JOHNSON & JOHNSON

Form 10-K

February 20, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OF

THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 30, 2018

Commission file number

1-3215

JOHNSON & JOHNSON

(Exact name of registrant as specified in its charter) New Jersey 22-1024240

(State of incorporation) (I.R.S. Employer Identification No.)

One Johnson & Johnson Plaza

08933

New Brunswick, New Jersey

(Address of principal executive offices) (Zip Code)

p Code)

Registrant's telephone number, including area code: (732) 524-0400

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT Title of each class

Name of each exchange on which registered

Common Stock, Par Value \$1.00
4.75% Notes Due November 2019
0.250% Notes Due January 2022
0.650% Notes Due May 2024
5.50% Notes Due November 2024
1.150% Notes Due November 2028
1.650% Notes Due May 2035
New York Stock Exchange

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 Exchange 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 Exchange Act 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 every Interactive Data File required to be submitted 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 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. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or 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 b Accelerated filer o

Non-accelerated filer o Smaller reporting company o

Emerging growth company o

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. o

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

The aggregate market value of the Common Stock held by non-affiliates computed by reference to the price at which the Common Stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was approximately \$325 billion.

On February 15, 2019, there were 2,663,138,579 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Parts I and III: Portions of registrant's proxy statement for its 2019 annual meeting of shareholders filed within 120 days after the close of the registrant's fiscal year (the "Proxy Statement"), are incorporated by reference to this report on Form 10-K (this "Report").

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This Annual Report on Form 10-K and Johnson & Johnson's other publicly available documents contain "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Management and representatives of Johnson & Johnson and its subsidiaries (the "Company") also may from time to time make forward-looking statements. Forward-looking statements do not relate strictly to historical or current facts and reflect management's assumptions, views, plans, objectives and projections about the future. Forward-looking statements may be identified by the use of words such as "plans," "expects," "will," "anticipates," "estimates" and other words of similar meaning in conjunction with, among other things: discussions of future operations; expected operating results and financial performance; impact of planned acquisitions and dispositions; the Company's strategy for growth; product development; regulatory approvals; market position and expenditures.

Because forward-looking statements are based on current beliefs, expectations and assumptions regarding future events, they are subject to uncertainties, risks and changes that are difficult to predict and many of which are outside of the Company's control. Investors should realize that if underlying assumptions prove inaccurate, or known or unknown risks or uncertainties materialize, the Company's actual results and financial condition could vary materially from expectations and projections expressed or implied in its forward-looking statements. Investors are therefore cautioned not to rely on these forward-looking statements. Risks and uncertainties include, but are not limited to:

Risks Related to Product Development, Market Success and Competition

Challenges and uncertainties inherent in innovation and development of new and improved products and technologies on which the Company's continued growth and success depend, including uncertainty of clinical outcomes, additional analysis of existing clinical data, obtaining regulatory approvals, health plan coverage and customer access, and initial and continued commercial success;

Challenges to the Company's ability to obtain and protect adequate patent and other intellectual property rights for new and existing products and technologies in the United States and other important markets;

The impact of patent expirations, typically followed by the introduction of competing biosimilars and generics and resulting revenue and market share losses;

Increasingly aggressive and frequent challenges to the Company's patents by competitors and others seeking to launch competing generic, biosimilar or other products and increased receptivity of courts, the United States Patent and Trademark Office and other decision makers to such challenges, potentially resulting in loss of market exclusivity and rapid decline in sales for the relevant product sooner than expected;

• Competition in research and development of new and improved products, processes and technologies, which can result in product and process obsolescence;

Competition to reach agreement with third parties for collaboration, licensing, development and marketing agreements for products and technologies;

Competition based on cost-effectiveness, product performance, technological advances and patents attained by competitors; and

Allegations that the Company's products infringe the patents and other intellectual property rights of third parties, which could adversely affect the Company's ability to sell the products in question and require the payment of money damages and future royalties.

Risks Related to Product Liability, Litigation and Regulatory Activity

contracting strategies;

Product efficacy or safety concerns, whether or not based on scientific evidence, potentially resulting in product withdrawals, recalls, regulatory action on the part of the United States Food and Drug Administration (or international counterparts), declining sales, reputational damage, increased litigation expense and share price impact; Impact, including declining sales and reputational damage, of significant litigation or government action adverse to the Company, including product liability claims and allegations related to pharmaceutical marketing practices and

Impact of an adverse judgment or settlement and the adequacy of reserves related to legal proceedings, including patent litigation, product liability, personal injury claims, securities class actions, government investigations,

employment and other legal proceedings;

Increased scrutiny of the health care industry by government agencies and state attorneys general resulting in investigations and prosecutions, which carry the risk of significant civil and criminal penalties, including, but not limited to, debarment from government business;

Failure to meet compliance obligations in the McNEIL-PPC, Inc. Consent Decree or any other compliance agreements with governments or government agencies, which could result in significant sanctions;

Potential changes to applicable laws and regulations affecting United States and international operations, including relating to: approval of new products; licensing and patent rights; sales and promotion of health care products; access to, and reimbursement and pricing for, health care products and services; environmental protection and sourcing of raw materials;

Compliance with local regulations and laws that may restrict the Company's ability to manufacture or sell its products in relevant markets including, requirements to comply with medical device reporting regulations and other requirements such as the European Union's Medical Devices Regulation;

Changes in domestic and international tax laws and regulations, including changes related to The Tax Cuts and Jobs Act in the United States, the Federal Act on Tax Reform and AHV Financing in Switzerland, increasing audit scrutiny by tax authorities around the world and exposures to additional tax liabilities potentially in excess of existing reserves; and

Issuance of new or revised accounting standards by the Financial Accounting Standards Board and regulations by the Securities and Exchange Commission.

Risks Related to the Company's Strategic Initiatives and Healthcare Market Trends

Pricing pressures resulting from trends toward health care cost containment, including the continued consolidation among health care providers and other market participants, trends toward managed care, the shift toward governments increasingly becoming the primary payers of health care expenses, significant new entrants to the health care markets seeking to reduce costs and government pressure on companies to voluntarily reduce costs and price increases; Restricted spending patterns of individual, institutional and governmental purchasers of health care products and services due to economic hardship and budgetary constraints;

Challenges to the Company's ability to realize its strategy for growth including through externally sourced innovations, such as development collaborations, strategic acquisitions, licensing and marketing agreements, and the potential heightened costs of any such external arrangements due to competitive pressures;

The potential that the expected strategic benefits and opportunities from any planned or completed acquisition or divestiture by the Company may not be realized or may take longer to realize than expected; and

The potential that the expected benefits and opportunities related to past and ongoing restructuring actions may not be realized or may take longer to realize than expected.

Risks Related to Economic Conditions, Financial Markets and Operating Internationally

Market conditions and the possibility that the Company's share repurchase program may be delayed, suspended or discontinued;

Impact of inflation and fluctuations in interest rates and currency exchange rates and the potential effect of such fluctuations on revenues, expenses and resulting margins;

Potential changes in export/import and trade laws, regulations and policies of the United States and other countries, including any increased trade restrictions or tariffs and potential drug reimportation legislation;

The impact on international operations from financial instability in international economies, sovereign risk, possible imposition of governmental controls and restrictive economic policies, and unstable international governments and legal systems;

Changes to global climate, extreme weather and natural disasters that could affect demand for the Company's products and services, cause disruptions in manufacturing and distribution networks, alter the availability of goods and services within the supply chain, and affect the overall design and integrity of the Company's products and operations; and

• The impact of armed conflicts and terrorist attacks in the United States and other parts of the world including social and economic disruptions and instability of financial and other markets.

Risks Related to Supply Chain and Operations

Difficulties and delays in manufacturing, internally through third party providers or otherwise within the supply chain, that may lead to voluntary or involuntary business interruptions or shutdowns, product shortages, withdrawals or suspensions of products from the market, and potential regulatory action;

Interruptions and breaches of the Company's information technology systems or those of the Company's vendors which, could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action;

Reliance on global supply chains and production and distribution processes that are complex and subject to increasing regulatory requirements that may adversely affect supply, sourcing and pricing of materials used in the Company's products; and

The potential that the expected benefits and opportunities related to restructuring actions contemplated for the global supply chain may not be realized or may take longer to realize than expected, including due to any required approvals from applicable regulatory authorities. Disruptions associated with the announced global supply chain actions may adversely affect supply and sourcing of materials used in the Company's products.

Investors also should carefully read the Risk Factors described in Item 1A of this Annual Report on Form 10-K for a description of certain risks that could, among other things, cause the Company's actual results to differ materially from those expressed in its forward-looking statements. Investors should understand that it is not possible to predict or identify all such factors and should not consider the risks described above and in Item 1A to be a complete statement of all potential risks and uncertainties. The Company does not undertake to publicly update any forward-looking statement that may be made from time to time, whether as a result of new information or future events or developments.

PART I

Item 1. BUSINESS

General

Johnson & Johnson and its subsidiaries (the Company) have approximately 135,100 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. Johnson & Johnson is a holding company, which has more than 260 operating companies conducting business in virtually all countries of the world. The Company's primary focus is products related to human health and well-being. Johnson & Johnson was incorporated in the State of New Jersey in 1887.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Company's three business segments: Consumer, Pharmaceutical and Medical Devices. Within the strategic parameters provided by the Committee, senior management groups at U.S. and international operating companies are each responsible for their own strategic plans and the day-to-day operations of those companies. Each subsidiary within the business segments is, with limited exceptions, managed by residents of the country where located. Segments of Business

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. Additional information required by this item is incorporated herein by reference to the narrative and tabular descriptions of segments and operating results under: "Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition" of this Report; and Note 18 "Segments of Business and Geographic Areas" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Consumer

The Consumer segment includes a broad range of products used in the baby care, oral care, beauty, over-the-counter pharmaceutical, women's health and wound care markets. Baby Care includes the JOHNSON'S line of products. Oral Care includes the LISTERINE® product line. Major brands in Beauty include the AVEENO®; CLEAN & CLEAR®; DABAOTM; JOHNSON & Mult; LE PETITE MARSEILLAIS®; NEUTROGENA® and OGX® product lines. Over-the-counter medicines include the broad family of TYLENOL® acetaminophen products; SUDAFED® cold, flu and allergy products; BENADRYL® and ZYRTEC® allergy products; MOTRIN® IB ibuprofen products; and the PEPCID® line of acid reflux products. Major brands in Women's Health outside of North America are STAYFREE® and CAREFREE® sanitary pads and o.b.® tampon brands. Wound Care brands include the BAND-AID® Brand Adhesive Bandages and NEOSPORIN® First Aid product lines. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world.

The Pharmaceutical segment is focused on six therapeutic areas: Immunology (e.g., rheumatoid arthritis, inflammatory bowel disease and psoriasis), Infectious Diseases and Vaccines (e.g., HIV/AIDS), Neuroscience (e.g.,

mood disorders, neurodegenerative disorders and schizophrenia), Oncology (e.g., prostate cancer and hematologic malignancies), Cardiovascular and Metabolism (e.g., thrombosis and diabetes) and Pulmonary Hypertension (e.g., Pulmonary Arterial Hypertension). Medicines in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. Key products in the Pharmaceutical segment include: REMICADE® (infliximab), a treatment for a number of immune-mediated inflammatory diseases; SIMPONI® (golimumab), a subcutaneous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis and moderately active to severely active ulcerative colitis; SIMPONI ARIA® (golimumab), an intravenous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis and active ankylosing spondylitis; STELARA® (ustekinumab), a treatment for adults and children with moderate to severe plaque psoriasis, for adults with active psoriatic arthritis, and for adults with moderately to severely active Crohn's disease; TREMFYA® (guselkumab), a treatment for adults with moderate to severe plaque psoriasis; EDURANT® (rilpivirine), INTELENCE® (etravirine), PREZISTA® (darunavir) and PREZCOBIX®/REZOLSTA® (darunavir/cobicistat), antiretroviral medicines for the treatment of human immunodeficiency virus (HIV-1) in combination with other antiretroviral products and SYMTUZA® (darunavir/cobicistat/emtricitabine/tenofovir alafenamide), a once-daily single tablet regimen for the treatment of HIV; CONCERTA® (methylphenidate HCl) extended-release tablets CII, a treatment for attention deficit hyperactivity

disorder; INVEGA SUSTENNA®/XEPLION® (paliperidone palmitate), for the treatment of schizophrenia and schizoaffective disorder in adults; INVEGA TRINZA®/TREVICTA® (paliperidone palmitate), for the treatment of schizophrenia in patients after they have been adequately treated with INVEGA SUSTENNA® for at least four months; RISPERDAL CONSTA® (risperidone long-acting injection), for the treatment of schizophrenia and the maintenance treatment of Bipolar 1 Disorder in adults; ZYTIGA® (abiraterone acetate), a treatment for metastatic castration-

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resistant prostate cancer (CRPC) and metastatic high-risk castration-sensitive prostate cancer; IMBRUVICA® (ibrutinib), a treatment for certain B-cell malignancies, or blood cancers, chronic graft versus host disease and Waldenström's Macroglobulinemia; DARZALEX® (daratumumab), a treatment for relapsed/refractory multiple myeloma; VELCADE® (bortezomib), a treatment for multiple myeloma mantle cell lymphoma; PROCRIT®/EPREX® (epoetin alfa), a treatment for chemotherapy-induced anemia and patients with chronic kidney disease; XARELTO® (rivaroxaban), an oral anticoagulant for the prevention of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE) in patients undergoing hip or knee replacement surgery, to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, and for the treatment and reduction of risk of recurrence of DVT and PE; INVOKANA® (canagliflozin), for the treatment of adults with type 2 diabetes; INVOKAMET®/VOKANAMET® (canagliflozin/metformin HCl), a combination therapy of fixed doses of canagliflozin and metformin hydrochloride for the treatment of adults with type 2 diabetes; and INVOKAMET® XR (canagliflozin/metformin hydrochloride extended-release), a once-daily, fixed-dose combination therapy of canagliflozin and metformin hydrochloride extended-release, for the treatment of adults with type 2 diabetes; OPSUMIT® (macitentan) as monotherapy or in combination, indicated for the long-term treatment of pulmonary arterial hypertension (PAH); UPTRAVI® (selexipag), the only approved oral, selective IP receptor agonist targeting a prostacyclin pathway in PAH. Many of these medicines were developed in collaboration with strategic partners or are licensed from other companies and maintain active lifecycle development programs.

Medical Devices

The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, interventional solutions (cardiovascular and neurovascular), diabetes care (divested in the fiscal fourth quarter of 2018) and eye health fields. These products are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics. They include orthopaedic products; general surgery, biosurgical, endomechanical and energy products; electrophysiology products to treat cardiovascular disease; sterilization and disinfection products to reduce surgical infection; and vision products such as disposable contact lenses and ophthalmic products related to cataract and laser refractive surgery. Geographic Areas

The business of Johnson & Johnson is conducted by more than 260 operating companies located in more than 60 countries, including the U.S., which sell products in virtually all countries throughout the world. The products made and sold in the international business include many of those described above under "– Segments of Business – Consumer," "– Pharmaceutical" and "– Medical Devices." However, the principal markets, products and methods of distribution in the international business vary with the country and the culture. The products sold in international business include those developed in the U.S. and by subsidiaries abroad.

Investments and activities in some countries outside the U.S. are subject to higher risks than comparable U.S. activities because the investment and commercial climate may be influenced by financial instability in international economies, restrictive economic policies and political and legal system uncertainties.

Raw Materials

Raw materials essential to the Company's business are generally readily available from multiple sources. Where there are exceptions, the temporary unavailability of those raw materials would not likely have a material adverse effect on the financial results of the Company.

Patents

The Company's subsidiaries have made a practice of obtaining patent protection on their products and processes where possible. They own, or are licensed under, a significant number of patents in the U.S. and other countries relating to their products, product uses, formulations and manufacturing processes, which in the aggregate are believed to be of material importance to the Company in the operation of its businesses. The Company's subsidiaries face patent challenges from third parties, including challenges seeking to manufacture and market generic and biosimilar versions of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. Significant legal proceedings and claims involving the Company's patent and other intellectual property are described in Note 21, "Legal Proceedings—Intellectual Property" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Sales of the Company's 2rd largest product, STELARA® (ustekinumab), accounted for approximately 6.3% of the Company's total revenues for fiscal 2018. Accordingly, the patents related to this product are believed to be material to the Company.

There is one set of granted patents related specifically to STELARA®. This set of patents is owned by Janssen Biotech, Inc., a wholly-owned subsidiary of Johnson & Johnson. These patents are in force in the U.S. and many countries outside the

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United States. In the U.S., the latest projected expiration date for patents in this set is 2023 due to a patent term extension. In Europe, the latest projected expiration date for patents in this set is 2024 due to a Supplemental Patent Certificate (patent term extension). In most other countries, the latest projected expiration date is 2021. In addition to competing in the immunology market with STELARA®, the Company is currently marketing SIMPONI® (golimumab) and SIMPONI ARIA® (golimumab), next generation immunology products with remaining patent lives of up to six years. The Company also markets REMICADE® (infliximab) in the immunology market which is the Company's largest product. Patents on this product have expired and the Food and Drug Administration approved the first infliximab biosimilar for sale in the U.S. in 2016, and a number of such products have been launched since then. For a more extensive description of legal matters regarding the patents related to REMICADE®, see Note 21 "Legal Proceedings - Intellectual Property - Pharmaceutical - REMICADE® Related Cases" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Trademarks

The Company's subsidiaries have made a practice of selling their products under trademarks and of obtaining protection for these trademarks by all available means. These trademarks are protected by registration in the U.S. and other countries where such products are marketed. The Company considers these trademarks in the aggregate to be of material importance in the operation of its businesses.

Seasonality

Worldwide sales do not reflect any significant degree of seasonality; however, spending has been heavier in the fourth quarter of each year than in other quarters. This reflects increased spending decisions, principally for advertising and research and development activity.

Competition

In all of their product lines, the Company's subsidiaries compete with companies both locally and globally. Competition exists in all product lines without regard to the number and size of the competing companies involved. Competition in research, both internally and externally sourced, involving the development and the improvement of new and existing products and processes, is particularly significant. The development of new and innovative products, as well as protecting the underlying intellectual property of the Company's product portfolio, is important to the Company's success in all areas of its business. The competitive environment requires substantial investments in continuing research. In addition, the development and maintenance of customer demand for the Company's consumer products involve significant expenditures for advertising and promotion.

Environment

The Company is subject to a variety of U.S. and international environmental protection measures. The Company believes that its operations comply in all material respects with applicable environmental laws and regulations. The Company's compliance with these requirements did not change during the past year, and is not expected to have a material effect upon its capital expenditures, cash flows, earnings or competitive position.

Regulation

The Company's businesses are subject to varying degrees of governmental regulation in the countries in which operations are conducted, and the general trend is toward increasingly stringent regulation. In the U.S., the drug, device and cosmetic industries have long been subject to regulation by various federal and state agencies, primarily as to product safety, efficacy, manufacturing, advertising, labeling and safety reporting. The exercise of broad regulatory powers by the U.S. Food and Drug Administration (the FDA) continues to result in increases in the amounts of testing and documentation required for FDA approval of new drugs and devices and a corresponding increase in the expense of product introduction. Similar trends are also evident in major markets outside of the U.S. The new medical device regulatory framework and the new privacy regulations in Europe are examples of such increased regulation.

The costs of human health care have been and continue to be a subject of study, investigation and regulation by governmental agencies and legislative bodies around the world. In the U.S., attention has been focused on drug prices and profits and programs that encourage doctors to write prescriptions for particular drugs, or to recommend, use or purchase particular medical devices. Payers have become a more potent force in the market place and increased attention is being paid to drug and medical device pricing, appropriate drug and medical device utilization and the quality and costs of health care generally.

U.S. government agencies continue to implement the extensive requirements of the Patient Protection and Affordable Care Act (the ACA). These have both positive and negative impacts on the U.S. healthcare industry with much remaining uncertain as to how various provisions of the ACA, and potential modification or repeal of ACA provisions, will ultimately affect the industry.

The regulatory agencies under whose purview the Company operates have administrative powers that may subject it to actions such as product withdrawals, recalls, seizure of products and other civil and criminal sanctions. In some cases, the Company's subsidiaries may deem it advisable to initiate product recalls.

In addition, business practices in the health care industry have come under increased scrutiny, particularly in the U.S., by government agencies and state attorneys general, and resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Further, the Company relies on global supply chains, and production and distribution processes, that are complex, are subject to increasing regulatory requirements, and may be faced with unexpected changes such as those resulting from Brexit, that may affect sourcing, supply and pricing of materials used in the Company's products. These processes also are subject to lengthy regulatory approvals.

Available Information

The Company's main corporate website address is www.jnj.com. All of the Company's SEC filings are also available on the Company's website at www.investor.jnj.com/sec.cfm, as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at www.sec.gov. In addition, the written charters of the Audit Committee, the Compensation & Benefits Committee, the Nominating & Corporate Governance Committee, the Regulatory Compliance Committee and the Science, Technology & Sustainability Committee of the Board of Directors and the Company's Principles of Corporate Governance, Code of Business Conduct (for employees),