nonprofit public health agencies; pharmaceutical companies; and healthcare workers.

#### **BD** Diagnostics

BD Diagnostics provides products for the safe collection and transport of diagnostics specimens, as well as instruments and reagent systems to detect a broad range of infectious diseases, healthcare-associated infections (HAIs) and cancers. BD Diagnostics principal products include integrated systems for specimen collection; safety-engineered blood collection products and systems; automated blood culturing systems; molecular testing systems for infectious diseases and women shealth; microorganism identification and drug susceptibility systems; liquid-based cytology systems for cervical cancer screening; rapid diagnostic assays; and plated media. BD Diagnostics serves hospitals, laboratories and clinics; reference laboratories; blood banks; healthcare workers; public health agencies; physicians office practices; and industrial and food microbiology laboratories.

#### **BD** Biosciences

BD Biosciences produces research and clinical tools that facilitate the study of cells, and the components of cells, to gain a better understanding of normal and disease processes. That information is used to aid the discovery and development of new drugs and vaccines, and to improve the diagnosis and management of diseases. BD Biosciences principal product lines include fluorescence-activated cell sorters and analyzers; monoclonal antibodies and kits for performing cell analysis; reagent systems for life science research; cell imaging systems; laboratory products for tissue culture and fluid handling; diagnostic assays; and cell culture media supplements for biopharmaceutical manufacturing. The primary customers served by BD Biosciences

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are research and clinical laboratories; academic and government institutions; pharmaceutical and biotechnology companies; hospitals; and blood banks.

#### **Acquisitions**

During the second quarter of 2011, BD acquired 100% of the outstanding shares of Accuri Cytometers, Inc, a company that develops and manufactures personal flow cytometers for researchers. The fair value of consideration transferred totaled \$205 million, net of cash acquired.

During the fourth quarter of 2011, BD acquired 100% of the outstanding shares of Carmel Pharma Inc., a Swedish company that manufactures the PhaSeal® System, a closed-system drug transfer device for the safe handling of hazardous drugs that are packaged in vials. The fair value of consideration transferred was \$287 million, net of cash acquired.

Additional information regarding these acquisitions is contained in Note 9 to the consolidated financial statements contained in Item 8, Financial Statements and Supplementary Data, which is incorporated herein by reference.

#### **International Operations**

BD s products are manufactured and sold worldwide. For reporting purposes, we organize our operations outside the United States as follows: Europe (which includes the Middle East and Africa); Japan; Asia Pacific (which includes Australia and all of Asia except Japan); Latin America (which includes Mexico and Brazil) and Canada. The principal products sold by BD outside the United States are needles and syringes; insulin syringes and pen needles; diagnostic systems; BD Vacutainer<sup>tm</sup> brand blood collection products; BD Hypak<sup>tm</sup> brand prefillable syringe systems; infusion therapy products; flow cytometry instruments and reagents; and disposable laboratory products. BD has manufacturing operations outside the United States in Brazil, Canada, China, France, Germany, Hungary, India, Ireland, Japan, Mexico, Pakistan, Singapore, South Korea, Spain, Sweden and the United Kingdom. Geographic information with respect to BD s operations is included under the heading Geographic Information in Note 6 to the consolidated financial statements included in Item 8, Financial Statements and Supplementary Data, and is incorporated herein by reference.

Foreign economic conditions and exchange rate fluctuations have caused the profitability related to foreign revenues to fluctuate more than the profitability related to domestic revenues. BD believes its activities in some countries outside the United States involve greater risk than its domestic business due to the factors cited herein, as well as the economic environment, local commercial and economic policies and political uncertainties. See further discussion of this risk in Item 1A. Risk Factors.

#### Distribution

BD s products are marketed in the United States and internationally through independent distribution channels and directly to end-users by BD and independent sales representatives. No customer accounted for 10% or more of revenues in fiscal year 2011. Order backlog is not material to BD s business inasmuch as orders for BD products generally are received and filled on a current basis, except for items temporarily out of stock. BD s worldwide sales are not generally seasonal, with the exception of certain medical devices in the BD Medical segment, and respiratory and flu diagnostic products in the BD Diagnostics segment, that relate to seasonal diseases such as influenza.

#### **Raw Materials**

BD purchases many different types of raw materials, including plastics, glass, metals, textiles, paper products, agricultural products, electronic and mechanical sub-assemblies and various biological, chemical and petrochemical products. Certain raw materials (primarily related to the BD Biosciences segment) are not available from multiple sources. In the case of certain principal raw materials that are available from multiple sources, for various reasons (including quality assurance and cost effectiveness), BD elects to purchase these raw materials from sole suppliers. In cases where there are regulatory requirements relating to qualification of suppliers, BD may not be able to

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establish additional or replacement sources on a timely basis. While BD works closely with its suppliers to ensure continuity of supply, the termination, reduction or interruption in supply of these sole-sourced raw materials could impact our ability to manufacture and sell certain of our products.

#### **Research and Development**

BD conducts its research and development ( R&D ) activities at its operating units and at BD Technologies in Research Triangle Park, North Carolina. The majority of BD s R&D activities are conducted in the United States. Outside the United States, BD conducts R&D activities at BD Diagnostic Systems in Quebec City, Canada and Suzhou, China, BD Pharmaceutical Systems in Pont de Claix, France, and BD Medical Surgical Systems in Tuas, Singapore. BD also collaborates with certain universities, medical centers and other entities on R&D programs, and retains individual consultants to support its efforts in specialized fields. BD spent approximately \$476 million, \$431 million and \$405 million on research and development during the fiscal years ended September 30, 2011, 2010 and 2009, respectively. Fiscal 2011 spending included a \$9 million charge resulting from the discontinuance of a research program.

#### **Intellectual Property and Licenses**

BD owns significant intellectual property, including patents, patent applications, technology, trade secrets, know-how, copyrights and trademarks in the United States and other countries. BD is also licensed under domestic and foreign patents, patent applications, technology, trade secrets, know-how, copyrights and trademarks owned by others. In the aggregate, these intellectual property assets and licenses are of material importance to BD s business. BD believes, however, that no single patent, technology, trademark, intellectual property asset or license is material in relation to BD s business as a whole, or to any business segment.

#### Competition

BD operates in the increasingly complex and challenging medical technology marketplace whose dynamics are changing. Technological advances and scientific discoveries have accelerated the pace of change in medical technology, the regulatory environment of medical products is becoming more complex and vigorous, and economic conditions have resulted in a challenging market. Companies of varying sizes compete in the global medical technology field. Some are more specialized than BD with respect to particular markets, and some have greater financial resources than BD. New companies have entered the field, particularly in the areas of molecular diagnostics, safety-engineered devices and in the life sciences, and established companies have diversified their business activities into the medical technology area. Other firms engaged in the distribution of medical technology products have become manufacturers of medical devices and instruments as well. Acquisitions and collaborations by and among companies seeking a competitive advantage also affect the competitive environment. In addition, the entry into the market of manufacturers located in China and other low-cost manufacturing locations are creating increased pricing pressures, particularly in developing markets. Some competitors have also established manufacturing sites or have contracted with suppliers located in these countries as a means to lower their costs. New entrants may also appear, particularly from these low-cost countries.

BD competes in this evolving marketplace on the basis of many factors, including price, quality, innovation, service, reputation, distribution and promotion. The impact of these factors on BD s competitive position varies among BD s various product offerings. In order to remain competitive in the industries in which it operates, BD continues to make investments in research and development, quality management, quality improvement, product innovation and productivity improvement in support of its core strategy to increase revenue growth by focusing on products that deliver greater benefits to patients, healthcare workers and researchers.

### **Third-Party Reimbursement**

Healthcare providers and related facilities are generally reimbursed for their services through numerous payment systems managed by various governmental agencies worldwide (e.g., Medicare and Medicaid in the

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United States, the National Health Service in the United Kingdom, the Joint Federal Committee in Germany, the Commission d Evaluation des Produits et prestations in France, the Ministry for Health, Labor and Welfare in Japan, the Ministry of Health and the National Development and Reform Commission in China, among many others), private insurance companies, and managed care organizations. The manner and level of reimbursement in any given case may depend on the site of care, the procedure(s) performed, the final patient diagnosis, the device(s) and/or drug(s) utilized, the available budget, or a combination of these factors, and coverage and payment levels are determined at each payer s discretion. The coverage policies and reimbursement levels of these third-party payers may impact the decisions of healthcare providers and facilities regarding which medical products they purchase and the prices they are willing to pay for those products. Thus, changes in reimbursement level or method may either positively or negatively impact sales of BD products.

While BD is actively engaged in promoting the value of its products for payers and patients, and it employs various efforts and resources to positively impact coverage, coding and payment processes in this regard, it has no direct control over payer decision-making with respect to coverage and payment levels for BD products. Additionally, we expect many payers to continue to explore cost-containment strategies (e.g., comparative and cost-effectiveness analyses, so-called pay-for-performance programs implemented by various public and private payers, and expansion of payment bundling schemes such as Accountable Care Organizations (ACOs), DRG programs, and other such methods that shift medical cost risk to providers) that could potentially impact coverage and/or payment levels for current or future BD products.

As BD s product offerings are diverse across many healthcare settings, they are affected to varying degrees by the many payment systems. Therefore, individual countries, product lines or product classes may be impacted by changes to these systems. Notably, the recently-enacted healthcare reform legislation in the United States (i.e., the Patient Protection and Affordable Care Act (PPACA)) provides for numerous, substantive changes to U.S. healthcare payment systems. Many of the changes set forth in this statute have only recently been promulgated through formal regulations and most of them have yet to be implemented. At this time, it remains unclear whether, or how, the implementation of regulations pursuant to the PPACA might affect payments for BD products. See Item 1A. Risk Factors for a further discussion.

#### Regulation

BD s medical technology products and operations are subject to regulation by the U.S. Food and Drug Administration (FDA) and various other federal and state agencies, as well as by foreign governmental agencies. These agencies enforce laws and regulations that govern the development, testing, manufacturing, labeling, advertising, marketing and distribution, and market surveillance of BD s medical products. The scope of the activities of these agencies, particularly in the Europe, Japan and Asia Pacific regions in which BD operates, has been increasing.

BD actively maintains FDA/ISO Quality Systems that establish standards for its product design, manufacturing, and distribution processes. Prior to marketing or selling most of its products, BD must secure approval from the FDA and counterpart non-U.S. regulatory agencies. Following the introduction of a product, these agencies engage in periodic reviews of BD s quality systems, as well as product performance, and advertising and promotional materials. These regulatory controls, as well as any changes in FDA policies, can affect the time and cost associated with the development, introduction and continued availability of new products. Where possible, BD anticipates these factors in its product development and planning processes.

These agencies possess the authority to take various administrative and legal actions against BD, such as product recalls, product seizures and other civil and criminal sanctions. BD also undertakes voluntary compliance actions such as voluntary recalls.

BD also is subject to various federal and state laws, and laws outside the United States, concerning healthcare fraud and abuse (including false claims laws and anti-kickback laws), global anti-corruption, transportation, safety and health, and customs and exports. Many of the agencies enforcing these laws have increased their enforcement activities with respect to medical device manufacturers in recent years. This

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appears to be part of a general trend toward increased regulation and enforcement activity within and outside the United States.

BD believes it is in compliance in all material respects with applicable law and the regulations promulgated by the applicable agencies (including, without limitation, environmental laws and regulations), and that such compliance has not had, and will not have, a material adverse effect on our operations or results. See Item 3. Legal Proceedings.

#### **Employees**

As of September 30, 2011, BD had 29,369 employees, of whom 12,041 were employed in the U.S. (including Puerto Rico). BD believes that its employee relations are satisfactory.

#### **Other Matters**

Becton Dickinson France, S.A. (BD-France), a subsidiary of BD, was listed among approximately 2,200 other companies in an October 27, 2005 report of the Independent Inquiry Committee (IIC) of the United Nations (UN) as having been involved in humanitarian contracts in which unauthorized payments were suspected of having been made to the Iraqi Government in connection with the UN's Oil-for-Food Programme (the Programme). In connection with the IIC's report, Becton Dickinson AG, a Swiss subsidiary of BD, received a letter of inquiry from the Vendor Review Committee (VRC) of the United Nations Procurement Service dated November 22, 2005. The letter of inquiry said that the VRC is reviewing Becton Dickinson AG's registration status in light of BD-France being listed in the IIC's report and asked us for any information we might be able to provide relating to the findings of the report. BD conducted an internal review and found no evidence that BD or any BD employee made, authorized, or approved improper payments to the Iraqi Government in connection with the Programme. The representative utilized by BD in Iraq also unequivocally denied having made any such payments, and BD was unable to find any evidence of such payments being made by this representative. BD reported the results of its internal review to the VRC. In May 2008, BD received a letter from the UN stating that Becton Dickinson AG had been suspended from the UN Secretariat Procurement Division's vendor roster for a minimum period of six months. We have requested that Becton Dickinson AG be reinstated. BD believes that the suspension has not had, and will not have, a material adverse effect on BD.

In May 2007, the French Judicial Police conducted searches of BD-France s offices in France with respect to the matters that were the subject of the 2005 IIC report. We were informed that BD-France is one of a number of companies named in the IIC report that is being investigated by the French Judicial Police. In June 2009, the Belgian Federal Police contacted BD to interview certain individuals and review documents related to sales made under the Programme. We are cooperating fully with these investigations.

#### **Available Information**

BD maintains a website at <a href="https://www.bd.com">www.bd.com</a>. BD also makes available its Annual Reports on Form 10-K, its Quarterly Reports on Form 10-Q, and its Current Reports on Form 8-K (and amendments to those reports) as soon as reasonably practicable after those reports are electronically filed with, or furnished to, the Securities and Exchange Commission (SEC). These filings may be obtained and printed free of charge at <a href="https://www.bd.com/investors">www.bd.com/investors</a>. In addition, the written charters of the Audit Committee, the Compensation and Benefits Committee, the Corporate Governance and Nominating Committee, the Executive Committee and the Science, Innovation and Technology Committee of the Board of Directors, BD s Corporate Governance Principles and its Code of Conduct, are available at BD s website at <a href="https://www.bd.com/investors/corporate\_governance/">www.bd.com/investors/corporate\_governance/</a>. Printed copies of these materials, BD s 2011 Annual Report on Form 10-K, and BD s reports and statements filed with, or furnished to, the SEC, may be obtained, without charge, by contacting the Corporate Secretary, BD, 1 Becton Drive, Franklin Lakes, New Jersey 07417-1880, telephone 201-847-6800. In addition, the SEC maintains an internet site that contains reports, proxy and information statements,

and other information regarding issues that file electronically with the SEC at www.sec.gov.

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BD also routinely posts important information for investors on its website at *www.bd.com/investors*. BD may use this website as a means of disclosing material, non-public information and for complying with its disclosure obligations under Regulation FD adopted by the SEC. Accordingly, investors should monitor the Investor Relations portion of BD s website noted above, in addition to following BD s press releases, SEC filings, and public conference calls and webcasts. Our website and the information contained therein or connected thereto shall not be deemed to be incorporated into this Annual Report.

#### **Forward-Looking Statements**

BD and its representatives may from time-to-time make certain forward-looking statements in publicly-released materials, both written and oral, including statements contained in filings with the SEC and in our reports to shareholders. Additional information regarding our forward-looking statements is contained in Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations.

#### Item 1A. Risk Factors.

An investment in BD involves a variety of risks and uncertainties. The following describes some of the significant risks that could adversely affect BD s business, financial condition, operating results or cash flows.

#### Current economic conditions could continue to adversely affect our operations.

The global economic conditions may result in a decrease in the demand for our products and services, increased pricing pressure, longer sales cycles, and slower adoption of new technologies. During fiscal year 2011, our revenue growth was adversely affected by conditions in the healthcare industry, including lower healthcare utilization, particularly in the U.S. and western Europe, cost containment efforts by governments and other payors for healthcare services and other factors. These conditions resulted in weaker overall customer demand and increased pricing pressure for some of our products. We anticipate that these industry conditions will continue for the foreseeable future. In addition, while the economic downturn has not impaired our ability to access credit markets to date, there can be no assurance that these conditions will not adversely affect our ability to do so in the future. The current macroeconomic conditions may also adversely affect our suppliers, and there can be no assurances that BD will not experience any interruptions in supply in the future. We have also experienced delays in collecting receivables in certain countries in western Europe, and we may experience similar delays in these and other jurisdictions experiencing liquidity problems. The continued weakness in world economic makes the strength and timing of any economic recovery uncertain, and there can be no assurance that global economic conditions will not deteriorate further.

#### We are subject to foreign currency exchange risk.

Over half of our fiscal year 2011 revenues were derived from international operations. Our revenues outside the United States may be adversely affected by fluctuations in foreign currency exchange rates. A discussion of the financial impact of exchange rate fluctuations and the ways and extent to which we may attempt to address any impact is contained in Item. 7, Management s Discussion of Financial Condition and Results of Operations. Any hedging activities we engage in may only offset a portion of the adverse financial impact resulting from unfavorable changes in foreign currency exchange rates. We cannot predict with any certainty changes in foreign currency exchange rates or the degree to which we can address these risks.

Changes in reimbursement practices of third-party payers could affect the demand for our products and the prices at which they are sold.

Our sales depend, in part, on the extent to which healthcare providers and facilities are reimbursed by government authorities, private insurers and other third-party payers for the costs of our products. The coverage policies and reimbursement levels of third-party payers, which can vary among public and private sources, may affect which products customers purchase and the prices they are willing to pay for these products in a particular jurisdiction. Legislative or administrative reforms to reimbursement systems in the United States (as part of healthcare reform or otherwise, as discussed below) or abroad could significantly

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reduce reimbursement for procedures using BD products, or result in denial of reimbursement for those products. See Third-Party Reimbursement under Item 1. Business.

#### Federal healthcare reform may adversely affect our results of operations.

The Patient Protection and Affordable Care Act (the PPACA) was enacted in March 2010. Under the PPACA, beginning in 2013, medical device manufacturers, such as BD, will pay a 2.3% excise tax on U.S. sales of certain medical devices. Sales of BD products that we estimate to be subject to this tax represented about 80% of BD s total U.S. revenues in fiscal year 2011. We cannot predict with any certainty what other impact the PPACA may have on our business. The PPACA reduces Medicare and Medicaid payments to hospitals, clinical laboratories and pharmaceutical companies, and could otherwise reduce the volume of medical procedures. These factors, in turn, could result in reduced demand for our products and increased downward pricing pressure. It is also possible that the PPACA will result in lower reimbursements for our products. While the PPACA is intended to expand health insurance coverage to uninsured persons in the United States, the impact of any overall increase in access to healthcare on sales of BD s products remains uncertain.

#### Efforts to reduce the U.S. federal deficit could adversely affect our results of operations.

As part of the law passed in August 2011 to extend the federal debt limit and reduce government spending, a bipartisan committee was established to identify up to \$1.5 trillion in cuts to federal programs. On November 21, 2011, the joint committee announced that it would not reach an agreement by the prescribed deadline, which will trigger an automatic \$1.2 trillion in additional spending cuts in the absence of further legislative action. Half of the automatic reductions would come from lowering the caps imposed on domestic discretionary spending and cutting domestic entitlement programs, including reductions in payments to Medicare providers. Government research funding could also be impacted as part of any deficit reduction. Any such reductions in government healthcare spending or research funding could result in reduced demand for our products or additional pricing pressure.

#### Price volatility could adversely affect costs associated with our operations.

Our results of operations could be negatively impacted by price volatility in the cost of raw materials, components, freight and energy. In particular, BD purchases supplies of resins, which are oil-based components used in the manufacture of certain products. Any significant increases in resin purchase costs could impact future operating results. Increases in the price of oil can also increase BD s costs for packaging and transportation. New laws or regulations adopted in response to climate change could also increase energy costs and the costs of certain raw materials and components. These cost increases may adversely affect our profitability.

# BD s future growth is dependent upon the development of new products, and there can be no assurance that such products will be developed.

A significant element of our strategy is to increase revenue growth by focusing on products that deliver greater benefits to patients, healthcare workers and researchers. The development of these products requires significant research and development, clinical trials and regulatory approvals. The results of our product development efforts may be affected by a number of factors, including BD s ability to innovate, develop and manufacture new products, complete clinical trials, obtain regulatory approvals and reimbursement in the United States and abroad, or gain and maintain market approval of our products. In addition, patents attained by others can preclude or delay our commercialization of a product. There can be no assurance that any products now in development or that we may seek to develop in the future will achieve technological feasibility, obtain regulatory approval, or gain market acceptance.

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#### We cannot guarantee that any of BD s strategic acquisitions, investments or alliances will be successful.

As part of our strategy to increase revenue growth, we seek to supplement our internal growth through strategic acquisitions, investments and alliances. Such transactions are inherently risky. The success of any acquisition, investment or alliance may be affected by a number of factors, including our ability to properly assess and value the potential business opportunity or to successfully integrate any business we may acquire into our existing business. There can be no assurance that any past or future transaction will be successful.

#### The medical technology industry is very competitive.

The medical technology industry is subject to rapid technological changes, and we face significant competition across our product lines and in each market in which our products are sold. We face this competition from a wide range of companies. These include large medical device companies, some of which may have greater financial and marketing resources than we do. We also face competition from firms that are more specialized than we are with respect to particular markets. Other firms engaged in the distribution of medical technology products have become manufacturers of medical devices and instruments as well. In some instances, competitors, including pharmaceutical companies, also offer, or are attempting to develop, alternative therapies for disease states that may be delivered without a medical device. The development of new or improved products, processes or technologies by other companies (such as needle-free injection technology) may render our products or proposed products obsolete or less competitive. In addition, increasing customer demand for more environmentally-friendly products is creating another basis on which BD must compete. The entry into the market of manufacturers located in China and other low-cost manufacturing locations is also creating pricing pressure, particularly in developing markets. Some competitors have also established manufacturing sites or have contracted with suppliers located in these countries as a means to lower their costs. New entrants may also appear, particularly from these low-cost countries.

#### Consolidation in the healthcare industry could adversely affect BD s future revenues and operating income.

The medical technology industry has experienced a significant amount of consolidation. As a result of this consolidation, competition to provide goods and services to customers has increased. In addition, group purchasing organizations and integrated health delivery networks have served to concentrate purchasing decisions for some customers, which has also placed pricing pressure on medical device suppliers. Further consolidation in the industry could exert additional pressure on the prices of our products.

#### The international operations of BD s business may subject BD to certain business risks.

BD operations outside the United States subject BD to certain risks, including the effects of fluctuations in foreign currency exchange (discussed above); the effects of local economic conditions; changes in foreign regulatory requirements; local product preferences; difficulty in establishing, staffing and managing foreign operations; differing labor regulations; changes in tax laws; potential political instability; trade barriers; weakening or loss of the protection of intellectual property rights in some countries; and restrictions on the transfer of capital across borders. The success of our operations outside the United States will depend, in part, on our ability to acquire or form and maintain alliances with local companies and make necessary infrastructure enhancements to, among other things, our production facilities and distribution networks.

# Reductions in customers research budgets or government funding may adversely affect our BD Biosciences segment.

Our BD Biosciences segment sells products to researchers at pharmaceutical and biotechnology companies, academic institutions, government laboratories and private foundations. Research and development spending of our customers

can fluctuate based on spending priorities and general economic conditions. A number of these customers are also dependent for their funding upon grants from U.S. government agencies, such as the U.S. National Institutes of Health ( NIH ) and agencies in other countries. The level of government funding of research and development is unpredictable. There have been instances where NIH

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grants have been frozen or otherwise unavailable for extended periods. The availability of governmental research funding may also continue to be adversely affected by the current economic downturn. Any reduction or delay in governmental funding could cause our customers to delay or forego purchases of our products.

# A reduction or interruption in the supply of certain raw materials and components would adversely affect BD s manufacturing operations and related product sales.

BD purchases many different types of raw materials and components. Certain raw materials (primarily related to the BD Biosciences segment) and components are not available from multiple sources. In addition, for quality assurance, cost-effectiveness and other reasons, BD elects to purchase certain raw materials and components from sole suppliers. The supply of these materials can be disrupted for a number of reasons, including current economic conditions as described above. While we work with suppliers to ensure continuity of supply, no assurance can be given that these efforts will be successful. In addition, where there are regulatory requirements relating to the qualification of suppliers, we may not be able to establish additional or replacement sources on a timely basis. The termination, reduction or interruption in supply of these sole-sourced raw materials and components could impact our ability to manufacture and sell certain of our products.

# Interruption of our manufacturing operations could adversely affect BD s future revenues and operating income.

We have manufacturing sites all over the world. In addition, in some instances, the manufacturing of certain of our product lines is concentrated in one or more of our plants. As a result, weather, natural disasters (including pandemics), terrorism, political change, failure to follow specific internal protocols and procedures, equipment malfunction, environmental factors or damage to one or more of our facilities could adversely affect our ability to manufacture our products.

#### BD is subject to a number of pending lawsuits.

BD is a defendant in a number of pending lawsuits, including purported class action lawsuits for, among other things, alleged antitrust violations and patent infringement, and could be subject to additional lawsuits in the future. A more detailed description of these lawsuits is contained in Item 3. Legal Proceedings. Given the uncertain nature of litigation generally, we are not able in all cases to estimate the amount or range of loss that could result from an unfavorable outcome of the litigation to which we are a party. In view of these uncertainties, we could incur charges in excess of any currently established accruals and, to the extent available, excess liability insurance. Any such future charges, individually or in the aggregate, could adversely affect BD s results of operations and cash flows.

#### BD is subject to extensive regulation.

BD is subject to extensive regulation by the FDA pursuant to the Federal Food, Drug and Cosmetic Act, by comparable agencies in foreign countries, and by other regulatory agencies and governing bodies. Most of BD s products must receive clearance or approval from the FDA or counterpart regulatory agencies in other countries before they can be marketed or sold. The process for obtaining marketing approval or clearance may take a significant period of time and require the expenditure of substantial resources, and these have been increasing due to increased requirements from the FDA for supporting data for submissions. The process may also require changes to our products or result in limitations on the indicated uses of the products. Also, governmental agencies may impose new requirements regarding registration, labeling or prohibited materials that may require us to modify or re-register products already on the market or otherwise impact our ability to market our products in those countries. Once clearance or approval has been obtained for a product, there is an obligation to ensure that all applicable FDA and other regulatory requirements continue to be met.

Following the introduction of a product, these agencies also periodically review our manufacturing processes and product performance. Our failure to comply with the applicable good manufacturing practices, adverse event reporting, clinical trial and other requirements of these agencies could delay or prevent the

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production, marketing or sale of our products and result in fines, delays or suspensions of regulatory clearances, closure of manufacturing sites, seizures or recalls of products and damage to our reputation. Recent changes in enforcement practice by the FDA and other agencies have resulted in increased enforcement activity, which increases the compliance risk for BD and other companies in our industry.

#### Product defects could adversely affect the results of our operations.

The design, manufacture and marketing of medical devices involve certain inherent risks. Manufacturing or design defects, unanticipated use of our products, or inadequate disclosure of risks relating to the use of our products can lead to injury or other adverse events. These events could lead to recalls or safety alerts relating to our products (either voluntary or required by the FDA or similar governmental authorities in other countries), and could result, in certain cases, in the removal of a product from the market. A recall could result in significant costs, as well as negative publicity and damage to our reputation that could reduce demand for our products. Personal injuries relating to the use of our products can also result in product liability claims being brought against us. In some circumstances, such adverse events could also cause delays in new product approvals.

#### We may experience difficulties implementing our enterprise resource planning system.

We are engaged in a project to upgrade our enterprise resource planning ( ERP ) system. Our ERP system is critical to our ability to accurately maintain books and records, record transactions, provide important information to our management and prepare our financial statements. The design and implementation of the new ERP system has required, and will continue to require, the investment of significant financial and human resources. The total cost needed to implement the new ERP system may turn out to be more than we currently anticipate. In addition, we may not be able to successfully implement the new ERP system without experiencing difficulties. Any disruptions, delays or deficiencies in the design and implementation of the new ERP system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business.

#### Our operations are dependent in part on patents and other intellectual property assets.

Many of BD s businesses rely on patent, trademark and other intellectual property assets. While we do not believe that the loss of any one patent or other intellectual property asset would materially adversely affect BD operations, these intellectual property assets, in the aggregate, are of material importance to our business. BD can lose the protection afforded by these intellectual property assets through patent expirations, legal challenges or governmental action. Patents attained by competitors, particularly as patents on our products expire, may also adversely affect our competitive position. The loss of a significant portion of our portfolio of intellectual property assets may have an adverse effect on our earnings, financial condition or cash flows. In addition, competitors may claim that BD products infringe upon their intellectual property. Resolving any intellectual property claim can be costly and time-consuming.

#### Natural disasters, war and other events could adversely affect BD s future revenues and operating income.

Natural disasters (including pandemics), war, terrorism, labor disruptions and international conflicts, and actions taken by the United States and other governments, or by our customers or suppliers, in response to such events, could cause significant economic disruption and political and social instability in the United States and in areas outside of the United States in which we operate. These events could result in decreased demand for our products, adversely affect our manufacturing and distribution capabilities, or increase the costs for or cause interruptions in the supply of materials from our suppliers.

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#### We need to attract and retain key employees to be competitive.

Our ability to compete effectively depends upon our ability to attract and retain executives and other key employees, including people in technical, marketing, sales and research positions. Competition for experienced employees, particularly for persons with specialized skills, can be intense. BD s ability to recruit such talent will depend on a number of factors, including compensation and benefits, work location and work environment. If we cannot effectively recruit and retain qualified executives and employees, our business could be adversely affected.

#### Item 1B. Unresolved Staff Comments.

None.

#### Item 2. Properties.

BD s executive offices are located in Franklin Lakes, New Jersey. As of November 1, 2011, BD owned and leased 180 facilities throughout the world comprising approximately 17,081,296 square feet of manufacturing, warehousing, administrative and research facilities. The U.S. facilities, including Puerto Rico, comprise approximately 7,018,934 square feet of owned and 2,416,594 square feet of leased space. The international facilities comprise approximately 6,197,567 square feet of owned and 1,448,201 square feet of leased space. Sales offices and distribution centers included in the total square footage are also located throughout the world.

Operations in each of BD s business segments are conducted at both U.S. and international locations. Particularly in the international marketplace, facilities often serve more than one business segment and are used for multiple purposes, such as administrative/sales, manufacturing and/or warehousing/distribution. BD generally seeks to own its manufacturing facilities, although some are leased. The following table summarizes property information by business segment.

Sites	Corporate	BD Biosciences	BD Diagnostics	BD Medical	Mixed(A)	Total
Leased	3	10	8	59	46	126
Owned	2	6	13	24	9	54
Total	5	16	21	83	55	180
Square feet	1,003,608	1,141,319	2,747,797	7,507,547	4,681,025	17,081,296

#### (A) Facilities used by more than one business segment.

BD believes that its facilities are of good construction and in good physical condition, are suitable and adequate for the operations conducted at those facilities, and are, with minor exceptions, fully utilized and operating at normal capacity.

The U.S. facilities are located in Arizona, California, Connecticut, Florida, Georgia, Illinois, Indiana, Maryland, Massachusetts, Michigan, Minnesota, Nebraska, New Jersey, North Carolina, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Washington, DC, Washington, Wisconsin and Puerto Rico.

The international facilities are grouped as follows:

*Europe*, which includes facilities in Austria, Belgium, the Czech Republic, Denmark, England, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Kenya, Norway, Poland, Russia, Saudi Arabia, South Africa, Spain, Sweden, Switzerland, Turkey and the United Arab Emirates.

Japan.

*Asia Pacific*, which includes facilities in Australia, China, India, Indonesia, Malaysia, New Zealand, Pakistan, the Philippines, Singapore, South Korea, Taiwan, Thailand and Vietnam.

Latin America, which includes facilities in Argentina, Brazil, Chile, Colombia, Costa Rica, Mexico, Peru and Venezuela.

Canada.

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#### Item 3. Legal Proceedings.

BD is named as a defendant in the following purported class action suits brought on behalf of distributors and other entities that purchase BD s products (the Distributor Plaintiffs ), alleging that BD violated federal antitrust laws, resulting in the charging of higher prices for BD s products to the plaintiffs and other purported class members.

Case	Court	Date Filed
Louisiana Wholesale Drug Company, Inc., et. al. vs. Becton Dickinson and Company	U.S. District Court, Newark, New Jersey	March 25, 2005
SAJ Distributors, Inc. et. al. vs. Becton	U.S. District Court, Eastern District of	September 6, 2005
Dickinson & Co.	Pennsylvania	
Dik Drug Company, et. al. vs. Becton,	U.S. District Court, Newark, New Jersey	September 12, 2005
Dickinson and Company		
American Sales Company, Inc. et. al. vs.	U.S. District Court, Eastern District of	October 3, 2005
Becton, Dickinson & Co.	Pennsylvania	
Park Surgical Co. Inc. et. al. vs. Becton,	U.S. District Court, Eastern District of	October 26, 2005
Dickinson and Company	Pennsylvania	