As filed with the Securities and Exchange Commission on June 27, 2019

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

FORM 20-F

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR 12(g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended March 31, 2019

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

OR

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report
Commission file number: 001-38757

Takeda Yakuhin Kogyo Kabushiki Kaisha
(Exact name of registrant as specified in its charter)

Takeda Pharmaceutical Company Limited
(Translation of registrant's name into English)

Japan	**1-1, Nihonbashi-Honcho 2-Chome Chuo-ku, Tokyo 103-8668, Japan**
(Jurisdiction of incorporation or organization)	**(Address of principal executive offices)**

Costa Saroukos
1-1, Nihonbashi-Honcho 2-Chome
Chuo-ku, Tokyo 103-8668, Japan
Tel: +81 3 3278-2306
Fax: +81 3 3278-2268
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of Each Class	Trading Symbols	Name of Each Exchange On Which Registered
American Depositary Shares Representing Common Stock	**TAK**	**New York Stock Exchange**
Common Stock, no par value*		

* Listed not for trading, but only in connection with the registration of the American Depositary Shares, pursuant to the requirements of the Securities and Exchange Commission.

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

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:
None

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

118,250,000 ADSs outstanding as of March 31, 2019

1,565,005,908 shares of common stock as of March 31, 2019

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

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. 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 the registrant has submitted electronically every interactive data file required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) 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 whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Emerging growth company ☐

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, 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. ☐

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐ International Financial Reporting Standards as issued by the International Accounting Standards Board ☒ Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. ☐ Item 17 ☐ Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

(APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PAST FIVE YEARS)

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes ☐ No ☐

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As used in this annual report, references to the "Company," "Takeda," "we," "us" and "our" are to Takeda Pharmaceutical Company Limited and, except as the context otherwise requires, its consolidated subsidiaries.

In this annual report, we present our audited consolidated financial statements as of March 31, 2018 and 2019 and for the fiscal years ended March 31, 2017, 2018 and 2019. Our consolidated financial statements are prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board ("IFRS"). The term IFRS also includes International Accounting Standards ("IAS") and the related interpretations of the committees (Standard Interpretations Committee and International Financial Reporting Interpretations Committee).

As used in this annual report, "yen," "¥" or "JPY" means the lawful currency of Japan, "U.S. dollar," "$" or "USD" means the lawful currency of the United States of America ("U.S."), "pound sterling" or "£" means the lawful currency of the United Kingdom and "euro," "€" or "EUR" means the lawful currency of the member states of the European Monetary Union.

As used in this annual report, "ADS" means an American Depositary Share, representing 0.5 shares of the Company's common stock, and "ADR" means an American Depositary Receipt evidencing one or more ADSs. See "Item 12. Description of Securities Other Than Equity Securities—D. American Depositary Shares."

As used in this annual report, except as the context otherwise requires, the "Companies Act" means the Companies Act of Japan.

Amounts shown in this annual report have been rounded to the nearest indicated digit unless otherwise specified. In tables and graphs with rounded figures, sums may not add up due to rounding.

Special Note Regarding Forward-Looking Statements

This annual report contains forward-looking statements. These statements appear in a number of places in this annual report and include statements regarding the intent, belief, or current and future expectations of our management with respect to our business, financial condition and results of operations. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "intend," "project," "plan," "aim," "seek," "target," "anticipate," "believe," "estimate," "predict," "potential" or the negative of these terms or other similar terminology. These statements are not guarantees of future performance and are subject to various risks and uncertainties. Actual results, performance or achievements, or those of our industry, may differ materially from any future results, performance or achievements expressed or implied by these forward-looking statements. In addition, these forward-looking statements are necessarily dependent upon assumptions, estimates and data that may be incorrect or imprecise and involve known and unknown risks and uncertainties. These forward-looking statements involve statements regarding:

- our ability to achieve the expected benefits of our acquisition of Shire plc (including, except as the context otherwise requires, its consolidated subsidiaries "Shire");
- our goals and strategies;
- our ability to develop and bring to market new products;
- expected changes in our revenue, costs, expenditures, operating income or other components of our results;
- expected changes in the pharmaceutical industry or in government policies and regulations relating to it;
- developments regarding or the outcome of any litigation or other legal, administrative, regulatory or governmental proceedings;
- information regarding competition within our industry; or
- the effect of economic, political, legislative or other developments on our business or results of operations.

Forward-looking statements regarding operating income and operating results are particularly subject to a variety of assumptions, some or all of which may not be realized. Accordingly, the forward-looking statements included in this annual report should not be interpreted as predictions or representations of future events or circumstances.

Potential risks and uncertainties include those identified and discussed in "Item 3. Key Information—D. Risk Factors," "Item 5. Operating and Financial Review and Prospects," "Item 4. Information on the Company" and elsewhere in this annual report. Given these risks and uncertainties, undue reliance should not be placed on any forward-looking statements, which speak only as of the date of this annual report. Except as required by law, we disclaim any obligation to update or review any forward-looking statements contained in this annual report, whether as a result of new information, future events or otherwise.

Item 1. Identity of Directors, Senior Management and Advisers

A. Directors and Senior Management.

Not applicable.

B. Advisers.

Not applicable.

C. Auditors.

Not applicable.

Item 2. Offer Statistics and Expected Timetable

A. Offer Statistics.

Not applicable.

B. Method and Expected Timetable.

Not applicable.

Item 3. Key Information

A. Selected Financial Data.

The following table presents selected financial information as of and for the years ended March 31, 2015, 2016, 2017, 2018 and 2019, derived from our consolidated financial statements. These financial statements are prepared in accordance with IFRS.

The selected consolidated financial information set forth below should be read in conjunction with Item 5. "Operating and Financial Review and Prospects" and our consolidated financial statements and notes thereto included in this annual report.

	For the fiscal year ended March 31,				
	2015	2016	2017	2018	2019
	(billions of yen, except share and per share data and where designated as U.S. dollar)				
Selected Statements of Operations Data:					
Revenue	¥ 1,777.8	¥ 1,807.4	¥ 1,732.1	¥ 1,770.5	¥ 2,097.2
Operating (loss) profit	(129.3)	130.8	155.9	241.8	205.0
Share of profit (loss) of investments accounted for using the equity method	1.3	(0.0)	(1.5)	(32.2)	(43.6)
(Loss) profit before tax	(145.4)	120.5	143.3	217.2	94.9
Net (loss) profit for the year	(143.0)	83.5	115.5	186.7	109.0
Net (loss) profit attributable to owners of the Company	(145.8)	80.2	114.9	186.9	109.1
Per share amounts					
Basic (losses) earnings	¥ (185.37)	¥ 102.26	¥ 147.15	¥ 239.35	¥ 113.50
Diluted (losses) earnings	(185.37)	101.71	146.26	237.56	112.86
Annual cash dividends	180.00	180.00	180.00	180.00	180.00
Cash dividends in U.S. dollars[(1)]	$ 1.50	$ 1.60	$ 1.62	$ 1.69	$ 1.63
Selected Statements of Financial Position Data:					
Cash and cash equivalents	¥ 652.1	¥ 451.4	¥ 319.5	¥ 294.5	¥ 702.1
Total assets	4,296.2	3,824.1	4,346.8	4,106.5	13,872.3
Total bonds and loans	729.4	768.2	1,144.9	985.7	5,751.0
Total liabilities	2,090.0	1,812.9	2,397.8	2,089.1	8,708.7
Total equity	2,206.2	2,011.2	1,949.0	2,017.4	5,163.6
Other Data:					
Number of shares outstanding at end of period (in thousands)	789,924	790,284	790,521	794,688	1,565,006

Note:

(1) Calculated using the Japanese yen—U.S. dollar exchange rate as of March 31 of each respective year, based on the noon buying rate in New York City for cable transfers in foreign currencies as certified for customs purposes by the Federal Reserve Bank of New York.

B. Capitalization and Indebtedness.

Not applicable.

C. Reasons for the Offer and Use of Proceeds.

Not applicable.

D. Risk Factors.

Any investment in our common stock or ADSs involves risk. Investors should carefully consider, in light of their own financial circumstances and investment objectives, the following risks before making an investment decision with respect to our common stock or ADSs. If any of the following risks actually occurs, it could have a material adverse effect on our business, financial condition, results of operations and future prospects, and the market value of our common stock or ADSs may be adversely affected.

The risks discussed below are those that we believe are material, but these risks and uncertainties may not be the only risks that we face. Additional risks that are not known to us at this time, or that are currently believed to be not material, could also have a material adverse effect on our business, financial condition, results of operations, future prospects and the market value of our common stock or ADSs.

Risks Relating to the Shire Acquisition

We may fail to realize the anticipated benefits of the Shire Acquisition and expect to continue to record significant expenses related to it.

On January 8, 2019, we acquired the entire issued and to-be-issued share capital of Shire pursuant to a Scheme of Arrangement under the laws of Jersey (the "Shire Acquisition"). The success of the Shire Acquisition depends on our ability to realize the anticipated growth opportunities and synergies leading to cost savings we expect from combining the companies' businesses. We will need to continue to devote significant time and resources to the reorganization of our personnel structure, enhancement of cost-efficiency and the strengthening of management and operational functions in order to realize the anticipated synergies of the Shire Acquisition. We expect to incur non-recurring cash costs totaling approximately $3.0 billion in connection with the integration of Shire in the first three fiscal years following the completion of the Shire Acquisition.

Furthermore, in connection with the Shire Acquisition and the application of our inventory policies to the acquired businesses, we recognized significant non-cash expenses relating to the unwinding of fair value adjustments to inventory as a component of cost of sales in the fiscal year ended March 31, 2019 and expect that such expenses will increase in future fiscal years. We also recorded significant intangible assets in connection with the Shire Acquisition and, as a result, amortization and impairment losses increased significantly in the fiscal year ended March 31, 2019, and are expected to continue to increase in the fiscal year ending March 31, 2020.

As a result of the non-recurring cash costs in connection with the integration of Shire, the continued expenses relating to the unwinding of fair value adjustments to inventory, the increase in amortization and impairment losses on certain intangible assets and ongoing financial expenses (such as interest expenses) related to the Shire Acquisition, we expect to record a net loss in the fiscal year ending March 31, 2020. We expect certain of these expenses to continue into the fiscal year ending March 31, 2021.

We recorded significant amounts of goodwill in connection with the Shire Acquisition, and, if we are unable to achieve the anticipated benefits of this acquisition, we could be required to recognize significant impairment losses related to such goodwill and to intangible assets recorded in connection with the acquisition, potentially up to their full value.

The expected synergies of the Shire Acquisition and the projected cash costs necessary to achieve the synergies may be affected by changes in the overall economic, political and regulatory environment, including applicable tax regimes and fluctuations in foreign exchange rates, and the realization of the other risks relating to our business described herein. Furthermore, the integration process may divert management's attention from other strategic opportunities and the day-to-day operation of our business. If we are not able to successfully manage the integration process and create a unified business culture, the anticipated benefits of the acquisition and subsequent integration may not be realized fully or at all or may take longer or prove more costly to realize than expected.

Although integration activities are underway, we may face significant challenges in integrating the organizations, business cultures, procedures and operations of Takeda and Shire, including:

- integrating personnel, operations and systems, such as research and development, manufacturing, distribution, marketing and promotional activities and information technology systems, while maintaining focus on selling and promoting existing and newly acquired or produced products;
- inability to realize expected benefits from newly acquired or produced products, including pipeline products under development;
- coordinating and integrating geographically dispersed organizations;
- changes or conflicts in the standards, controls, procedures and accounting and other policies, as well as business cultures and compensation structures;
- the need to manage, train and integrate Shire's personnel, who may have limited experience with the respective companies' business lines and products, and to retain existing employees, particularly high-skilled or other key employees and senior members of the management team;
- maintaining and growing Shire's customer base;
- incremental tax exposure based on the differences in our corporate structure and Shire's, including the exposure of each of the legacy Takeda businesses and the legacy Shire businesses to new tax regimes, particularly, in the case of Shire, to Japanese tax rules;
- maintaining business relationships with suppliers, third-party alliance partners and other key counterparties; and
- inefficiencies associated with the integration of the operations of the two companies.

Additionally, because we issued a significant number of additional shares of our common stock as part of the consideration for the Shire Acquisition, a failure to achieve the anticipated benefits of the Shire Acquisition could negatively affect our earnings per share.

We are subject to additional risks arising from the acquired businesses of Shire, particularly its plasma-derived and rare disease therapies, and from the legal, regulatory and tax regimes that Shire operated under.

We have assumed the risks related to Shire's businesses, which differ from, or will amplify, certain risks we faced prior to the Shire Acquisition. For example, markets outside Japan, particularly the United States, represent a larger portion of the legacy Shire business than ours, and our overall exposure to these markets has increased following the completion of the Shire Acquisition. Additionally, the acquired Shire businesses include new areas for us, such as rare diseases and plasma-derived therapies. Plasma-derived therapies, in particular, present significant challenges relating to the sourcing and transportation of plasma, and production and distribution of plasma-derived products, all of which are complex and subject to extensive regulation, in addition to being capital intensive. If we are unable to manage this new business effectively, we may lose market share or customer confidence, be required to record charges related to idle capacity or impairment on facilities or take other actions which could materially and adversely affect the plasma-derived therapies business. Moreover, sales for the rare disease portfolio we acquired as part of the Shire Acquisition are particularly concentrated among small groups of customers, and we may be disproportionately affected by changes in their purchasing patterns, including if we are unable to appropriately manage this business.

Furthermore, we have become subject to additional legal, regulatory and tax regimes applicable to the acquired businesses of Shire, many of which are complex and could subject us to additional risks or liabilities. For example, the legacy Shire business is subject to evolving and complex tax laws in various jurisdictions and Shire routinely obtained advice on tax matters, including the tax treatment of the break fee of $1.635 billion it received in connection with the terminated offer to acquire Shire made by AbbVie, Inc. in 2014. In this respect, the Irish Revenue issued an assessment received by Shire on November 28, 2018 for €398 million on the basis that the break fee was a taxable capital gain. Based on continued advice that no tax liability should arise from the break fee, Shire has appealed this assessment and the appeals process is continuing. However, the appeal may not be successful and at this time the outcome is unknown. In addition, in connection with its acquisition of Baxalta Incorporated ("Baxalta") in 2016, Shire agreed to indemnify Baxter International Inc., its affiliates and each of their respective officers, directors and employees against certain tax-related losses if the merger of Baxalta and Shire causes the prior spin-off of Baxalta by Baxter and related transactions to fail to qualify as tax-free. Although Shire received an opinion of tax counsel that the merger will not cause such prior transactions to fail to qualify as tax-free, such opinion is not binding on the tax authorities and the potential tax indemnification obligations are not limited in amount.

If we are unable to effectively manage these additional risks, our business, results of operations or financial conditions could be materially and adversely affected.

We have substantial debt, including a significant amount incurred in connection with the Shire Acquisition, which may limit our ability to execute our business strategy, refinance existing debt or incur new debt, and if we are unable to meet our goals for deleveraging, we could be at a greater risk of a downgrade of our credit ratings.

Our consolidated bonds and loans were ¥5,751.0 billion as of March 31, 2019, the majority of which was incurred in connection with the Shire Acquisition or represents indebtedness of Shire now included on our consolidated balance sheet. This significant amount of aggregate debt and the substantial amount of cash required for payments of interest and principal could adversely affect our liquidity. In particular, if we are unable to realize the anticipated benefits of the Shire Acquisition, we may not be able to service our indebtedness. We are also required to comply with certain covenants within various financing arrangements and violations of such covenants may require the acceleration and immediate repayment of the indebtedness, which may in turn have a material adverse effect on our financial condition. In particular, under the Loan Agreement with Japan Bank for International Cooperation ("JBIC") that we entered into in December 2018 (the "JBIC Loan") for an aggregate principal amount of $3.7 billion, our profit before tax must not be negative for two consecutive years. As discussed above, we expect to continue to record significant expenses related to the Shire Acquisition and we expect certain of these costs to continue in the fiscal years ending March 31, 2020 and 2021. We may fail to realize the anticipated benefits of the Shire Acquisition, and expect to continue to record significant expenses related to it. If we record a net loss before tax in both of the fiscal years ending March 31, 2020 and 2021, and are unable to negotiate a waiver or otherwise prevent the acceleration of amounts due under the JBIC Loan, the amounts due thereunder and under our other financing arrangements containing cross-default provisions may become immediately due and payable, thus requiring us to refinance such debt which may result in increased interest costs. Furthermore, we may desire to or be required from time to time to incur additional borrowings, including in relation to the repayment or refinancing any of the Term Loan Credit Agreement that we entered into on June 8, 2018 (the "Term Loan Credit Agreement") for an aggregate principal amount of $7.5 billion, the JBIC Loan, or any other indebtedness incurred in connection with the Shire Acquisition, such as the U.S. dollar and Euro-denominated bonds issued in November 2018 or the subordinated hybrid bonds issued in June 2019, or Shire's previously existing indebtedness. Our ability to arrange a re-financing will depend on our financial position and performance, prevailing market conditions and other factors beyond our control. Moreover, if we decide to refinance indebtedness as it comes due, our overall leverage may not necessarily decrease.

We aim to decrease our leverage, with a target ratio of net debt to Adjusted EBITDA[(1)] of 2x or less within three to five years following the January 2019 completion of the Shire Acquisition and we have begun the process of disposal of certain non-core assets to generate cash in order to increase the pace of deleveraging. However, we may not be able to meet these goals if we are unable to sufficiently decrease our overall indebtedness, or if we are unable to achieve sufficient increases in earnings to offset our increased levels of debt. We may also not be successful in selecting non-core assets for disposal, and disposals may affect our business, financial condition or results of operations adversely, leading to larger-than-expected decreases in earnings. We may also not be able to dispose of such assets successfully in a manner that allows us to meet our goals or at all.

[(1)] We define EBITDA as net profit before income tax expenses, depreciation and amortization and net interest expense. We define Adjusted EBITDA as EBITDA further adjusted to exclude impairment losses, other operating expenses and income (excluding depreciation and amortization), finance expenses and income (excluding net interest expense), our share of loss from investments accounted for under the equity method and other items that management believes are unrelated to our core operations such as purchase accounting effects and transaction related costs.

If we are unable to decrease our leverage, we may be unable to improve our credit ratings or be subject to ratings downgrades or other adverse actions by third-party ratings agencies. In May 2018, Moody's (Japan) K.K. lowered our credit rating to A2 from A1, reflecting its expectations for our overall levels of leverage in the future, even in the absence of the Shire Acquisition, and in December 2018 Moody's (Japan) K.K. further lowered our credit rating to Baa2, reflecting the increase in our ratio of net debt to Adjusted EBITDA after giving effect to the Shire Acquisition. In February 2019, S&P Global Ratings downgraded our ratings to BBB+, also in light of our aggregate debt and earnings profile following the Shire Acquisition. If we are unable to improve our credit ratings or if our credit ratings are further downgraded, it may negatively influence the terms for the refinancing of our existing debt or new borrowings on terms that we would consider to be commercially reasonable.

Risks Relating to Our Business

Research and development of pharmaceutical products are expensive and subject to significant uncertainties, and we may be unsuccessful in bringing commercially successful products to market or recouping development costs.

Our ability to continue to grow our business depends significantly on the success of our research and development activities in identifying, developing and successfully commercializing new products in a timely and cost-effective manner. To accomplish this, we commit substantial efforts, funds and other resources to research and development, both in-house and through collaborations with third parties. However, these research and development programs are expensive and involve intensive preclinical evaluation and clinical trials in connection with a highly complex and lengthy regulatory approval process. See "—If we fail to comply with government regulations over product development, regulatory approvals and reimbursement requirements, our business could be adversely affected." The research and development process for a new pharmaceutical product also requires us to attract and retain sufficient numbers of highly-skilled employees and can take up to 10 years to 15 years or longer from discovery to commercial launch. Moreover, even if we successfully develop and bring to market new products, there is only a limited available patent life in which to recoup these development costs.

During each stage of the approval process and post-approval life cycle of our products, there is a substantial risk that we will encounter serious obstacles, including the following:

- unfavorable results from preclinical testing of a new compound;
- difficulty in enrolling patients in clinical trials, or delays or clinical trial holds at clinical trial sites;
- delays in completing formulation and other testing and work necessary to support an application for regulatory approval;
- adverse reactions to the product candidate or indications of other safety concerns;
- insufficient clinical trial data to support the safety or efficacy of the product candidate;
- difficulty or delays in obtaining all necessary regulatory approvals in each jurisdiction where we propose to market such products;
- failure to bring a product to market prior to a competitor, or to develop a product sufficiently differentiated from a competing product to achieve significant market share;
- difficulty in obtaining reimbursement at satisfactory rates for our approved products from governments and insurers;
- difficulty in obtaining regulatory approval for additional indications;
- failure to enter into or implement successful alliances for the development and/or commercialization of products;
- inability to manufacture sufficient quantities of a product candidate for development or commercialization activities in a timely or cost-efficient manner; and
- the degree of market acceptance of any approved product candidate by the medical community, including physicians, healthcare professionals and patients, will depend on a number of factors, including relative convenience and ease of administration, the prevalence and severity of any adverse reactions, availability of alternative treatments, pricing and our sales and marketing strategy.

In addition, to the extent that new regulations raise the costs of obtaining and maintaining product authorizations or limit the economic value of a new product to its originator, our profitability and growth prospects could be diminished. Development of new and innovative products can also require the use of emerging platforms and technologies for which regulations either do not yet exist or are under development or modification. This may lead to greater uncertainty and risk in establishing the necessary data for approvals to conduct clinical trials and/or receiving marketing approvals.

As a result of the foregoing or other factors, we may decide to abandon the development of potential pipeline products in which we have invested significant resources, even where the product is in the late stages of development. Moreover, there can also be no assurance that we will be successful in bringing new products to market, marketing them, achieving sufficient acceptance thereof and recouping our investments in their development. For example, our pipeline compounds may not receive regulatory approval, become commercially successful or achieve satisfactory rates of reimbursement. Additionally, products approved for use and successfully marketed in one market may be unable to obtain regulatory approval, become commercially successful or achieve satisfactory rates of reimbursement in other markets. As a result, we may be unable to earn returns on investments that we originally anticipated or at all, or may be forced to revise our research and development strategy, and our business, financial condition and results of operations could be materially and adversely affected.

If we fail to comply with government regulations over product development, regulatory approvals and reimbursement requirements, our business could be adversely affected.

Obtaining marketing approval for pharmaceutical products is a lengthy, complex and highly regulated process that requires intensive preclinical and clinical data, and the approval process can vary significantly depending on the regulatory authority. Relevant health authorities may, at the time of the filing of the application for a marketing authorization, or later during their review, impose requirements that can evolve over time, including requiring additional clinical trials, and such authorities may delay or refuse to grant approval. Even where we have obtained marketing approval for a product in one or more major markets, we may need to invest significant time and resources in applying for approval in other markets, and there is no assurance that we will be able to obtain such approval. In recent years, health authorities have become increasingly focused on product safety and on the risk/benefit profile of pharmaceutical products, which could lead to more burdensome and costly approval processes and negatively affect our ability to obtain regulatory approval for products under development. For example, the U.S. Food and Drug Administration (the "FDA"), the European Medicines Agency (the "EMA"), and the Pharmaceuticals and Medical Devices Agency (the "PMDA") in Japan have been implementing strict requirements for approval, particularly in terms of the volume of data needed to demonstrate a product's efficacy and safety.

Even after regulatory approval is obtained, marketed products are subject to various post-approval requirements, including continual review, risk evaluations, comparative effectiveness studies and, in some cases, requirements to conduct post-approval clinical trials to gather additional safety and other data. Regulatory authorities in many countries have worked to enhance post-approval monitoring in recent years, which has increased post-approval regulatory burdens. Post-regulatory approval reviews and data analyses can lead to the issuance of recommendations by government agencies, health professional and patients or other specialized organizations regarding the use of products; for example, a recommendation to limit the patient population of a drug's indication, the imposition of marketing restrictions, including changes in product labeling, or the suspension or withdrawal of the product. Any such action can result in reductions in sales volume and/or new or increased concerns about the adverse reactions or efficacy of a product. These substantial regulatory requirements have, over time, increased the costs associated with maintaining regulatory approvals and achieving reimbursement for our products.

If the regulatory approval process or post-approval, reimbursement, monitoring or other requirements become significantly more burdensome in any of our major markets, we could become subject to increased costs and may be unable to obtain or maintain approval to market our products. Any such adverse changes could materially and adversely affect our business, results of operations or financial condition.

If we fail to comply with laws and regulations governing the sales and marketing of our products, our business could be adversely affected.

We engage in various marketing, promotional and educational activities pertaining to, as well as the sale of, pharmaceutical products in a number of jurisdictions around the world. The promotion, marketing and sale of pharmaceutical products and medical devices is highly regulated and the sales and marketing practices of market participants such as us have been subject to increasing supervision by governmental authorities, and we believe that this trend will continue.

For example, in the United States, our sales and marketing activities are monitored by a number of regulatory authorities and law enforcement agencies, including the U.S. Department of Health and Human Services (the "HHS"), the FDA, the U.S. Department of Justice, the U.S. Securities and Exchange Commission (the "SEC") and the Drug Enforcement Administration (the "DEA"). These authorities and agencies and their equivalents in other countries have broad authority to investigate market participants for potential violations of laws relating to the sale, marketing and promotion of pharmaceutical products and medical devices, including the False Claims Act, the Anti-Kickback Statute, the United Kingdom (the "UK") Bribery Act of 2010 and the Foreign Corrupt Practices Act, among others, for alleged improper conduct, including corrupt payments to government officials, improper payments to medical professionals, off-label marketing of pharmaceutical products and medical devices, and the submission of false claims for reimbursement by the federal government. Healthcare companies may also be subject to enforcement actions or prosecution for such improper conduct. Any inquiries or investigations into the operations of, or enforcement or other regulatory action against, us by such authorities could result in significant defense costs, fines, penalties and injunctive or administrative remedies, distract management to the detriment of the business, result in the exclusion of certain products, or us as a whole, from government reimbursement programs or subject us to regulatory controls or government monitoring of its activities in the future. We are also subject to certain ongoing investigations by governmental agencies.

Government policies and other pressures to reduce medical costs could have an adverse effect on sales of our pharmaceutical products.

We are subject to governmental regulations mandating price controls in various countries in which we operate. The growth of overall healthcare costs as a percentage of gross domestic product in many countries means that governments and payers are under intense pressure to control spending even more tightly. See "Item 4. Information on the Company—B. Business Overview—Third Party Reimbursement and Pricing."

In the United States, there has been increasing pricing pressure from managed care groups and institutional and governmental purchasers. In particular, as managed care groups have grown in size due to market consolidation, pharmaceutical companies have faced increased pressure in pricing and usage negotiations, and there is fierce competition among pharmaceutical companies to have their products included in the care providers' formularies. Moreover, as a result of the changing legislative and regulatory environment in the United States we have experienced heightened pricing pressure on, and limitations on access to, our branded pharmaceutical products sold in the United States. There has been increasing attention paid to the level of pricing of pharmaceutical products by policymakers and stakeholders, which could lead to political pressure or legislative, regulatory or other efforts to introduce lower prices, and change how the pharmaceutical supply chain could operate. In addition, there are efforts by the federal government to reduce spending on the Medicare and Medicaid programs, including proposals by the Congressional Budget Office to require pharmaceutical companies to pay a minimum rebate on drug products covered under Medicare Part D for low-income beneficiaries and to cap federal Medicaid payments to the states. Congressional proposals to convert the Medicare fee-for-service program into a premium support program could also lead to significant reductions

in Medicare spending. The future of the U.S. healthcare legislation, as well as the potential impact of any new legislation, is uncertain, but we expect the health care industry in the United States will continue to be subject to increasing pricing and spending pressure, including from regulation and political and legal action.

In Japan, manufacturers of pharmaceutical products must have new products listed on the National Health Insurance (the "NHI") price list published by the Ministry of Health, Labour and Welfare of Japan (the "MHLW") for the coverage under the public medical care insurance systems. The NHI price list provides rates for calculating the price of pharmaceutical products used in medical services provided under various public medical care insurance systems. Prices on the NHI price list have been subject to revision generally once every two years on the basis of the actual prices at which the pharmaceutical products are purchased by medical institutions in Japan after discounts and rebates are deducted from listed price. The average price of previously listed products generally decreases as a result of these price revisions. The Japanese government is currently undertaking healthcare reform initiatives with a goal of sustaining the universal coverage of the NHI program, and is addressing the efficient use of drugs, including promotion of generic use with a target of 80% penetration by volume by September 2020 with respect to products for which market exclusivity has expired. As part of these initiatives, the NHI price list is expected to be revised annually from April 1, 2021, which could lead to more frequent downward price revisions. In addition, cost-effectiveness analysis was officially introduced by the MHLW in April 2019. Products on the NHI price list nominated based on pre-defined criteria, such as the innovativeness and the financial impact, will be subject to review, and subject to price adjustments depending on outcome of this review.

In Europe, as in the United States, drug prices have been subject to downward pressure due to measures implemented in each country to control drug costs, and prices continue to come under pressure due to parallel imports, generic competition, increasing use of health technology assessment based upon cost-effectiveness and other factors. European pricing and reimbursement authorities have also intensified efforts to increase transparency of prices as well as exchange of information among the various European pricing authorities in order to raise pressure towards the industry. This pricing debate has impacted the overall political climate in Europe and has triggered a European policy initiative to review the pharmaceutical industry's intellectual property incentives with a particular emphasis on orphan drugs. Any new legislation in this area would take at least two to three years to be adopted but could have significant impact on our business model. We are also facing similar pricing pressures in other regions, such as various emerging countries.

We expect these efforts to control costs to continue as healthcare payers around the globe, in particular government-controlled health authorities, publicly funded or subsidized health programs, insurance companies and managed care organizations (the "MCOs"), increasingly pursue initiatives to reduce the overall cost of healthcare, restrict access to higher-priced new medicines, increase the use of generics and impose overall price revisions. Such further implementation of these policies could have a material adverse effect on our business, financial condition and results of operations.

The expiration or loss of patent or regulatory data protection over our products or patent infringement by generic manufacturers could lead to significant competition from generic versions of the relevant product and lead to declines in market share and price levels of our products.

Our pharmaceutical products are generally protected for a defined period by various patents (including those covering drug substance, drug product, approved indications, methods of administration, methods of manufacturing, formulations and dosages) and/or regulatory exclusivity, which are intended to provide us with exclusive rights to market the products for the life of the patent or duration of the regulatory data protection period. The loss of market exclusivity for pharmaceutical products opens such products to competition from generic substitutes that are typically priced significantly lower than the original products, which typically adversely affects the market share and prices of the original products.

Generic substitutes have high market shares in a number of key markets, including the United States, Europe and many emerging countries, and the adverse effects of the launch of generic products are particularly significant in such markets. The introduction of generic versions of a pharmaceutical product typically leads to a swift and substantial decline in the sales of the original product. Our active life cycle management efforts cannot fully mitigate the impact of competition from generics. In the United States and the European Union ("EU"), for example, political pressure to reduce spending on prescription drugs has led to legislation and other measures that encourage the use of generic products. In Japan, the government is implementing various measures to control drug costs, including by encouraging medical practitioners to use and prescribe generic drugs, and in June 2017 announced its intention to raise generic drug penetration with respect to products for which market exclusivity has expired to 80% by volume by September 2020. Legislation has also been passed in the United States and Europe encouraging the use of biosimilar products. Similar to generics, biosimilars aim to provide less expensive versions of innovative biologic products. New legislation has provided abbreviated pathways for the approval and marketing of biosimilar products, which may affect the profitability and commercial viability of our biologic products.

Certain of our products have begun to, or are expected over the next several years to, face declining sales due to the loss of market exclusivity. For example, following the expiration of patent protection over bortezomib, the active ingredient in *VELCADE*, one of our largest selling products in the United States, a competing bortezomib-containing product has been introduced. This has led to a decrease in sales of *VELCADE*, and further entry of competing products could result in substantial additional declines. Such decreases may accelerate following the scheduled expiration of patent protection over the formulation of *VELCADE* in 2022, or earlier if a competitor is able to develop a way to formulate *VELCADE* in a manner that does not infringe the relevant patent or succeed in getting the formulation patent invalidated. Patent protections over *VYVANSE*, which we acquired as part of the Shire Acquisition and which was Shire's largest selling product, are scheduled to expire in 2023, which we anticipate will lead to declines in sales. In addition, as patent protection has expired for *PANTOPRAZOLE* in many major markets including the United States and the EU, sales of *PANTOPRAZOLE* have continued to decline in those markets.

We may also be subject to competition from generic drug manufacturers prior to the expiration of patents if a manufacturer successfully challenges the validity of our patents, or if the manufacturer believes that the benefits of launching the generic drug "at risk" (prior to the expiration of our patent) outweigh the costs of defending infringement litigation. If such a competitor launches a generic product "at risk" before the initiation or

completion of court proceedings, a court may decline to grant us a preliminary injunction to halt further "at risk" sales and remove the infringing product from the market. While we may be entitled to obtain damages subsequently, the amount we may ultimately be awarded and able to collect may be insufficient to compensate for the loss of sales and other harm caused to us. Furthermore, if we lose patent protection as a result of an adverse court decision or a settlement, in certain jurisdictions, we may face the risk that government and private third-party payers and purchasers of pharmaceutical products may claim damages alleging they have over-reimbursed or overpaid for a drug.

If our patent and other intellectual property rights are infringed by generic drug manufacturers or other third parties, we may not be able to take full advantage of the potential or existing demand for our products. The protection that we are able to obtain for our prescription drugs varies from product to product and country to country and may not always be sufficient because of local variations in issued patents, or differences in national law or legal systems, including inconsistency in the enforcement or application of law and limitations on the availability of meaningful legal remedies. In particular, patent protection in emerging markets is often less certain than in developed markets. Certain countries may also engage in compulsory licensing of pharmaceutical intellectual property to other manufacturers as a result of local political pressure. Furthermore, the attention of our management and other personnel could be diverted from their normal business activities if we decide to litigate against such infringement. The realization of any such risks could adversely and materially affect our business, financial condition and results of operations.

We are subject to the risk of intellectual property infringement claims directed at us by third parties.

We are subject to the risk of infringement claims directed at us by third parties, even if we do not knowingly infringe on any valid third-party intellectual property rights. Although we monitor our operations to prevent infringement on the intellectual property rights of third parties, if we are found to have infringed the intellectual property rights of others or if we agree to settle infringement claims, we may be required to recall the relevant products, terminate manufacturing and sales of such products, pay significant damages or pay significant royalties.

We evaluate any such infringement claims to assess the likelihood of unfavorable outcomes and to estimate, if possible, the amount of potential losses. Based on these assessments and estimates, and in keeping with applicable accounting and disclosure standards, we establish reserves and/or disclose the relevant litigation claims or decide not to establish reserves or disclose litigation claims. These assessments and estimates are based on the information available to our management at such time and involve a significant amount of management judgment. Actual outcomes or losses may differ materially from those envisioned by our current assessments and estimates. Although the parties to such patent and intellectual property disputes in the pharmaceutical industry have often settled through licensing or similar arrangements, the costs associated with these arrangements may be substantial and could include the payment of ongoing royalties. Furthermore, the necessary licenses may not be available on acceptable terms or at all. Therefore, if we are unable to successfully defend against infringement claims by third parties, our financial results could be materially and adversely affected.

The illegal distribution and sale by third parties of counterfeit versions of our products or products stolen from us could have an adverse effect on our reputation and business.

Third parties may illegally distribute and sell counterfeit versions of our products, which do not meet the rigorous manufacturing and testing standards to which our products are subject. A patient who receives a counterfeit drug may be at risk for a number of dangerous health consequences. Reports of adverse reactions to counterfeit drugs or increased levels of counterfeiting could materially affect patient confidence in our products, which could have a material adverse effect on our reputation and financial results. In addition, thefts at warehouses, at plants, or in transit of inventory that is not properly stored or that is sold through unauthorized channels could materially and adversely affect patient safety, our reputation and our results of operations.

We may not be able to adequately expand our product portfolio through third-party alliance arrangements.

We expect that we will continue to rely on third parties for key aspects of our business, including the discovery and development of new products, in-licensing products, and the marketing and distribution of approved products. A major part of our research and development strategy is to initiate alliances with third parties in the biotechnology industry, academia and the public sector, and we believe that the overall strength of our research and development program and product pipeline depends on our ability to identify and initiate partnerships, in-licensing arrangements and other collaborations with third parties. However, there can be no assurance that any of our third-party alliances will lead to the successful development and marketing of new products. Moreover, reliance on third-party alliances subjects us to a number of risks, including:

- We may be unable to identify suitable opportunities at a reasonable cost and on terms that are acceptable to us due to active and intense competition among pharmaceutical groups for alliance opportunities or other factors;
- Entering into in-licensing or partnership agreements may require the payment of significant "milestones" well before the relevant products are placed in the market, without any assurance that such investments will ultimately become profitable in the long term. To the extent such milestone payments are recorded as assets on our balance sheet, any termination of the relevant partnership could require us to recognize an impairment loss up to the full value of such asset;
- When we research and market our products through collaboration arrangements, the performance of certain key tasks or functions are the responsibility of our collaboration partners, who may not perform effectively or otherwise meet our expectations; and
- Decisions may be under the control of or subject to the approval of our collaboration partners, and we may have differing views or be unable to agree upon an appropriate course of action. Any conflicts or difficulties that we may have with our partners during the course of these agreements or at the time of their renewal or renegotiation or any disruption in the relationships with our partners may affect the development, launch and/or marketing of certain of our products or product candidates.

In addition, a licensor may attempt to terminate its license agreement with us or elect not to renew it to pursue other marketing opportunities. Our licensors could also merge with or be acquired by another company or experience financial or other setbacks unrelated to our licensing arrangements. Any of these events may force us to abandon a development project and adversely affect our ability to adequately expand or maintain our product portfolio.

Our operating results and financial condition may fluctuate due to a number of factors and may not be comparable across periods.

Our operating results and financial condition may fluctuate from quarter to quarter and year to year for a number of reasons, including acquisitions, divestitures, major product launches, patent expiration or expiration of regulatory data protection for key products and other reasons. In particular, as part of our efforts to refocus our business portfolio, we have recently entered into a number of significant transactions that are expected to affect our results of operations, including:

- the Shire Acquisition;
- the acquisition of TiGenix NV in July 2018;
- the divestment of Wako Pure Chemical Industries, Ltd. ("Wako Pure Chemical"), one of our consolidated subsidiaries, to FUJIFILM Corporation in April 2017;
- the acquisition of ARIAD Pharmaceuticals, Inc. ("ARIAD") in February 2017; and
- the transfer of certain long-listed products, consisting of products for which patent protection and regulatory data protection have expired, to Teva Takeda Yakuhin Ltd., a wholly-owned subsidiary of Teva Takeda Pharma Ltd., a joint venture we formed with Teva Pharmaceutical Industries Ltd., in April 2016, and the subsequent sale of seven additional long-listed products in May 2017.

We intend to continue to pursue both acquisitions of new businesses and dispositions of existing businesses in the future. As a result, period-to-period comparisons of our results of operations may not always be directly comparable, and these comparisons should not be relied upon as an indication of future performance. Our operating results and financial condition are also subject to fluctuations from the risks described throughout this section.

We have significant global operations, which expose us to additional risks.

Our global operations, which encompass approximately 80 countries and regions across the world, are subject to a number of risks, including the following:

- difficulties in monitoring and coordinating research and development, marketing, supply-chain and other operations in a large number of jurisdictions;
- risks related to various laws, regulations and policies, including those implemented following changes in political leadership and trade, capital and exchange controls;
- changes with respect to taxation, including impositions or increases of withholding and other taxes on remittances and other payments by our overseas subsidiaries;
- varying standards and practices in the legal, regulatory and business cultures in which we operate, including potential inability to enforce contracts or intellectual property rights;
- trade restrictions and changes in tariffs;
- complex sanctions regimes in various countries such as the United States, the EU and other jurisdictions, violations of which could lead to fines or other penalties;
- risks related to political instability and uncertain business environments;
- changes in the political, economic or social climate, including inter-country relationships;
- acts of terrorism, war, epidemics and other sources of social disruption; and
- difficulties associated with managing local personnel and preventing misconduct by local third-party alliance partners.

Any one or more of these or other factors could increase our costs, reduce our revenues, or disrupt our operations, with possible material adverse effects on our business, financial condition and results of operations. Further expansion overseas has been one of our key strategies, and, in the fiscal year ended March 31, 2019, regions outside of Japan accounted for 72.8% of our consolidated revenue, with the United States in particular contributing 39.5% of consolidated revenue, and we anticipate that these proportions will further increase once Shire's businesses have been included in our consolidated results of operations for a full fiscal year. We expect that markets outside Japan, particularly the United States and also Europe, Canada and emerging markets, will continue to be increasingly important to our business and results of operations, increasing the likelihood that any of these risks is realized.

We may not be able to realize the expected benefits of our investments in emerging markets.

We have been taking steps to grow our business in emerging markets, which we define to include Russia/Commonwealth of Independent States ("CIS"), Latin America, Asia (excluding Japan) and Other (including the Middle East, Oceania and Africa). Our revenue from emerging markets was ¥291.6 billion (or 13.9% of our total revenue) for the fiscal year ended March 31, 2019, and we intend to pursue further growth in such emerging markets.

However, there is no guarantee that our efforts to expand sales in emerging markets will succeed. Some countries may be especially vulnerable to periods of global financial instability or may have very limited resources to spend on healthcare. Emerging markets present particular challenges in obtaining funding, achieving market access for our products and successfully ensuring that we receive appropriate levels of reimbursement. Emerging markets also tend to require substantial efforts in patient support and other programs. All of these factors may adversely affect the profitability of our businesses in these emerging markets.

In order to successfully implement our emerging markets strategy, we must also attract and retain qualified personnel, despite the possibility that some emerging markets may have a relatively limited number of persons with the required skills and training. We may also be required to increase our reliance on third-party agents within less-developed markets, which may put us at increased risk of liability. In addition, many emerging markets have currencies that fluctuate substantially, and if such currencies are devalued and we cannot offset the devaluations, our financial performance in such countries may be adversely affected. Further, many emerging markets have relatively weak intellectual property protection and inadequate protection against crime, including counterfeiting, corruption and fraud. Operations in certain emerging countries, where corruption may be more prevalent than in more developed countries and where internal compliance practices may not be well established, may also pose challenges from a legal and regulatory compliance perspective.

For reasons including but not limited to the above, sales within emerging markets carry significant risks, and the realization of such risks could have a material adverse effect on our business, financial condition and results of operations.

We face risks relating to the expected exit of the United Kingdom from the European Union.

On June 23, 2016, the United Kingdom held a remain-or-leave referendum on the United Kingdom's membership within the European Union, the result of which favored the exit of the United Kingdom from the EU (commonly known as "Brexit"). A process of negotiation will likely determine the future terms of the United Kingdom's relationship with the EU, as well as whether the United Kingdom will be able to continue to benefit from the EU's free trade and similar agreements. Additionally, Brexit has impacted the EMA, which is the primary regulator of the pharmaceutical industry in the EU and which has stated that it expects to lose about 25% of its 900 staff members due to the EMA's relocation from London to Amsterdam as a result of Brexit. The EMA has developed a business continuity plan that allows EMA to temporarily scale back or temporarily suspend lower priority activities during the relocation and as it prepares for Brexit. For example, the EMA noted in its annual report for 2018 that, in order to be able to concentrate on Brexit and the EMA's relocation to Amsterdam, it had to delay updating its guidelines on the development of new medicines to treat hemophilia A and B. Delays in EMA processes such as this caused by Brexit may adversely affect or delay our business, including our ability to develop and market new or existing products in the EU.

The timing of Brexit and potential impact of Brexit on our market share, sales, profitability and results of operations is unclear. Depending on the terms of Brexit and any continuing impact on the EMA, economic conditions in the United Kingdom, the European Union and global markets may be adversely affected by reduced growth and volatility. The uncertainty before, during and after the period of negotiation is also expected to have a negative economic impact and increase volatility in the markets, particularly in the Eurozone. Such volatility and negative economic impact could, in turn, adversely affect our revenues, financial condition or results of operations.

Our results of operations and financial condition may be adversely affected by foreign currency exchange rate fluctuations.

We manufacture and sell products to customers in numerous countries, and we have entered and will enter into acquisition, licensing, borrowings or other financial transactions that give rise to translation and transaction risks related to foreign currency exposure. Fluctuations in currency exchange rates in the markets where we are active could negatively affect our results of operations, financial position and cash flows. For the fiscal year ended March 31, 2019, 72.8% of our sales were in markets outside Japan, and we expect this proportion to be even higher for subsequent fiscal periods, due to anticipated increases in overseas sales of growth driver products and the contribution of Shire's results to our results of operations, particularly in the U.S. market. Our consolidated financial statements are presented in Japanese yen, and by translating the foreign currency financial statements of our foreign subsidiaries into yen, the amounts of our revenue, operating profit, assets and equity, on a consolidated basis, are affected by prevailing rates of exchange.

We utilize certain hedging measures with respect to some of our foreign currency transactions. However, such hedging measures do not cover all of our exposures and, even to the extent they do, they may only delay, or may otherwise be unable to completely eliminate, the impact of fluctuations in foreign currency exchange rates.

Our reliance on third parties for the performance of certain key business functions, particularly product manufacture and commercialization, heightens the risks faced by our business.

We rely on suppliers, vendors and partners, including alliances with other pharmaceutical companies, for certain key aspects of our business, including manufacture and commercialization of products, support for information technology systems and certain human resource functions. We do not control these partners, but we depend on them in ways that may be significant to us. If these parties fail to meet our expectations or fulfill their obligations to us, we may fail to receive the expected benefits. In addition, if any of these third parties fails to comply with applicable laws and regulations in the course of its performance of services for us, there is a risk that we may be held responsible for such violations as well. This risk is particularly serious in emerging markets, where corruption is often prevalent and where many of the third parties on which we rely do not have internal compliance resources comparable to our own. Any such failures by third parties, in emerging markets or elsewhere, could adversely affect our business, reputation, financial condition or results of operations.

Our dependence on third parties for the inputs for our products subjects us to various risks, and changes in the costs of materials may adversely affect our profitability.

Although we develop and manufacture the active ingredients used in some of our products at our own facilities, we are dependent on third-party suppliers for a substantial portion of the raw materials and compounds used in the products we produce. The price and availability of the raw materials for our products, including chemical compounds and biologics, are subject to the effects of weather, natural disasters, market forces, the economic environment, fuel costs and foreign exchange rates. If our cost for such materials increases, we may not be able to make corresponding increases in the prices of our products due to market conditions or our relationships with our customers, and as a result, our profitability could be materially and adversely affected.

In particular, we rely on third-party suppliers of key manufacturing inputs of certain drug products, including, but not limited to, *ADCETRIS, ADVATE*, *ADYNOVATE*, *ALUNBRIG, CINRYZE*, *CUVITRU*, *ENTYVIO, FEIBA*, *FIRAZYR*, *GATTEX/REVESTIVE*, *HYQVIA*, *LEUPRON, MEPACT, NINLARO, TAKHZYRO,* and *VELCADE*. Furthermore, certain active ingredients for these products are sourced from a single supplier. We also rely in part on third-party sources to provide the donated plasma necessary for our plasma-derived therapies. In addition, although we dual-source certain key products and/or active ingredients, we currently rely on a single source for production of the final drug product for certain of our products, including, but not limited to, *ADDERALL XR*, *ADYNOVATE*, *ALOFISEL, ALUNBRIG, CINRYZE*, *CUVITRU*, *FIRAZYR*, *HYQVIA*, *LIALDA, MEPACT, NINLARO, PENTASA* and *TAKHZYRO*. Sources of some materials may be limited to a single supplier, and if such supplier faces any difficulty in supplying the materials, we may not be able to find an alternative supplier in a timely manner or at all. If materials become unavailable or if quality problems related to the materials arise, we may be forced to halt production and sales of products that use them. In the event that any of our third-party suppliers is delayed in its delivery of such raw materials or compounds, is unable to deliver the full quantity ordered by us at the appropriate level of quality, or is unable to deliver any raw materials or compounds at all, our ability to sell our products in the quantities demanded by the market may be impaired, which could damage our reputation and relationships with customers and patients. In such a case, our business and results of operations could be adversely affected.

The manufacture of our products is technically complex and highly regulated, and supply interruptions, product recalls or other production problems caused by unforeseen events may reduce sales, adversely affect our operating results and financial condition and delay the launch of new products.

The manufacture of our products is technically complex and highly regulated, and as a result we may experience difficulties or delays including but not limited to the following:

- seizure or recalls of products or shut-downs of manufacturing plants;
- problems with business continuity, including as a result of a natural or man-made disaster, at one of our facilities or at a critical supplier or vendor;
- failure by us or by any of our vendors or suppliers to comply with Good Manufacturing Practice and other applicable regulations and quality assurance guidelines, which could lead to manufacturing shutdowns, product shortages and delays in product manufacturing;
- problems with manufacturing, quality assurance/quality control or supply, or governmental approval delays, due to our consolidation and rationalization of manufacturing facilities and the sale or closure of certain sites;
- failure of a sole source or single source supplier to provide us with necessary raw materials, supplies or finished goods for an extended period of time, which could impact continuous supply;
- failure of a third-party manufacturer to supply us with semi-finished or finished products on time;
- construction or regulatory approval delays related to new facilities or the expansion of existing facilities;
- additional costs related to deficiencies identified by regulatory agencies in connection with inspections of our facilities, and enforcement, remedial or punitive actions by regulatory authorities if we fail to remedy any deficiencies; and
- other manufacturing or distribution problems including limits to manufacturing capacity due to regulatory requirements (e.g. Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH") regulation in the EU), changes in the types of products produced, physical limitations or other business interruptions that could impact continuous supply.

The development and manufacture of biologics including products added to our portfolio following the completion of the Shire Acquisition and stem cell therapies resulting from our acquisition of Tigenix NV in July 2018, present heightened or additional risks. The manufacture of biologics, including stem cell products, is highly complex and is characterized by inherent risks and challenges, such as raw material inconsistencies, logistical

and sourcing challenges, significant quality control and assurance requirements, manufacturing complexity (including heightened regulatory requirements) and significant manual processing. Unlike products that rely on chemicals for efficacy, such as most pharmaceuticals, biologics are difficult to characterize due to the inherent variability of biological input materials. As a result, assays of the finished product may not be sufficient to ensure that the product will perform in the intended manner. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in, among other things, lot failures, product recalls, product liability claims or insufficient inventory, which could be costly to us or result in reputational damage.

Any of the above may reduce sales, delay the launch of new products, and adversely affect our business, financial condition and results of operations.

We are involved in litigation relating to our operations on an ongoing basis, and such litigation could result in financial losses or harm our business.

We are involved in various litigation relating to our operations on an ongoing basis, including claims related to product liability and intellectual property as well as to antitrust, sales and marketing and other regulatory regimes. Given the inherent unpredictability of litigation, it is possible that an adverse outcome in one or more pending or future litigation matters could have a material adverse effect on our operating results or cash flows. For a description of certain ongoing litigation, see Note 32 to our audited consolidated financial statements included in this annual report.

Economic and financial conditions may have a material adverse effect on our business, financial condition and results of operations.

Growth of the global pharmaceutical market has become increasingly tied to global economic growth. In this context, a substantial and lasting slowdown of the global economy or major national economies could negatively affect growth in the global pharmaceutical market and, as a result, adversely affect our business. In particular, weak economic conditions can have a particularly adverse impact on pharmaceutical demand in markets having significant co-pays or lacking a developed third-party payer system, as individual patients may delay or decrease out-of-pocket healthcare expenditures. Negative economic developments could also reduce the sources of funding for national social security systems, leading to heightened pressure on drug prices, increased substitution of generic drugs, and the exclusion of certain products from formularies.

Following the global financial crisis in 2008, economic growth continues to be stagnant in major developed countries while the pace of growth in many emerging economies has declined. The Brexit referendum in the U.K, political volatility in the United States following recent mid-term elections, continued instability in the Middle East and North Korea and global developments in trade and security policy have increased political and economic uncertainty. To the extent that economic or financial conditions weaken in any of our major operating markets, demand for our products or product pricing could be negatively affected. In addition, to the extent that economic and financial conditions negatively affect the global business environment, we could experience a disruption or delay in the performance of third parties on which we rely for parts of our business, including collaboration partners and suppliers. Such disruptions or delays could have a material and adverse effect on our business, financial condition and results of operations.

We may have difficulty maintaining the competitiveness of our products.

The pharmaceutical industry is highly competitive, and in order to maintain the competitiveness of our product portfolio, we are required to maintain ongoing, extensive research for technological innovations, including new compounds, to develop and commercialize existing pipeline products, to expand our product portfolio through acquisitions and in-licensing, and to market our products effectively, including by communicating the efficacy, safety and value of our products to healthcare professionals. However, healthcare professionals and consumers may choose competitors' products over ours nonetheless, if they perceive these products to be safer, more reliable, more effective, easier to administer or less expensive. The success of any product depends on our ability to effectively communicate with and educate the healthcare professionals and patients and convince them of the advantage of our products over those of our competitors. We often carry out costly clinical trials even after our products have been launched to produce data to be utilized for these purposes, but such trials do not always produce the desired outcomes. Furthermore, many of our competitors have greater financial and other resources to conduct such trials in more detail and with larger patient populations, which may ultimately enable them to promote their products more effectively than we do. Moreover, if relevant regulators increase their approvals of new therapies developed by competitors for the conditions treated by our products, such as in order to increase the number of treatment options available for rare or orphan diseases, our business and results of operations could be materially and adversely affected.

For example, in recent years, competitors have introduced additional plasma-based hemophilia products, or such products have been approved for additional uses, which may affect (and in certain cases has affected) sales of our plasma-based hemophilia products, such as *FEIBA*. Moreover, certain competitors are developing other hemophilia therapies, including gene-based therapies, which, if successfully introduced, could also harm sales of our plasma-based therapies. Increased competition from new products or therapies could similarly affect our other products.

In Japan, reduced approval times for drugs already marketed outside Japan have led to increased competition through the introduction of such drugs into the Japanese market by foreign competitors. In addition, new competing products or the development of superior medical technologies and other treatment options could make our products or technologies lose their competitiveness or become obsolete. As discussed above, our products are also subject to competition from inexpensive generic versions of our products, as well as generic versions of our competitors' products, upon the expiration or loss of related patent protection and regulatory data protection, which may result in loss of market share. If we are unable to maintain the competitiveness of our products, our business, financial position and results of operations could be materially and adversely affected.

Our products may have unanticipated adverse effects or possible adverse effects, which may restrict use of the product or give rise to product liability claims.

As a pharmaceutical company, we are subject to significant risks related to product liability. Unanticipated adverse reactions or unfavorable publicity from complaints concerning any of our products, or those of our competitors, could have an adverse effect on our ability to obtain or maintain regulatory approvals or successfully market our products, and may even result in recalls, withdrawal of regulatory approval or adverse labeling of the product.

While our products are subject to comprehensive clinical trials and rigorous statistical analysis during the development process prior to approval, there are inherent limitations with regard to the design of such trials, including the limited number of patients enrolled in such trials, the limited time used to measure the efficacy of the product and the limited ability to perform long-term monitoring. In the event that such unanticipated adverse reactions are discovered, we may be required to add descriptions of the adverse reactions as "precautions" to the packaging of our products, recall and terminate sales of products or conduct costly post-launch clinical trials. Furthermore, concerns relating to potential adverse reactions could arise among consumers or medical professionals, and such concerns, whether justified or not, could have an adverse effect on sales of our products and our reputation. We could also be subject to product liability litigation by patients who have suffered or claim to have suffered such adverse reactions resulting in harm to their health.

Although we maintain product liability insurance at coverage levels that we believe are appropriate, we could be subject to product liability that significantly exceeds such levels. Product liability coverage is also increasingly difficult and costly to obtain, and may not be available in the future on acceptable terms. Therefore, in the future, it is possible that we may need to rely increasingly on self-insurance for the management of product liability risk. In cases where we self-insure, the legal costs that we would bear for handling such claims and potential indemnifications to be paid to claimants could materially and adversely affect our financial condition. In addition, the negative publicity from product liability claims, whether or not justified, may damage our reputation and may negatively impact the number of prescriptions of the product in question or our other products. As a result, our business, financial condition and results of operations could be materially and adversely affected.

We may not be able to attract and retain key management and other personnel.

In order to produce, develop, support and market our products, we depend on the expertise and leadership of our senior management team and other key members of our organization. The loss of key members of our organization, including senior members of our scientific and management teams, high-quality researchers and development specialists, could delay or prevent the achievement of major business objectives. The market for such talents has become increasingly competitive, including in specific geographic regions and in specialized fields such as clinical development and biosciences, and we are required to invest heavily in the recruitment, training and retention of qualified individuals, including salary and other compensation to reward performance and incentivize employees. Despite our efforts to retain them, key employees could terminate their employment with us for any reason or for no reason, and there is no assurance that we will be able to attract or retain key employees and successfully manage them. Our inability to attract, integrate and retain highly skilled personnel, particularly those in leadership positions, may weaken our succession plans and may materially adversely affect our ability to implement our strategy and meet our strategic objectives, which could ultimately adversely affect our business and results of operations.

We are increasingly dependent on information technology systems and our systems and infrastructure face the risk of theft, exposure, tampering or other intrusions.

A variety of important processes relating to the research and development, production and sale of our products depend heavily on our information systems, including cloud-based computing, or those of third party providers to whom we outsource certain business functions, including the storage and transfer of critical, confidential, sensitive or personal information regarding our patients, clinical trial subjects, vendors, customers, employees and others. The size and complexity of these computer systems make them potentially vulnerable to service interruptions, malicious intrusions and random attacks. Cyber-attacks are increasing in frequency, sophistication and intensity. Such attacks are made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, "hacktivists," nation-states and others. Cyber-attacks could include the deployment of harmful malware, denial of service attacks, worms, social engineering and other means to affect service reliability and threaten data confidentiality, integrity and availability. The development and maintenance of systems to safeguard against such attacks is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly more sophisticated. Moreover, the costs related to these security measures are expected to continue to increase. Despite our efforts, the possibility of a future data compromise cannot be eliminated entirely, and risks associated with intrusion, exposure, tampering, and theft remain. For "zero-day threats," or new vectors of attack which are currently unknown, the risk that our defenses will be inadequate are particularly pronounced.

If our data systems are compromised, our business operations may be impaired, we may lose profitable opportunities, or the value of those opportunities may be diminished, and we may lose revenue because of unlicensed use of our intellectual property or confidential or proprietary information. Cyber-attacks could significantly impact the availability of data systems that are essential to conducting routine business operations across the company, including product manufacturing or clinical development, and the recovery efforts could be both time consuming and costly. If personal information of our customers or employees is misappropriated, our reputation with our customers and employees may be injured resulting in loss of business and/or morale, and we may incur costs to remediate possible injury to our customers and employees or be required to pay fines or take other action with respect to judicial or regulatory actions arising out of such incidents. Data privacy or security breaches by employees and others with permitted access to our systems, including in some cases third-party service providers to which we may outsource certain business functions, may also pose a risk that sensitive data, including intellectual property or personal information, will be exposed to unauthorized persons or to the public.

Changes in data privacy and protection laws and regulations, particularly in Europe, or any failure to comply with such laws and regulations, could adversely affect our business and financial results.

We are subject to laws and regulations globally regarding privacy, data protection, and data security, including those related to the collection, storage, handling, use, disclosure, transfer, and security of personal data. Significant uncertainty exists as privacy and data protection laws may be interpreted and applied differently from country to country and may create inconsistent or conflicting requirements. For example, the EU's General Data Protection Regulation (the "GDPR"), which imposes additional obligations on companies regarding the handling of personal data and provides certain individual privacy rights to persons whose data is processed, became effective on May 25, 2018. Moreover, significant regulatory fines may be imposed on us for violation of these requirements, particularly in the case of the GDPR, which are set at a maximum of the higher of €20 million or 4% of annual global turnover for the most serious breaches, or the higher of €10 million or 2% of annual global turnover for certain others. There is also significant uncertainty as to how the various EU member states or individual regulators will implement and interpret the GDPR, and we are still in the process of identifying and unifying differences between our and Shire's historical GPDR compliance practices. Furthermore, legislators and regulators in the United States are proposing new and more robust cybersecurity rules in light of the recent broad-based cyberattacks at a number of companies. Compliance with existing, proposed and recently enacted laws (including implementation of the privacy and process enhancements called for under GDPR) and regulations can be costly; any failure to comply with these regulatory standards could subject us to legal and reputational risks. Misuse of or failure to secure personal information could also result in violation of data privacy laws and regulations, proceedings against us by governmental entities or others or damage to our reputation and credibility and could also have a negative impact on revenues and profits.

Social media platforms and new technologies present risks and challenges for our reputation and business.

Consumers, the media, pharmaceutical companies and other parties increasingly use social media and other new technologies to communicate about pharmaceutical products and the diseases they are intended to treat. For pharmaceutical companies, the use of these technologies requires specific attention, monitoring programs and moderation of comments. For example, negative or inaccurate posts or comments about us or our products on any social media networking platforms could damage our reputation and business. Social media could also be used to bring negative attention to us or to the pharmaceutical industry as a whole, which could in turn cause reputational harm to us and negatively impact our business. The nature of evidence-based health care, however, may prevent us from rapidly and adequately defending our interests against such comments. In addition, our employees and partners may use social media and mobile technologies inappropriately, which may expose us to liability, or which could lead to breaches of data security, loss of trade secrets or other intellectual property or public disclosure of sensitive information, including information about our employees, clinical trial subjects or customers.

Sales to wholesalers are concentrated, which exposes us to credit risks and pricing pressures.

A significant portion of our global sales are made to a relatively small number of wholesale distributors, retail chains and other purchasing groups. In the fiscal year ended March 31, 2019, our largest wholesale distributor accounted for 10.8% of our total revenue. If one of our significant wholesale distributors encounters financial or other difficulties, such distributor may decrease the amount of business that it does with us, and we may be unable to collect the amounts that the distributor owes us on a timely basis or at all. Furthermore, the concentration of wholesale distributors has been increasing through mergers and acquisitions. In addition to increased credit risks, this has resulted in such distributors gaining additional purchasing leverage, which may increase pricing pressure on our products. Such credit concentration risks and pricing pressure could adversely affect our business, financial condition and results of operations.

We face risks from the pursuit of acquisitions, and the anticipated benefits and synergies resulting from acquisitions may not be realized.

We regularly pursue acquisitions for a number of reasons, including strengthening our pipeline, complementing existing lines of business, adding research and development capabilities or pursuing other synergies. The pursuit of these acquisitions requires the commitment of significant management and capital resources in various stages, from the exploration of potential acquisition targets to the negotiation and execution of an acquisition to the integration of an acquired business into our own. The required commitment of time and resources may divert the attention of management or capital or other resources away from our day-to-day business. Moreover, we may not be able to recoup the investment of capital or other resources through the successful integration of acquired businesses, including the realization of any expected cost or other synergies. Specifically, we may encounter the following difficulties:

- We may face significant challenges in combining the infrastructure, management and information systems of acquired companies with ours, including integrating research and development, manufacturing, distribution, marketing and promotion activities and information technology systems;
- There may be difficulties in conforming standards, controls, procedures and accounting and other policies, as well as business cultures and compensation structures;
- We may not be able to retain key personnel at acquired companies, or our own employees may be motivated to leave due to acquisitions;
- We may not be successful in identifying and eliminating redundancies and achieving other cost savings as expected; and
- We may not be able to successfully realize benefits from acquired products, including pipeline products under development.

Integrating the operations of multiple new businesses with that of our own is a complex process that requires significant management attention and resources. The integration process may disrupt our existing and other newly acquired businesses and, if implemented ineffectively, could have an adverse impact not only on our ability to realize the benefits of a given acquisition but also on the results of our existing operations. Integration-related risks may be heightened in cases where acquired businesses' operations, employees or customers are located outside our major markets and we incur

higher costs than anticipated due to regulatory changes, environmental factors or foreign exchange fluctuations. We continue to pursue strategic business acquisitions globally as a key part of our continuous growth strategy. If we are not able to achieve the anticipated benefits of any future acquisitions in full or in a timely manner, we could be required to recognize impairment losses, we may not be able to recoup our investment, and our business, financial position and results of operations could be materially and adversely affected. Particularly, we may be unable to achieve the expected revenues pursuant to licensing, co-promotion or co-development agreements or collaborations. We may also assume unexpected contingent or other liabilities, or be required to mark up the fair value of liabilities (or mark down the fair value of assets) acquired upon the close of an acquisition.

We may incur substantial costs due to our environmental compliance efforts or claims relating to our use, manufacture, handling, storage or disposal of hazardous materials.

Our research and development and manufacturing processes use hazardous materials, including chemicals and radioactive and biological materials, and produce hazardous waste. National and local laws and regulations in many of the jurisdictions in which we operate impose substantial potential liability for the improper use, manufacture, handling, storage and disposal of hazardous materials as well as for land contamination, and, in some cases, this liability may continue over long periods of time. Despite our compliance efforts, we cannot completely eliminate the risk of accidental contamination and any resultant injury from these materials. For example, real properties that we owned or used in the past or that we own or use now or in the future may contain detected or undetected contamination resulting from our manufacturing operations at those sites or the activities of prior owners or occupants. We may suffer from expenses, claims or liability which may fall outside of or exceed our insurance coverage. Furthermore, changes to current environmental laws and regulations may impose further compliance requirements on us that may impair our research, development and production efforts as well as our other business activities.

We may suffer large losses in the event of a natural or other disaster, such as an earthquake, terrorist attack or other catastrophic event, in any of the markets in which we operate.

Japan and other regions in the world in which we operate are subject to the risk of earthquakes and other natural disasters, including volcanic eruptions, tidal waves, typhoons, floods and hurricanes. For example, the Great East Japan Earthquake and subsequent tsunami that occurred in March 2011 caused unprecedented property and other damage, although we did not incur any significant damage to our facilities. In addition, other events outside our control, such as war, civil or political unrest, deliberate acts of sabotage, or industrial accidents such as fire and explosion, whether due to human or equipment error, could damage, cause operational interruptions, or otherwise adversely affect certain of our manufacturing or other facilities as well as potentially cause injury or death to our personnel. In the event of a major natural disaster or other uncontrollable event or accident, our facilities, particularly our production plants, may experience catastrophic loss, operations at such facilities may be halted, shipments of products may be suspended or delayed and large losses and expenses to repair or replace facilities may be incurred. Such negative consequences could cause product shortages, significant losses of sales or require significant unexpected expenditures, and materially adversely affect our business, financial condition and results of operations. In addition, our business may also be adversely affected if our suppliers or business partners were to experience a catastrophic loss due to natural disasters, accidents or other uncontrollable events.

Although we purchase comprehensive global insurance to cover property damage and consequent business interruption for certain potential losses at sites owned by us and at certain critical supplier sites, we do not maintain earthquake insurance in Japan, and our insurance policies may not be adequate to cover all possible losses and expenses.

We may have to recognize additional charges on our statements of income due to impairment of goodwill, other intangible assets and equity method investments.

We carry significant amounts of goodwill and intangible assets on our balance sheet as a result of past acquisitions, including the Shire Acquisition. As of March 31, 2019, we had goodwill of ¥4,161.4 billion and intangible assets of ¥4,860.4 billion. Goodwill and intangible assets recorded in relation to acquisitions are recognized on our balance sheet on the acquisition date. Under IFRS, we are required to examine such assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. See "Item 5. Operating and Financial Review and Prospects—A. Operating Results—Critical Accounting Policies—Impairment of Goodwill and Intangible Assets."

We occasionally enter into business ventures with third-party entities where we have significant influence over the decisions on financial and operating policies, but do not have control or joint control (referred to as "investments in associates"). We also enter into joint arrangements whereby we and the other parties that have joint control of the arrangement have rights to the net assets of the arrangement (referred to as "joint venture"). We account for these investments using the equity method of accounting. As of March 31, 2019, the carrying amount of investments accounted for using the equity method was ¥114.7 billion. Under IFRS, at each reporting period, we are required to determine whether there is objective evidence that the investment in each associate or joint venture is impaired.

The recognition of such impairment charges may adversely affect our business, financial condition and results of operations.

If we fail to maintain effective internal control over financial reporting, the accuracy and timeliness of our financial reporting may be adversely affected, which could cause investors to lose confidence in our reported financial information and may lead to a decline in the trading price of our ADSs.

Our common stock is currently listed on the Tokyo Stock Exchange and other local Japanese stock exchanges, and we have established internal control over financial reporting pursuant to the requirements applicable to companies listed only in Japan. In addition, our ADSs are listed on the New York Stock Exchange (the "NYSE"), making us subject to, among other things, the requirements under the Sarbanes-Oxley Act of 2002 (the

"Sarbanes-Oxley Act"). The standards for internal control over financial reporting under the Sarbanes-Oxley Act are significantly more extensive than those applicable to companies listed only in Japan. For example, we will be required, pursuant to Section 404 of the Sarbanes-Oxley Act ("Section 404"), to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting, as well as a statement that our independent registered public accounting firm has issued an opinion on our internal control over financial reporting. Pursuant to the instructions to Form 20-F, we expect to include this report in our next annual report filed with the SEC, which we currently expect will be filed by no later than July 31, 2020. We are still in the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404.

Neither our management nor independent registered public accounting firm has ever performed a comprehensive evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act because no such evaluation has been required, and we cannot be certain that material weaknesses in our internal control over financial reporting will not develop or be identified. Any failure to achieve and maintain adequate internal control over financial reporting or to implement required, new or improved controls, or difficulties encountered in their implementation could cause material weaknesses or other deficiencies in our internal control over financial reporting in the future. If we are unable to successfully remediate any material weaknesses or other deficiencies in our internal control over financial reporting, the accuracy and timing of our financial reporting may be adversely affected, and investors may lose confidence in our financial reporting, and the price of our ADSs may decline as a result. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on the NYSE.

We are subject to additional risk due to uncertainty relating to the calculation of LIBOR, EURIBOR and other reference rates and their potential discontinuance.

The JBIC Loan and the Term Loan Credit Agreement are subject to a floating interest rate calculated in reference to LIBOR, while the floating rate Euro-denominated senior notes we issued in connection with the Shire Acquisition are subject to floating rate interest calculated in reference to EURIBOR. LIBOR, EURIBOR and other interest rate, equity, commodity, foreign exchange rate and other types of indices which are deemed to be "benchmarks" are the subject of ongoing national, international and other regulatory guidance and proposals for reform. Some of these reforms are already effective while others are still to be implemented. These reforms may cause such "benchmarks" to perform differently than they have performed in the past or to be discontinued entirely or may have other consequences that cannot be predicted, which could have a material adverse effect on our financial condition or results of operations or require us to seek to amend the terms of the relevant indebtedness, which may require significant additional time, effort or money in the form of consent payments or otherwise, and may not be possible on cost-efficient terms or at all.

In particular, regulators and law enforcement agencies in the United Kingdom and elsewhere are conducting criminal and civil investigations into whether the banks that contribute information to the British Banker Association (the "BBA") in connection with the daily calculation of LIBOR may have been under-reporting or otherwise manipulating or attempting to manipulate LIBOR. A number of BBA members banks have entered into settlements with their regulators and law enforcement agencies, as well as the ICE Benchmark Administration (the current administrator of LIBOR), which may result in changes to the manner in which LIBOR is determined or the establishment of alternative reference rates. On July 27, 2017, the Chief Executive of the U.K. Financial Conduct Authority (the "FCA"), which regulates LIBOR, announced that the FCA will no longer persuade or compel banks to submit rates for the calculation of LIBOR after 2021. Such announcement indicates that the continuation of LIBOR on the current basis cannot and will not be guaranteed after 2021. Notwithstanding the foregoing, it appears highly likely that LIBOR will be discontinued or modified by 2021. A number of alternatives to LIBOR have been proposed or are being developed, but it is not clear which, if any, will be adopted. Any of these alternative methods may result in interest payments that are higher than expected or that do not otherwise correlate over time with the payments that would have been made on such indebtedness for the interest periods if the applicable LIBOR rate was available in its current form. More generally, any of the foregoing changes, any other changes to LIBOR as a result of national, international and other regulatory guidance and proposals for reform or other initiatives or investigations, or any further uncertainty surrounding the implementation of such changes, could have a material adverse effect on affected indebtedness.

At this time, it is not possible to predict the effect that these developments, any discontinuance, modification or other reforms to LIBOR, EURIBOR or any other reference rate, or the establishment of alternative reference rates may have on LIBOR, EURIBOR, other benchmarks or floating rate indebtedness.

Risks Relating to the ADSs

A holder of ADSs has fewer rights than a holder of our common stock has, and a holder of ADSs has to act through the depositary to exercise those rights.

The rights of shareholders under Japanese law to take various actions, including voting their shares, receiving dividends and distributions, bringing derivative actions, examining a company's accounting books and records and exercising appraisal rights, are available only to holders of record. Because the depositary, through its custodian agents, is the record holder of the shares underlying the ADSs, only the depositary can exercise those rights in connection with the deposited shares. Pursuant to the deposit agreement, the depositary will endeavor, to the extent practicable, to make efforts to vote or cause to be voted the shares underlying the ADSs as instructed by the holders and will pay to the holders the dividends and distributions collected from the Company. The depositary and its agents may not be able to send voting instructions to holders of ADSs or carry out their voting instructions in a timely manner. Furthermore, the depositary and its agents will not be responsible for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, holders of ADSs may not be able to exercise their right to vote. Moreover, in the capacity as an ADS holder, such holder will not be able to bring a derivative action, examine the Company's accounting books or records or exercise appraisal rights except through the depositary.

Rights of shareholders under Japanese law may be more limited than under the laws of other jurisdictions.

Our Articles of Incorporation, Regulations of the Board of Directors, Regulations of the Audit and Supervisory Committee and the Companies Act govern our corporate affairs. Legal principles relating to such matters as the validity of corporate procedures, directors' and officers' fiduciary duties, and shareholders' rights may be different from those that would apply to a non-Japanese company. Shareholders' rights under Japanese law may not be as extensive as shareholders' rights under the laws of other jurisdictions. ADS holders may have more difficulty in asserting their rights as a shareholder than such holders would as shareholders of a corporation organized in another jurisdiction. In addition, Japanese courts may not be willing to enforce liabilities against the Company in actions brought in Japan that are based upon the securities laws of other jurisdictions.

Because of daily price range limitations under Japanese stock exchange rules, a holder of ADSs who has surrendered his or her ADSs in favor of shares of our common stock may not be able to sell his/her shares of our common stock at a particular price on any particular trading day, or at all.

Stock prices on Japanese stock exchanges are determined on a real-time basis by the equilibrium between bids and offers. These exchanges are order-driven markets without specialists or market makers to guide price formation. To prevent excessive volatility, these exchanges set daily upward and downward price fluctuation limits for each stock, based on the previous day's closing price. Although transactions may continue at the upward or downward limit price if the limit price is reached on a particular trading day, no transactions may take place outside these limits. Consequently, a holder of ADSs who has surrendered his or her ADSs in favor of shares of our common stock wishing to sell on a Japanese stock exchange at a price above or below the relevant daily limit may not be able to sell his or her shares at such price on a particular trading day, or at all.

U.S. investors may have difficulty in serving process or enforcing a judgment against us or our directors or executive officers.

We are a limited liability, joint stock corporation incorporated under the laws of Japan. Many of our directors and executive officers reside in Japan, Europe or elsewhere outside of the United States, and a large portion of our assets and the assets of these persons are located in Japan and elsewhere outside the United States. It may not be possible, therefore, for U.S. investors to effect service of process within the United States upon us or these persons or to enforce against us or these persons judgments obtained in U.S. courts predicated upon the civil liability provisions of the federal securities laws of the United States. There is doubt as to the enforceability in Japan, in original actions or in actions for enforcement of judgment of U.S. courts, of liabilities predicated solely upon the federal securities laws of the United States.

Investors holding less than a full unit of shares will have limited rights as shareholders.

Our Articles of Incorporation provide that 100 shares of our common stock constitute one unit. Although holders of ADSs may withdraw shares of our common stock constituting less than one unit, in connection with the direct holding of the shares of our common stock, the Companies Act imposes significant restrictions and limitations on holders of shares of our common stock that do not constitute a full unit. In general, holders of shares of our common stock constituting less than one unit do not have the right to vote with respect to those shares.

Dividend payments and the amount you may realize upon a sale of our ADSs will be affected by fluctuations in the exchange rate between the U.S. dollar and the Japanese yen.

Cash dividends, if any, in respect of the shares of our common stock represented by our ADSs will be paid to the depositary in Japanese yen and then converted by the depositary into U.S. dollars, subject to certain conditions. Accordingly, fluctuations in the exchange rate between the Japanese yen and the U.S. dollar will affect, among other things, the U.S. dollar amounts a holder of ADSs will receive from the depositary in respect of dividends, the U.S. dollar value of the proceeds that a holder of ADSs would receive upon sale in Japan of the shares of our common stock obtained upon surrender of ADSs and the secondary market price of ADSs.

Our shareholders of record on a given record date may not receive the dividend they anticipate.

The customary dividend payout practice of publicly listed companies in Japan may significantly differ from the practices widely followed or otherwise deemed necessary or fair in foreign markets. We ultimately have a discretion to determine any dividend payment amount to our shareholders of record as of a record date, including whether we will make any dividend payment to such shareholders at all, only after such record date. For that reason, our shareholders of record on a given record date may not receive the dividends they anticipate.

ADS holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable outcomes to the plaintiff(s) in any such action.

The deposit agreement governing the ADSs provides that, to the fullest extent permitted by law, ADS holders waive the right to a jury trial for any claim they may have against us or the depositary arising out of or relating to our shares, the ADSs or the deposit agreement, which may include any claim under the U.S. federal securities laws.

If we or the depositary were to oppose a jury trial based on this waiver, the court would have to determine whether the waiver was enforceable based on the facts and circumstances of the case in accordance with applicable state and federal law. To our knowledge, the enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the federal securities laws has not been finally adjudicated by the United States Supreme Court. However, we believe that a contractual pre-dispute jury trial waiver provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement, or by a federal or state court in the City of New York, which has jurisdiction over matters arising under the deposit agreement. In determining whether to enforce a contractual pre-dispute jury trial waiver, courts will generally consider whether

a party knowingly, intelligently and voluntarily waived the right to a jury trial. We believe that this would be the case with respect to the deposit agreement and the ADSs. It is advisable that prospective investors consult legal counsel regarding the jury waiver provision before investing in the ADSs.

As a result, if a holder or beneficial owner of ADSs brings a claim against us or the depositary in connection with matters arising under the deposit agreement or the ADSs, including claims under federal securities laws, such holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us or the depositary. If a lawsuit is brought against us or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have, including outcomes that could be less favorable to the plaintiff(s) in any such action.

Nevertheless, if this jury trial waiver is not enforced under applicable law, an action could proceed under the terms of the deposit agreement with a jury trial. No condition, stipulation or provision of the deposit agreement or the ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with any substantive provision of the U.S. federal securities laws and the rules and regulations promulgated thereunder.

Item 4. Information on the Company

A. History and Development of the Company.

We are a global, values-based, research and development driven biopharmaceutical company with operations in approximately 80 countries. We bring highly innovative, life changing medicines to patients across the globe, with prescription drugs marketed directly or through our partners in approximately 100 countries worldwide. Our global workforce is committed to bringing better health and a brighter future to patients. We develop and market pharmaceutical products to treat a broad range of medical conditions including GI diseases, cancer, neurological and psychiatric diseases, and rare diseases including immunology and hematology, as well as plasma-derived therapies and vaccines. We are also committed to our corporate social responsibility program, which is dedicated to global health, and our access to medicine strategy, which aims to increase access to innovative and potentially lifesaving medicines for patients with some of the highest unmet medical needs across the world.

Our 238-year history started in 1781, when Chobei Takeda began selling traditional Japanese and Chinese medicines in Doshomachi, Osaka. After Japan's Meiji Restoration opened the country to increase overseas trade in the late 1860s, we were one of the first companies to begin importing western medicines into Japan. In 1895, we began our pharmaceutical manufacturing business, and our research division was formed in 1914, allowing us to begin to introduce our own pharmaceutical products. In 1925, we were incorporated as Chobei Takeda & Co., Ltd. and our name was later changed to Takeda Pharmaceutical Company Limited. In 1949, our shares were listed on the Tokyo and Osaka stock exchanges. We began expanding into overseas markets in the 1960s, first in Asia and, subsequently, other markets around the world. We began enhancing our overseas business infrastructure in the late 1990s, with the formation of new subsidiaries in the United States and Europe.

Since 2014, our efforts have been focused on enhancements to our research and development capabilities and successful cross-border merger and acquisition activities and post-acquisition integration. For example, in February 2017, we acquired ARIAD, a commercial-stage biotechnology company and in July 2018, we acquired TiGenix NV, an advanced biopharmaceutical company developing novel stem cell therapies for serious medical conditions, with the aim to bring new treatment options to patients with gastrointestinal disorders.

Most recently, in January 2019, we completed our acquisition of Shire. With the Shire Acquisition, we have taken the next major step in our development into a global pharmaceutical company. The Shire Acquisition allows us to create a global, values-based, research and development-driven biopharmaceutical company with an attractive geographic footprint with a significantly increased presence in the United States, an important and innovation-driven market. Specifically, the Shire Acquisition strengthens our core therapeutic areas, bringing together Takeda and Shire's complementary positions in GI and neuroscience and providing leading positions in rare diseases and plasma-derived therapies to complement our existing strength in oncology and focused efforts in vaccines. It also creates a highly complementary, robust, modality-diverse pipeline and a strengthened research and development engine focused on innovation.

During the three fiscal years ended March 31, 2019, we have also divested a number of businesses and assets in non-core areas. For example, in April 2017, we completed the sale of our shares in Wako Pure Chemical to FUIJIFILM Corporation and in December 2017, we entered into an agreement with Takashimaya Company Limited to sell our Tokyo Takeda building and the Takeda Shin-Edobashi building. Further, in July 2018, we sold and divested all our shares and assets in Multilab Indústria e Comércio de Produtos Farmacêuticos Ltda. to Novamed Fabricação de Produtos Farmacêuticos Ltda and in August 2018, we sold and divested all our shares and assets in Guangdong Techpool Bio-Pharma Co., Ltd. to Shanghai Pharmaceutical Holding Co. Ltd. We will continue to divest certain businesses and assets as we integrate Shire and focus on our core business. For example, on May 9, 2019, we announced the sales of two of our non-core businesses, Xiidra® (lifitegrast ophthalmic solution) and TachoSil™ (Fibrin Sealant Patch). For additional details on these transactions, see Note 33 to our audited consolidated financial statements included in this annual report.

Our principal capital expenditures during the three fiscal years ended March 31, 2019 consisted of additions to property, plant and equipment and additions to intangible assets. In the fiscal years ended March 31, 2017, 2018 and 2019, excluding acquisitions, we made capital expenditures (consisting of the additions to property, plant and equipment and intangible assets recorded on our consolidated balance sheet) of ¥148.1 billion, ¥124.1 billion and ¥244.6 billion, respectively, including the following highlights:

- In the fiscal year ended March 31, 2017, we invested ¥8.3 billion to prepare the manufacturing facility in Brooklyn Park, Minnesota acquired from Baxalta US. Inc. for the production of *ENTYVIO*;

- In the fiscal year ended March 31, 2018, we invested ¥17.9 billion to construct our new global headquarters in Tokyo. We also invested ¥11.4 billion to purchase manufacturing equipment at our German subsidiary, Takeda GmbH, including ¥4.9 billion in equipment for manufacturing of vaccines for dengue fever; and
- In the fiscal year ended March 31, 2019, we received an additional 20-year extension agreement (from 2030 to 2050) for our two leased properties in Cambridge, Massachusetts. The total lease liability for these properties including this renewal option that we are reasonably certain to exercise is ¥88.8 billion as of March 31, 2019.

We currently have various capital expenditures projects in process, the most significant of which includes the construction of a biologics facility in Dunboyne, Ireland, which will be funded through internally generated cash flows.

The address of our global head office is 1-1, Nihonbashi-Honcho 2-Chome, Chuo-ku, Tokyo, 103-8668, Japan; telephone number: 81-3-3278-2306. Takeda's agent in the United States in connection with this annual report is Shire HGT, Inc., 300 Shire Way, Lexington, MA 02421 U.S.A., telephone number: 1-617-349-0200.

The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at www.sec.gov. As a foreign private issuer, we are exempt from the rules under the Securities Exchange Act of 1934 (the "Exchange Act") prescribing the furnishing and content of proxy statements to shareholders. Our corporate website is www.takeda.com.

B. Business Overview.

We are a global, values-based, research and development-driven biopharmaceutical company with an innovative portfolio, engaged primarily in the research, development, production and marketing of pharmaceutical products. Our mission is to strive towards a better health and a brighter future for people worldwide through leading innovation in medicine. Our culture is based on the achievement of this mission by acting with integrity, fairness, honesty and perseverance and prioritizing the patient, trust, reputation and the business.

Our three strategic priorities to drive sustainable mid to long-term growth are business area focus, our research and development engine and financial strength.

We are focused on five key business areas of GI, rare diseases, plasma-derived therapies, oncology, and neuroscience. We believe these five business areas will drive our future growth. We have been making targeted acquisitions and divestitures to further increase our level of focus on these areas and plan to continue to refine our business portfolio going forward.

Our research and development engine is based on a therapeutic area focus, a leading partnership model and patient-centric, science-driven culture of innovation. Our strengthened and revitalized research and development engine is focused on the therapeutic areas of oncology, GI, rare diseases and neuroscience with targeted investments in plasma-derived therapies and vaccines. In order to deliver value in areas of high unmet medical needs, we strive to progress our pipelines by focusing on innovative medicines.

Our financial strength involves driving margin expansion and generating cash flows to invest in the business, to deleverage and to return cash to shareholders. We also are prioritizing selected disposal of non-core assets to generate cash in order to accelerate the pace of deleveraging.

We are also focused on successfully executing the integration of Shire while sustaining business momentum. The execution of our integration plan is underway and we believe that the integration will have relatively minimal disruption on the business and pipeline due to the strong strategic and geographic fit of the two companies. We also believe that we will experience minimal disruption to our research and development efforts as we are adding rare diseases to our already defined research and development model. We believe a smooth integration will result in a stronger and more innovative portfolio supported by a lean and focused organization.

Our key growth driver products will be derived from 14 global brands in five business areas and include: *ENTYVIO*, *GATTEX/REVESTIVE, ALOFISEL, NATPARA, ADYNOVATE/ADYNOVI, TAKHZYRO, ELAPRASE, VPRIV, GAMMAGARD LIQUID, HYQVIA, CUVITRU, ALBUMIN/ FLEXBUMIN, NINLARO, and ALUNBRIG*.

The following is a summary of our principal products by key business area. Revenues attributable to products acquired as part of the Shire Acquisition for the year ended March 31, 2019 given in this section refer to revenues recorded on our consolidated statement of income following the completion of the Shire Acquisition on January 8, 2019.

In GI, our principal products include:

- *ENTYVIO* (vedolizumab), a treatment for moderate to severe ulcerative colitis and Crohn's disease. Sales of *ENTYVIO* have grown strongly since its launch in 2014 to become our top selling product in the fiscal year ended March 31, 2019. *ENTYVIO* is now approved in more than 50 countries worldwide, and we continue to seek approval for *ENTYVIO* in additional countries. In the fiscal year ended March 31, 2019, our revenue from *ENTYVIO* was ¥269.2 billion.

- *TAKECAB* (vonoprazan fumurate), a treatment for acid-related diseases. *TAKECAB* was launched in Japan in 2015 and has achieved significant growth following the expiration of the prescription limitation period in March 2016. In the fiscal year ended March 31, 2019, our revenue from *TAKECAB* was ¥58.2 billion.
- *GATTEX/REVESTIVE* (teduglutide [rDNA origin]) for injection is the first prescription medicine for the long-term treatment of adults with short bowel syndrome ("SBS") who are dependent on parenteral support. We added *GATTEX/REVESTIVE* to our GI portfolio with the acquisition of Shire, which was completed in January 2019. In May 2019, the FDA approved extending the indication of *GATTEX* for children 1 year of age and older with SBS. In the fiscal year ended March 31, 2019, our revenue from *GATTEX/REVESTIVE* was ¥12.8 billion.
- *ALOFISEL* (darvadstrocel), previously Cx601, a treatment for complex perianal fistulas in adult patients with nonactive/mildly active luminal Crohn's disease, when fistulas have shown an inadequate response to at least one conventional or biologic therapy. *ALOFISEL* was approved in the EU in 2018 which marked the first allogenic stem cell therapy to receive central marketing authorization ("MA") approval in Europe. In the fiscal year ended March 31, 2019, our revenue from *ALOFISEL* was ¥0.05 billion.

In rare diseases, our principal products are:

- *NATPARA/NATPAR* (parathyroid hormone) for injection is indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism ("HPT"). HPT is a rare condition in which the parathyroid glands fail to produce sufficient amounts of parathyroid hormone ("PTH") or where the PTH lacks biologic activity. We added *NATPARA/NATPAR* to our rare diseases portfolio with the acquisition of Shire, which was completed in January 2019. In the fiscal year ended March 31, 2019, our revenue from *NATPARA/NATPAR* was ¥7.1 billion.
- *ADYNOVATE/ADYNOVI* (antihemophilic factor (recombinant) [PEGylated]) is an extended half-life recombinant factor VIII treatment for hemophilia A based on *ADVATE. ADYNOVATE/ADYNOVI* uses the same manufacturing process as *ADVATE* and adds a proven technology, PEGylation (a chemical process that prolongs the amount of time a compound remains in circulation, potentially allowing for fewer injections), which we exclusively licensed from Nektar Therapeutics. We added *ADYNOVATE/ADYNOVI* to our rare diseases portfolio with the acquisition of Shire, which was completed in January 2019. In the fiscal year ended March 31, 2019, our revenue from *ADYNOVATE/ADYNOVI* was ¥10.7 billion.
- *TAKHZYRO* (lanadelumab-flyo) injection, a fully human monoclonal antibody that specifically binds and decreases plasma kallikrein. *TAKHZYRO* is the only monoclonal antibody (mAb) that provides targeted inhibition of plasma kallikrein, an enzyme which is chronically uncontrolled in people with hereditary angioedema ("HAE"), to help prevent attacks. We added *TAKHZYRO* to our rare diseases portfolio with the acquisition of Shire, which was completed in January 2019. In the fiscal year ended March 31, 2019, our revenue from *TAKHZYRO* was ¥9.7 billion.
- *ELAPRASE* (idursulfase), an enzyme replacement treatment for Hunter syndrome (also known as Mucopolysaccharidosis Type II or MPS II). We added *ELAPRASE* to our rare diseases portfolio with the acquisition of Shire, which was completed in January 2019. In the fiscal year ended March 31, 2019, our revenue from *ELAPRASE* was ¥15.1 billion.
- *REPLAGAL* (agalsidase alfa for infusion), an enzyme replacement marketed for the treatment of Fabry disease outside of the U.S. Fabry disease is a rare, inherited genetic disorder resulting from a deficiency in the activity of the lysosomal enzyme alpha-galactosidase A, which is involved in the breakdown of fats. We added *REPLAGAL* to our rare diseases portfolio with the acquisition of Shire, which was completed in January 2019. In the fiscal year ended March 31, 2019, our revenue from *REPLAGAL* was ¥11.4 billion.
- *VPRIV* (velaglucerase alfa for injection), an enzyme replacement treatment for type 1 Gaucher disease. We added *VPRIV* to our rare diseases portfolio with the acquisition of Shire, which was completed in January 2019. In the fiscal year ended March 31, 2019, our revenue from *VPRIV* was ¥8.7 billion.

In the fiscal year ended March 31, 2019, our revenue from plasma-derived therapy products was ¥111.7 billion. In plasma-derived therapies, our principal products are:

- *GAMMAGARD LIQUID* (Immune Globulin Intravenous (Human) 10%), a liquid formulation of the antibody replacement therapy immunoglobulin ("IG") product. *GAMMAGARD LIQUID* is used to treat adult and pediatric patients two years of age or older with primary immunodeficiencies ("PID") and can be administered either intravenously or subcutaneously. *GAMMAGARD LIQUID* is also used to treat adult patients with multifocal motor neuropathy ("MMN") administered intravenously. *KIOVIG* is the brand name used for *GAMMAGARD LIQUID* in many countries outside of the U.S. *KIOVIG* is approved in Europe for use by patients with PID and certain secondary immunodeficiencies, and for adults with MMN. We added *GAMMAGARD LIQUID* to our plasma-derived therapies portfolio with the acquisition of Shire, which was completed in January 2019.
- *GAMMAGARD S/D* [Immune Globulin Intravenous (Human)] IgA less than 1 μg/mL in a 5% solution is indicated for the treatment of PID in patients two years old and older. *GAMMAGARD S/D* is also indicated for prevention of bacterial infections in hypogammaglobulinemia and/or recurrent bacterial infections associated with Bcell chronic lymphocytic leukemia ("CLL"), treatment of adult patients with chronic idiopathic thrombocytopenic purpura ("ITP") to increase platelet count and to prevent and/or control bleeding, and prevention of coronary artery aneurysms associated with Kawasaki Syndrome in pediatric patients. *GAMMAGARD S/D* is provided for patients who require a low IgA content in their IV treatment (IgA less than 1 μg/mL in a 5% solution). We added *GAMMAGARD S/D* to our plasma-derived therapies portfolio with the acquisition of Shire, which was completed in January 2019.
- *HYQVIA* [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] is a product consisting of human normal IG and recombinant human hyaluronidase (licensed from Halozyme). *HYQVIA* is the only subcutaneous IG treatment for PID patients

with a dosing regimen requiring only one infusion up to once per month and one injection site per infusion to deliver a full therapeutic dose of IG. We added *HYQVIA* to our plasma-derived therapies portfolio with the acquisition of Shire, which was completed in January 2019. *HYQVIA* is approved in Europe for use by patients with PID syndromes and myeloma or CLL with severe secondary hypogammaglobulinemia and recurrent infections, and in the United States for adults with PID.

- *CUVITRU* is an Immune Globulin Subcutaneous (Human) ("IGSC"), 20% Solution indicated as replacement therapy for primary humoral immunodeficiency in adult and pediatric patients two years of age and older. *CUVITRU* is also indicated in the EU for the treatment of certain secondary immunodeficiencies. *CUVITRU* is the only 20% subcutaneous IG treatment option without proline and with the ability to infuse up to 60 mL (12 grams) per site and 60 mL per hour, per site as tolerated, resulting in fewer infusion sites and shorter infusion durations compared to other conventional subcutaneous IG treatments. We added *CUVITRU* to our plasma-derived therapies portfolio with the acquisition of Shire, which was completed in January 2019.
- *FLEXBUMIN* (Human Albumin in a bag) and Human Albumin (glass) are available as 5% and 25% solutions. Both products are indicated for hypovolemia, hypoalbuminemia due to general causes and burns, and for use during cardiopulmonary bypass surgery as a component of the pump prime. *FLEXBUMIN* 25% is also indicated for hypoalbuminemia associated with adult respiratory distress syndrome ("ARDS") and nephrosis, and hemolytic disease of the newborn ("HDN"). We added *FLEXBUMIN* to our plasma-derived therapies portfolio with the acquisition of Shire, which was completed in January 2019.

In oncology, our principal products include:

- *NINLARO* (ixazomib), the first oral proteasome inhibitor for the treatment of multiple myeloma ("MM"). *NINLARO* has experienced a strong uptake in sales since launching in the United States in 2015. *NINLARO* was approved in the EU in 2016 and in Japan in 2017, and we are seeking marketing authorization in a number of additional countries. In the fiscal year ended March 31, 2019, revenue from *NINLARO* was ¥62.2 billion.
- *ADCETRIS* (brentuximab vedotin), an anti-cancer agent used to treat Hodgkin lymphoma ("HL") and systemic anaplastic large cell lymphoma ("sALCL"). *ADCETRIS* was launched in the United States, the EU and Japan in 2011, 2012 and 2014, respectively. *ADCETRIS* has received marketing authorization by regulatory authorities in more than 60 countries worldwide. We jointly develop *ADCETRIS* with Seattle Genetics, Inc. and have commercialization rights in countries outside the United States and Canada. In the fiscal year ended March 31, 2019, our revenue from *ADCETRIS* was ¥42.9 billion.
- *ALUNBRIG* (brigatinib), an orally administered small molecule anaplastic lymphoma kinase ("ALK") inhibitor used to treat non-small cell lung cancer ("NSCLC"). *ALUNBRIG* was developed by ARIAD Pharmaceuticals. *ALUNBRIG* was granted accelerated approval in the United States in April 2017, and the European Commission granted the product marketing authorization in November 2018. In the fiscal year ended March 31, 2019, our revenue from *ALUNBRIG* was ¥5.2 billion.

In neuroscience, our principal products are:

- *VYVANSE* (lisdexamfetamine dimesylate) is a stimulant medication indicated for the treatment of attention deficit hyperactivity disorder ("ADHD") in patients ages six and above and for the treatment of moderate to severe binge eating disorder in adults. We added *VYVANSE* to our neuroscience portfolio with the acquisition of Shire, which was completed in January 2019. In the fiscal year ended March 31, 2019, our revenue from *VYVANSE* was ¥49.4 billion.
- *TRINTELLIX* (vortioxetine), an antidepressant indicated for the treatment of major depressive disorder in adults. *TRINTELLIX* was co-developed with H. Lundbeck A/S, and was launched in 2014 in the United States. We have commercialization rights in the United States and Japan. In the fiscal year ended March 31, 2019, our revenue from *TRINTELLIX* was ¥57.6 billion in the United States.

For a breakdown of revenues by geographic region, see Note 4 to our audited consolidated financial statements included in this annual report.

Research and Development

Research and development of pharmaceutical products is a lengthy and expensive process that can span more than 10 years. The process includes evaluations of the product's efficacy and safety, application for approval and investigation and approval by regulatory authorities. Only a small number of compounds pass such detailed investigation and are used in clinical treatments. Once approved, there is ongoing research and development support for marketed products, including medical affairs and other investments.

Clinical trials, which comply with regional and international regulatory guidelines, generally take five to seven years or longer and require substantial expenditures. As a result, only a small fraction of compounds that enter the clinical trials results in commercially viable products. In general, clinical trials are performed in accordance with the guidelines set by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. The relevant regulatory authorities are the MHLW for Japan, the FDA for the United States and the EMA for the EU.

The three phases of human clinical trials, which may overlap with each other, are as follows:

Phase I ("P-I") clinical trials	Conducted using a small group of healthy adult volunteers in order to evaluate safety and absorption, distribution, metabolism and excretion of the drug.
Phase II ("P-II") clinical trials	Conducted using a small group of patient volunteers in order to evaluate safety, efficacy, dosage and administration methods. P-II clinical trials may be divided into two sub-categories, P-IIa and P-IIb. P-IIa are usually pilot studies designed to demonstrate clinical efficacy or biological activity. P-IIb studies look to find the optimum dose at which the drug shows biological activity with minimal side-effects.
Phase III ("P-III") clinical trials	Conducted using a large number of patient volunteers in order to evaluate safety and efficacy in comparison to other medications already available or placebo.

Of these three phases, Phase III requires the largest expenditures and thus the decision to proceed with Phase III testing is a critical business decision in the drug development process. For those drug candidates that pass Phase III clinical trials, a New Drug Application ("NDA") or a Marketing Authorization Application ("MAA") is submitted to the relevant governmental authorities for approval and subsequent launch of the drug. The preparation of an NDA or MAA involves considerable data collection, verification, analysis and expense. Even after the launch of the product, health authorities require post-marketing surveillance of adverse events, and they may request a post-marketing study to provide additional information regarding the risks and benefits of the product.

In July 2016, we initiated a five-year research and development transformation program to re-invigorate the pipeline and build an agile, global research and development organization driven by innovative science. A significant component of the program has been an intensive focus in the following three key areas:

- Therapeutic area focus: Leveraging therapeutic area expertise to progress innovative assets.
- Partnerships and capabilities: Enhancing capabilities internally and through external collaborations.
- Innovative research engine: Developing new technologies and new modalities to treat disease.

Our research and development efforts are focused in four key therapeutic areas of oncology, GI, rare diseases and neuroscience, plus the plasma-derived therapies and vaccines business areas.

We have also concentrated our in-house research and development operations in Japan and the United States. We intend to integrate the legacy Shire research and development operations into ours.

Our key in-house research and development facilities include:

- *Shonan Heath Innovation Park:* Located in Fujisawa and Kamakura in Kanagawa Prefecture in Japan, the Shonan Health Innovation Park ("Shonan iPark") was established in 2011 as the Shonan Research Center, and is our primary location for neuroscience research. In April 2018, we launched Shonan iPark by transforming the Shonan Research Center to enhance scientific innovation. Shonan iPark aims to gather 3,000 researchers by the year 2020 and become a place where experts from the pharmaceutical industry, including venture start-ups, government and academia, can gather and incubate and accelerate research initiatives to create health solutions.
- *Boston Research and Development Site:* Our Boston research and development hub is located in Cambridge, Massachusetts in the United States. Our Boston site is the center of our global oncology and GI research and development and also supports research and development in other therapeutic areas including plasma-derived therapies and vaccines, and research in immunomodulation and biologics.
- *San Diego Research and Development Site:* Our research and development site located in San Diego, California in the United States supports research and development of specialized technologies in the GI and neuroscience areas.

In addition to our concentrated efforts to increase our in-house research and development capabilities, external partnerships with third-party partners are a key component of our strategy for enhancing our research and development pipeline. In the fiscal year ended March 31, 2019, we entered into more than 40 such new partnerships. Our strategy to expand and diversify our external partnerships allows us to take part in research of a wide variety of new products and increases the chances that we will be able to take part in a major research-related breakthrough. See "–Licensing and Collaboration" for further information on our research and development collaborations.

The following summarizes our research and development activities within each of our therapeutic and business areas. The compounds in our pipeline disclosed within the key therapeutic and business areas below are in various stages of development, and the contents of the pipeline may change as compounds currently under development are removed and new compounds are introduced. Whether the compounds listed below are ever successfully released as products depends on various factors, including the results of pre-clinical and clinical trials, market conditions for various drugs and regulatory approvals. The listings in the tables below are limited to the U.S., EU, Japan, and China, but we are also conducting development activities in other regions. "Global" refers to U.S., EU, Japan, and China.

Oncology

In oncology, we endeavor to deliver novel medicines to patients with cancer worldwide through the commitment to breakthrough innovation and a passion for improving the lives of patients. This therapeutic area focuses on three key areas (1) building on our foundational expertise in hematologic

malignancies through continued investment in lifecycle management programs for marketed products *NINLARO*, *ADCETRIS* and *ICLUSIG*, as well as in pipeline assets in multiple myeloma, acute myeloid leukemia and myelodysplastic syndromes and other blood cancers, (2) further developing our portfolio in lung cancer and (3) pursuing novel immuno-oncology targets and next-generation platforms with external partners, as well as exploring innovative cell therapies.

Our oncology pipeline as of May 14, 2019 (the date of our annual earnings release), along with notes for major subsequent developments, is as follows:

Development code <generic name> Brand name (country/region)[(1)]	**Drug class (administration route)**	**Indications/additional formulations**	**Stage by country/region**[(2)]		**In-house/In-license**
SGN-35 <Brentuximab vedotin> *ADCETRIS* (EU, Japan)	CD30 monoclonal antibody-drug Conjugate (injection)	Front line Peripheral T-cell Lymphoma ("PTCL")	EU Japan	P-III Filed (March 2019)	In-license (Seattle Genetics, Inc.)
		Relapsed/ refractory Hodgkin lymphoma	China	Filed (March 2019)	
		Relapsed/ refractory systemic anaplastic large-cell lymphoma ("sALCL")	China	Filed (March 2019)	
<brigatinib> *ALUNBRIG* (U.S., EU)	ALK inhibitor (oral)	1L ALK-positive non-small cell lung cancer	U.S. EU China	P-III P-III P-I	In-house
		2L ALK-positive non-small cell lung cancer in patients previously treated with ALK inhibitors	Japan China	P-II(a) P-II(a)	
		2L ALK-positive non-small cell lung cancer in patients progress on 2nd generation TKI (tyrosine kinase inhibitors)	Global	P-II	
		2L ALK-positive non-small cell lung cancer (head to head with alectinib)	Global	P-III	

Development code <generic name> Brand name (country/region)[1]	Drug class (administration route)	Indications/additional formulations	Stage by country/region[2]		In-house/In-license
MLN9708 <ixazomib> *NINLARO*	Proteasome inhibitor (oral)	Newly diagnosed multiple myeloma	Global	P-III	In-house
		Maintenance therapy in patients with newly diagnosed multiple myeloma following autologous stem cell transplant	Japan U.S. EU China	Filed (April 2019) P-III P-III P-III	
		Maintenance therapy in patients with newly diagnosed multiple myeloma not treated with stem cell transplant	Global	P-III	
		Relapsed/refractory primary amyloidosis	Global	P-III[3]	
		Relapsed/refractory multiple myeloma (doublet regimen with dexamethasone)	U.S. EU Japan	P-III P-III P-III	
		Relapsed/refractory multiple myeloma (triplet regimen with daratumumab and dexamethasone)	Global	P-II	
<ponatinib> *ICLUSIG*	BCR-ABL inhibitor (oral)	Front line Philadelphia chromosome-positive acute lymphoblastic leukemia	U.S.	P-III	In-house
		Dose ranging study for TKI resistant patients with chronic-phase chronic myeloid leukemia	U.S.	P-II(b)	
TAK-924 <pevonedistat>	NEDD 8 activating enzyme inhibitor (injection)	High-risk myelodysplastic syndromes, chronic myelomonocytic leukemia, low-blast acute myelogenous leukemia	U.S. EU Japan	P-III P-III P-III	In-house
TAK-385 <relugolix>	LH-RH antagonist (oral)	Prostate cancer	Japan China	P-III P-I	In-house
<cabozantinib>	Multi-targeted kinase inhibitor (oral)	1L renal cell carcinoma in combination with nivolumab	Japan	P-III	In-license (Exelixis, Inc.)
		2L renal cell carcinoma	Japan	Filed (April 2019)	
		2L hepatocellular carcinoma	Japan	P-II(a)	

Development code <generic name> Brand name (country/region)[1]	Drug class (administration route)	Indications/additional formulations	Stage by country/region[2]		In-house/In-license
<niraparib>	PARPl/2 inhibitor (oral)	Ovarian cancer - maintenance	Japan	P-II	In-license (GlaxoSmithKline plc)
		Ovarian cancer – salvage	Japan	P-II	
TAK-228 <sapanisertib>	mTORCl/2 inhibitor (oral)	Endometrial cancer	U.S.	P-II(b)	In-house
TAK-659 <->	SYK/FLT3 kinase inhibitor (oral)	Diffuse large 8-cell lymphoma	-	P-II(a)	In-house
		Hematologic malignancies	-	P-I	
TAK-931 < ->	CDC7 inhibitor (oral)	Squamous esophageal cancer, squamous non-small cell lung cancer	-	P-II(a)	In-house
TAK-788 <->	EGFR/ HER2 exon 20 inhibitor (oral)	Non-small cell lung cancer with Exon-20 insertion	Global	P-II	In-house
TAK-079 <->	Anti-CD38 monoclonal antibody (injection)	Relapsed/refractory multiple myeloma	-	P-I	In-house
		Systemic lupus erythematosus	-	P-I	
TAK-164 <->	Anti-guanylyl cyclase C antibody drug conjugate (injection)	GI malignancies	-	P-I	In-house
TAK-573 <- >	CD38-targeted lgG4 genetically fused with an attenuated IFNa (injection)	Relapsed/refractory Multiple myeloma	-	P-I	In-license (Teva Pharmaceutical Industries Ltd.)
TAK-981 <- >	SUMO inhibitor (injection)	Multiple cancers	-	P-I	In-house
TAK-252/SL-279252	PD-1-Fc-OX40L (injection)	Solid tumors	-	P-I	In-license (Shattuck Labs, Inc.)

Notes:

(1) Brand name and country/region indicate the brand name and country in which the specific asset has already been approved for any indication in any of the U.S., EU, Japan or China and Takeda has commercialization rights for such asset.

(2) Country/region in this column denote where a clinical study is ongoing or a filing has been made with our specific intention to pursue approval in any of the U.S., EU, Japan or China.

(3) On June 6, 2019, Takeda announced that this P-III trial did not meet the first of two primary endpoints and Takeda decided to discontinue this trial.

GI

In GI, we focus on delivering innovative, life-changing therapeutics for patients with GI and liver diseases. We are expanding our position in specialty GI with *ENTYVIO* and progressing a pipeline built through partnerships exploring opportunities in motility disorders, celiac disease, liver disease and the microbiome.

Our GI pipeline as of May 14, 2019 (the date of our annual earnings release), along with notes for major subsequent developments, is as follows:

Development Code <generic name> Brand name (country/region)[1]	**Drug class (administration route)**	**Indications/additional formulations**	**Stage by country/region**[2]		**In-house/In-license**
MLN0002 <vedolizumab> *ENTYVIO*	Humanized monoclonal antibody against a47 integrin (injection)	Crohn's disease	Japan China	Filed (July 2018)[3] P-III	In-house
		Ulcerative colitis	China	P-III	
		Subcutaneous formulation for ulcerative colitis	U.S. EU Japan	Filed (March 2019) Filed (March 2019) P-III	
		Subcutaneous formulation for Crohn's disease	U.S. EU Japan	P-III Filed (March 2019) P-III	
		Adalimumab head-to-head in patients with ulcerative colitis	Global	P-III	
		Graft-versus-host disease prophylaxis in patients undergoing allogeneic hematopoietic stem cell transplantation	Europe	P-III	
Cx601 <darvadstrocel> *ALOFISEL* (EU)	A suspension of allogeneic expanded adipose-derived stem cell (injection)	Refractory complex perianal fistulas in patients with Crohn's disease	U.S. Japan	P-III P-III	In-house
TAK-438 <vonoprazan> *TAKECAB*	Potassium-competitive acid blocker (oral)	Acid-related diseases	China	Filed (February 2018)	In-house
		Gastro-esophageal reflux disease in patients who have a partial response following treatment with a proton pump inhibitor	EU	P-II(b)	
TAK-633/SHP633 <teduglutide> *GATTEX* (U.S.)/ *REVESTIVE* (EU)	GLP-2 analogue (injection)	Short bowel syndrome, pediatric indication	U.S.	Filed (September 2018)[4]	In-house
			Japan	P-III	
		Short bowel syndrome, adult	Japan	P-III	
TAK-721/SHP621 <Budesonide>	Glucocorti costeroid (oral)	Eosinophilic esophagitis	U.S.	P-III	In-house (Partnership with UCSD and Fortis Advisors)
TAK-906[5] < ->	Dopamine D2/D3 receptor antagonist (oral)	Gastroparesis	-	P-II(b)	In-house

Development Code <generic name> Brand name (country/region)[1]	Drug class (administration route)	Indications/additional formulations	Stage by country/region[2]		In-house/In-license
TAK-954 <->	5-HT_4-hydroxytryptamine receptor agonist (injection)	Post-operative gastrointestinal dysfunction	-	P-II(b)	In-license (Theravance Biopharma, Inc.)
TIMP-GLIA <->	Tolerizing Immune Modifying nanoParticle (TIMP) (injection)	Celiac disease	-	P-II(a)	In-license (Cour Pharmaceutical Development Company, Inc.)
TAK-951 <->	Peptide agent	Nausea and vomiting	-	P-I	In-house
TAK-671 <->	Protease inhibitor (injection)	Acute pancreatitis	-	P-I	In-house (Co-development with Samsung Bioepis Co, Ltd)
TAK-018/EB8018 <->	FimH antagonist (oral)	Crohn's disease	-	P-I	In-license (Enterome Bioscience SA)
TAK-681 <->	GLP-2 long-acting analogue (injection)	Short bowel syndrome	-	P-I	In-house
Kuma062 <->	Glutenase (oral)	Celiac disease	-	P-I	In-license (PvP Biologics, Inc.)

Notes:

(1) Brand name and country/region indicate the brand name and country in which the specific asset has already been approved for any indication in any of the U.S., EU, Japan or China and Takeda has commercialization rights for such asset.

(2) Country/region in this column denote where a clinical study is ongoing or a filing has been made with our specific intention to pursue approval in any of the U.S., EU, Japan or China.

(3) On May 22, 2019, Takeda announced that the MHLW approved an additional indication for the treatment of moderately to severely active Crohn's disease in Japan.

(4) On May 17, 2019, Takeda announced that the FDA approved extending this indication to pediatric patients 1 year of age and older with short bowel syndrome who need additional nutrition or fluids from intravenous feeding (parenteral support).

(5) TAK-906 was previously known as ATC 1906. In March 2017, Takeda executed its option right to acquire Altos Therapeutics, LLC.

Rare diseases

We acquired our rare disease business and pipeline through our acquisition of Shire. We focus on (1) rare immunology (e.g., Hereditary angioedema) including through recently launched *TAKHZYRO* to transform the treatment paradigm, (2) rare hematology with the broadest portfolio across our competitors in hematology and (3) rare metabolic diseases, focused on addressing with approved treatments for Fabry disease, Hunter syndrome and Gaucher disease.

Our rare disease pipeline as of May 14, 2019 (the date of our annual earnings release), along with notes for major subsequent developments, is as follows:

Development Code <generic name> Brand name (country/region)[1]	Drug class (administration route)	Indications/additional formulations	Stage by country/region[2]		In-house/In-license
TAK-743/SHP643 <lanadelumab> *TAKHZYRO* (U.S., EU)	Plasma kallikrein inhibitor (injection)	Hereditary angioedema	China	Filed (December 2018)	In-house
TAK-672/SHP672 <-> *OBIZUR* (U.S., EU)	Antihemophilic factor [recombinant], porcine sequence (injection)	Congenital hemophilia A with inhibitors	U.S. EU	P-III P-III	Purchased (IPSEN)

Development Code <generic name> Brand name (country/region)[1]	Drug class (administration route)	Indications/additional formulations	Stage by country/region[2]		In-house/In-license
TAK-577/SHP677 <-> VONVENDI U.S.), VEYVONDI (EU)	von Willebrand factor [recombinant] (injection)	Prophylactic treatment of von Willebrand disease	Global	P-III	In-house
		Pediatric on-demand treatment of von Willebrand disease	Global	P-III	In-house
TAK-660/SHP660 <-> *ADYNOVATE* (U.S.), *ADYNOVI* (EU)	Antihemophilic Factor (recombinant), PEGylated (injection)	Pediatric hemophilia A	EU	P-III	In-house
TAK-755/SHP655 <->	Replacement of the deficient-ADAMTS13 enzyme (injection)	Congenital thrombotic thrombocytopenic purpura	U.S. EU	P-III P-III	In-license (KM Biologics, Co, Ltd.)
TAK-620/SHP620 <maribavir>	Benzimidazole riboside inhibitor (oral)	Cytomegalovirus infection in transplant patients	U.S. EU	P-III P-III	In-license (GlaxoSmithKline plc)
TAK-607 /SHP607 <->	Insulin- like Growth Factor / IGF Binding Protein (injection)	Chronic lung disease	-	P-II	In-house
TAK-609/SHP609 <->	Recombinant human iduronate-2 -sulfatase for intrathecal administration (injection)	Hunter syndrome central nervous system (“CNS”)	U.S. EU	P-II P-II	In-house
cTAK-611/SHP611 <->	Recombinant human arylsulfatase A (injection)	Metachromatic leukodystrophy	-	P-I/II	In-house
TAK-754/SHP654 <->	Gene therapy to restore endogenous FVIII expression	Hemophilia A	-	P-I/II	In-license (Askepios Biopharmaceutical, Inc.)
TAK-531/SHP631 <->	Fusion protein of iduronate-2-sulfatase +antibody (injection)	Hunter syndrome CNS	-	P-I	In-license (ArmaGen, Inc.)
TAK-834/SHP634 <-> *NATPARA* (U.S.), *NATPAR* (EU)	Parathyroid hormone (injection)	Hypoparathyroidism	Japan	P-I	In-house

Notes:

(1) Brand name and country/region indicate the brand name and country in which the specific asset has already been approved for any indication in any of the U.S., EU, Japan or China and Takeda has commercialization rights for such asset.

(2) Country/region in this column denote where a clinical study is ongoing or a filing has been made with our specific intention to pursue approval in any of the U.S., EU, Japan or China.

Neuroscience

In neuroscience, we aim to bring innovative medicines to patients suffering from neurologic and psychiatric diseases for whom there are no treatments available. We are expanding our presence in psychiatric diseases through continued investment in *TRINTELLIX* for major depressive disorder and the ADHD portfolio acquired from Shire. We are also building our pipeline in neurology (e.g., Alzheimer's disease, Parkinson's disease) and selected rare CNS diseases through a combination of in-house expertise and collaboration with partners.

Our neuroscience pipeline as of May 14, 2019 (the date of our annual earnings release), along with notes for major subsequent developments, is as follows:

Development Code <generic name> Brand name (country/region)[(1)]	**Drug class (administration route)**	**Indications/additional formulations**	**Stage by country/region**[(2)]		**In-house/In-license**
Lu AA21004 <vortioxetine> *TRINTELLIX*	Multimodal anti-depressant (oral)	Major depressive disorder	Japan	Filed (September 2018)	In-license (H. Lundbeck A/S)
TAK-815/SHP615 <midazolam> *BUCCOLAM* (EU)	GABA Allosteric Modulator (oral)	Status epilepticus (seizures)	Japan	P-III	In-house
TAK-831 <->	D-amino acid oxidase ("DAAO") inhibitor (oral)	Negative symptoms and/or cognitive impairment associated with schizophrenia	-	P-II(a)	In-house
TAK-935 <->	CH24H inhibitor (oral)	Rare pediatric epilepsies	-	P-II(a)	In-house (Co-development with Ovid Therapeutics)
WVE-120101 <->	mHTT SNP1 antisense oligonucleotide (injection)	Huntington's disease	-	P-I/II	In-license (Wave Life Sciences Ltd.)
WVE-120102 <->	mHTT SNP2 antisense oligonucleotide (injection)	Huntington's disease	-	P-I/II	In-license (Wave Life Sciences Ltd.)
TAK-041 <->	GPR139 agonist (oral)	Negative symptoms and/or cognitive impairment associated with schizophrenia	-	P-I	In-house
MEDI1341 <->	Alpha-synuclein antibody (injection)	Parkinson's disease	-	P-I	In-license (AstraZeneca plc)
TAK-418 <->	LSDl1 inhibitor (oral)	Kabuki syndrome	-	P-I	In-house
TAK-653 <->	AMPA receptor potentiator (oral)	Treatment resistant depression	-	P-I	In-house
TAK-925 <->	Orexin 2R agonist (injection)	Narcolepsy	-	P-I	In-house

Notes:

(1) Brand name and country/region indicate the brand name and country in which the specific asset has already been approved for any indication in any of the U.S., EU, Japan or China and Takeda has commercialization rights for such asset.

(2) Country/region in this column denote where a clinical study is ongoing or a filing has been made with our specific intention to pursue approval in any of the U.S., EU, Japan or China.

Plasma-derived therapies

We acquired our plasma derived therapies business and pipeline through our acquisition of Shire. In plasma-derived therapies, we focus on developing products which are essential for effectively treating patients with a variety of rare, life-threatening, chronic and genetic diseases across the world.

Our plasma-derived therapies pipeline as of May 14, 2019 (the date of our annual earnings release), along with notes for major subsequent developments, is as follows:

Development Code <generic name> Brand name (country/region)[1]	Drug class (administration route)	Indications/additional formulations	Stage by country/region[2]		In-house/In-license
TAK-616/SHP616 <-> *CINRYZE*	Cl INH inhibits the complement system (injection)	Hereditary angioedema	Japan	P-III	In-house
TAK-771/SHP671 <-> <IG Infusion 10% (Human)w/ Recombinant Human Hyaluronidase> *HYQVIA* (U.S., EU)	Immunoglobulin (lgG) + recombinant hyaluronidase replacement therapy (injection)	Pediatric indication for primary immunodeficiency	U.S.	P-III	In-house (Partnership with Halozyme Therapeutics, Inc.)
		Chronic inflammatory demyelinating polyradiculoneuropathy	U.S. EU	P-III P-III	

Notes:

(1) Brand name and country/region indicate the brand name and country in which the specific asset has already been approved for any indication in any of the U.S., EU, Japan or China and Takeda has commercialization rights for such asset.

(2) Country/region in this column denote where a clinical study is ongoing or a filing has been made with our specific intention to pursue approval in any of the U.S., EU, Japan or China.

Vaccines

In vaccines, we apply innovation to develop solutions to treat infectious diseases such as dengue, zika, norovirus, and polio. To support the expansion of our pipeline and the development of our programs, we entered in partnerships with government organizations (in Japan, the U.S., and Singapore) and leading global institutions. Such partnerships are essential to helping us build critical capabilities necessary to deliver on our programs and realize their full potential.

Our vaccines pipeline as of May 14, 2019 (the date of our annual earnings release), along with notes for major subsequent developments, is as follows:

Development Code <generic name> Brand name (country/region)[1]	Drug class (administration route)	Indications/additional formulations	Stage by country/region[2]		In-house/In-license
TAK-003 <->	Tetravalent dengue vaccine (injection)	Prevention of the dengue fever caused by dengue virus	-	P-III	In-house
TAK-214 <->	Norovirus vaccine (injection)	Prevention of the acute gastroenteritis caused by norovirus	-	P-II(b)	In-house
TAK-021 <->	EV71 vaccine (injection)	Prevention of hand, food, and mouth disease caused by enterovirus 71	-	P-I	In-house
TAK-426 <->	Zika vaccine (injection)	Prevention of zika virus infection	-	P-I	In-house (Partnership with the Biomedical Advanced Research and Development Authority – U.S. Government)

Notes:

(1) Brand name and country/region indicate the brand name and country in which the specific asset has already been approved for any indication in any of the U.S., EU, Japan or China and Takeda has commercialization rights for such asset.

(2) Country/region in this column denote where a clinical study is ongoing or a filing has been made with our specific intention to pursue approval in any of the U.S., EU, Japan or China.

Availability of Raw Materials

In the ordinary course of business, we purchase raw materials and supplies essential to our operations from suppliers around the world. While we develop and manufacture the active ingredients used in some of our products at our own facilities, we are dependent on third-party suppliers for a portion of the raw materials and compounds used in some of the other products we produce. We believe that, in the event we are unable to source any products or ingredients from any of our major suppliers, we could replace those products or substitute ingredients from other suppliers, although we may not be able to do so without significant difficulty or significant increases in our cost of goods sold. While efforts are made to diversify our sources of components and materials, in certain instances we acquire components and materials from a sole supplier.

We are dependent on human donors for the supply of human plasma. Human plasma is a critical active ingredient in our plasma derived therapies. We source human plasma internally and externally through a distinctive and flexible infrastructure, which provides us an enhanced capability with respect to the consistent delivery of high-quality plasma-based products. We own and operate plasma collection facilities, principally the U.S., Austria, Hungary and Czech Republic, and we also maintain relationships with other plasma suppliers to ensure that we retain the flexibility to meet market demand for our plasma-based therapies.

We closely monitor, continuously review and revise the supply sourcing strategy for our products to identify in a timely manner any risks in our supply chain, including risks arising from our dependency on outsourced manufacturing relationships with third party suppliers. Where necessary, inventory levels of either key materials and finished products are managed strategically to address potential risks relating to operational and quality issues, production capacity and single sourcing among others. For critical and new technology products, we have decided to make significant long-term capital investments to build internal manufacturing capacity and secure dual sources to reduce the current dependency on outsourced manufacturing relationship with third-party suppliers.

Manufacturing

Following the acquisition of Shire in January 2019, we will continue to operate locally with the ability to access global manufacturing and distribution networks as required.

The manufacture of our products is highly regulated by governmental health authorities around the world, including the FDA, EMA and PMDA. Furthermore, many of our products involve technically complex manufacturing processes or may require a supply of highly specialized raw materials.

We manufacture certain of our products in our own facilities worldwide. In addition, we source certain other of our products from third-party contract manufacturers. We have a network for over 300 contract manufacturers which support approximately 30% of our products in different capacities such as active pharmaceutical ingredients production and sourcing, bulk drug product, aseptic fill finish and final packaging. We manage the risks associated with reliance on single sources of production by carrying additional inventories.

Sales and Marketing

Our primary sales and marketing activities are organized around United States, Japan Pharma, Europe-Canada ("EUCAN") and Emerging Markets. These business units make focused investments that support growth potential in the market and enhance efficiency.

The United States is the largest pharmaceutical market in the world. The United States business unit focuses on recently approved products such as *ENTYVIO*, *TRINTELLIX, ADYNOVATE,* and *TAKHZYRO* as well as continuing to grow more established products such as *VYVANSE*, *ADVATE* and *GAMMAGARD LIQUID*. These and other principal products are supported by significant marketing and sales force promotion.

The Japan Pharma business unit focuses on retaining our position as one of the leading pharmaceutical companies in our home market of Japan, where the government is driving stricter control of drug prices and promoting the penetration of generics.

The EUCAN business unit focuses on a specialized approach in the European and Canadian markets, where public insurance has set a higher bar for the reimbursement of medicines, requiring innovation and differentiation for the products to be reimbursed. As Canada's health insurance system is very similar to that of Europe, the Canadian market is managed by the EUCAN business unit.

The Emerging Markets business unit focuses on maximizing growth potential in areas across Asia Pacific, Greater China, Latin America, Near East, Middle East and Africa and Russia/ CIS.

Intellectual Property

An important part of our business strategy is to protect our products and technologies using patents and trademarks, to the extent available. We rely on trade secrets, proprietary know-how, technological innovations and contractual arrangements with third parties to maintain and enhance our competitive position. Our commercial success depends, in part, upon our ability to obtain and enforce strong patents, to maintain trade secret protection, to operate without infringing the proprietary rights of others and to comply with the terms of licenses granted to it. Due to the lengthy development periods for new drugs, the high costs of research and development and the small percentage of researched compounds that reach the market, the protection of intellectual property plays an important role in the return of investments for research and development of a new drug.

We seek patent protection for proprietary technology whenever possible in the U.S., Japan and major European countries. Where practicable, we seek patent protection in other countries on a selective basis. In all cases, we endeavor to either obtain patent protection itself or support patent applications through licensors. Patents are our primary means of protecting the technologies we use. Patents provide the holder with the right to exclude others from using an invention related to a pharmaceutical product. We use various types of patents to protect our pharmaceutical products, including substance patents, which cover active ingredients, as well as patents covering usage, manufacturing processes and formulation of drugs.

Our low molecule products (small molecules) are mainly protected by substance patents. While the expiration of a substance patent usually results in a loss of market exclusivity for the protected pharmaceutical products, commercial benefits may continue to be protected by non-substance patents such as patents relating to the use of such substance, patents relating to the method of use of such substance, patents relating the manufacturing method of such substance, and patents relating to the new composition or formulation of such substance. The products can be also protected by regulatory data protection under relevant law in each country even if the substance patent expired. While our biologics products can and may be protected by one or more substance patents, certain products may be protected by non-substance patents and/or regulatory data protection. However, for biologics, patent protection may be less important than for traditional pharmaceutical products, as similar products for the same indication and/or biosimilars may be developed and marketed by competitors without infringing on our patents.

In the United States, patents generally expire twenty years after the filing date of the application, subject to potential patent term adjustments for delays in patent issuance based upon certain delays in prosecution by the United States Patent and Trademark Office. A U.S. pharmaceutical patent that claims a product, method of treatment using a product or method of manufacturing a product may also be eligible for a patent term extension based on the time the FDA took to approve the product. This type of extension may only extend the patent term for a maximum of five years and may not extend the patent term beyond fourteen years from regulatory approval. Only one patent may be extended for any product based on FDA delay. In addition to patent exclusivities, the FDA may provide data or market exclusivity for a new chemical entity or an “orphan drug,” each of which run in parallel to any patent protection. Regulatory data protection or exclusivity prevents a potential generic competitor from relying on clinical trial data that were generated by the sponsor when establishing the safety and efficacy of its competing product for a period of five years for a new chemical entity, or seven years for an orphan drug. Market exclusivity prohibits any marketing of the same drug for the same indication.

In Japan, a patent can be issued for active pharmaceutical ingredients by the Japan Patent Office (“JPO”). Although methods of treatment, such as dosage and administration, are not patentable in Japan, pharmaceutical compositions for a specific dosage or administration method as well as processes to make a pharmaceutical composition are patentable. Patents in Japan generally expire 20 years after the filing date of the patent application. Patents for pharmaceuticals may be extended for up to five years, depending on the amount of time spent for the drug approval process. Japan also has a regulatory data protection system called a “re-examination period” of eight years for pharmaceuticals that contain new active pharmaceutical ingredients and four years to six years for new indications and formulations and a ten-year orphan drug exclusivity system.

In the EU, patent applications may be filed in the European Patent Office (“EPO”) or in a country in Europe. The EPO system permits a single application to be granted for the EU, plus certain other non-EU countries, such as Switzerland and Turkey. When the EPO grants a patent, it is then validated in the countries that the patent owner designates. The term of a patent granted by the EPO or a European country office is generally 20 years from the filing date of the patent application. Pharmaceutical patents covering an approved medicinal product can be granted a further period of exclusivity under the Supplementary Protection Certificate (“SPC”) system. SPCs are designed to compensate the owner of the patent for the time it took to receive marketing authorization by the European Medicines Agency or the National Health Authorities. An SPC may be granted to provide, in combination with the patent, up to 15 years of exclusivity from the date of the first European marketing authorization. However, an SPC cannot last longer than five years. The SPC duration can additionally be extended by a further Pediatric Extension of six months if the SPC relates to a medicinal product for children for which data has been submitted according to a Pediatric Investigation Plan ("PIP"). The post-grant phase of patents, including the SPC system, is currently administered on a country-by-country basis under national laws. Therefore, although regulations concerning patents and SPCs have been created at EPO and EU level, respectively, due to different national implementation they may not always lead to the same result, for example, if challenged at National Courts in the various EU countries. The EU also provides a system of regulatory data exclusivity for authorized human medicines, which runs in parallel to any patent protection. The system for drugs being approved today is usually referred to as “8+2+1” rule because it provides an initial period of eight years of data exclusivity, during which a competitor cannot rely on the relevant data, a further period of two years of market exclusivity, during which the data can be used to support applications for marketing authorization but the competitive product cannot be launched and a possible one-year extension of the market exclusivity period if, during the initial eight-year data exclusivity period, the sponsor registered a new therapeutic indication for the concerned drug. However, the additional one-year extension is only available if either no therapy exists for the new indication or if the concerned product provides for the new indication a "significant clinical benefit over existing therapies". This system applies both to national and centralized authorizations. The EU also has an orphan drug exclusivity system for medicines similar to the U.S system. If a medicine is designated as an orphan drug, it benefits from ten years of market exclusivity, during which time a similar medicine for the same indication will not receive marketing authorization. Under certain circumstances, this exclusivity can be extended with a two-year Pediatric Extension for completion of a PIP.

Worldwide, we experience challenges in the area of intellectual property from factors such as the penetration of generic versions of our products following the expiry of the relevant patents and the launch by competitors of over-the-counter versions of our products. Our Global General Counsel is responsible for the oversight of our Intellectual Property operations, as well as our legal operations. Our Intellectual Property Department supports our overall corporate strategy by focusing efforts on three main themes:

- maximization of the value of our products and research pipeline and protection of related rights aligned to the strategies of our therapeutic area units;
- facilitation of more dynamic harnessing of external innovation through partner alliance support; and
- securing and protection of intellectual property rights around the world, including in emerging markets.

As infringement of our intellectual property rights poses a risk of loss of expected earnings derived from those rights, we have internal processes in place to manage patents and other intellectual property. This program includes both remaining vigilant against patent infringement by others as well as exercising caution, starting at the research and development stage, to ensure that our products and activities do not violate intellectual property rights held by others.

In the regular course of business, our patents may be challenged by third parties. We are party to litigation or other proceedings relating to intellectual property rights. Details of material ongoing litigation are provided in Note 32 to our audited consolidated financial statements included in this annual report.

The following table describes our outstanding substance patents and the regulatory data protection ("RDP") (US and EU) or re-examination period ("RP") (Japan) for the indicated product by territory and expiry date. The table includes RDP or RP information only if the protection provided by regulatory exclusivity exceeds the patent expiry. Patent term extensions ("PTE"), supplemental protection certificates ("SPC"), and pediatric exclusivity periods ("PEP") are reflected in the expiry dates to the extent they have been granted by the issuing authority. For PTE's, SPC's, and PEP's in which the application is in process but not yet granted, the extended expiry is separately provided.

Our biologic products may face or already face competition from companies who produce similar products for the same indications, and/or biosimilars, regardless of expiry dates below. Certain of the European patents are the subject of supplemental protection certificates that provide additional protection for the product in certain countries beyond the dates listed in the table.

Our product	Japan expiry dates[1][2]	U.S. expiry dates[1]	EU expiry dates[1]
GI:			
ENTYVIO	Patent: — RP: July 2026[2]	Patent: September 2021 RDP: May 2026	Patent: August 2017 (Extended expiry of August 2022 in certain countries) RDP: May 2024
PANTOPRAZOLE	Patent: —	Patent: —	Patent: —
DEXILANT	Not commercialized	Patent: —	Patent: —
TAKECAB[3]	Patent: August 2031	Patent: —[3]	Patent: —[3]
AMITIZA[4]	Patent: —[4]	Patent: May 2021[5]	Not commercialized
GATTEX/REVESTIVE	Patent: —	Patent: October 2020[6]	Patent: — RDP: September 2024
LIALDA/MEZAVANT[3]	Patent: —[3] RP: September 2022[2]	Patent: —	Patent: —
Rare Diseases			
VPRIV	Patent: — RP: July 2024[2]	Patent: —	Patent: — RDP: August 2022
ELAPRASE	Patent: —	Patent: September 2019	Patent: —
REPLAGAL	Patent: —	Not commercialized	Patent: —
NATPARA	Patent: —	Patent: — RDP: January 2027	Patent: — RDP: April 2029
FIRAZYR	Patent: — RP: September 2028[2]	Patent: July 2019	Patent: — RDP: July 2020
ADVATE	Patent: —	Patent: —	Patent: —
ADYNOVATE	Patent: January 2026	Patent: February 2026 RDP: November 2027	Patent: January 2028 if granted RDP: January 2028
FEIBA[7]	Patent: —	Patent: —	Patent: —
HEMOFIL[7]	Not commercialized	Patent: —	Not commercialized
IMMUNATE[7]	Patent: —	Not commercialized	Patent: —
IMMUNINE[7]	Not commercialized	Not commercialized	Patent: —
TAKHZYRO	January 2031 Extended expiry of November 2034 if PTE granted	December 2031, February 2032, March 2032 Extended expiry of August 2032 if PTE granted	January 2031 Extended expiry of January 2036 if SPC granted

Our product	Japan expiry dates[1][2]	U.S. expiry dates[1]	EU expiry dates[1]
KALBITOR	Not commercialized	December 2023	Not commercialized
CINRYZE[7]	Patent: — RDP: October 2020	Patent: — RDP: October 2020	Patent: —
GAMMAGARD LIQUID[7]	Not commercialized	Patent: —	Patent: —
ALBUMIN IN GLASS[7]	Not commercialized	Patent: —	Patent: —
HYQVIA[7]	Not commercialized	Patent: — RDP: September 2026	Patent: — RDP: May 2024
CUVITRU[7]	Not commercialized	Patent: — RDP: September 2028	Patent: — RDP: July 2027
FLEXBUMIN[7]	Not commercialized	Patent: —	Patent: —
Oncology:			
LEUPLIN/ENANTONE	Patent: — RP: September 2019[2][8]	Patent: —	Patent: —
VELCADE[3]	Patent: —[3]	Patent: —	Patent: —[3]
NINLARO	Patent: July 2031	Patent: August 2027 Extended expiry of November 2029 if PTE granted	Patent: November 2031
ADCETRIS[4]	Patent: April 2022, April 2026 [9]	Patent: —[4]	Patent: October 2027
ALUNBRIG	Patent: May 2029 Extended expiry of February 2033 if PTE granted	Patent: July 2030 Extended expiry of April 2031 if PTE granted	Patent: May 2029 Extended expiry of November 2033 if SPC granted
ICLUSIG[3]	Patent: —[3]	Patent: January 2027	Patent: —[3]
VECTIBIX[4]	Patent: August 2022	Patent: —[4]	Patent: —[4]
Neuroscience:			
TRINTELLIX [4]	Patent: October 2022 Extended expiry of October 2027 if PTE granted	Patent: June 2026 Extended expiry of December 2026 if PTE granted	Patent: —[4]
VYVANSE	Patent: June 2024 Extended expiry of June 2029 if PTE granted RP: March 2027[2]	Patent: February 2023	Patent: June 2024 (Extended expiry of February 2028 or March 2029 in certain countries)
ADDERALL XR	Not commercialized	Patent: —	Not commercialized
ROZEREM	Patent: March 2022	Patent: July 2019	Not commercialized
REMINYL	Patent: —	Patent: —	Patent: —
INTUNIV	Patent: — RP: March 2025[2]	Patent: —	Patent: — RDP: September 2025
Other:			
NESINA	Patent: April 2028	Patent: June 2028	Patent: September 2028
ULORIC[4]	Patent: —[4]	Patent: —	Patent: —[4]
COLCRYS	Not commercialized	Patent: —	Not commercialized
LOTRIGA[4]	Patent: — RP: September 2020[2]	Patent: — [4]	Patent: — [4]
AZILVA	Patent: — RP: October 2021[2]	Not commercialized	Not commercialized

Notes:

(1) A "-" within the table indicates the substance patent is expired or not applicable.
(2) In Japan, an application for a generic product is filed after the re-examination period ends, and the product is listed in the approval and drug price listing after a regulatory review. Therefore, the generic product would enter the market after a certain period of time from the expiry of the re-examination period.
(3) This product is not sold by Takeda in all regions because of out-licensing agreements to third parties.
(4) This product is not sold by Takeda in all regions because of in-licensing agreements from third parties exclusive to certain regions. See "-Business Overview" principal products descriptions and "-Licensing and Collaboration" for further information on the licensing agreements.
(5) Generic may be introduced after January 2021 (or earlier under certain circumstances) based on a settlement with an ANDA filer.
(6) Generic may be introduced after March 2023 based on a settlement with an ANDA filer.
(7) Relates to plasma-derived therapies products.
(8) *LEUPLIN/ENANTONE* has a re-examination period in Japan for formulation(6M) through September 2019.
(9) Generic/biosimilar may be introduced after July 2026 dependent on when access to the U.S. or European market is available.

Licensing and Collaboration

In the ordinary course of business, we enter into arrangements for licensing and collaboration for the development and commercialization of products with third parties. Our business does not materially depend on any one of these arrangements. Instead they form a portion of our strategy and give us the ability to leverage a mix of internal and external resources to develop and commercialize new products. Certain of the agreements which that have led to successful commercialization to date are summarized below:

- *ADCETRIS*: We entered into a Collaboration Agreement with Seattle Genetics in 2009 for the global co-development of *ADCETRIS* and its commercialization around the world (other than the U.S. and Canada, where *ADCETRIS* is commercialized by Seattle Genetics). We may be required to pay milestone payments related to regulatory and commercial progress by us under the collaboration. We also pay tiered royalties with percentages ranging from the mid-teens and to the mid-twenties based on net sales of *ADCETRIS* within our licensed territories. We and Seattle Genetics equally co-fund the cost of selected development activities conducted under the collaboration. Either party may terminate the collaboration for cause, or by mutual consent. We may terminate the collaboration at will, and Seattle Genetics may terminate the collaboration in certain circumstances. If neither party terminates the collaboration agreement, then the agreement automatically terminates on the expiration of all payment obligations. As of March 31, 2019, our aggregate potential development and commercial milestone payments under the *ADCETRIS* collaboration were $47.5 million.

- *TRINTELLIX:* We entered into a License, Development, Supply and Commercialization Agreement with H. Lundbeck A/S in September 2007 for the exclusive co-development and co-commercialization in the United States and Japan of several compounds in Lundbeck's pipeline for the treatment of mood and anxiety disorders, under which agreement we commercialize *TRINTELLIX* in the U.S. *TRINTELLIX* has not yet been launched in Japan. Under the agreement, we and Lundbeck have agreed to jointly develop the relevant compounds, with most of development funding from us. Revenues for *TRINTELLIX* are booked by us, and we pay to Lundbeck a portion of our sales, as well as tiered royalties ranging from the mid-teens to twenties on the portion of sales retained by us. We have also agreed to pay to Lundbeck certain development and commercialization milestone payments relating to regulatory and commercial progress under the collaboration. The term of the agreement is indefinite, but the agreement may be terminated by mutual decision of the parties or for cause. As of March 31, 2019, our aggregate potential development and commercial milestone payments under the *TRINTELLIX* collaboration were $130.0 million.

- *AMITIZA:* In October 2004, we entered into an agreement with Sucampo Pharmaceuticals (subsequently acquired by Mallinckrodt) to purchase, develop and commercialize *AMITIZA* for gastrointestinal indications in the U.S. and Canada. The initial term of the agreement is through December 31, 2020, after which the agreement continues automatically until terminated by us. We purchase *AMITIZA* from Mallinckrodt under the agreement at an agreed upon price and pay tiered royalties on sales in North America ranging from the high teens to mid-twenties, resetting each year. Beginning on January 1, 2021, we will share equally with Mallinckrodt in the net annual sales revenue from branded *AMITIZA* sales. We have agreed to fund development costs, including regulatory-required studies, subject to agreed-upon caps, with excess costs being shared equally, with certain exceptions. We have a similar agreement with Mallinckrodt covering the rest of the world, except for Japan and the People's Republic of China. We have agreed to additional commercial milestone payments contingent on the achievement of certain net sales revenue targets, and to provide a minimum annual commercial investment during the term of the agreement, which we may reduce when a generic equivalent enters the market. As of March 31, 2019, our aggregate potential commercial milestone payments under the AMITIZA collaboration were $50.0 million.

Our other research and development licensing and collaboration arrangements include, but are not limited to, the following:

Partner	Country	Description of collaboration
Oncology:		
Adimab LLC	U.S.	Agreement for the discovery, development and commercialization of three monoclonal antibodies and three CD3 Bi-Specific antibodies for oncology indications.
Centre d'Immunologie de Marseille-Luminy	France	Collaboration agreement to bring together expertise of Bernard Malissen group in innate biology with our BacTrap capabilities to identify novel targets and pathways in myeloid cells.
ASKA Pharmaceutical Co.	Japan	Licensing agreement to grant exclusive commercialization rights for uterine fibroids and exclusive development and commercialization rights for endometriosis for Japan to maximize the product value of relugolix (TAK-385).

Partner	Country	Description of collaboration
Crescendo Biologics Ltd.	UK	Collaboration and licensing agreement for the discovery, development and commercialization of Humabody®-based therapeutics for cancer indications.
Exelixis, Inc.	U.S.	Exclusive licensing agreement to commercialize and further clinical development of cabozantinib in Japan. We receive exclusive commercial rights for all potential future cabozantinib indications in Japan, including advanced renal cell carcinoma, for which cabozantinib is marketed in the U.S. and EU as CABOMETYX™ tablets.
GammaDelta Therapeutics Ltd. ("GammaDelta Therapeutics")	UK	Collaboration agreement to develop GammaDelta Therapeutics' novel T cell platform based on the unique properties of gamma delta T cells derived from human tissues. The companies intend to use this novel platform to discover and develop new immunotherapies in oncology.
HaemaLogiX Pty. Ltd.	Australia	Research collaboration and licensing agreement for the development of new therapeutics to novel antigens in multiple myeloma.
Heidelberg Pharma GmbH	Germany	Antibody-drug-conjugate ("ADC") research collaboration on two targets and licensing agreement (α-amanitin payload and proprietary linker).
ImmunoGen, Inc. ("ImmunoGen")	U.S.	Licensing agreement for exclusive rights to use ImmunoGen's ADC technology to develop and commercialize targeted anticancer therapeutics for up to two undisclosed targets.
Maverick Therapeutics Inc. ("Maverick")	U.S.	Collaboration agreement for the development of Maverick's T cell engagement platform created specifically to improve the utility of T cell redirection therapy for the treatment of cancer. Under the agreement, we have the exclusive right to purchase Maverick after five years.
Myovant Sciences Ltd. ("Myovant")	Switzerland	We granted Myovant an exclusive, worldwide license (excluding Japan and certain other Asian countries) to relugolix (TAK-385) and an exclusive, worldwide license to MVT-602 (TAK-448).
Memorial Sloan Kettering Cancer Center	U.S.	Alliance to discover and develop novel chimeric antigen receptor T ("CAR-T") cell products for the potential treatment of hematological malignancies and solid tumors. This partnership pursues the development of therapies that redirect T cell immunity against liquid or solid tumors.
Molecular Templates, Inc. ("MTEM")	U.S.	Collaboration agreement related to oncology drug discovery programs. The collaboration will apply MTEM's engineered toxin bodies technology platform to potential therapeutic targets. In September 2018, this collaboration was expanded for the joint development and commercialization of CD38-targeted engineered toxin bodies for the treatment of patients with diseases such as multiple myeloma.
National Cancer Center of Japan	Japan	Partnership agreement with the National Cancer Center of Japan to develop basic research to clinical development by promoting exchanges among researchers, physicians, and others engaged in anti-cancer drug discovery and cancer biology research.
Nektar Therapeutics ("Nektar")	U.S.	Collaboration agreement to explore the combination of Nektar's lead immuno-oncology candidate, the CD122-biased agonist NKTR-214, with five oncology compounds from our cancer portfolio.
Noile-Immune Biotech Inc. ("Noile-Immune")	Japan	Collaboration agreement to develop next generation CAR-T cell therapy. We have exclusive options to obtain licensing rights for the development and commercialization of Noile-Immune's pipeline and products resulting from this partnership.
Shattuck Labs Inc. ("Shattuck")	U.S.	Collaboration agreement to explore and develop checkpoint fusion proteins using Shattuck's Agonist Redirected Checkpoint platform that have the potential to become highly differentiated, next-generation immunotherapies. We will hold options for exclusive global development and commercialization rights for up to four molecules resulting from the collaboration.
GlaxoSmithKline plc	UK	Exclusive licensing agreement to develop and commercialize novel cancer therapy niraparib for the treatment of all tumor types in Japan, and all tumor types excluding prostate cancer in South Korea, Taiwan, Russia and Australia.
Teva Pharmaceutical Industries Ltd. ("Teva")	Israel	Multi-target discovery collaboration agreement for access to Teva's attenukine platform including a license to TEV-48573, a CD38 targeted antibody fused with attenuated interferon alpha for the treatment of multiple myeloma.
GI:		
Ambys Medicines ("Ambys")	U.S.	Partnership to collaborate on transformative therapies for the treatment of serious liver diseases. Ambys is applying novel modalities, cell and gene therapy to restore liver function and prevent the progression to liver failure for diseases that are untreatable or poorly treated today. Under the terms of the agreement, we receive an option to ex-U.S. commercialization rights for the first four products that reach an investigational NDA.
Arcturus Therapeutics, Inc. ("Arcturus")	U.S.	Agreement to develop RNA-based therapeutics for the treatment of non-alcoholic steatohepatitis and other gastrointestinal related disorders using Arcturus' wholly-owned LUNA™ lipid-meditated delivery systems and UNA Oligomer chemistry.
Beacon Discovery ("Beacon")	U.S.	Multi-year drug discovery collaboration on a few G-protein coupled receptors ("GPCRs") that play an important role in the pathology of gastrointestinal disorders. The agreement grants us worldwide rights to develop, manufacture and commercialize products resulting from the collaboration.

Partner	Country	Description of collaboration
Cour Pharmaceutical Development Company, Inc. (“Cour”)	U.S.	Agreement to research and develop novel immune modulating therapies for the potential treatment of celiac disease and other gastrointestinal disease using Cour's Tolerizing Immune Modifying nano Particle ("TIMP") platform to co-develop TIMP-Gliadin.
Enterome Bioscience SA	France	Agreement for a strategic drug discovery collaboration to research and develop potential new therapeutics directed at microbiome targets thought to play crucial roles in gastrointestinal disorders, including IBDs such as ulcerative colitis and motility disorders such as irritable bowel syndrome. The agreement includes a global license and co-development of EB8018/TAK-018 in Crohn's disease.
Finch Therapeutics Group, Inc. (“Finch”)	U.S.	Global collaboration agreement to jointly develop FIN-524, a live biotherapeutic product composed of cultured bacterial strains linked to favorable clinical outcomes in studies of microbiota transplantations in IBD. We obtain the exclusive worldwide rights to develop and commercialize FIN-524 and rights to follow-on products in IBD. We and Finch may elect to extend this collaboration to additional and related indications on similar terms.
Hemoshear Therapeutics, LLC ("Hemoshear")	U.S.	Collaboration agreement for novel target and therapeutic development for liver diseases, including nonalcoholic steatohepatitis. We will receive exclusive access to Hemoshear’s proprietary disease modeling platform to discover and develop best-in-class therapeutics for specific liver diseases.
Janssen Pharmaceuticals, Inc.	Belgium	Exclusive license agreement to develop and market prucalopride as a treatment for chronic constipation in the U.S. Motegrity, approved in December 2018.
NuBiyota LLC (“NuBiyota”)	Canada	Agreement for the development of Microbial Ecosystem Therapeutic products for GI indications with a high unmet medical need. We will collaborate with NuBiyota to advance oral microbial consortia products developed by using NuBiyota’s microbiome platform for GI indications.
PvP Biologics, Inc. (“PvP”)	U.S.	Global agreement for the development of KumaMax, a novel enzyme designed to break down the immune-reactive parts of gluten in the stomach. We will provide financing for PvP to conduct research and development through Phase I proof-of-principle studies and obtain an exclusive option to acquire PvP following receipt of a pre-defined data package.
Samsung Bioepis Co, Ltd	South Korea	Strategic collaboration agreement to jointly fund and co-develop multiple novel biologic therapies in unmet disease areas. The program’s first therapeutic candidate is TAK-671, which is intended to treat severe acute pancreatitis.
Theravance Biopharma Inc	Ireland	Global license, development and commercialization agreement for TD-8954, a selective 5-HT4 receptor agonist being investigated for potential use in the treatment of GI motility disorders, including enteral feeding intolerance (“EFI”). TD-8954 is being developed for the short-term use with EFI to achieve early nutritional adequacy in critically ill patients at high nutritional risk, an indication for which the compound received the FDA Fast Track Designation.
UCSD/Fortis Advisors LLC	U.S.	Technology license to develop oral budesonide formulation (TAK-721/SHP621) for treatment of eosinophilic esophagitis.
Rare diseases:		
AB Biosciences, Inc.	U.S.	Research collaboration agreement to potentially develop assets for rare disease with pan-receptor interacting molecules targeted for specific immunological conditions with a focus on autoimmune modulated inflammatory diseases.
ArmaGen, Inc.	U.S.	Worldwide licensing and collaboration agreement to develop AGT-182 (TAK-531/SHP631), an investigational enzyme replacement therapy for potential treatment of both the central nervous system ("CNS") and somatic (body-related) manifestations of Hunter syndrome.
Asklepios Biopharmaceutical, Inc.	U.S.	Agreement for multiple research and development collaborations using FVIII gene therapy for the treatment of hemophilia A and B.
BioMarin Pharmaceutical Inc.	U.S.	Agreement for the in-license of enabling technology for the exogenous replacement of iduronate-2-sulfatase with Idursulfase-IT in patients via direct delivery to the CNS for the long-term treatment of Hunter syndrome in patients with cognitive impairment in order to slow progression of cognitive impairment (TAK-609/SHP609).
GlaxoSmithKline plc (“GSK”)	UK	In-license agreement between GSK and University of Michigan for TAK-620/SHP620 (marabivir) in the treatment of human cytomegalovirus.
Harrington Discovery Institute at University Hospitals in Cleveland, Ohio	U.S.	Collaboration agreement for the advancement of medicines for rare diseases.
IPSEN	France	Purchase agreement to develop Obizur for the treatment of Acquired Hemophilia A, including for patients with Congenital Hemophilia A with inhibitors indication in elective or emergency surgery.
KM Biologics Co., Ltd.	Japan	Collaboration agreement to jointly development TAK-755/SHP655 to overcome the ADAMTS13 deficiency.
NanoMedSyn	France	Pre-clinical research collaboration agreement to evaluate a potential enzyme replacement therapy using NanoMedSyn's proprietary synthetic derivatives named AMFA.

Partner	Country	Description of collaboration
Novimmune SA	Switzerland	Agreement for the exclusive worldwide rights to develop and commercialize an innovative, bi-specific antibody in pre-clinical development for the treatment of hemophilia A.
Rani Therapeutics	U.S.	Research collaboration agreement to evaluate a micro tablet pill technology for oral delivery of FVIII therapy in hemophilia.
Ultragenyx Pharmaceutical Inc.	U.S.	Collaboration agreement to develop and commercialize therapies for rare genetic diseases.
Xenetic Biosciences, Inc.	U.S.	Exclusive research and development license agreement for PolyXen delivery technology for hemophilia factors VII, VIII, IX, X.
Neuroscience:		
AstraZeneca plc ("AstraZeneca")	UK	Collaboration agreement to jointly develop and commercialize MEDI1341, an alpha-synuclein antibody currently in development as a potential treatment for Parkinson's disease. AstraZeneca will lead Phase I development while we will lead future clinical development activities. The companies will share equally future development and commercialization costs as well as any future revenues.
Denali Therapeutics Inc. ("Denali")	U.S.	Strategic option and collaboration agreement to develop and commercialize up to three specified therapeutic product candidates for neurodegenerative diseases incorporating Denali's antibody transport vehicle platform for increased exposure of biotherapeutic products in the brain.
Mindstrong Health	U.S.	Collaboration to explore development of digital biomarkers for selected mental health conditions, in particular schizophrenia and treatment-resistant depression.
Ovid Therapeutics Inc. ("Ovid")	U.S.	Agreement to clinically develop and commercialize a novel, potent and highly selective CH24H inhibitor, in rare pediatric epilepsies (TAK-935). We received equity in Ovid and may be eligible to receive certain milestone payments based on the advancement of TAK-935. We will lead commercialization in Japan and have the option to lead commercialization in Asia and other selected geographies. Ovid will lead clinical development activities and commercialization of TAK-935 in the United States, Europe, Canada and Israel.
StrideBio Inc.	U.S.	Collaboration and license agreement to develop in vivo Adeno-Associated Virus ("AAV") based therapies for Friedreich's Ataxia and two additional undisclosed targets.
Wave Life Sciences Ltd.	Singapore	Research, development and commercial collaboration and multi-program option agreement to develop antisense oligonucleotides for genetically-defined neurological diseases. The first component of the collaboration will focus on programs targeting Huntington's disease, amyotrophic lateral sclerosis, frontotemporal dementia and spinocerebellar ataxia type 3. The second component of the collaboration provides us with the rights to exclusively license multiple preclinical programs targeting other neurological disorders including Alzheimer's disease and Parkinson's disease.
Plasma derived therapies:		
Halozyme Therapeutics, Inc. ("Halozyme")	U.S.	In-license agreement for Halozyme's proprietary ENHANZE™ platform technology to increase dispersion and absorption of HyQvia. On-going development work for a US pediatric indication to treat primary and secondary immunodeficiencies and a Phase 3 indication in Chronic Inflammatory Demyelinating Polyradiculoneuropathy.
Kamada Ltd.	Israel	In-license agreement to develop and commercialize Alpha-1 proteinase inhibitor (Glassia); Exclusive supply and distribution of Glassia in the US, Canada, Australia and New Zealand; Development of protocol for post market commitment trial ongoing.
Vaccines:		
Biological E. Limited	India	We agreed to transfer existing measles and acellular pertussis vaccine bulk production technology to develop low-cost combination vaccines for India, China and low- and middle-income countries.
U.S. Government - The Biomedical Advanced Research and Development Authority ("BARDA")	U.S.	Partnership to develop a Zika vaccine (TAK-426, our Zika vaccination candidate) to support the Zika response in the U.S. and affected regions around the world. Selected by BARDA, a division of the Office of the Assistant Secretary for Preparedness and Response ("ASPR"), within the U.S. Department of Health and Human Services.
Zydus Cadila	India	Partnership agreement to address the global threat of chikungunya and develop a chikungunya vaccine an emerging infectious disease in Africa, Asia and the Indian subcontinent.
Other / Multiple Therapeutic Areas:		
Bridge Medicines	U.S.	Partnership with Tri-Institutional Therapeutics Discovery Institute, Bay City Capital and Deerfield Management in the establishment of Bridge Medicines. Research projects accepted into the Tri-Institutional Therapeutics Discovery Institute will be able to graduate to Bridge Medicines, where they will be given financial, operational and managerial support to move seamlessly from validating proof-of-concept studies to clinical trials.
Center for IPS Cell Research Application, Kyoto University	Japan	Ten-year collaboration and establishment of a joint research program to develop clinical applications of induced pluripotent stem cells in therapeutic areas including cancer, heart failure, diabetes mellitus, neuro-degenerative disorders and intractable muscle diseases.

Partner	Country	Description of collaboration
HiFiBiO Inc.	U.S.	Collaboration for functional therapeutics high-throughput antibody discovery platform that enables identification of antibodies for rare events, for discovery of therapeutic antibodies for GI and Oncology therapeutic areas.
HitGen Ltd. ("HitGen")	China	Agreement that HitGen will apply its advanced technology platform, based on DNA-encoded library design, synthesis and screening, to discover novel leads which will be licensed exclusively to us.
lsogenica Ltd. ("Isogenica")	UK	Agreement with Isogenica for access to a sdAb (single-domain antibody) platform to generate a toolbox of VHH (Variable domain of Heavy chain of Heavy chain antibody) for various immune cells, and we are targeting pathway validation and pipeline development across our GI and Oncology portfolio.
Numerate, Inc.	U.S.	Agreement for joint-discovery programs aimed at identifying clinical candidates for use in our core therapeutic areas, namely GI, oncology and neuroscience.
Portal Instruments, Inc. ("Portal")	U.S.	Collaboration with Portal to develop and commercialize Portal's needle-free drug delivery device for potential use with our investigational or approved biologic medicines.
Recursion Pharmaceuticals	U.S.	Agreement to provide pre-clinical candidates for our TAK-celerator™ development pipeline.
Schrödinger, LLC ("Schrödinger")	U.S.	Multi-target research collaboration combining Schrödinger's in silico platform-driven drug discovery capabilities with our deep therapeutic area knowledge and expertise in structural biology.
Seattle Collaboration	U.S.	Research alliance, Seattle Partnership for Research on Innovative Therapies ("SPRInT"), aiming to accelerate the translation of Fred Hutchinson Cancer Research Center's and University of Washington's cutting-edge discoveries into treatments for human disease, with a focus on GI, oncology and neuroscience.
Stanford University	U.S.	Collaboration with Stanford University to form the Stanford Alliance for Innovative Medicines ("Stanford AIM") to develop innovative treatments and therapies in a more effective manner.
Tri-Institutional Therapeutics Discovery Institute ("Tri-I TDI")	U.S.	Partnered with the Tri-I TDI, a collaboration of academia institution and industry to more effectively develop innovative treatments and therapies.

Competition

Competition in our market is based on, among other things, product safety, efficacy, convenience of dosing, reliability, availability and prices. Competitors include large international companies whose capabilities cover the entire product creation process from research and development to production and marketing as well as smaller companies that focus on selling generic versions of products for which patent protection and regulatory data protection have lapsed.

We also face competition from generic drugs that enter the market when our patent protection or regulatory exclusivity expires. See "—Intellectual Property" for additional description of our patents. Additionally, we may face competition from our own introduction of new products with similar treatments as our older products.

The competition we face often differs by product and geographic market, and companies emerge and fall away as competitors over time due to innovations, merger activity and other business and market changes.

The following table shows the principal sources of competition for our main products:

Our product	Principal competing product	Primary manufacturer or distributor
GI:		
DEXILANT, PANTOPRAZOLE (Protonix)	generic lansoprazole, esomeprazole	—
ENTYVIO	*Remicade* *Humira* *Simponi* *Stelara* *Cimzia* generic infliximab	Janssen Biotech Abbvie Janssen Biotech Janssen Biotech UCB —
TAKECAB	*Nexium* generic lansoprazole, omeprazole	AstraZeneca —
GATTEX/REVESTIVE	*Zorbtive* *Nutrestore*	EMD/Serono Emmaus LifeSciences

Our product	Principal competing product	Primary manufacturer or distributor
ALOFISEL	*Autologous tissue, chronic seton usage*	
	Remicade	Johnson & Johnson's
Rare Diseases:		
ADVATE and ADYNOVATE	*Xyntha/Refacto AF*	Pfizer and Sobi
	Kogenate	Bayer
	Helixate	CSL
	Kovaltry	Bayer
	Iblias	CSL
	Eloctate/Elocta	Sanofi and Sobi
	Novoeight	Novo Nordisk
	Nuwiq	Octapharma
	Afstyla	CSL
	Hemlibra	Roche
TAKHZYRO	*Haegarda*	CSL
	Berinert	CSL
REPLAGAL	*Fabrazyme*	Genzyme
	Galafold	Amicus
	Fabagal	Isu Abaxis
VPRIV	*Cerezyme*	Genzyme
	Elelyso/uplyso	Pfizer/Protalix
	Zavesca	Actelion
	Cerdelga	Genzyme
	Cerezyme	Isu Abxis
Plasma-derived therapies		
GAMMAGARD LIQUID, KIOVIG	*Privigen*	CSL
	Carimune	CSL
	Gamunex-C	Grifols
	Flebogamma	Grifols
	Bivigam	Biotest
	Gammaked	Kendrion
	Gammaplex	BPL
	Octagam	Octapharma
	Panzya	Octapharma
GAMMAGARD LIQUID, GAMMAGARD SD, HYQVIA, CUVITRU	*Hizentra*	CSL
	Gamunex-C	Grifols
	Gammanorm	Octapharma
FLEXBUMIN and Human Albumin	*Alburex/Alburx*	CSL
	Albumnar	CSL
	Plasbumin	Grifols
	Albutein	Grifols
	Albunorm	Octapharma
	Kedbumin	Kendrion
Oncology:		
ADCETRIS	chemotherapy regimens	—
ALUNBRIG	*Xalkori*	Pfizer
	Zykadia	Novartis
	Alecensa	Roche

Our product	Principal competing product	Primary manufacturer or distributor
ICLUSIG	*Gleevec* *Tasigna* *Sprycel* *Bosulif*	Novartis Novartis Bristol-Myers Squibb Pfizer
LEUPRORELIN (LEUPLIN)	*Zoladex* generic leuprorelin	AstraZeneca —
NINLARO, VELCADE	*Revlimid* *Pomalyst/Imnovid* *Kyprolis* *Darzalex* *Empliciti*	Celgene Celgene Amgen Janssen Biotech Bristol-Myers Squibb
Neuroscience:		
TRINTELLIX	*Viibryd* *Fetzima* generic duloxetine, escitalopram	Allergan Allergan —
VYVANSE	generic mixed salts of a single-entity amphetamine product generic mixed salts of a single-entity amphetamine product, extended release generic methylphenidate, extended release	— — —
Other:		
AZILVA	generic candesartan, olmesartan	—
NESINA	*Januvia* generic pioglitazone	Merck Co., Inc. —

Regulation

The pharmaceutical industry is subject to extensive global regulation by regional, national, state and local agencies. The regulatory agencies and their regulations govern the testing, approval, production, labeling, distribution, post-market surveillance, advertising, dissemination of information and promotion of our products. The following is a description of the major regulations affecting our products in the United States, Japan and the EU, our largest markets.

The introduction of new pharmaceutical products generally entails a lengthy approval process. Products must be authorized or registered prior to marketing, and such authorization or registration must subsequently be maintained. In recent years, the registration process has required increased testing and documentation for the approval of new drugs, with a corresponding increase in the expense of product introduction. To register a pharmaceutical product, a registration dossier containing evidence establishing the safety, efficacy and quality of the product must be submitted to regulatory authorities. Generally, a therapeutic product must be registered in each country in which it will be sold. It is possible that a drug can be registered and marketed in one country while the registration authority in another country may, prior to registration, request additional information from the pharmaceutical company or even reject the product. It is also possible that a drug may be approved for different indications in different countries. The registration process generally takes between six months and several years, depending on the country, the quality of the data submitted, the efficiency of the registration authority's procedures and the nature of the product. Many countries provide for accelerated processing of registration applications for innovative products of therapeutic interest. In recent years, efforts have been made among the U.S., Japan and the EU to harmonize registration requirements to achieve shorter development and registration times for medical products.

United States

In the United States, applications for drug registration are submitted to and reviewed by the FDA, which regulates the testing, manufacturing, labeling and approval for marketing of pharmaceutical products intended for commercialization. The FDA continues to monitor the safety of pharmaceutical products after they have been approved for sale in the U.S. market. When a pharmaceutical company has gathered data to demonstrate a drug's safety, efficacy and quality, it may file for the drug an NDA or Biologics License Application ("BLA"), along with information regarding the clinical experiences of patients tested in the drug's clinical trials. A supplemental new drug application ("sNDA") or BLA amendment must be filed for new indications for a previously approved drug.

Once an application is submitted, the FDA assigns reviewers from its staff, including experts in biopharmaceutics, chemistry, clinical microbiology, pharmacology/toxicology, and statistics. After a complete review, these content experts then provide written evaluations of the NDA or BLA. These evaluations are consolidated and are used by senior FDA staff in its final evaluation of the NDA or BLA. Based on that final evaluation, the FDA then provides to the NDA or BLA's sponsor an approval, or a "complete response" letter if the NDA or BLA application is not approved. If not approved, the letter will state the specific deficiencies in the NDA or BLA which need to be addressed. The sponsor must then submit an adequate

response to the deficiencies to restart the review procedure. Once the FDA has approved an NDA, BLA, sNDA or BLA amendment, the company can make the new drug available for physicians to prescribe. The drug owner must submit periodic reports to the FDA, including any cases of adverse reactions. For some medications, the FDA requires additional post-approval studies (Phase IV) to evaluate long-term effects or to gather information on the use of the product under specified conditions. Throughout the life cycle of a product, the FDA requires compliance with standards relating to good laboratory, clinical and manufacturing practices. The FDA also requires compliance with rules pertaining to the manner in which we may promote our products.

The Drug Price Competition and Patent Restoration Term Act of 1984, known as the Hatch-Waxman Act, established the application procedures for obtaining FDA approval for generic forms of brand-name drugs. Under these procedures, instead of conducting full-scale pre-clinical and clinical trials, the FDA can accept data establishing that the drug formulation, which is the subject of an abbreviated application, is bio-equivalent and has the same therapeutic effect as the previously approved drug, among other requirements. This act also provides market exclusivity provisions for brand-name drugs that can delay the submission and/or the approval of abbreviated new drug applications (the "ANDAs"), which are the applications for generic drug registrations. The Orphan Drug Act of 1983 grants seven years of exclusive marketing rights to a specific drug for a specific orphan indication. The term "orphan drug" refers, generally, to a drug that treats a rare disease affecting fewer than 200,000 persons in the U.S. Market exclusivity provisions are distinct from patent protections and apply equally to patented and non-patented drug products.

While the Hatch-Waxman Act addresses the development and entrance of generic products, the Patent Protection and Affordable Care Act (the "ACA") amended the Public Health Service Act to create an abbreviated licensure pathway for biological products that are demonstrated to be "biosimilar" to or "interchangeable" with an FDA-licensed biological product. The Biologics Price Competition and Innovation Act of 2009 allows for approval of a biosimilar if data substantiates that the product is "highly similar" to an approved and existing biological product. Furthermore, as codified in the 2016 Physician Fee Schedule Final Rule, effective January 1, 2016, the physician reimbursement amount for a biosimilar is based on the average sales price (the "ASP") of all National Drug Codes (the "NDCs") assigned to the biosimilars included within the same billing and payment code. Similar to a non-biologic product, an interchangeable biological product may be substituted for the reference product by a pharmacist without the intervention of the health care provider who prescribed the reference product. Generally, there will be a common physician reimbursement limit and Healthcare Common Procedure Coding System (the "HCPCS") code for those biosimilars referenced to the original product filed under the BLA.

Japan

Manufacturers and sellers of drugs, quasi-drugs, cosmetics, medical devices and regenerative medical products (collectively the "Designated Products") in Japan are subject to the supervision of the Minister of Health, Labour and Welfare (the "Minister") primarily under the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics of Japan (the "Pharmaceutical Act").

Under the Pharmaceutical Act, a person is required to obtain from the Minister the relevant licenses in order to conduct the business of manufacturing, marketing or selling Designated Products.

Applications for the approval of new products are made through the PMDA. The data of results of clinical trials and other pertinent data must be attached for an application for approval. If the drugs, medical devices or regenerative medical products under application are of types designated by ministerial ordinance of the MHLW, the attached data mentioned above must be obtained in compliance with the standards established by the Minister, such as the Good Laboratory Practice (the "GLP") and the Good Clinical Practice (the "GCP"). Once an application for approval is submitted, a review team is formed, which consists of specialized officials of the PMDA, including chemistry/manufacturing, non-clinical, clinical, and biostatistics. Team evaluation results are passed to the PMDA's external experts, who then report back to the PMDA. After a further team evaluation, a report is provided to the Minister; the Minister makes a final determination for approval and refers this to the Council on Drugs and Foods Sanitation, which then advises the MHLW on final approvability. Marketing and distribution approvals require a review to determine whether or not the product in the application is suitable as a drug to be manufactured and distributed by a person who has obtained a manufacturing and distribution business license for the type of drug concerned, and to confirm that the product has been manufactured in a plant compliant with Good Manufacturing Practice.

Once the MHLW has approved the application, the company can make the new drug available for physicians to prescribe. After that, the MHLW lists its NHI price within 60 days (or 90 days at the latest) from the approval, and physicians can obtain reimbursement. For some medications, the MHLW requires additional post-marketing studies (Phase IV) to further evaluate safety and/or to gather information concerning the quality, efficacy, and safety of the product under specified conditions. The MHLW also requires the drug's sponsor to submit periodic safety update reports. Within three months from the specified re-examination period, which is designated at the time of the approval of the application for the new product, the company must submit a re-examination application to enable the drug's quality, efficacy, and safety to be reassessed against approved labeling by the PMDA.

The Pharmaceutical Act also provides for special regulations applicable to drugs, quasi-drugs, cosmetics and medical devices made of biological raw materials. These regulations impose various obligations on manufacturers and other persons in relation to manufacturing facilities, explanation to patients, labeling on products, record-keeping and reporting to the Minister.

Under the Pharmaceutical Act, the Minister may take various measures to supervise manufacturing and marketing license holders of Designated Products. The Minister has authority to order manufacturing and marketing license holders to temporarily suspend the marketing, leasing or providing of the Designated Products to prevent risks, or increases in risks, to the public health. Also, the Minister may revoke a license or approval granted to a manufacturing and marketing license holders or order a temporary business suspension under certain limited circumstances such as violation of laws relating to drugs.

European Union

In the EU, there are three main procedures for application for authorization to market pharmaceutical products in the EU Member States: the Centralized Procedure, the Mutual Recognition Procedure (the "MRP") and the Decentralized Procedure ("the DCP"). It is also possible to obtain a pure national authorization for products intended for commercialization in a single EU Member State only, or for additional indications for licensed products.

Under the Centralized Procedure, applications are made to the EMA for an authorization which is valid throughout the EU. The Centralized Procedure is mandatory for all biotechnology products and for new chemical entities in cancer, neurodegenerative disorders, diabetes and AIDS, autoimmune diseases or other immune dysfunctions and optional for other new chemical entities or innovative medicinal products or in the interest of public health. When a pharmaceutical company has gathered data which it believes sufficiently demonstrates a drug's safety, efficacy and quality, then the company may submit an application to the EMA. The EMA then receives and validates the application and the Committee for Medicinal Products for Human Use (the "CHMP") appoints a Rapporteur and Co-Rapporteur to lead review of the dossier. The entire review cycle must be completed within 210 days, although there is a "clock stop" at day 120, which allows the company to respond to questions set forth in the Rapporteur and Co-Rapporteur's Assessment Report. After the company's complete response is submitted to the EMA, the clock restarts on day 121. If there are further aspects of the dossier requiring clarification, the EMA will then request an Oral Explanation on day 180, in which case the sponsor must appear before the CHMP to provide the requested additional information. On day 210, the CHMP will then take a vote to recommend the approval or non-approval of the application. The final decision under this Centralized Procedure is a European Community decision which is binding in its entirety on all EU Member States. This decision occurs on average 60 days after a positive CHMP recommendation. In the case of a negative opinion, a written request for re-examination of the opinion can be made by the applicant within a time limit of 15 days from the date of the opinion. The detailed grounds for re-examination must be submitted to the EMA within 60 days from the date of the opinion. In the EU, biosimilars are approved under a specialized pathway of the centralized procedure. Similar to the pathway in the U.S., applicants seek and obtain regulatory approval for a biosimilar once the data exclusivity period for the original reference product has expired relying in part on the data submitted for the original reference product together with data evidencing that the biosimilar is "highly similar" in terms of quality, safety and efficacy to the original reference product authorized in the European Economic Area.

Under both the MRP and DCP, the assessment is led by a single EU Member State, called the Reference Member State (the "RMS"), which then liaises with other EU Member States, known as the concerned member states (the "CMSs"). In the MRP, the company first obtains a marketing authorization in the RMS, which is then recognized by the CMSs in 90 days. In the DCP, the application is done simultaneously in the RMS and all CMSs. During the DCP, the RMS drafts an assessment report within 120 days. Within an additional 90 days, the CMSs review the application and can issue objections or requests for additional information. On day 90, each CMS must be assured that the product is safe and effective, and that it will cause no risks to the public health. Once an agreement has been reached, each member state grants national marketing authorizations for the product.

After the Marketing Authorizations have been granted, the company must submit periodic safety reports to the EMA, if approval was granted under the Centralized Procedure, or to the National Health Authorities, if approval was granted under the DCP or the MRP. In addition, several pharmacovigilance measures must be implemented and monitored including Adverse Event collection, evaluation and expedited reporting and implementation, as well as update Risk Management Plans. For some medications, post approval studies (Phase IV) may be required to complement available data with additional data to evaluate long term effects (called a Post Approval Safety Study) or to gather additional efficacy data (called a Post Approval Efficacy Study).

European Marketing Authorizations have an initial duration of five years. After this first five-year period, the holder of the marketing authorization must apply for its renewal, which may be granted based on the competent authority's full benefit-risk review of the product. Once renewed, the marketing authorization is generally valid for an unlimited period. Any Marketing Authorization which is not followed within three years of its granting by the actual placing on the market in any EU member state of the corresponding medicinal product ceases to be valid.

Third Party Reimbursement and Pricing

We consider domestic and international competitive conditions, such as the price of competing products, in setting and revising the price of our pharmaceutical products. Government regulation also has a significant effect in determining the price of pharmaceutical products in many of the countries in which we operate due to the fact that government policy in many countries has emphasized and purchasers continue to seek large discounts on pharmaceutical products.

United States

In the United States our sales are subject to various rebate programs and government programs, which vary depending on the type and can have a significant impact on our results. The most significant of these include rebates associated with commercial managed care, Medicaid, Medicare and government programs.

Commercial Managed Care

Payers negotiate rebates to reduce the pricing of products, and use formularies to encourage members to utilize preferred products to manage their costs. Exclusion from a formulary, or a disfavored formulary position, can directly reduce product usage. Consolidation of payers, pharmacy benefit managers and pharmacies may result in increasing rebates and other discounts due to the purchasing power of the consolidated entities. Copay assistance to help patients afford their prescribed drugs may also affect product usage. In recent years, some states such as California and Massachusetts, have

passed legislation that limits the use of manufacturer sponsored copay assistance programs, and some payers have limited manufacturer copay assistance benefits to patients.

Medicaid

Medicaid is a state administered program adhering to federal requirements that provides healthcare coverage to eligible low-income adults, children, pregnant women, elderly adults and people with disabilities.

Takeda must pay rebates on purchases of our products under the Medicaid Drug Rebate Program. Takeda must also calculate and report to government agencies the amount of the rebate. The required calculations are complex, and a misrepresentation in the reported information may expose Takeda to penalties. We are required to report any revisions to prior calculations, which could affect the rebate liability for prior quarters.

Medicare

The Medicare Prescription Drug Program has two arms, Medicare Part D and Medicare Part B. Medicare Part D is a voluntary offering available to Medicare beneficiaries through private health insurance plans that contract with the government to deliver this benefit. Medicare Part B covers some drugs, under the medical benefit, that are among the most biologically complex; these medicines are generally administered in a doctor's office or hospital outpatient setting.

Takeda offers rebates on purchases of pharmaceutical products covered under Medicare Part D. In addition, Takeda and other pharmaceutical manufacturers are required to provide a discount of 70% on drugs used in the Medicare Part D coverage gap. Takeda must also calculate and report specific prices to government agencies, including Average Sales Price used by the Medicare Part B program. The required calculations are complex, and a misrepresentation in the reported pricing may expose Takeda to penalties.

340B and Federal Agency Discounted Pricing

Takeda must offer discounted pricing for purchases by certain designated health care entities and federal agencies under certain federal programs, including the Public Health Service (PHS) pharmaceutical pricing program (340B) and the Federal Supply Schedule (FSS.)

Health Care System Reform

Any sudden change to the current health care system runs the risk of restricting patient access and placing all parties at financial risk. Spurred by the Administration's priority to bring down the cost of drug prices, a number of changes to the Medicare Part D and Part B programs are being proposed - these changes may impact patient access and affordability, and may adversely affect our business by impacting demand for, or pricing of, our products. The Trump Administration's Blueprint to Lower Drug Prices and Reduce Out of Pocket Costs and the resulting regulatory activity has already changed the way companies behave with fewer and lower price increases in 2018 than 2017.

Japan

In Japan, manufacturers of pharmaceutical products must have new products listed on the National Health Insurance (the NHI), a price list published by the Ministry of Health, Labour and Welfare of Japan (the MHLW). The NHI price list provides rates for calculating the price of pharmaceutical products used in medical services provided under various public medical care insurance systems. Prices on the NHI price list have been subject to revisions generally once every two years based on the actual prices at which the pharmaceutical products are purchased by medical institutions in Japan after discounts and rebates from listed price. The average price of previously listed products generally decreases as a result of these price revisions. The Japanese government is currently undertaking healthcare reform initiatives with the goal of sustaining the universal coverage of the NHI program, and is addressing the efficient use of drugs, including promotion of generic use with a target of 80% penetration by volume by September 2020 with respect to products for which market exclusivity has expired. As part of these initiatives, the NHI price list is expected to be revised annually from April 1, 2021, which could lead to more frequent downward price revisions. In addition, cost-effectiveness analysis was officially introduced by the MHLW from April 2019. Products on the NHI price list nominated based on pre-defined criteria, such as the innovativeness and the financial impact, will be subject to review, and subject to price adjustments depending on outcome of this review.

European Union

In the EU, our operations are subject to significant price and marketing regulations. Many governments in the EU are introducing healthcare reforms to curb increasing healthcare costs. The governments in the EU influence the price of pharmaceutical products through their control of national healthcare systems that fund a large part of the cost of such products to patients. The general downward pressure on healthcare costs, particularly regarding prescription drugs, has been increasing. In addition, prices for marketed products are referenced within and amongst the EU Member States, which further affects pricing in each EU Member State. As an additional control for healthcare budgets, some EU Member States have passed legislation to impose further mandatory rebates for pharmaceutical products and financial claw-backs on the pharmaceutical industry. In this regard, many countries have health technology assessment organizations that use formal economic metrics such as cost-effectiveness to determine prices, coverage and reimbursement of new therapies, and these organizations are expanding in established and emerging markets. We expect that countries will continue to take aggressive actions to seek to reduce expenditures on drugs and biologics. Similarly, fiscal constraints may also affect the extent to which countries are willing to approve new and innovative therapies and/or allow access to new treatments.

Furthermore, the European Union is currently undergoing an analysis of the rewards extended for intellectual property of pharmaceutical products as well as the overall regulatory framework for the approval and commercialization of all medicinal products. This may lead to significant changes in the way drugs are approved and commercialized as well as the duration of exclusivity, in particular for orphan drugs. These changes are likely to affect the market within a 3-5-year timeframe.

Other

Many other countries around the world are also taking steps to control prescription drug prices. For example, in 2017, China - one of our most important Emerging Growth Markets - organized national price negotiations for certain products directly linked to national drug reimbursement, which will apply nationwide both in public and military hospitals. Drug prices in China may further decline due to a stated national policy of reducing healthcare costs, including continued strategic initiatives specifically designed to reduce drug prices. Canada has proposed amendments to its Patented Medicines Regulations that could reduce prices for specialty medicines, such as biologics and medicines for rare diseases.

C. Organizational Structure.

We are a holding company and administer our business through a number of subsidiaries worldwide. Information about Takeda's organizational structure, including a list of our subsidiaries, their country of incorporation and residence and our proportion of ownership interest, is included in Note 29 to the audited consolidated financial statements included in this annual report.

D. Property, Plant and Equipment.

Our registered head office is located in Osaka, Japan and our global head office is located in Tokyo, Japan. We generally own our facilities or have entered into long-term lease arrangements for them.

As of March 31, 2019, the net book values of the buildings and structures, land, machinery and vehicles and tools, furniture and fixtures we owned were ¥692.5 billion, ¥101.4 billion, ¥335.8 billion and ¥47.1 billion, respectively. We own the substantial majority of our facilities, none of which are subject to any material encumbrances. The following table describes our major facilities as of March 31, 2019:

Group company	Name of facility (location)	Type of facility
Takeda Pharmaceutical Company Limited	Head Office (Chuo-ku, Osaka and others)	Administrative and sales
Takeda Pharmaceutical Company Limited	Global Head Office (Chuo-ku, Tokyo)	Administrative and sales
Takeda Pharmaceutical Company Limited	Osaka Plant (Yodogawa-ku, Osaka)	Manufacturing, Research and development
Takeda Pharmaceutical Company Limited	Hikari Plant (Hikari, Yamaguchi)	Manufacturing, Research and development
Takeda Pharmaceutical Company Limited	Shonan Health Innovation Park (Fujisawa, Kanagawa)	Research
Takeda Real Estate Co, Ltd.	Takeda Midosuji Building and others (Chuo-ku, Tokyo)	Administrative and sales
Nihon Pharmaceutical Co. Ltd.	Osaka Plant and other (Izumisano, Osaka)	Manufacturing, Research and development
Takeda Healthcare Products Co., Ltd.	Head Office, Plant (Fukuchiyama, Kyoto)	Manufacturing
Millennium Pharmaceuticals, Inc.	Head Office, Plant and other properties (Cambridge, Massachusetts, U.S.)	Research and development
Baxalta U.S. Inc	Head Office (Covington, Georgia, U.S.)	Manufacturing, Warehouse, Administrative and sales
Shire Human Genetic Therapies, Inc	Head Office (Lexington, Massachusetts, U.S.)	Manufacturing, Warehouse, Administrative and sales
Baxter AG	Production facility and other (Orth an der Donau, Austria and Vienna, Austria)	Manufacturing, Distribution, Warehouse, Plasma centers and Administrative and sales
Baxalta Bioscience Manufacturing S.a.r.l.	Head Office (Neuchatel, Switzerland)	Manufacturing, Administrative and sales
Shire Pharmaceuticals Ireland Ltd.	Production facility (Dunboyne, Ireland)	Manufacturing
Baxalta Belgium Manufacturing SA	Production facility (Lessines, Belgium)	Manufacturing

Environmental Matters

We are subject to laws and regulations concerning the environment, safety matters, regulation of chemicals and product safety in the countries where we manufacture and sell our products or otherwise operate our business. These requirements include regulation of the handling, manufacture, transportation, use and disposal of materials, including the discharge of pollutants into the environment. In the normal course of our business, we are exposed to risks relating to possible releases of hazardous substances into the environment, which could cause environmental or property damage or personal injuries, and which could require remediation of contaminated soil and groundwater, in some cases over many years, regardless of whether the contamination was caused by us, or by previous occupants of the property. See "Item 3. Key Information—D. Risk Factors—We may incur substantial costs due to our environmental compliance efforts or claims relating to our use, manufacture, handling, storage or disposal of hazardous materials.

Item 4A. Unresolved Staff Comments

Not applicable.

Item 5. Operating and Financial Review and Prospects

You should read the following discussion of our operating and financial review and prospects together with our consolidated financial statements included in Item 18 in this annual report. Our consolidated financial statements are prepared in accordance with IFRS, as issued by the International Accounting Standard Boards ("IASB"). IFRS includes International Accounting Standard ("IAS") and related interpretations of the committees (SIC and IFRIC).

The following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of factors, including, but not limited to, those under Item 3. D "Risk Factors" and elsewhere in this annual report.

A. Operating Results.

Overview

We have grown both organically and through acquisitions, completing a series of major transactions that have resulted in growth in our areas of therapeutic, geographic and pipeline focus. In particular, our acquisition of Shire in January 2019 strengthened our presence in GI and neuroscience, while providing us with a leading position in rare disease and plasma driven therapies. It also enhanced our research and development pipeline and created a highly complementary, robust, modality-diverse pipeline. Commercially, the Shire Acquisition significantly strengthened our presence in the United States. As a result of the acquisition of Shire, we incurred significant indebtedness to finance the cash portion of the consideration. We plan to de-lever following the Shire Acquisition using cash flows from operations and we are initiating disposals of non-core assets to accelerate the pace of deleveraging and to refocus our business on our key business areas of GI, rare diseases, plasma-derived therapies, oncology, and neuroscience.

We organize our business as a single operating segment, reflecting the presentation of information to our management for the purposes of allocating resources, measuring performance and forecasting future periods. In the fiscal year ended March 31, 2019, our revenue was ¥2,097.2 billion, our operating profit was ¥205.0 billion.

Factors Affecting Our Results of Operations

Our results are affected by the global industry trends and operating environment as described in Item 4 of this annual report and other factors described below.

Acquisitions

We may acquire new businesses to expand our research and development capabilities (including expanding into new methodologies) and to acquire new products (whether in the development pipeline or at the marketing stage) or other strategic regions. Similarly, we regularly divest businesses and product lines to maintain our focus on our key growth drivers and to manage our portfolio.

We account for these acquisitions as business combinations and record the assets and liabilities acquired at fair value. Our results are impacted due to the impacts of purchase accounting, which typically includes fair value step-ups of inventory and property, plant and equipment and recognized material intangible assets which result in costs related to unwind of the step up and amortization expense, respectively, in future periods. Our results are also impacted due to additional interest expenses when an acquisition is financed with incremental borrowings.

On January 8, 2019, we acquired Shire for an aggregate consideration of ¥6.21 trillion, of which ¥3,029.4 billion was paid in cash and the remainder mainly in shares of our common stock. We incurred ¥3,295.9 billion in indebtedness in order to finance the cash portion of the consideration, and as a result of the Shire Acquisition assumed ¥1,603.2 billion of indebtedness of Shire which is included in our consolidated statement of financial position. We recorded goodwill of ¥3,087.4 billion and intangible assets of ¥3,899.3 billion in relation to the Shire Acquisition. The acquisition of Shire has significantly changed our business through, among other things, the significant expansion of our product portfolio and geographic presence. Our results will be significantly impacted by the Shire Acquisition with an increase to our revenues, and associated costs, and the impact of the acquisition including incremental amortization expenses related to the acquired intangible assets, incremental cost of sales resulting from the unwinding of the inventory fair value step up, the interest expense associated with the borrowings used to fund the acquisition, and the costs incurred to integrate the

business. We are actively engaged in integrating Shire and expect to be able to achieve significant, recurring pre-tax synergies of approximately $2.0 billion annually by the end of the third fiscal year after the completion of the Shire Acquisition, originating from efficiencies in the combined company's sales, marketing and administrative functions, research and development rationalization efforts and product manufacturing and supply. We estimate that the realization of these synergies will require non-recurring costs of approximately $3.0 billion in the first three fiscal years following the completion of the Shire Acquisition. We believe that the substantial cash flow generation expected to result from the Shire Acquisition will enable us to maintain our well-established dividend policy, and de-lever following completion. We have begun initiating the disposal of certain non-core assets and businesses to increase the pace of de-leveraging our debt.

On February 16, 2017, we acquired ARIAD Pharmaceuticals, Inc. for a net consideration of ¥583.1 billion. Headquartered in Cambridge, Massachusetts in the United States, ARIAD was a commercial-stage biotechnology company focusing on discovering, developing and commercializing precision therapies for patients with rare forms of chronic and acute leukemia, lung cancer and other rare cancers.

As a result of our acquisitions, and the impacts described above, our results year over year may not be comparable.

Divestitures

In addition to acquisitions, we divest businesses and product lines to maintain our focus on our key growth drivers and to manage our portfolio and to provide additional cash flow to accelerate the repayment of long-term borrowings.

In April 2017, we completed the sale of our shares in Wako Pure Chemical to FUJIFILM Corporation for a sale price of ¥198.5 billion, for which we recognized a gain of ¥106.3 billion in the fiscal year ended March 31, 2018. Wako Pure Chemical generated revenue of ¥76.6 billion and ¥79.1 billion for the fiscal years ended March 31, 2016 and 2017, respectively. There was no revenue recognized related to Wako Pure Chemical for the fiscal year ended March 31, 2018.

In April 2016, we transferred certain long-listed products in Japan to Teva Takeda Yakuhin Ltd., a wholly-owned subsidiary of Teva Takeda Pharma Ltd., a joint venture we formed with Teva Pharmaceutical Industries Ltd. in which we hold a 49% interest, representing shares of Teva Takeda Pharma Ltd. received as consideration for the transfer. At the time of the transfer, we recognized a gain for the difference between the fair value consideration received (shares of Teva Takeda Pharma Ltd.) and the carrying value of the business to the extent we disposed of the business. The remainder of the gain was deferred and will be amortized over a period of 15 years from the date of the transfer, representing the estimated useful life of the intangible assets associated with the products transferred. In the fiscal year ended March 31, 2017, we recognized a gain related to this transfer of ¥115.4 billion. ¥102.9 billion of such amount was the amount of the gain recognized at the time of disposal. The remainder represents the amount of the deferred gain amortized during such fiscal year. We receive income from the joint venture in the form of a supply and distribution fee, in addition to a 49% share of the joint venture's income or losses.

We have communicated our intention to continue to divest businesses that are not core to our operations and to reduce our borrowings with the proceeds. In May 2019, we announced the sale of Xiidra® (lifitegrast ophthalmic solution), which we obtained as part of the Shire Acquisition and the sale of Tachosil™, as described further in Note 33 to our audited consolidated financial statements included in this annual report.

Patent Protection and Generic Competition

For pharmaceutical products in particular, patent protection and/or regulatory exclusivity benefit our results of operations by restricting competition. Newly introduced products, particularly those which treat conditions for which alternative treatments may not be readily available, in particular may significantly contribute to sales. However, even protected products must compete with products of other manufacturers based on efficacy, lack of adverse reactions and price. On the other hand, the loss or expiration of patent protection or regulatory exclusivity with respect to any of our principal products could have a material adverse effect on our results of operations, as generic products, which tend to be quickly adopted once introduced, may enter the market. Some of our principal products face, or are expected to face, considerable competition due to the expiration of patent or other intellectual property protection. For example, following the expiration of patent protection over bortezomib, the active ingredient in *VELCADE*, one of our largest selling products in the United States, a competing bortezomib-containing product has been introduced. This has led to a decrease in sales of *VELCADE*, and further entry of competing products could result in substantial additional declines. In certain cases, generic competitors may successfully challenge the validity of patents, or the manufacturer may decide that the benefits of prematurely launching "at risk" the generic drug outweigh the costs of defending infringement litigation. In situations where the validity of patents or the value of the protection is challenged, we may record impairment losses with respect to the relevant intangible property.

Impact of the Availability of Raw Materials

Our results of operations may be impacted if we are not able to internally or externally source critical raw materials. For example, human plasma is a critical raw material in our plasma derived therapies. Efforts to increase the collection of plasma may include the contracting and regulatory approval of additional plasma collection facilities and plasma fractionation facilitates. During the year ended March 31, 2019, our results of operations were impacted by the fact that the demand to produce plasma derived therapies was greater than the supply of critical raw material needed.

Foreign Exchange Fluctuations

In the fiscal year ended March 31, 2019, 72.8% of our revenue was from outside of Japan, and we expect this ratio to further increase when we consolidate a full year of Shire results. Changes in foreign exchange rates, particularly for the U.S. dollar and the euro, relative to the yen, which is our reporting currency, will impact our revenues and expenses. When the yen weakens against other currencies, our revenues attributable to such other currencies increase, having a positive impact on our results of operations, which may be offset by increased expenses denominated in such currencies.

Conversely, when the yen strengthens against other currencies, our revenues attributable to such currencies decrease, having a negative impact on our results of operations, which may be offset by decreased expenses denominated in such currencies. To mitigate the risk exposed by foreign exchange fluctuations, we utilize certain hedging measures with respect to some of our significant foreign currency transactions, primarily forward exchange contracts, currency swaps and currency options for individually significant foreign currency transactions.

Periodic Trends

Our revenues, operating profit and net income were lower in the fourth quarter of each of the fiscal years ended March 31, 2017, 2018 and 2019, due mainly to fluctuations in sales in Japan. Japanese pharmaceutical product wholesalers generally control their inventory more tightly towards their fiscal year ends, typically March 31, which causes decreased revenue in the fourth fiscal quarter. Japanese pharmaceutical product wholesalers also tend to increase purchases ahead of the New Year holidays, causing a concentration of sales in our third fiscal quarter, from October 1 to December 31.

Critical Accounting Policies

Our consolidated financial statements have been prepared in accordance with IFRS. The preparation of our consolidated financial statements requires management to make estimates and assumptions that affect the reported amount of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reported period. On an ongoing basis, management evaluates its estimates and assumptions. Management bases its estimates and assumptions on historical experience and on various other factors that it believes to be reasonable at the time the estimates and assumptions are made. Actual outcomes may differ from those estimates and assumptions.

We believe the following critical accounting policies are affected by management's estimates and assumptions, changes to which could have a significant impact on our consolidated financial statements.

Revenue Recognition

Our revenue is primarily related to the sale of pharmaceutical products and is generally recognized when control of the products is passed to the customer in an amount that reflects the consideration to which we expect to be entitled in exchange for those products. Our gross sales are subject to various deductions, which are primarily composed of rebates and discounts to retail customers, government agencies, wholesalers, health insurance companies and managed healthcare organizations. These deductions represent estimates of the related obligations, requiring the use of judgement when estimating the effect of these sales deductions on gross sales for a reporting period. These adjustments are deducted from gross sales to arrive at net sales. The U.S. market has the most complex arrangements related to revenue deductions.

The following summarizes the nature of the most significant adjustments to revenue:

- U.S. Medicaid and Medicare: The U.S. Medicaid Drug Rebate Program is administered by state governments using state and federal funds to provide assistance to certain vulnerable and needy individuals and families. Calculating the rebates to be paid related to this program involves interpreting relevant regulations, which are subject to challenge or change in interpretative guidance by government authorities. Provisions for Medicaid rebates are calculated using a combination of historical experience, product and population growth, product pricing and the mix of contracts and specific terms in the individual state agreements. The U.S. Federal Medicare Program, which funds healthcare benefits to individuals age 65 or older and certain disabilities, provides prescription drug benefits under Part D section of the program. This benefit is provided and administrated through private prescription drug plans. Provisions for Medicare Part D rebates are calculated based on the terms of individual plan agreements, product sales and population growth, product pricing and the mix of contracts. There is often a time lag of several months between us recording the revenue deductions and our final accounting for Medicare and Medicaid rebates.
- Customer rebates: Customer rebates are offered to purchasing organizations, health insurance companies, managed healthcare organizations, and other direct and indirect customers to sustain and increase market share, and to ensure patient access to our products. Since rebates are contractually agreed upon, the related provisions are estimated based on the terms of the individual agreements, historical experience, and projected product growth rates.
- Wholesaler chargebacks: We have arrangements with certain indirect customers whereby the customer is able to buy products from wholesalers at reduced prices. A chargeback represents the difference between the invoice price to the wholesaler and the indirect customer's contractual discounted price. Provisions for estimating chargebacks are calculated based on the terms of each agreement, historical experience and product growth rates.
- Return reserves: When we sell a product providing a customer the right to return it, we record a provision for estimated sales returns based on our sales return policy and historical return rates. We estimate the proportion of recorded revenue that will result in a return by considering relevant factors, including past product returns activity, the estimated level of inventory in the distribution channel and the shelf life of products.

Because the amounts are estimated, they may not fully reflect the final outcome, and the amounts are subject to change dependent upon, amongst other things, the type of purchasing organization, end consumer, and product sales mix.

Historically, our adjustments of estimates, to reflect actual results or updated expectations, have not been material to our overall business. Product-specific rebates, however, can have a significant impact on year- over-year individual product growth trends. If any of our ratios, factors,

assessments, experiences or judgments are not indicative or accurate predictors of our future experience, our results could be materially affected. The sensitivity of our estimates can vary by program, type of customer and geographic location.

Impairment of Goodwill and Intangible Assets

We review long-lived intangible assets for impairment whenever events or changes in circumstance indicate that the asset's balance sheet carrying amount may not be recoverable. Goodwill and other currently not amortized intangible assets are reviewed for impairment at least annually. As of March 31, 2019, we have ¥4,161.4 billion of goodwill and ¥4,860.4 billion of intangible assets which in aggregate represent 65.0% of our total assets.

Intangible assets related to commercially marketed products are amortized using the straight-line method over the estimated useful life, which is based on expected exclusivity period, ranging from three to 20 years. Intangible assets related to in-process research and development ("IPR&D") product rights are not amortized until the product is approved for sale by regulatory authorities in specified markets. At that time, we will determine the useful life of the asset and begin amortization.

Assets are generally considered impaired when their balance sheet carrying amount exceeds their estimated recoverable amount. The recoverable amount is estimated for each individual asset or at the larger cash generating unit level when cash is generated in combination with other assets. Goodwill is allocated to cash generating units, or groups of cash generating units based on expected synergies as determined and the recoverable amount is estimated at the cash generating unit level. Our cash generating units are identified base on the smallest identifiable group of assets that generate independent cash inflows and are represented by the countries where we sell our products. The estimation of recoverable value requires us to make a number of assumptions including:

- amount and timing of projected future cash flows;
- behavior of competitors (launch of competing products, marketing initiatives, etc.);
- probability of obtaining regulatory approvals;
- future tax rates;
- terminal growth rate; and
- discount rate.

Events that may result in the change in cash flows include IPR&D projects which are not successfully developed, and/or commercially marketed products whose value becomes impaired, fail during development, are abandoned or subject to significant delay or do not receive the relevant regulatory approvals. If these events were to occur, we may not realize the future cash flows that we have estimated nor recover the value of the initial or subsequent R&D investments made subsequent to acquisition of the asset project.

Due to changes in these assumptions in subsequent periods, we have recognized impairments and reversal of impairments related to intangible assets during the periods presented. See Notes 11 and 12 to our audited consolidated financial statements.

Retirement and Other Post-Employment Benefit Plans

We sponsor pension and other post-employment benefit plans that cover a significant portion of our employees. We are required to make significant assumptions and estimates about future events in calculating the expense and the present value of the liability related to these plans. These include assumptions about the interest rates we apply to estimate future defined benefit obligations and net periodic pension expense, as well as rates of future pension increases. In addition, our actuarial consultants provide our management with historical statistical information such as withdrawal and mortality rates in connection with these estimates. Assumptions and estimates used by us may differ materially from the actual results we experience due to changing market and economic conditions, higher or lower withdrawal rates, and longer or shorter life spans of participants among other factors. See Note 22 to our audited consolidated financial statements for sensitivity information related to the most significant assumptions. A significant change in the assumptions in future periods could have a material impact on our consolidated financial statements. As of March 31, 2019, we have net defined benefit liabilities of ¥156.5 billion.

Business Combination – Fair value

Accounting for a business combination requires us to estimate the fair value of the assets acquired and liabilities assumed and the value of any contingent consideration. The estimate of fair value requires us to make a number of assumptions including estimated future cash flows, discount rates, development and approval milestones, expected market performance and for contingent consideration the likelihood of payment.

Contingent consideration is recorded at fair value at the end of each period. The changes in the fair value based on time value of money are recognized in Finance expenses while other changes are recognized in Other operating income or Other operating expenses on the consolidated statement of income. During the year ended March 31, 2019, the change in fair value of contingent consideration reduced the amount to be paid to us by ¥2.2 billion.

Our estimates are based on our prior experiences and industry knowledge. We believe that our estimates are reasonable, but actual outcomes could differ significantly from our estimates. A significant change in our estimates used to value acquired asset groups or business combinations could result in future write-downs of tangible or intangible assets acquired by us and could, therefore, materially impact our financial position and profitability. If the value of the liabilities assumed by us, including contingent liabilities, is determined to be significantly different from the amounts previously recorded in purchase accounting, we may need to record additional expenses, which could materially impact our financial position and profitability.

Legal Contingencies

We are involved in various legal proceedings primarily related to product liability and commercial liability arising in the normal course of our business. These contingencies are described in detail in Note 32 to our consolidated financial statements.

These and other contingencies are, by their nature, uncertain and based upon complex judgments and probabilities. The factors we consider in developing our provision for litigation and other contingent liability amounts include the merits and jurisdiction of the litigation, the nature and the number of other similar current and past litigation cases, the nature of the product and the current assessment of the science subject to the litigation, and the likelihood of settlement and current state of settlement discussions, if any. In addition, we record a provision for product liability claims incurred, but not filed, to the extent we can formulate a reasonable estimate of their costs based primarily on historical claims experience and data regarding product usage. We also consider the insurance coverage we have to diminish the exposure for periods covered by insurance. In assessing our insurance coverage, we consider the policy coverage limits and exclusions, the potential for denial of coverage by the insurance company, the financial condition of the insurers, and the possibility of and length of time for collection. Any provision and the related estimated insurance recoverable have been reflected on a gross basis as liabilities and assets, respectively, on our consolidated balance sheets. As of March 31, 2019, we have a provision of ¥46.8 billion for outstanding legal cases and other disputes.

Income Taxes

We prepare and file our tax returns based on an interpretation of tax laws and regulations, and we record estimates based on these judgments and interpretations. In the normal course of business, our tax returns are subject to examination by various taxing authorities, which may result in additional tax, interest or penalty assessment by these authorities. Inherent uncertainties exist in estimates of many tax positions due to changes in tax law resulting from legislation, regulation, and/or as concluded through the various jurisdictions' tax court systems. When we conclude that it is not probable that a taxing authority will accept an uncertain tax position, we recognize the best estimate of the expenditure required to settle a tax uncertainty. The amount of unrecognized tax benefits is adjusted for changes in facts and circumstances. For example, adjustments could result from significant amendments to existing tax law, the issuance of regulations or interpretations by the taxing authorities, new information obtained during a tax examination, or resolution of a tax examination. We believe our estimates for uncertain tax positions are appropriate and sufficient based on currently known facts and circumstances.

We also assess our deferred tax assets to determine the realizable amount at the end of each period. In assessing the recoverability of deferred tax assets, we consider the scheduled reversal of taxable temporary differences, projected future taxable profits, and tax planning strategies. Based on the level of historical taxable profits and projected future taxable profits during the periods in which the temporary differences become deductible, we determine the amount the tax benefits we believe are realizable. As of March 31, 2019, we had unrecognized deferred tax benefits of ¥259.4 billion. A change in our assumptions in future periods could have a significant impact on our income tax provision.

Restructuring Costs

We incur restructuring costs associated with planned initiatives to reduce our costs and in connection with the integration of our acquisitions. Our most significant restructuring costs are severance payments and lease termination costs. We establish a provision for restructuring costs when the plan has been approved, the cost can be estimated and the amount is probable of payment. The recognition of restructuring provision requires a number of estimates including timing of payments and the number of individuals that will ultimately remain with the company to receive severance. As a result of these estimates, the actual restructuring costs could differ from our estimates.

We expect to incur additional restructuring costs in the future related to the integration efforts associated with our acquisitions and divestitures. As of March 31, 2019, we have a provision of ¥49.7 billion for restructuring costs. See Note 23 to our audited consolidated financial statements included in this annual report for a further description of our restructuring provisions and the change between periods.

Results of Operations

The following table provides selected consolidated statements of income information for the years ended March 31, 2017, 2018 and 2019.

	For the fiscal year ended March 31,		
	2017	2018	2019
	(billions of yen)		
Revenue	¥ 1,732.1	¥ 1,770.5	¥ 2,097.2
Cost of Sales	(558.8)	(495.9)	(659.7)
Selling, general and administrative expenses	(619.1)	(628.1)	(717.6)
Research and development expenses	(312.3)	(325.4)	(368.3)
Amortization and impairment losses on intangible assets associated with products	(156.7)	(122.1)	(203.4)
Other operating income	143.5	169.4	159.9
Other operating expenses	(72.9)	(126.6)	(103.2)
Operating profit	155.9	241.8	205.0
Finance income	12.3	39.5	16.8
Finance expenses	(23.2)	(31.9)	(83.3)
Share of loss of investments accounted for using the equity method	(1.5)	(32.2)	(43.6)
Profit before tax	143.3	217.2	94.9
Income tax (expense) benefit	(27.8)	(30.5)	14.1
Net profit for the year	¥ 115.5	¥ 186.7	¥ 109.0

Fiscal Year Ended March 31, 2019 compared with the Fiscal Year Ended March 31, 2018

Our results of operations for the fiscal year ended March 31, 2019 have been significantly impacted the Shire Acquisition. The following summarizes the impact on our results of operations in the year end March 31, 2019 and on the change in our results between years.

	For the fiscal year ended March 31,							
	Consolidated financial results			Impact from the Shire Acquisition				Remaining change
	2018	2019	Change versus previous year	Shire operations	Purchase accounting	Acquisition/ integration costs	Total impact from Shire Acquisition	Change versus previous year
				(billions of yen)				
Revenue	¥ 1,770.5	¥ 2,097.2	¥ 326.7	¥ 309.2	¥ —	¥ —	¥ 309.2	¥ 17.5
Cost of sales	(495.9)	(659.7)	(163.8)	(101.6)	(81.7)	—	(183.3)	19.6
Selling, general and administrative expenses	(628.1)	(717.6)	(89.5)	(98.5)	(0.6)	(23.8)	(122.9)	33.4
Research and development expenses	(325.4)	(368.3)	(42.9)	(43.0)	—	(1.6)	(44.6)	1.7
Amortization and impairment losses on intangibles assets associated with products	(122.1)	(203.4)	(81.2)	(0.0)	(99.2)	—	(99.2)	18.0
Other operating income	169.4	159.9	(9.5)	(1.4)	—	—	(1.4)	(8.2)
Other operating expenses	(126.6)	(103.2)	23.4	(4.9)	—	(59.6)	(64.5)	88.0
Operating profit	241.8	205.0	(36.8)	59.8	(181.6)	(85.0)	(206.8)	170.0
Finance income	39.5	16.8	(22.7)	0.0	0.2	—	0.2	(22.9)
Finance expense	(31.9)	(83.3)	(51.4)	(10.6)	(4.2)	(41.3)	(56.1)	4.8
Share of (loss) profit of investments accounted for using the equity method	(32.2)	(43.6)	(11.4)	0.3	—	—	0.3	(11.7)
Profit before income tax	217.2	94.9	(122.3)	49.4	(185.6)	(126.3)	(262.5)	140.2
Income tax (expense) benefit	(30.5)	14.1	44.6	(11.3)	44.0	26.1	58.7	(14.1)
Net profit for the year	¥ 186.7	¥ 109.0	¥ (77.7)	¥ 38.1	¥ (141.7)	¥ (100.2)	¥ (203.8)	¥ 126.1

Revenue. Revenue increased ¥326.7 billion, or 18.5%, to ¥2,097.2 billion for the fiscal year ended March 31, 2019, including ¥309.2 billion resulting from the Shire Acquisition.

The remaining increase of ¥17.5 billion, or 1.0%, resulted from the continued expansion from three business areas (GI, oncology, and neuroscience), which was partially offset by the divestitures and the unfavorable impact of foreign currency movements.

The following shows revenue by geographic region:

	For the fiscal year ended March 31,			
	2018		2019	
	(billions of yen, except percentages)			
Revenue:				
Japan	¥ 580.3	32.8%	¥ 571.0	27.2%
United States	598.3	33.8	829.0	39.5
Europe and Canada	313.7	17.7	405.6	19.3
Russia/CIS	68.2	3.9	59.7	2.8
Latin America	75.7	4.3	88.1	4.2
Asia (excluding Japan)	104.0	5.9	105.4	5.0
Other[(1)]	30.2	1.7	38.3	1.8
Total	¥ 1,770.5	100.0%	¥ 2,097.2	100.0%

Note:
(1) Other region includes Middle East, Oceania and Africa.

We rely on our key prescription drug products to generate a significant portion of our revenue. The following products had the most significant impact on our results of operations.

	For the fiscal year ended March 31,			
	2018	2019	Change versus the previous year	
	(billions of yen, except for percentages)			
GI:				
ENTYVIO	¥ 201.4	¥ 269.2	¥ 67.8	33.7%
DEXILANT	65.7	69.2	3.5	5.3
PANTOPROZOLE	65.8	61.6	(4.2)	(6.4)
TAKECAB	48.5	58.2	9.8	20.1
AMITIZA	33.8	33.0	(0.9)	(2.5)
Oncology:				
VELCADE	137.3	127.9	(9.4)	(6.9)
LEUPRORELIN	108.1	110.1	2.0	1.9
NINLARO	46.4	62.2	15.7	33.9
ADCETRIS	38.5	42.9	4.4	11.4
ICLUSIG	23.1	28.7	5.6	24.1
ALUNBRIG	2.8	5.2	2.4	84.0
Neuroscience:				
TRINTRELLIX	48.4	57.6	9.2	19.0
Others:				
AZILVA	64.0	70.8	6.8	10.6
ALOGLIPTIN	50.2	54.8	4.6	9.1
ULORIC	46.8	51.1	4.3	9.1
COLCRYS	40.3	30.0	(10.3)	(25.4)
Products acquired from Shire:				
IMMUNOGLOBULIN	—	62.2	62.2	N/A
VYVANSE	—	49.4	49.4	N/A
ADVATE	—	32.1	32.1	N/A
ALBUMIN	—	15.8	15.8	N/A
GATTEX/REVESTIVE	—	12.8	12.8	N/A
ADYNOVATE	—	10.7	10.7	N/A
TAKHZYRO	—	9.7	9.7	N/A
NATPARA	—	7.1	7.1	N/A

Change in revenue was primarily attributable to the following products:

- *GI.* In GI, revenue was driven by Takeda's top-selling product *ENTYVIO* (for ulcerative colitis and Crohn's disease) with sales of ¥269.2 billion in the fiscal year ended March 31, 2019, an increase of ¥67.8 billion, or 33.7%. This increase was mainly attributable to *ENTYVIO*'s steady expansion of patient share in the bio-naïve segment. Takeda obtained an NDA approval in July 2018 in Japan for the treatment of patients with moderately to severely active ulcerative colitis and launched the product in November 2018. Sales of *TAKECAB* (for acid-related diseases) were ¥58.2 billion in the fiscal year ended March 31, 2019, an increase of ¥9.8 billion, or 20.1%, versus the previous year. The increase was driven by the expansion of new prescriptions in the Japanese market due to *TAKECAB*'s efficacy in reflux esophagitis and the prevention of recurrence of gastric ulcers during low-dose aspirin administration.
- *Oncology*. In oncology, sales of *NINLARO* (for multiple myeloma) were ¥62.2 billion, an increase of ¥15.7 billion, or 33.9%, versus the previous year. Strong performance in several regions, particularly in the United States continued to contribute to the growth. *NINLARO* is a once-weekly oral proteasome inhibitor with a profile of efficacy, safety, and convenience. Additionally, sales of *ADCETRIS* (for malignant lymphomas) increased by ¥4.4 billion, or 11.4%, reflecting strong performance particularly in Japan and Brazil. Sales of *ICLUSIG* (for leukemia) and *ALUNBRIG* (for lung cancer), obtained through the acquisition of ARIAD in February 2017, grew by ¥5.6 billion, or 24.1% and ¥2.4 billion, or 84.0%, respectively. Sales of *VELCADE* (for multiple myeloma), which lost market exclusivity in the United States in previous year, decreased by ¥9.4 billion, or 6.9%.

- *Neuroscience*. In neuroscience, sales of *TRINTELLIX* (for major depressive disorder) were ¥57.6 billion in the fiscal year ended March 31, 2019, an increase of ¥9.2 billion, or 19.0%, versus the previous year. Prescribers and patients increasingly made *TRINTELLIX* part of their comprehensive approach to treat major depressive disorder.

The decrease in revenue resulting from divestitures was primarily due to the sale of seven long-listed products in Japan to Teva Takeda Yakuhin Ltd. in May 2017, the disposition of Guangdong Techpool Bio-Pharma Co., Ltd. in May 2018, and the termination Takeda's co-promotion and distribution of *XELJANZ* in Japan in March 2018.

Shire contributed ¥309.2 billion to our revenue from the date of acquisition. As part of the integration, Takeda's distribution channel policies were applied to the products acquired from Shire. This resulted in a one-time destocking at wholesalers as they lowered their days-on-hand of inventory of commercial products, which resulted in lower revenue for products acquired from Shire. The sales were primarily from the following products:

- *GI.* In GI, revenue was ¥21.5 billion primarily from the sales of *GATTEX*/*REVESTIVE* (for the treatment of short bowel syndrome) that were ¥12.8 billion.
- *Rare diseases.* In rare diseases, revenue was ¥111.2 billion including sales of *ADVATE* and *ADYNOVATE* (both for the treatment of hemophilia A), *TAKHZYRO* (for the preventive treatment of hereditary angioedema), and *NATPARA* (for the treatment of hypoparathyroidism) of ¥32.1 billion, ¥10.7 billion, ¥9.7 billion, and ¥7.1 billion, respectively.
- *Plasma derived therapies.* In plasma derived therapies, revenue was ¥96.3 billion including sales of *IMMUNOGLOBULIN* (mainly for the treatment of primary immunodeficiency and multifocal motor neuropathy) and *ALBUMIN* (primarily used for the hypovolemia and hypoalbuminemia) of ¥62.2 billion and ¥15.8 billion, respectively.
- *Neuroscience*. In Neuroscience, revenue was ¥60.1 billion including sales of *VYVANSE* (for the treatment of ADHD and moderate to severe binge eating disorder) of ¥49.4 billion.

Cost of sales. Cost of sales increased ¥163.8 billion, or 33.0%, to ¥659.7 billion for the fiscal year ended March 31, 2019. This includes ¥101.6 billion related to sales of products acquired as part of the Shire Acquisition and the impact of ¥81.7 billion mainly due to non-cash charge from the unwinding of the fair value step up on the inventory from the Shire Acquisition. This increase was offset by a decrease in remaining cost of sales of ¥19.6 billion, or 3.9%, primarily due to a more favorable product mix.

Selling, general and administrative ("SG&A") expenses. SG&A expenses increased ¥89.5 billion, or 14.2%, to ¥717.6 billion for the fiscal year ended March 31, 2019, primarily due to acquisition of Shire's operations in our results of ¥98.5 billion and related acquisition costs of ¥23.8 billion. This increase was partially offset by a decrease of remaining SG&A expenses of ¥33.4 billion due to a favorable impact of our global operating expense reduction initiative as well as lower long-term share-based incentive payments to management.

Research and development expenses. Research and development expenses increased ¥42.9 billion, or 13.2%, to ¥368.3 billion, primarily resulting from the acquisition of Shire. The remainder of our research and development expenses remained steady compared to the previous year.

Amortization and impairment losses on intangible assets associated with products. Amortization and impairment losses on intangible assets associated with products increased by ¥81.2 billion, or 66.5%, to ¥203.4 billion for the fiscal year ended March 31, 2019. This represents an increase of ¥99.2 billion related to amortization of intangible assets recorded in the Shire Acquisition and a ¥22.6 billion reversal of the *COLCRYS* impairment recorded in the previous year. This increase was offset by lower amortization expense of ¥36.7 billion, which related to the *VELCADE* intangible asset being fully amortized within the previous year.

Other operating income. Other operating income decreased ¥9.5 billion, or 5.6%, to ¥159.9 billion for the fiscal year ended March 31, 2019. The decrease was primarily due to the net impact of ¥106.3 billion gain on the sale of Wako Pure Chemical Industries, Ltd. recorded in the previous year, whereas we recorded a ¥50.3 billion gain on sale of property, plant and equipment and investment property including Takeda's old headquarter building in Tokyo as well as a ¥38.2 billion gain on sale of shares of the subsidiary, to which respective real estate businesses were transferred in the current year.

Other operating expenses. Other operating expenses decreased ¥23.4 billion, or 18.5%, to ¥103.2 billion for the fiscal year ended March 31, 2019 which was a decrease of ¥88.0 billion partially offset by ¥59.6 billion of Shire integration costs. The decrease was primarily due to a decrease of ¥22.8 billion in restructuring expense and other costs incurred in the prior year that did not reoccur in the current fiscal year such as a ¥41.5 billion loss on the liquidation of a foreign subsidiary.

Net financial income / (expense). Net financial expense was a ¥66.4 billion in the current year, an increase of ¥74.1 billion compared to the previous year, which includes ¥41.3 billion mainly related to interest on borrowings used to partially fund the Shire Acquisition. The remaining increase is primarily due to a gain on an investment of ¥30.4 billion that was included in financial income in the prior year and is no longer be included in financial income upon adoption of a new accounting standard.

Shares of loss of associates accounted for using the equity method. Shares of loss of associates accounted for using the equity method were ¥43.6 billion, an increase of ¥11.4 billion from the previous year. This primarily relates to Takeda's share of an impairment charge recognized by Teva Takeda Pharma Ltd. Teva Takeda Pharma Ltd. operates a business of long-listed products and generics and conducted a revaluation of its assets in response to changes in the business environment.

Income tax expenses. Income tax expenses decreased ¥44.6 billion, or 146.3% from ¥30.5 billion for the fiscal year ended March 31, 2018 to tax benefit of ¥14.1 billion for the fiscal year ended March 31, 2019. This decrease was mainly due to tax benefit of ¥58.7 billion resulting from the Shire Acquisition. Excluding the Shire Acquisition impact, the remaining income tax expenses increased ¥14.1 billion mainly due to an increase in profit before tax, as well as the impact from the enactment of the Tax Cuts and Jobs Act (Tax Reform) in the U.S. in the previous year. These factors were partially offset by capital loss related to restructuring of subsidiaries in the current year.

Fiscal Year Ended March 31, 2018 compared with the Fiscal Year Ended March 31, 2017

Revenue. Revenue increased ¥38.5 billion, or 2.2%, from ¥1,732.1 billion for the fiscal year ended March 31, 2017 to ¥1,770.5 billion for the fiscal year ended March 31, 2018. During the fiscal year ended March 31, 2018, our revenue decreased by ¥94.3 billion as a result of divestitures, which primarily consisted of ¥79.1 billion attributable to the divestiture of Wako Pure Chemical in April 2017 and ¥11.1 billion attributable to the termination of the commercialization agreement for *CONTRAVE* in the U.S. in August 2016. Excluding the impact of divestitures, our revenues increased by ¥132.8 billion primarily due to growth in our core therapeutic areas of GI, oncology and neuroscience, which includes the favorable impact of the strengthening of the U.S. dollar and Euro against the yen as compared to the prior year.

The following shows revenue by geographic region:

	For the fiscal year ended March 31,			
	2017		2018	
	(billions of yen, except for percentages)			
Revenue:				
Japan	¥ 655.3	37.8%	¥ 580.3	32.8%
United States	520.2	30.0	598.3	33.8
Europe and Canada	279.7	16.1	313.7	17.7
Russia/CIS	57.5	3.3	68.2	3.9
Latin America	72.5	4.2	75.7	4.3
Asia (excluding Japan)	112.8	6.5	104.0	5.9
Other[(1)]	34	2.0	30.2	1.7
Total	¥ 1,732.1	100.0%	¥ 1,770.5	100.0%

Note:
(1) Other region includes Middle East, Oceania and Africa.

The following table shows revenue, including royalty income and service income, for our key prescription drug products by geographic region:

	For the fiscal year ended March 31,			
	2017	2018	Change versus previous year	
	(billions of yen, except for percentages)			
ENTYVIO				
United States	¥ 99.6	¥ 133.6	¥ 34.0	34.1%
Europe and Canada	39.5	60.2	20.7	52.4
Emerging Markets	4.0	7.5	3.5	87.5
Total	¥ 143.2	¥ 201.4	¥ 58.2	40.6 %
NINLARO				
Japan	¥ —	¥ 2.5	¥ 2.5	N/A
United States	29.1	39.4	10.3	35.4 %
Europe and Canada	0.2	4.0	3.8	1,900.0
Emerging Markets	0.1	0.6	0.5	500.0
Total	¥ 29.4	¥ 46.4	¥ 17.0	57.8 %
VELCADE				
United States	¥ 112.9	¥ 113.7	¥ 0.8	0.7 %
Other than United States	24.7	23.6	(1.1)	(4.5)
Total	¥ 137.6	¥ 137.3	¥ (0.3)	(0.2)%
ADCETRIS				
Japan	¥ 3.3	¥ 3.8	¥ 0.5	15.2 %

	For the fiscal year ended March 31,			
	2017	2018	Change versus previous year	
	(billions of yen, except for percentages)			
Europe	17.5	20.1	2.6	14.9
Emerging Markets	9.3	14.3	5.0	53.8
Total	¥ 30.1	¥ 38.5	¥ 8.4	27.9 %
TAKECAB				
Japan[1]	¥ 34.1	¥ 48.5	N/A	N/A
Total	¥ 34.1	¥ 48.5	N/A	N/A
TRINTELLIX[2]				
United States	¥ 31.9	¥ 48.4	¥ 16.5	51.7 %
Total	¥ 31.9	¥ 48.4	¥ 16.5	51.7 %
LEUPRORELIN				
Japan (product name: *LEUPLIN*)[1]	¥ 48.6	¥ 41.2	N/A	N/A
United States	18.3	19.7	1.4	7.7 %
Europe and Canada	31.1	34.5	3.4	10.9
Emerging Markets	16.3	12.7	(3.6)	(22.1)
Total	¥ 114.2	¥ 108.1	N/A	N/A
DEXILANT				
United States	¥ 49.7	¥ 49.5	¥ (0.2)	(0.4)%
Europe and Canada	5.7	6.4	0.7	12.3
Emerging Markets	7.3	9.9	2.6	35.6
Total	¥ 62.6	¥ 65.7	¥ 3.1	5.0 %
AZILVA				
Japan[1]	¥66.9	¥64.0	N/A	N/A
Total	¥ 66.9	¥ 64.0	N/A	N/A
ALOGLIPTIN				
Japan (product name: *NESINA*)[1]	¥ 32.9	¥ 26.6	N/A	N/A
United States	5.2	6.0	0.8	15.4 %
Europe and Canada	6.1	9.0	2.9	47.5
Emerging Markets	4.9	8.6	3.7	75.5
Total	¥ 49.1	¥ 50.2	N/A	N/A
ULORIC				
United States	¥ 41.4	¥ 45.8	¥ 4.4	10.6 %
Europe and Canada	0.7	0.8	0.1	14.3
Emerging Markets	0.1	0.3	0.2	200.0
Total	¥ 42.2	¥ 46.8	¥ 4.6	10.9 %
COLCRYS				
United States	¥38.9	¥40.3	¥1.4	3.6 %
Total	¥ 38.9	¥ 40.3	¥ 1.4	3.6 %
AMITIZA				
United States	¥ 33.7	¥ 33.7	¥ —	0.0 %
Europe and Canada	0.1	0.1	—	—
Total	¥ 33.8	¥ 33.8	¥ —	0.0 %
PANTOPRAZOLE				
United States	¥ 10.1	¥ 7.2	¥ (2.9)	(28.7)%
Europe and Canada	30.5	30.6	0.1	0.3
Emerging Markets	33.7	28.0	(5.7)	(16.9)
Total	¥ 74.2	¥ 65.8	¥ (8.4)	(11.3)%
LANSOPRAZOLE				
Japan[1][3]	¥ 8.1	¥ 4.6	N/A	N/A

	For the fiscal year ended March 31,					
	2017		2018		Change versus previous year	
	(billions of yen, except for percentages)					
United States		20.0		15.2	(4.8)	(24.0)%
Europe and Canada		7.1		7.2	0.1	1.4
Emerging Markets		9.2		9.7	0.5	5.4
Total	¥	44.4	¥	36.8	N/A	N/A
CANDESARTAN						
Japan[(1)]	¥	14.8	¥	2.6	N/A	N/A
United States		0.6		0.7	0.1	16.7 %
Europe and Canada		9.3		9.5	0.2	2.2
Emerging Markets		9.5		9.2	(0.3)	(3.2)
Total	¥	34.2	¥	22.0	N/A	N/A

Notes:

(1) Beginning from the fiscal year ended March 31, 2019, sales of certain products in Japan are disclosed on a net basis, deducting items such as discounts and rebates, in alignment with the global managerial approach applied to individual product sales for the fiscal year ended March 31, 2018. Sales of individual products have been revised retroactively on a net basis to enable year-on-year comparisons. This reclassification has no impact on Takeda's financial statements and does not represent a correction of figures from the prior fiscal periods. Figures for the fiscal year ended March 31, 2017 have not been reclassified retroactively.

(2) *TRINTELLIX* is the brand name used since June 2016 for the product previously marketed as *BRINTELLIX* in the United States. The formulations, indication and dosages of *TRINTELLIX* remain the same as that of *BRINTELLIX*.

(3) Products excluding fixed dose combinations were transferred to Teva Takeda Yakuhin Ltd., a wholly-owned subsidiary of Teva Takeda Pharma Ltd., a joint venture in Japan we formed with Teva Pharmaceutical Industries Ltd., in April 2016. Fixed dose combinations were sold to Teva Takeda Yakuhin Ltd. in May 2017. Amounts presented above represent supply sales to Teva Takeda Yakuhin Ltd., following such transfers.

Change in revenue in our three key therapeutic areas of GI, oncology and neuroscience was primarily attributable to the following products:

- *GI*. In the therapeutic area of GI, revenue grew 23.5% compared to the previous fiscal year. Revenue attributable to *ENTYVIO* was ¥201.4 billion in the fiscal year ended March 31, 2018, an increase of ¥58.2 billion, or 40.6%, compared to the previous fiscal year as a result of increase in sales volume, making *ENTYVIO* our top-selling product. Revenue attributable to *TAKECAB* was ¥48.5 billion (or ¥55.1 billion on a gross basis) in the fiscal year ended March 31, 2018, compared to ¥34.1 billion on a gross basis in the previous fiscal year, with prescriptions in Japan as a result of a higher overall volume due to *TAKECAB*'s efficacy in reflux esophagitis and the prevention of recurrence of gastric ulcers during low-dose aspirin administration.
- *Oncology.* In the therapeutic area of oncology, revenue grew 14.6% compared to the previous fiscal year. Revenue attributable to *NINLARO* was ¥46.4 billion, an increase of ¥17.1 billion, or 58.1% compared to the previous fiscal year, reflecting market penetration across several regions, particularly in the United States. Revenue attributable to *ICLUSIG*, which was obtained through the acquisition of ARIAD in February 2017, was ¥23.1 billion, its first full-year contribution to our revenue growth in this key therapeutic area. *ALUNBRIG*, also obtained through the acquisition of ARIAD, was launched in the United States in May 2017, and revenue attributable to it in the fiscal year ended March 31, 2018 was ¥2.8 billion. Revenue attributable to *VELCADE* decreased slightly to ¥137.3 billion in the fiscal year ended March 31, 2018 from ¥137.6 billion in the previous fiscal year.
- *Neuroscience*. In the therapeutic area of neuroscience, revenue grew 24.5% compared to the previous fiscal year. Revenue attributable to *TRINTELLIX* was ¥48.4 billion, an increase of ¥16.5 billion, or 51.6%, versus the previous year, reflecting higher volumes as a result of expansion of market share in the U.S. branded antidepressant market, driven by our patient engagement initiatives.

Cost of sales. Cost of sales decreased ¥62.8 billion, or 11.2%, from ¥558.8 billion for the fiscal year ended March 31, 2017 to ¥495.9 billion for the fiscal year ended March 31, 2018. Cost of sales as a percentage of revenue decreased from 32.3% in the fiscal year ended March 31, 2017 to 28.0% in the fiscal year ended March 31, 2018. The decreases in cost of sales, both overall and relative to revenues, was primarily due to the disposition of Wako Pure Chemical in April 2017, which generally had lower-margin products, as well as the effect of other changes to our product mix due to the faster growth of higher margin products, such as *ENTYVIO* and *NINLARO*, relative to other products.

Selling, general and administrative expenses. Selling, general and administrative expenses increased ¥9.0 billion, or 1.5%, from ¥619.1 billion for the fiscal year ended March 31, 2017 to ¥628.1 billion for the fiscal year ended March 31, 2018, mainly due to increased long-term incentive payments to management, higher co-promotion expenses related to increased sales of *TAKECAB* in Japan and higher compensation costs, which contributed ¥2.6 billion, ¥4.8 billion and ¥3.8 billion, respectively. However, selling, general and administrative expenses increased at a lower rate than revenue, reflecting our overall cost reduction efforts.

Research and development expenses. Research and development expenses increased ¥13.1 billion, or 4.2%, from ¥312.3 billion for the fiscal year ended March 31, 2017 to ¥325.4 billion for the fiscal year ended March 31, 2018, mainly due to our pursuit of increased research and development projects and the effect of a weaker Japanese yen.

Amortization and impairment losses on intangible assets associated with products. Amortization and impairment losses on intangible assets associated with products decreased ¥34.6 billion, or 22.1%, from ¥156.7 billion for the fiscal year ended March 31, 2017 to ¥122.1 billion for the fiscal year ended March 31, 2018. This was primarily driven by a decrease of impairment losses on intangible assets of ¥48.2 billion, including a ¥22.6 billion reversal of the previous impairment related to *COLCRYS*, reflecting updated estimates about the amount of impairment due to better-than-expected sales performance. This was offset in part by increased amortization of intangible assets of ¥13.6 billion, resulting from the inclusion of amortization of intangible assets acquired in the ARIAD acquisition.

Other operating income. Other operating income increased by ¥25.9 billion, or 18.0%, from ¥143.5 billion for the fiscal year ended March 31, 2017 to ¥169.4 billion for the fiscal year ended March 31, 2018, driven mainly by ¥106.3 billion representing a gain on the sale of Wako Pure Chemical in April 2017, ¥27.5 billion representing a gain on divestments to Teva Takeda Yakuhin Ltd. and ¥18.8 billion representing a gain on sales of property, plant and equipment and investment property. Other operating income in the previous fiscal year was primarily driven by a ¥115.4 billion gain on divestments to Teva Takeda Yakuhin Ltd and a ¥12.0 billion gain from the reversal of contingent consideration liability reflecting decreased expected sales of *COLCRYS*.

Other operating expenses. Other operating expenses increased ¥53.7 billion, or 73.6%, to ¥126.6 billion for the fiscal year ended March 31, 2018, as compared to ¥72.9 billion for the fiscal year ended March 31, 2017. This was driven by a loss on liquidation of a foreign subsidiary of ¥41.5 billion primarily reflecting the recognition of cumulative translation losses and an increase in fair value of contingent consideration of ¥10.5 billion driven by an increase in projected sales primarily for *COLCRYS*.

Income tax (expenses). Income tax expenses increased ¥2.7 billion, or 9.6%, from ¥27.8 billion for the fiscal year ended March 31, 2017 to ¥30.5 billion for the fiscal year ended March 31, 2018. This increase was mainly due to the tax impact of ¥22.8 billion resulting from the increase in profit before tax compared to the previous fiscal year, as well as the effect of additional tax benefits recognized for the year ended March 31, 2017, resulting from reduction of share capital of a subsidiary, which was responsible for an increase of ¥8.9 billion. These increases were offset in part by the positive impact of the enactment of U.S. tax reforms, principally related to the revaluation of net deferred tax liability at a lower enacted tax rate and improved recoverability of deferred tax assets, which resulted in a decrease of ¥27.5 billion.

B. Liquidity and Capital Resources.

Sources and Uses of Liquidity

Our liquidity requirements mainly relate to operating cash, capital expenditures, contractual obligations, repayment of indebtedness and payment of interest and dividends. Our operating cash requirements include cash outlays for research and development expenses, milestone payments, sales and marketing expenses, personnel and other general and administrative costs and raw material costs. Income tax payments also require significant cash outlays as well as working capital financing.

Our capital expenditures for tangible assets consist primarily of enhancing and streamlining our production facilities, replacing fully depreciated items, and promoting efficiency of our operations. Our capital expenditures for intangible assets represent mainly milestone payments related to licensed products, where such assets have been acquired from third-party partners, as well as software development expenditures. Our capital expenditures, which consist of additions to property, plant and equipment and intangible assets recorded on our consolidated balance sheets, were ¥148.1 billion, ¥124.1 billion and ¥244.6 billion for the fiscal years ended March 31, 2017, 2018, and 2019, respectively. As of March 31, 2019, we had contractual commitments for the acquisition of property, plant and equipment of ¥34.0 billion.

Our dividend payments for the fiscal years ended March 31, 2017, 2018 and 2019 were ¥141.7 billion, ¥141.9 billion and ¥143.0 billion, respectively. It is our intention to continue to return capital to shareholders using dividends at an annual level of ¥180 per share, consisting of interim and fiscal year-end dividends of ¥90 per share. See "Item 8. Financial Information-A. Consolidated Statements and Other Financial Information-Dividends" for a description of our dividend policy.

We are required to make interest and principal payments on our outstanding borrowings. As of March 31, 2019, we have ¥122.7 billion of interest due within one year and ¥988.1 billion of principal payments on our borrowings due within one year. See "-Borrowings and Financial Obligations."

Our sources of liquidity include cash and cash equivalents on hand, short-term commercial paper, committed borrowing lines from financial institutions and long-term debt financing from global capital markets. We monitor and adjust the amount of foreign cash based on projected cash flow requirements. As the majority of our business is conducted outside Japan, we hold a significant portion of cash outside of Japan. Our ability to use foreign cash to fund cash flow requirements in Japan may be impacted by local regulations and, to a lesser extent, income taxes associated with transferring cash to Japan.

As of March 31, 2019, we held ¥702.1 billion in cash and cash equivalents on hand and ¥300.0 billion in undrawn commitment line. We believe that working capital is sufficient for our current business requirements. Furthermore, we continually seek to ensure that our level of liquidity and access to capital market funding continues to be maintained to successfully support our business operations.

Consolidated Cash Flows

The following table shows information about our consolidated cash flows during the fiscal years ended March 31, 2017, 2018 and 2019:

	For the fiscal year ended March 31,		
	2017	2018	2019
		(billions of yen)	
Net cash from operating activities	¥ 261.4	¥ 377.9	¥ 328.5
Net cash used in investing activities	(655.7)	(93.3)	(2,835.7)
Net cash from (used in) financing activities	289.9	(326.2)	2,946.2
Net increase (decrease) in cash and cash equivalents	¥ (104.4)	¥ (41.7)	¥ 439.0
Cash and cash equivalents at the beginning of the year	451.4	319.5	294.5
Effects of exchange rate changes on cash and cash equivalents	(5.7)	(4.6)	(31.3)
Net increase (decrease) in cash and cash equivalents resulting from a transfer to assets held for sale	(21.8)	21.3	(0.1)
Cash and cash equivalents at the end of the year	¥ 319.5	¥ 294.5	¥ 702.1

Fiscal Year Ended March 31, 2019 compared with the Fiscal Year Ended March 31, 2018

Net cash from operating activities was ¥328.5 billion for the fiscal year ended March 31, 2019 compared to ¥377.9 billion for the fiscal year ended March 31, 2018. The decrease of ¥49.4 billion was driven by a decrease in net profit of ¥77.7 billion and the impacts of certain unfavorable adjustments including the lower income tax expenses of ¥44.6 billion primarily attributable to non-cash tax benefit on the impact of purchase accounting of the Shire acquisition, the loss on liquidation of foreign operations of ¥41.5 billion recorded in the previous fiscal year, as well as the effect of changes in assets and liabilities such as higher employee bonus payments in the fiscal year ended March 31, 2019.

These were partially offset by certain favorable non-cash adjustments such as the increase in depreciation and amortization of ¥90.3 billion mainly attributable to intangible assets recorded upon the acquisition of Shire and the decrease in inventories by ¥45.0 billion primarily attributable to unwinding of the fair value step up recorded in relation to the Shire Acquisition. This also includes other favorable adjustments such as the increase in net financial income and expenses by ¥74.1 billion primarily due to the financial expense recorded in connection with the acquisition of Shire.

Net cash used in investing activities was ¥2,835.7 billion for the fiscal year ended March 31, 2019, compared to ¥93.3 billion for the fiscal year ended March 31, 2018. This significant increase was primarily attributable to ¥2,891.9 billion of net consideration paid for the acquisition of Shire. This was offset by ¥50.7 billion proceeds from the sale of real estate primarily attributable to the sale of our former headquarters building in the current fiscal year.

Net cash used in financing activities was ¥2,946.2 billion for the fiscal year ended March 31, 2019, compared to net cash used in financing activities of ¥326.2 billion for the fiscal year ended March 31, 2018. The current fiscal year mainly includes an increase of short-term loans of ¥367.3 billion and ¥2,795.9 billion proceeds from bonds and long-term loans of mainly for the acquisition of Shire.

Fiscal Year Ended March 31, 2018 compared with the Fiscal Year Ended March 31, 2017

Net cash from operating activities increased by ¥116.5 billion from ¥261.4 billion in the fiscal year ended March 31, 2017 to ¥377.9 billion in the fiscal year ended March 31, 2018, primarily due to the impact of a higher net profit of ¥71.2 billion and the effect of certain favorable non-cash expenses and other adjustments, including a gain on divestment of a business of ¥87.9 billion, a loss on liquidation of foreign operations of ¥41.5 billion as well as a ¥30.7 billion loss relating to the share of loss of associates. Additional sources of operating cash flow were a ¥9.8 billion decrease in inventories as a result of management effort to reduce inventory levels during the fiscal year ended March 31, 2018. These sources of cash were partially offset by a higher impairment loss of ¥37.8 billion in fiscal year ended March 31, 2017 and a gain on sale of a business of ¥106.6 billion during the fiscal year ended March 31, 2018.

Net cash used in investing activities was ¥93.3 billion for the fiscal year ended March 31, 2018, compared to ¥655.7 billion for the fiscal year ended March 31, 2017. This decrease was primarily attributable to ¥583.1 billion of net consideration paid for the acquisition of ARIAD in the fiscal year ended March 31, 2017. The decrease also reflects the effect of a payment of ¥71.8 billion into a restricted cash account in the fiscal year ended March 31, 2018 in preparation for the acquisition of TiGenix NV. This was offset by ¥84.5 billion proceeds from the divestment of Wako Pure Chemical in the same fiscal year.

Net cash used in financing activities was ¥326.2 billion for the fiscal year ended March 31, 2018, compared to net cash from financing activities of ¥289.9 billion for the fiscal year ended March 31, 2017. This was primarily the result of repayments of ¥403.9 billion of short-term bridge loans, ¥337.2 billion of proceeds from long-term loans related mainly to the refinancing of the bridge loan for the ARIAD acquisition, and repayments of other long-term loans of ¥80.0 billion in the fiscal year ended March 31, 2018, compared to ¥407.0 billion of proceeds primarily from such short-term bridge loans in the previous fiscal year.

Borrowings and Financial Obligations

Our total bonds and loans are ¥985.7 billion and ¥5,751.0 billion as of March 31, 2018 and 2019, respectively. These borrowings include unsecured bonds and senior notes issued by Takeda in prior years, syndicated loans entered into by Takeda in prior years, borrowings obtained to fund a portion of the Shire acquisition, and debt assumed in connection with the Shire acquisition and included in our consolidated statement of financial position. Our borrowings are mainly linked to acquisitions and therefore are not exposed to seasonality.

The increase in bonds and loans relates to financing obtained to fund a portion of the Shire Acquisition and the debt assumed from Shire. In connection with the Shire Acquisition, we entered into various borrowing arrangements as described in further detail below, including bridge financing that was subsequently repaid. The borrowings entered into during the fiscal year ended March 31, 2019 that remain outstanding at the end of the fiscal year are as follows:

- Term Loan Credit Agreement with a total aggregate principal amount of $7.5 billion denominated in U.S. dollar and Euro was entered into on June 8, 2018 and fully drawn in early January 2019. The proceeds drawn were used to fund a portion of the cash consideration payable in connection with the Shire Acquisition. The borrowings under the Term Loan Credit Agreement are unsecured and accrue interest based on floating rates, and will mature on January 3, 2024.
- Euro denominated senior notes with a total aggregate principal amount of €7.5 billion were issued in November 2018 together with U.S. dollar denominated senior notes with a total aggregate principal amount of $5.5 billion (collectively, the "2018 Notes"). The 2018 Notes were issued in the following series:
    - €1,250.0 million aggregate principal amount of 0.375% Senior Notes due November 21, 2020, €1,000.0 million aggregate principal amount of the Senior Floating Rate Notes due November 21, 2020, €1,500.0 million aggregate principal amount of 1.125% Senior Notes due November 21, 2022, €750.0 million aggregate principal amount of the Senior Floating Rate Notes due November 21, 2022, €1,500.0 million aggregate principal amount of 2.250% Senior Notes due November 21, 2026, and €1,500.0 million aggregate principal amount of 3.000% Senior Notes due November 21, 2030.
    - $1,000.0 million aggregate principal amount of 3.800% Senior Notes due November 26, 2020, $1,250.0 million aggregate principal amount of 4.000% Senior Notes due November 26, 2021, $1,500.0 million aggregate principal amount of 4.400% Senior Notes due November 26, 2023, and $1,750.0 million aggregate principal amount of 5.000% Senior Notes due November 26, 2028.

  The 2018 Notes were issued in private placements in reliance on exemptions from registration under the U.S. Securities Act of 1933 (the "Securities Act"). Interest on the series of 2018 Notes, which are subject to fixed rates, is payable annually (in the case of the Euro-denominated 2018 Notes) or semi-annually (in the case of the dollar-denominated 2018 Notes) in arrears. Interest on the series of 2018 Notes which are subject to floating rates is determined by reference to three-month EURIBOR plus an applicable spread, reset quarterly, and is payable quarterly in arrears.
- An unsecured JBIC Loan Agreement for an aggregate principal amount $3.7 billion was entered into December 2018. The JBIC Loan was fully drawn down in early January 2019 and will mature on December 11, 2025. The borrowings under the Term Loan Credit Agreement are unsecured and accrue interest based on floating rates.
- A ¥500 billion Senior Short-Term Loan ("SSTL") Facility Agreement entered into in October 2018. The SSTL was fully drawn in early January 2019 and the proceeds were used to fund a portion of the cash consideration payable in connection with the Shire Acquisition. The SSTL has a maturity of up to six months from the date of draw down at our option. In October 2018, we entered into a Subordinated Loan Agreement providing for borrowings up to the same principal amount of the SSTL in order to allow for the refinancing of any borrowings under the SSTL. However, the SSTL was repaid in June 2019 using the proceeds from the offering of our Hybrid Bonds, described below, and no borrowings were made under the Subordinated Loan Agreement. Both the SSTL and Subordinated Loan Agreement were cancelled in June 2019.

In connection with the Shire Acquisition, various borrowing arrangements previously held by Shire as described in further detail below were assumed and are included in our consolidated statement of financial position. Such borrowings that remain outstanding at the end of the fiscal year are as follows:

- USD denominated senior notes (the "SAIIDAC Notes") issued by Shire Acquisitions Investments Ireland Designated Activity Company ("SAIIDAC"), a wholly-owned subsidiary of Shire, and guaranteed by us. The SAIIDAC Notes have a total aggregate principal amount of $12.1 billion as of March 31, 2019. Interest is payable semi-annually in arrears. The following series of SAIIDAC Notes were outstanding as of March 31, 2019: $3,300.0 million aggregate principal amount of 1.900% notes due September 23, 2019, $3,300.0 million aggregate principal amount of 2.400% notes due September 23, 2021, $2,500.0 million aggregate principal amount of 2.875% notes due September 23, 2023 and $3,000.0 million aggregate principal amount of 3.200% notes due 2026.
- USD denominated senior notes (the "Baxalta Notes") issued by Baxalta and guaranteed by us. The Baxalta Notes have a total aggregate principal amount of $1.925 billion as of March 31, 2019. Interest on the Baxalta Notes is payable semi-annually in arrears. The following series of Baxalta Notes were outstanding as of March 31, 2019: $404.5 million aggregate principal amount of 2.875% senior notes due June 23, 2020, $219.4 million aggregate principal amount of 3.600% senior notes due June 23, 2022, $800.5 million aggregate principal amount of 4.000% senior notes due June 23, 2025 and $500.4 million aggregate principal amount of 5.250% senior notes due June 23, 2045.

On June 6, 2019, we issued hybrid bonds (subordinated bonds) (“Hybrid Bonds”) with an aggregate principal amount of ¥500 billion. We used the proceeds from this Hybrid Bond offering to repay the SSTL.

The Hybrid Bonds will mature on June 6, 2079. Under the terms and conditions of the Hybrid Bond, we may make an early repayment of all of the principal of the Hybrid Bonds on each interest payment date beginning October 6, 2024. Interest is payable semi-annually at a rate per annum subject to revision. The Hybrid Bonds are unsecured and we are not subject to any financial covenants.

We currently have a Japanese unsecured commercial paper program in place to facilitate short-term liquidity management. We further have short-term commitment line of ¥300 billion which are undrawn as of March 31, 2019.

We have certain borrowings outstanding as of March 31, 2019, that have restrictive financial covenants. The most restrictive of these covenants is that our profit before tax must not be negative for two consecutive years, which is contained in the JBIC Loan Agreement described above. As of March 31, 2019, we are in compliance with all such covenants. There are no restrictions on the ability to draw from the commitment line.

For further description of our borrowings, see Note 20 to our audited consolidated financial statements included in this annual report.

Credit Ratings

Our credit ratings, which reflect each rating agency’s opinion of our financial strength, operating performance and ability to meet our obligations, as of the date of this annual report are as follows:

Rating agency	Category	Rating	Rating structure
S&P Global Ratings	Issuer credit rating/foreign currency long-term and local currency long-term	BBB+	Fourth highest of 11 rating categories and first within the category based on modifiers (e.g. BBB+, BBB and BBB- are within the same category).
	Issuer credit rating (short-term)	A-2	Second highest of six rating categories
Moody’s	Long-term issuer rating and Long-term senior unsecured rating	Baa2	Fourth highest of nine rating categories and second highest within the category based on modifiers (e.g., Baa1, Baa2 and Baa3 are within the same category).

The ratings are not a recommendation to buy, sell or hold securities. The ratings are subject to revision or withdrawal at any time by the assigning rating agency. Each of the financial strength ratings should be evaluated independently.

C. Research and Development, Patents and Licenses, etc.

The information required by this item is set forth in "Item 4.B Business Overview - Research and Development" of this annual report.

D. Trend Information.

The information required by this item is set forth in "Item 5.A Operating and Financial Review and Prospects - Operating Results" of this annual report.

E. Off-Balance Sheet Arrangements.

Milestone Payments

Under the terms of our collaborations with third parties for the development of new products, we may be required to make payments for the achievement of certain milestones related to the development of pipeline products and the launch and subsequent marketing of new products. As of March 31, 2018, and 2019, the contractual amount of potential milestone payments totaled ¥517.0 billion and ¥655.5 billion, respectively, in each case excluding potential commercial milestone payments for pipeline products under development.

F. Tabular Disclosure of Contractual Obligations.

The following table summarizes our contractual obligations as of March 31, 2019:

	Total contractual amount[1]	Less than one year	One to three years	Three to five years	More than five years
			(billions of yen)		
Bonds and loans: [2] [3]					
Bonds	¥ 3,790.2	¥ 507.2	¥ 1,197.7	¥ 849.0	¥ 1,236.3
Loans	2,780.3	603.6	228.1	978.4	970.2
Purchase obligations for property, plant and equipment	34.0	34.0	—	—	—
Finance lease obligations	333.1	6.9	18.4	19.4	288.5
Operating lease obligations	233.6	31.2	52.7	38.4	111.3
Contributions to defined benefit plans[4]	7.8	7.8	—	—	—
Total[5] [6]	¥ 7,179.0	¥ 1,190.7	¥ 1,496.9	¥ 1,885.2	¥ 2,606.3

Notes:

(1) Obligations denominated in currencies other than yen have been translated into yen using period-end exchange rates for the fiscal year ended March 31, 2019 and may fluctuate due to changes in exchange rates.
(2) Repayment obligations may be accelerated if we breach the relevant covenants under the relevant instruments.
(3) Includes interest payment obligations.
(4) Pension and post-retirement contributions cannot be determined beyond the fiscal year ending March 31, 2020 because the timing of funding is uncertain and dependent on future movements in interest rates and investment returns, changes in laws and regulations and other variables.
(5) Does not include contractual obligations whose timing we are unable to estimate, including defined benefit contribution obligations, litigation reserves and long-term income tax liability and does not include liabilities recorded at fair value as amounts will fluctuate based on any changes in fair value including derivative liabilities and contingent consideration. Milestone payments that are dependent on the occurrence of certain future events are not included.
(6) Does not include purchase orders entered into for purchases made in the normal course of business.

G. Safe Harbor.

Statements in Item 5.E and Item 5.F of this annual report that are not statements of historical fact, constitute "forward-looking statements." See Special Note Regarding Forward-Looking Statements" on page 2 of this annual report. The Company is relying on the safe harbor provided in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act, as amended, in making such forward-looking statements.

Item 6. Directors, Senior Management and Employees

A. Directors and Senior Management.

Directors

The following table provides information about Directors of the Company as of the date of this annual report.

Name (Date of birth)	Responsibilities and status within Takeda	Business experience	End of term
Christophe Weber (November 14, 1966)	Representative Director, President and Chief Executive Officer ("CEO")	Christophe Weber is President and CEO of Takeda. He joined Takeda in April 2014 as Chief Operating Officer and Corporate Officer, was named President and Representative Director in June 2014 and was subsequently appointed Chief Executive Officer in April 2015. Prior to joining Takeda, Mr. Weber held positions of increasing responsibility at GlaxoSmithKline, including President and General Manager at GlaxoSmithKline Vaccines, Chief Executive Officer of GlaxoSmithKline Biologicals SA in Belgium, and member of the GlaxoSmithKline global Corporate Executive Team. From 2008 to 2010, Mr. Weber served as Asia Pacific SVP and Regional Director at GlaxoSmithKline Asia Pacific in Singapore.	Note 1

Name (Date of birth)	Responsibilities and status within Takeda	Business experience	End of term
Costa Saroukos (April 15, 1971)	Director and Chief Financial Officer ("CFO")	Costa Saroukos has been Takeda's Chief Financial Officer since April 2018. He was appointed as Corporate Officer in April 2018 and Director in June 2019. Mr. Saroukos has over 20 years of experience in both the private and public sectors, having held a number of finance leadership positions with financial responsibility for businesses in over 100 countries across Asia-Pacific, Europe, Africa and the Middle East. Mr. Saroukos has been with Takeda since May 2015, as CFO of the Europe and Canada business unit, significantly contributing to the transformation of the business unit towards a specialty healthcare provider. Prior to joining Takeda, Mr. Saroukos was at Allergan as Head of Finance and Business Development for the Asia-Pacific region, including China and Japan. He was also Finance Director for Greater China and Japan. Previously, he spent 13 years at Merck & Co. in roles of increasing responsibility, including Executive Finance Director for EEMEA (Eastern Europe, Middle East and Africa), Finance Director of South Korea and Head of Internal Audit Asia Pacific and Global Joint Ventures.	Note 1
Masato Iwasaki, Ph.D. (November 6, 1958)	Director and President, Japan Pharma Business Unit	Masato Iwasaki is the President of Takeda's Japan Pharma Business Unit. He joined Takeda in 1985 and had an extensive career in roles of increasing responsibility in sales and marketing under the Pharmaceutical Marketing Division. In 2003, Dr. Iwasaki was appointed Manager of Strategic Product Planning and Project Leader for the Cardiovascular and Metabolic franchise. He was appointed Senior Vice President of the Strategic Product Planning department in 2008. In 2010, Dr. Iwasaki was named Corporate Officer. Dr. Iwasaki has been a Director and Member of our board of directors since 2012 and was named President of the Japan Pharma Business Unit in 2015.	Note 1
Andrew S. Plump, M.D., Ph.D. (October 13, 1965)	Director and President, Research and Development	Andrew S. Plump, MD., Ph.D., is the President of Research and Development at Takeda. Dr. Plump joined Takeda as Chief Medical and Scientific Officer ("CMSO") in 2015. In his position, he leads our global research and development organization, where he provides strategic direction and oversight. Prior to joining Takeda, Dr. Plump served as Senior Vice President, Research and Translational Medicine, Deputy to the President of research and development at Sanofi, where he was responsible for global research and translational medicine across all therapeutic areas. Dr. Plump also spent more than 10 years at Merck in a Clinical Pharmacology group, working on programs in neurodegeneration, immunology, metabolism and infectious diseases.	Note 1
Olivier Bohuon (January 3, 1959)	External Director	Olivier Bohuon has been an External Director with Takeda since January 2019. Prior to his appointment, Mr. Bohuon was an External Director of Shire. Mr. Bohuon currently also holds the position of External Director and Vice Chairman at LEO Pharma A/S. Mr. Bohuon has previously served as External Director at Virbac SA, External Director at Smiths Group plc, Chief Executive Officer of Smith & Nephew plc, Chief Executive Officer and President of Pierre Fabre Group SA and as President of Abbott Pharmaceuticals; a division of US-based Abbott Laboratories. He has also held diverse commercial leadership positions at GlaxoSmithKline and its predecessor companies in France.	Note 1

Name (Date of birth)	Responsibilities and status within Takeda	Business experience	End of term
Ian Clark (August 27, 1960)	External Director	Ian Clark has been an External Director with Takeda since January 2019. Prior to his appointment, Mr. Clark was an External Director of Shire plc. He also currently holds External Directorships at Agios Pharmaceuticals, Inc., Corvus Pharmaceuticals, Inc., Guardant Health, Inc., AVROBIO Inc. and Forty Seven Inc. Mr. Clark served as CEO and Director of Genentech Inc. (part of the Roche Group) and Head of North American Commercial Operations for Roche until 2016. From 2003 to 2010 he held the positions of Head of Global Product Strategy and Chief Marketing Officer, Executive Vice President —Commercial Operations and Senior Vice President and General Manager—BioOncology at Genentech.	Note 1
Yoshiaki Fujimori (July 3, 1951)	External Director	Yoshiaki Fujimori has served as External Director of Takeda since June 2016. Mr. Fujimori currently also serves as Advisor of LIXIL Group Corporation. He previously served as External Director of Tokyo Electric Power Company, Incorporated (currently Tokyo Electric Power Company Holdings, Incorporated) and in a number of senior leadership positions within the LIXIL Group, including Representative Director, Chairman and CEO of LIXIL Corporation. Mr. Fujimori has also served in a number of senior positions in the General Electric Group, including Chairman of GE Japan Corporation and Chairman, President and CEO of General Electric Japan Ltd.	Note 1
Steven Gillis, PhD (April 25, 1953)	External Director	Dr. Steven Gillis has been and External Director with Takeda since January 2019. Prior to his appointment, Dr. Gillis was an External Director of Shire plc. He also currently holds the positions of Managing Director at ARCH Venture Partners, External Director of Pulmatrix, Inc., and External Director and Chairman, VBI Vaccines, Inc. Dr. Gillis was a founder and Director of Corixa Corporation, acquired by GlaxoSmithKline in 2005, and before that a founder and Director of Immunex Corporation.	Note 1
Masahiro Sakane (January 7, 1941)	External Director	Masahiro Sakane has served as External Director of Takeda since June 2014 and was appointed Chairman of the Board in June 2017. Mr. Sakane currently also serves as Councilor of Komatsu Ltd., and External Director of Kajima Corporation. Mr. Sakane started his career at Komatsu Ltd. in April 1963. In the Komatsu group, he served in several senior leadership positions including Chairman of the Board and Representative Director and President and Representative Director of Komatsu Ltd. and Chief Operating Officer ("COO") of Komatsu Dresser Company (currently Komatsu America Corp.). Mr. Sakane has also served as External Director of Nomura Holdings, Inc., External Director of Nomura Securities Co., Ltd., External Director of Tokyo Electron Limited, External Director of Asahi Glass Company, Ltd. and Vice Chairman of Keidanren (Japan Business Federation).	Note 1
Toshiyuki Shiga (September 16, 1953)	External Director	Toshiyuki Shiga has served as External Director of Takeda since June 2016. Mr. Shiga currently also serves as Chairman and CEO of INCJ, Ltd. and Director of Nissan Motor Co., Ltd. Mr. Shiga started his career at Nissan Motor Co., Ltd. in April 1976. At Nissan Motor Co., Ltd., he served in a number of leadership positions including Vice Chairman, Chief Operating Officer and Senior Vice President (Officer). He has also served as Chairman of Japanese Automobile Manufacturers Association, Inc.Vice Chairman of KEIZAI DOYUKAI (Japan Association of Corporate Executives) and Chairman and CEO of Innovation Network Corporation of Japan.	Note 1

Name (Date of birth)	Responsibilities and status within Takeda	Business experience	End of term
Jean-Luc Butel (November 8, 1956)	External Director	Jean-Luc Butel served as External Director and member of the Audit and Supervisory Committee of Takeda from June 2016 to June 2019. He was appointed External Director who is not a member of the Audit and Supervisory Committee of Takeda in June 2019. He currently also serves as Global Healthcare Advisor, President of K8 Global Pte. Ltd and External Director of Novo Holdings A/S. Mr. Butel previously served as President, International, Corporate Vice President and Operating Committee Member of Baxter International Inc. and has held leadership positions at Medtronic, Inc., Johnson & Johnson, Becton, Dickinson and Company and Nippon Becton Dickinson Company, Ltd.	Note 1
Shiro Kuniya (February 22, 1957)	External Director	Shiro Kuniya served as External Director and Head of the Audit and Supervisory Committee of Takeda from June 2016 to June 2019. He was appointed External Director who is not a member of the Audit and Supervisory Committee of Takeda in June 2019. He currently also serves as Managing Partner of Oh-Ebashi LPC & Partners, External Director of NEXON Co., Ltd., External Director of EBARA CORPORATION and External Director of Sony Financial Holdings Inc. Mr. Kuniya was registered as an attorney-at-law (Osaka Bar Association) and joined Oh-Ebashi Law Offices in April 1982 and was also admitted to practice law in New York State in the United States in May 1987. He has also previously served as our Outside Corporate Auditor as well as Chairman of the Inter-Pacific Bar Association, Outside Corporate Auditor of NIDEC CORPORATION and Outside Corporate Auditor of Sunstar Inc.	Note 1
Yasuhiko Yamanaka (January 18, 1956)	Director (Audit and Supervisory Committee member)	Yasuhiko Yamanaka has served as Director and member of the Audit and Supervisory Committee of Takeda since June 2016. Mr. Yamanaka joined Takeda in April 1979 and has served in a number of leadership positions within the company, including Corporate Auditor, Special Missions, Special Missions assigned by President, Assistant to CEO, Globalization of the Company, Managing Director and Director.	Note 2
Koji Hatsukawa (September 25, 1951)	External Director (Head of Audit and Supervisory Committee)	Koji Hatsukawa has served as External Director and member of the Audit and Supervisory Committee of Takeda since June 2016. He was appointed Head of Audit and Supervisory Committee in June 2019. He currently also serves as Outside Audit and Supervisory Board Member of Fujitsu Limited and Audit and Supervisory Board Member of The Norinchukin Bank. Mr. Hatsukawa started his career at Price Waterhouse accounting office in March 1974. Mr. Hatsukawa has previously served CEO of PricewaterhouseCoopers Aarata and has held leadership positions at ChuoAoyama PricewaterhouseCoopers and Aoyama Audit Corporation. In addition, he has also served as an Audit and Supervisory Board Member of The Norinchukin Bank and Outside Audit and Supervisory Board Member of Accordia Golf co., Ltd.	Note 2
Emiko Higashi (November 6, 1958)	External Director (Audit and Supervisory Committee Member)	Emiko Higashi served as External Director who is not a member of the Audit and Supervisory Committee of Takeda from June 2016 to June 2019. She was appointed External Director who is a member of the Audit and Supervisory Committee of Takeda in June 2019. She currently also serves as Managing Director of Tomon Partners, LLC, External Director of MetLife Insurance K.K., External Director of KLA-Tencor Corporation and External Director of Rambus Inc. Ms. Higashi previously served as External Director of InvenSense Inc., CEO of Gilo Ventures, LLC, Managing Director of Investment Banking, Merrill Lynch & Co. and Director of Wasserstein Perella & Co., Inc.	Note 3

Name (Date of birth)	Responsibilities and status within Takeda	Business experience	End of term
Michel Orsinger (September 15, 1957)	External Director (Audit and Supervisory Committee Member)	Michel Orsinger has served as External Director who is not a member of the Audit and Supervisory Committee of Takeda from June 2016 to June 2019. He was appointed External Director who is a member of the Audit and Supervisory Committee of Takeda in June 2019. He previously served as a Member of Global Management Team of Johnson & Johnson, Worldwide Chairman, Global Orthopedics Group of DePuy Synthes Companies of Johnson & Johnson and President and Chief Executive Officer and Chief Operating Officer of Synthes, Inc. (currently Johnson & Johnson). He has also held several leadership positions at Novartis AG, including Chief Executive Officer and President of OTC Division Worldwide, Consumer Health; President of Global Medical Nutrition, Consumer Health; and Regional President of Europe, Middle East and Africa, Consumer Health.	Note 3

Notes:

(1) The term of office for Directors who are not members of the audit and supervisory committee is from the end of the ordinary general meeting of shareholders for the fiscal year ended March 31, 2019 through the end of the ordinary general meeting of shareholders for the fiscal year ending March 31, 2020.

(2) The term of office for Directors who are also audit and supervisory committee members is two years. The term of office for these Directors who are also audit and supervisory committee members is from the end of the ordinary general meeting of shareholders for the fiscal year ended March 31, 2018 through the end of the ordinary general meeting of shareholders for the fiscal year ending March 31, 2020.

(3) Notwithstanding the Note (2) above, the term of office for Emiko Higashi and Michel Orsinger, Directors who are audit and supervisory committee members, is from the end of the ordinary general meeting of shareholders for the fiscal year ended March 31, 2019 through the end of the ordinary general meeting of shareholders for the fiscal year ending March 31, 2020. Since they were appointed as substitutes for Shiro Kuniya and Jean-Luc Butel, who resigned as Directors who are audit and supervisory committee members at the end of the ordinary general meeting of shareholders for the fiscal year ended March 31, 2018, their term of office will remain until the expiration of Shiro Kuniya and Jean-Luc Butel as Directors who are audit and supervisory committee members, in accordance with the provision of the Articles of Incorporation of Takeda.

Executive Officers

The following table provides information about the Company's Executive Officers who are not also directors as of the date of this annual report.

Name (Date of birth)	Responsibilities and status within Takeda	Business experience
Marcello Agosti (June 2, 1971)	Global Business Development Officer	In January 2019, Marcello Agosti became Global Business Development Officer. Mr. Agosti is responsible for Takeda's Business Development activities, including mergers and acquisitions and corporate development. Mr. Agosti has led the Shire Acquisition and several other acquisitions for Takeda, including ARIAD Pharmaceuticals, transforming Takeda's global oncology portfolio and TiGenix, and strengthening the company's GI leadership position. Mr. Agosti has also led Takeda's Global Commercial organization since 2015, which included the successful launch of Takeda's first global brand, ENTYVIO, now approved in more than 60 countries. He has also held a number of leadership positions in Europe as Country Manager in France and in Italy and as Area Head of Southern and Eastern Europe. Prior to joining Takeda, Mr. Agosti worked in business development at Novartis in the U.K. and Switzerland was also a consultant at McKinsey & Co.

Name (Date of birth)	Responsibilities and status within Takeda	Business experience
Teresa Bitetti (September 21, 1962)	President, Global Oncology Business Unit	In April 2019, Teresa Bitetti joined Takeda as President of the Global Oncology Business Unit. She is responsible for oncology business activities. Prior to joining Takeda, Ms. Bitetti was the Senior Vice President, Head of Worldwide Oncology Commercialization at Bristol-Myers Squibb. In this role, Ms. Bitetti significantly enhanced the long term strategic direction of the immuno-oncology portfolio. In addition, she further enhanced the model of collaboration with the research and development team to ensure the long term success of its marketed and pipeline Oncology products. Some of her key leadership roles included, Senior Vice President and Head of U.S. Oncology where she was responsible for the launch of Opdivo, President and GM of BMS Canada, and Worldwide Head of the BMS Virology business. Prior to joining Bristol-Myers Squibb, Ms. Bitetti held various roles of increasing responsibility at Mobil Oil Corporation where she was part of the Capital Markets Group and was responsible for the investment of Mobil's worldwide pension assets.
Milano Furuta (February 26, 1978)	Corporate Strategy Officer and Chief of Staff	Milano Furuta joined Takeda's corporate strategy and business development team in Japan in 2010 and played a central role in the acquisition of a Switzerland-based pharmaceutical company. After working on its post-merger integration and other corporate projects in Switzerland, Mr. Furuta moved to Mexico where he led the Diabetes Business Unit and launched new products in the areas of cardiovascular and metabolism area. More recently, as Country Manager of Sweden, Mr. Furuta optimized commercial organization and launched new oncology products which drove the growth of the specialty care portfolio. From January 2019, he began his new role as Corporate Strategy Officer and Chief of Staff. Before joining Takeda, Mr. Furuta worked as an equity research analyst at an investment management firm in the U.S. for two years. Previously, he spent six years in banking and private equity investment in Japan, where he was engaged with several types of financial transactions including leveraged buyouts and debt restructuring.
Helen Giza (January 24, 1968)	Chief Integration and Divestiture Management Officer	In January 2019, Helen Giza became Chief Integration and Divestiture Management Officer. Ms. Giza is responsible for overseeing the success of the Shire integration into Takeda, as well as the organization's divestiture activities. Initially named as Takeda's Head of Integration in May 2018, Ms. Giza set up an integration team and built capabilities that are being leveraged post-close to ensure the combination happens at pace, and in a thoughtful, decisive and thorough manner. Previously, Ms. Giza served as Senior Vice President, CFO of the U.S. Business Unit for Takeda Pharmaceuticals, U.S.A, Inc. Ms. Giza has been involved in Takeda's transformation efforts serving as Executive sponsor of U.S. BPR (Business process re-design) implementation and Takeda Business Services initiative and was actively involved in the Global Opex program. Ms. Giza was also the Vice President of Finance and Controller at TAP Pharmaceutical Products Inc., a former joint venture between Takeda and Abbott. Prior to joining TAP, Ms. Giza spent eight years in the automotive supply industry in the U.K., holding a variety of finance leadership positions in large multinational companies. She joined Abbott U.K. in 1999 as plant controller and went on to hold finance roles in Abbott's international division.

Name (Date of birth)	Responsibilities and status within Takeda	Business experience
Gerard Greco, Ph.D. (February 8, 1962)	Global Quality Officer	In September 2014, Dr. Gerard Greco joined Takeda as Global Quality Officer. Dr. Greco has more than 35 years of experience in quality leadership roles in the pharmaceutical industry. At Takeda, Dr. Greco has introduced key transformations by creating a Global Quality Organization that aligns the quality units and establishes consistent quality systems and programs across the network. Prior to joining Takeda, Dr. Greco held positions of increasing responsibility at Johnson & Johnson, Wyeth Pharmaceuticals, Pfizer Inc. and Teva Pharmaceuticals, where he served as Senior Vice President of Global Quality Operations.
Haruhiko Hirate (August 8, 1957)	Corporate Communications and Public Affairs Officer	Haruhiko Hirate became Takeda's Corporate Communications and Public Affairs Officer in October 2014. He previously served as President of North Asia in 2011, and has held Corporate Officer and Senior Vice President positions at Takeda since 2010. Prior to joining Takeda, Mr. Hirate held the position of Representative Senior Managing Director at GlaxoSmithKline in Japan and, before that, Representative Director and President of Banyu Pharmaceuticals, the Japanese subsidiary of Merck & Co. He joined Banyu Pharmaceuticals in 2004 from his role as Senior Vice President at Merck & Co, based in the U.S. He had previously held the position of Representative Director and President at Roche Diagnostics based in Japan and before that, Asia Pacific Regional President of Draeger. Mr. Hirate began his career with Nissei Sangyo, a subsidiary of Hitachi, in 1980. During his career at Hitachi group companies, he worked with former Boehringer Manheim, and a series of overseas projects in the U.S. and Asia between 1980 and 1996. Well respected in the Japanese pharmaceutical industry, Mr. Hirate served as Director at the Federation of Pharmaceutical Manufacturers Associations of Japan and Chairman of the Pharmaceutical Research and Manufacturers of America ("PhRMA") Japan. In 2012, he became a member of the Japan Association of Corporate Executives. In 2014, he became Chairman of the International Affairs Committee at the Japan Pharmaceutical Manufacturers Association.
Julie Kim (June 6, 1970)	President, Plasma-Derived Therapies Business Unit	In January 2019, Julie Kim joined Takeda as President of the Plasma-Derived Therapies Business Unit and serves as a member of the Takeda Executive Team. She is responsible for building a sustainable, high growth business focused on meeting the large and growing global demand for plasma-derived products. Previously at Shire/Baxalta/Baxter, Julie has held a diverse number of senior roles. She led the access function for the entire Shire portfolio outside of the US, ran Global Franchises for Shire Hematology and Baxter Immunology, managed country organizations as North/South Europe Cluster Head for Baxalta Immunology and General Manager for Baxter UK/Ireland, among other roles. Julie started her career as a consultant in the US healthcare space. Julie is a member of the Global Board for the Plasma Protein Therapeutics Association (PPTA, a plasma industry organization). She is also a member of the Board for the Jeffrey Modell World Immunodeficiency Network, part of the Jeffrey Modell Foundation.

Name (Date of birth)	Responsibilities and status within Takeda	Business experience
Mwana Lugogo (January 30, 1970)	Chief Ethics and Compliance Officer	In October 2014, Mwana Lugogo became Takeda's Chief Ethics & Compliance Officer. Having joined Takeda in 2012, she initially established the Compliance function for our Growth & Emerging Markets Business Unit. In 2015, Ms. Lugogo was appointed to lead the newly-created Global Compliance function. In this role, she is the custodian of Takeda's Global Code of Conduct and is responsible for the global ethics & compliance program. She also ensures that ethical and reputational risks related to Takeda's business are identified and addressed. Before joining Takeda, Ms. Lugogo worked as an attorney in private practice in the U.S., U.K. and Central Asia for six years. In 2002, she moved into the corporate world with Interbrew in Belgium. She moved to Switzerland in 2009, when she joined the Legal department at Baxter Healthcare, responsible for Central and Eastern Europe, and Emerging Markets.
Ricardo Marek (May 30, 1970)	President, Growth and Emerging Markets Business Unit	Ricardo Marek is President of Growth and Emerging Markets ("GEM") Business Unit. Mr. Marek has over 25 years of experience in various industries and leadership roles. He has been with Takeda for eight years and over this time he simultaneously held the roles of Area Head for Latin America ("LATAM") since 2014, President for Brazil since 2013. Prior to that, he was CFO of Brazil. He led the realignment and restructuring of the LATAM area, positioning it as one of the top performers across EM BU, and Takeda Brazil as one of the top 10 pharmaceutical companies in the country. He also secured a number of acquisitions as well as launched the Oncology business in the region for Takeda's potentially life-saving and life-transforming medicines. Under his leadership, Takeda was recognized for the first time as a top employer in all seven countries across the LATAM region, and also received several other HR awards, such as Great Place to Work. Before joining Takeda in 2011, he was CFO for Organon International in the U.S., and Managing Director and Vice President Finance for the Akzo Nobel Group in Brazil. He also has experience in other industries such as chemicals and aerospace.
Yoshihiro Nakagawa (July 26, 1960)	Global General Counsel	In October 2014, Yoshihiro Nakagawa was appointed Corporate Officer and Global General Counsel of Takeda. He is responsible for the company's global legal and intellectual property organizations. Mr. Nakagawa joined the company in 1983. At that time, he served in varying roles of responsibility including reviewing, negotiating and drafting intellectual property and technology-related licensing agreements as a member of the Patent & Trademark Department. In 1995, he moved to the Legal Department, then spent more than two years in London as Company Secretary for Takeda Europe Holdings. Prior to his current appointment, Mr. Nakagawa served as Senior Vice President of the Legal Department at Takeda headquarters in Japan.
Giles Platford (April 26, 1978)	President, Europe and Canada Business Unit	Giles Platford is President of Europe and Canada Business Unit for Takeda. A seasoned industry leader with over 15 years of pharmaceutical experience, Giles was formerly President of Emerging Markets for Takeda, where he oversaw the launch of Takeda's innovative pipeline across the region, and led the design and roll-out of Takeda's global access to medicines program. Previously, Giles headed the Middle East, Turkey and Africa region where he strengthened controls and compliance whilst re-engineering the business for growth. He also held various leadership positions including General Manager Brazil, where he transformed Takeda into a top 10 pharma industry player, being externally recognized for the first time as one of the country's top employers and best companies to work for. Before joining Takeda in 2009, Giles spent eight years in Asia Pacific, where he assumed a number of business development, commercial and general Management roles.

Name (Date of birth)	Responsibilities and status within Takeda	Business experience
Ramona Sequeira (November 21, 1965)	President, United States Business Unit	Ramona Sequeira, President, United States Business Unit, is responsible for the company's commercial operations in the U.S. Ms. Sequeira joined Takeda in 2015. Through her work with Takeda and prior to that with Eli Lilly, Ms. Sequeira has over 25 years of experience in the pharmaceutical industry. She has led businesses in Canada, Europe and the U.S. Ms. Sequeira is committed to the industry's role in shaping a positive environment that rewards pharmaceutical innovation and ensures patients have access to innovative medicines that can help them have better health. She is a member of the PhRMA Board of Directors, and was appointed, Chair, State Committee, PhRMA in April 2018. She is also a member of the Board of Directors for Matter, a Chicago-based healthcare technology incubator, and was previously a board member of the Association of the British Pharmaceutical Industry. In addition, Ms. Sequeira is a member of the Board of Trustees for Lake Forest Academy, a college preparatory boarding and day school for grades 9 through 12 located in Lake Forest, Illinois. She is also a member of the Chicago Executive Club's board. Prior to Takeda, Ms. Sequeira received a B.Sc. with honors in molecular genetics and molecular biology from the University of Toronto, and later received an MBA from McMaster University in Canada.
Camilla Soenderby (February 19, 1972)	Chief Patient Value and Product Strategy Officer	In January 2019, Camilla Soenderby joined Takeda as Chief Patient Value and Product Strategy Officer. Having previously joined Shire in March 2018, Camilla led and oversaw Global Product Strategy, which comprised six franchises (rare diseases and specialty conditions) as well as Global Market Access, Global Patient Services and Global Commercial Operations. Prior to joining Shire, Camilla was Region Head for Roche Pharma with profit and loss responsibility for 11 countries in Central, South and Eastern Europe. Prior to that, she worked as General Manager for Abbott (now AbbVie), first in Sweden and later in the United Kingdom. She also held several operational and strategic roles of increasing responsibility at Schering Plough in Asia Pacific, including General Manager for Taiwan. Camilla began her career as a management consultant at McKinsey & Company focusing on the bio-pharmaceutical and medical device industries.
Padma Thiruvengadam (January 18, 1965)	Chief Human Resources Officer	Padma Thiruvengadam is a senior human resources executive with more than 25 years of experience developing and implementing leading-edge people strategies and organizational solutions. She was appointed as Takeda's Chief Human Resources Officer in June 2018 and is responsible for all HR strategies and programs supporting the company's global business. Prior to joining Takeda, she served as Chief People Officer for Lego, with responsibility for Human Resources and global organizational capability building. Previously, Ms. Thiruvengadam was Corporate Vice President ("CVP") and Chief Human Resources Officer with Integra Life Sciences. She joined Pfizer, first as Vice President, Human Resources for Oncology and subsequently led global integration activities for Pfizer Oncology following a major acquisition and later as Vice President, Asia Pacific and Canada for the group's Oncology Business Unit. Earlier in her career she worked as a Senior Vice President and Human Resources Executive at Bank of America.

Name (Date of birth)	Responsibilities and status within Takeda	Business experience
Rajeev Venkayya,M.D. (March 6, 1967)	President, Global Vaccine Business Unit	Dr. Rajeev Venkayya serves as President of the Vaccine Business Unit. He joined Takeda in 2012 to launch the global vaccine business, building upon a longstanding business in Japan. Since then, he has formed a global organization and established a high-impact vaccine pipeline that includes promising late-stage candidates for dengue and norovirus, gained through the acquisitions of LigoCyte and Inviragen Inc. He concurrently serves on the boards of two NGOs: CEPI (Coalition for Epidemic Preparedness Innovations), and IAVI (International AIDS Vaccine Initiative). Prior to Takeda, Dr. Venkayya served as Director of Vaccine Delivery in the Global Health Program at the Bill & Melinda Gates Foundation, where he was responsible for the Foundation's efforts in polio eradication and new vaccine introduction, and a grant portfolio of $500 million/year. While at the foundation, he served on the board of the Global Alliance for Vaccines and Immunization ("GAVI"). Dr. Venkayya was previously the Special Assistant to the President for Biodefense at the White House. In this capacity, he oversaw U. S. preparedness for bioterrorism and biological threats, and was responsible for the development and implementation of the National Strategy for Pandemic Influenza. He first came to Washington though the non-partisan White House Fellowship program in 2002. Dr. Venkayya was trained in pulmonary and critical care medicine and served as an Assistant Professor of Medicine in the Division of Pulmonary and Critical Care Medicine at the University of California, San Francisco. He also served as co-director of the Medical Intensive Care Unit and Director of the High-Risk Asthma Clinic at San Francisco General Hospital.
Thomas Wozniewski, Ph.D. (July 26, 1962)	Global Manufacturing and Supply Officer	In July 2014, Thomas Wozniewski, Ph.D. joined Takeda as Global Manufacturing and Supply Officer. He has more than 20 years of experience in the pharmaceutical industry. Dr. Wozniewski joined Takeda from Bayer Healthcare Switzerland, where he was Head of Product Supply Consumer Care. In this role, he was responsible for the end-to-end supply chain for all Bayer global OTC products. Prior to this, he served as Head of Global Pharmaceuticals Product Supply at Bayer Healthcare AG and Schering AG in Germany. While at Schering AG, he was also Head of Global Quality, Environment and Safety, leading the development and implementation of an Integrated Management System for the company. Dr. Wozniewski also worked at Boehringer Ingelheim, where he held several positions in quality and production.

B. Compensation.

The following table provides information about our executive officers whose compensation was greater than ¥100 million on an individual basis in the fiscal year ended March 31, 2019.

Name (Position)	Total consolidated compensation (millions of yen)	Company	Amount of consolidated compensation by type (millions of yen)			
			Base compensation	Bonus	Long-term incentive[1]	Other
Christophe Weber (Director)	1,758	Takeda	269[2]	638	851[3]	—
Masato Iwasaki (Director)	193	Takeda (Director portion)	16	67	51[5]	—
		Takeda (Employee portion)[4]	27	32	—	—
Andrew S. Plump (Director)	795	Takeda	12	—	—	—
		Takeda Pharmaceuticals International, Inc.[6]	115	378	255[7]	35[8]

Notes:

(1) Compensation expense related to the long-term incentive plan is recognized over multiple fiscal years, depending on the length of the period eligible for earning compensation. This column shows amounts recognized as expenses during the fiscal year ended March 31, 2019.
(2) Base compensation includes the grossed up amount paid for residence and pension allowance for the relevant officer (¥112 million).
(3) The amount recognized as an expense during the fiscal year, representing stock incentive plan (Board Incentive Plan) grants awarded in fiscal years 2015 - 2018.
(4) Shows the salary and other amounts earned as the President, Japan Pharma Business Unit. This employee portion of the bonus amount is not included in the limit outlined in the proposal "Payment of Bonuses to Directors who are not Audit and Supervisory Committee Members" as proposed at the 143th General Meeting of Shareholders held on June 27.
(5) The amount recognized as an expense during the fiscal year, representing stock incentive plan (Board Incentive Plan) grants awarded in fiscal years 2015 - 2018.
(6) Shows the salary and other amounts earned as the President, Research and Development of Takeda Pharmaceuticals International, Inc.
(7) The amount recognized as an expense during the fiscal year, representing stock incentive plan (Employee Stock Ownership Plan) grants awarded in fiscal years 2015 - 2018.
(8) Amounts of local retirement plan contributions and other additional benefits paid by Takeda Pharmaceuticals International, Inc. during the fiscal year ended March 31, 2019, as well as the amount equal to taxes on such amounts.

Share-based Compensation Payments

We maintain certain share-based compensation payment plans for the benefit of our directors and certain of our employees. In the fiscal years ended March 31, 2017, 2018 and 2019, we recorded total compensation expense related to our share-based payment plans of ¥17.4 billion, ¥22.2 billion and ¥18.8 billion, respectively, in our consolidated statements of income. For detailed information about our share-based compensation plans, including our stock option plan, stock incentive plan, phantom stock appreciation rights and restricted stock units, see Note 28 to our audited consolidated financial statements included in this annual report.

C. Board Practices.

See "—A. Directors and Senior Management." for information about the terms of service of the members of our Board of Directors and the committees thereof.

Corporate Governance Structure

Under the Companies Act, joint stock corporations in Japan may adopt a corporate governance structure comprised of a board of directors and an audit and supervisory committee, commonly referred to as the audit and supervisory committee system, in lieu of the traditional structure comprised of a board of directors and a board of corporate auditors or the alternative structure comprised of a board of directors and three statutory committees. The members of the audit and supervisory committee consist of three or more directors. We adopted the audit and supervisory committee system in June 2016, in order to increase transparency and independency of our board of directors, and further enhance our corporate governance, by establishing the systems of audit and supervision conducted by the Audit and Supervisory Committee and increasing the proportion of the number of External Directors and the diversity of our board of directors. This governance structure also enables us to enhance the separation of business execution and supervision by delegating certain decision-making authority to individual members of our board of directors, realizing increased agility in decision-making and helping the board of directors focus more on discussions of business strategies and particularly important business matters.

Board of Directors

Pursuant to the audit and supervisory committee system, our board of directors is comprised of directors who are audit and supervisory committee members and directors who are not. Our articles of incorporation provide for a board of directors consisting of no more than 12 members who are not audit and supervisory committee members and no more than four directors who are audit and supervisory committee members. All directors are elected by our shareholders at a general meeting of shareholders, with directors who are audit and supervisory committee members elected separately from other directors. The term of office for directors who are not audit and supervisory committee members expires at the close of the ordinary general meeting of shareholders held with respect to the last fiscal year ended within one year after their election, and the term of office for directors who are audit and supervisory committee members expires at the close of the ordinary general meeting of shareholders held with respect to the last fiscal year ended within two years after their election. The current terms of our directors are set forth under "Item 6. Directors, Senior Management and Employees —A. Directors and Senior Management." All directors may serve any number of consecutive terms. None of our directors have entered service contracts with us or any of our subsidiaries providing for benefits upon termination of employment.

Our board of directors has the ultimate responsibility for the administration of our affairs. Our board of directors, however, may delegate by its resolution some or all of its decision-making authority in respect of the execution of operational matters (excluding certain matters specified in the Companies Act) to individual directors and has delegated such decision-making authority as described below. Our board of directors elect one or more representative directors from among its members who are not audit and supervisory committee members. Each of the representative directors has the authority to represent us in the conduct of our affairs.

Audit and Supervisory Committee

Our directors who are audit and supervisory committee members are not required to be certified public accountants. They may not serve concurrently as executive directors, managers or any other type of employee for us or for any of our subsidiaries, or as accounting advisors or corporate

executive officers for any of our subsidiaries. In addition, more than half of our directors who are audit and supervisory committee members at any one time must be external directors as defined under the Companies Act, who have not served as executive directors, corporate executive officers, managers or any other type of employee for us or any of our subsidiaries for ten years prior to their election and fulfill certain other requirements specified in the Companies Act.

The audit and supervisory committee has a statutory duty to audit the administration of our affairs by our directors, to examine the financial statements and business reports to be submitted to the shareholders by a representative director, to prepare an audit report each year, to determine details of proposals concerning the appointment and dismissal of independent auditors and the refusal to reappoint independent auditors for submission to general meetings of shareholders and to determine the opinion on election, removal, resignation of or compensation for directors who are not audit and supervisory committee members, which may be expressed at a general meeting of shareholders. An audit and supervisory committee member may note his or her opinion in the audit report issued by the audit and supervisory committee if such an opinion differs from that expressed in the audit report. Additionally, our Audit and Supervisory Committee serves as our "audit committee" for the purposes of Rule 10A-3 under the Exchange Act. We are required to appoint and have appointed an independent auditor, who has a statutory duty of examining the financial statements to be submitted to the shareholders by a Representative Director and preparing its audit report thereon. KPMG AZSA LLC currently acts as our independent auditor.

Takeda Executive Team

As management tasks continue to diversify, we have established a Takeda executive team under the President and Chief Executive Officer, consisting of certain directors and employees in senior positions who manage and supervise our key functions, as well as a business review committee, which is responsible for consideration and determination of general management matters, a portfolio review committee, which is responsible for research and development and products-related matters, and a risk, ethics and compliance committee, which is responsible for internal audit, risk management and compliance matters. Our board of directors has delegated all of its decision-making authority in respect of operational matters (excluding certain matters specified in the Companies Act, as well as substantive matters valued at ¥100 billion or more or those matters which will have substantial impact on us or our stakeholders) to the President and Chief Executive Officer, two directors belonging to the business review committee and one director belonging to the portfolio review committee.

Nomination Committee and Compensation Committee

We also have voluntarily established a nomination committee and a compensation committee as advisory committees of the board of directors. The majority of each committee's members must be "External Members" (either external directors or external experts). Furthermore, at least one director who is an Audit and Supervisory Committee member must be assigned to each committee and each committee must be chaired by an external director. As of the date of this annual report, the nomination committee consists of one external director who serves as chairman, two other external directors and one other director who is not an external director, and the compensation committee consists of one external director who serves as chairman, one other external director and one other director who is not an external director. Together, the committees serve to ensure transparency and objectivity in decision-making relating to personnel matters for directors who are not external directors (including appropriate standards and procedures for appointment and reappointment and establishing and administering appropriate succession plans) and the compensation system (including appropriate levels of compensation for the directors, appropriate performance targets within the bonus system for directors and appropriate bonuses based on business results). Also, by resolution of the Board of Directors, the authority to decide the amount of individual remuneration of Internal Directors who are not Audit and Supervisory Committee members is delegated to the compensation committee, through which we have realized a more transparent process in determining individual remuneration.

Limitation of Liability of Directors

Our articles of incorporation provide that we may enter into agreements with our directors (excluding executive directors as defined under the Companies Act) to limit their respective liabilities to us arising from their failure to execute their duties in good faith and without gross negligence, subject to applicable laws and regulations. We have entered into such agreements with our external directors, which limit the maximum amount of their respective liabilities to us to the minimum amount stipulated by applicable laws and regulations, so long as those directors act in good faith and without gross negligence in performing their duties.

D. Employees.

As of March 31, 2019, we had 49,578 employees on a consolidated basis, of which 6,941 employees were based in Japan and 42,637 employees were based outside Japan.

We have concluded a collective bargaining agreement with the Takeda Pharmaceutical Workers Union, through which we have established sound relations with our employees in Japan. We hold regular dialogues with the union concerning, among other issues, conditions of employment and human resources practices. Similarly, all of our group companies hold discussions with their respective workers unions and employee representatives in accordance with local laws. We have an employee stock ownership association for employees of Takeda.

E. Share Ownership.

The following table shows the number of shares owned by our directors as of March 31, 2019.

Directors

Name	Number of shares held (of which, number of shares scheduled to be issued pursuant to equity - settled share-based compensation plans)
	(thousands of shares)
Christophe Weber	293.6
	(145.4)
Costa Saroukos	12.6
	(12.6)
Masato Iwasaki	21.8
	(8.6)
Andrew Plump	52.8
	(52.8)
Masahiro Sakane	5.4
	(4.5)
Olivier Bohuon	—
	—
Ian Clark	—
	—
Yoshiaki Fujimori	6.7
	(4.5)
Steven Gillis	—
	—
Toshiyuki Shiga	6.3
	(4.5)
Shiro Kuniya	6.3
	(4.5)
Jean-Luc Butel	6.5
	(6.5)
Yasuhiko Yamanaka	25.6
	(7.6)
Koji Hatsukawa	5.7
	(4.5)
Emiko Higashi	6.5
	(6.5)
Michel Orsinger	6.5
	(6.5)
Total	456.6
	(269.3)

Each of our directors held less than one percent of our total issued shares as of March 31, 2019. Shares held by directors have equal voting rights as common stock held by other holders.

For detailed information about our share-based compensation plans, including our stock option plan, stock incentive plan, phantom stock appreciation rights and restricted stock units, see Note 28 to our audited consolidated financial statements included in this annual report.

Item 7. Major Shareholders and Related Party Transactions

A. Major Shareholders.

The following table sets forth the number of shares held of record by each of our principal shareholders as well as the percentage of our issued shares held by each of our principal shareholders as of March 31, 2019.

Shareholder	Number of shares held of record	Percentage of issued shares[1]
	(thousands, except percentages)	
The Bank Of New York Mellon as Depositary Bank for Depositary Receipt Holders[2]	118,250	7.56%
The Master Trust Bank of Japan, Ltd. (Trust account)	109,549	7.00
Japan Trustee Services Bank, Ltd. (Trust account)	85,405	5.46
Nippon Life Insurance Company	35,360	2.26
Japan Trustee Services Bank, Ltd. (Trust account 5)	34,260	2.19
JP Morgan Chase Bank 380055	30,324	1.94
SSBTC Client Omnibus Account	26,787	1.71
State Street Bank West Client-Treaty 505234	24,673	1.58
State Street Bank and Trust Company 505001	23,775	1.52
Japan Trustee Services Bank, Ltd. (Trust account 1)	22,798	1.46
Total	511,183	32.66%

Notes:

(1) Percentage of issued shares excludes treasury stock held as of March 31, 2019. As of March 31, 2019, we held 10,225,845 shares of common stock as treasury stock, which include 165,150 shares held by us, 9,975,569 shares held in trust for our stock-based compensation plans and 85,126 shares held by equity-method affiliates (based on our ownership percentage in them). The total number of issued shares, less treasury stock, used to calculate percentages in the above table include such shares held in trust or by equity-method affiliates.

(2) During the year ended March 31, 2019, The Bank of New York Mellon acquired 118,250 thousand (or 7.56%) of our shares which represents a significant change from the past three years. This primarily represents shares issued to former shareholders of Shire in the form of ADSs in connection with the Shire Acquisition.

Our major shareholders of common stock have the same voting rights as other holders of common stock.

As of March 31, 2019, there were 322 record holders of our common stock with addresses in the United States, whose shareholdings represented approximately 28% of our outstanding common stock on that date. One such shareholder was The Bank of New York Mellon as depositary for holders of American Depositary Shares, which held 118.2 million shares, or 7.56% of the total number of shares in issue, as of such date. Because some of these shares were held by brokers or other nominees, the number of record holders with addresses in the United States might not fully reflect the number of beneficial owners in the United States.

To the extent known to us, we are not directly or indirectly owned or controlled by any other corporation, by any foreign government or by any other natural or legal person severally or jointly.

To our knowledge, there are no arrangements, the operation of which may at a subsequent date result in a change in control of us.

B. Related Party Transactions.

From time to time, we enter into agreements and engage in transactions with a number of subsidiaries and affiliates in the ordinary course of our business. Takeda has one major affiliate, Teva Takeda Pharma Ltd., to which Takeda sells products and acts as a sales agent. Total transactions with Teva Takeda Pharma Ltd. for the year ended March 31,2019 was ¥10.4 billion. The terms and conditions of the related party transactions are entered into on terms consistent with third-party transactions and considering market prices. In addition, the receivables and payables are settled in cash and consistent with terms of third party settlements.

C. Interests of Experts and Counsel.

Not applicable.

Item 8. Financial Information

A. Consolidated Statements and Other Financial Information.

Our audited consolidated financial statements are included under “Item 18—Financial Statements”.

Legal Proceedings

The information required by this item is set forth in our consolidated financial statements included in this annual report. See Note 32 to our audited consolidated financial statements included in this annual report for a detailed discussion of legal proceedings.

Dividends

Our capital resource management is based on the following:

- investments in our internal research and development pipeline, foundational technology and ability to develop and bring to market new products;
- dividends as an important tool for returning capital to shareholders, while emphasizing capital gains for shareholders through increased corporate value;
- the maintenance of an investment-grade credit rating; and
- disciplined alliances and acquisitions in order to strengthen our business around our key therapeutic areas.

As noted above, the return of capital to shareholders is one focus area for our management, and we believe our dividend policy is an important tool for accomplishing our goals.

The following table sets forth the dividends paid with respect to each of our fiscal years indicated.

Dividends declared and paid	Total dividends (billions of yen)	Dividends per share (yen)	Basis date	Effective date
April 1, 2016 to March 31, 2017				
Q1 2016	71.1	90.00	March 31, 2016	June 30, 2016
Q3 2016	71.1	90.00	September 30, 2016	December 1, 2016
April 1, 2017 to March 31, 2018				
Q1 2017	71.1	90.00	March 31, 2017	June 29, 2017
Q3 2017	71.2	90.00	September 30, 2017	December 1, 2017
April 1, 2018 to March 31, 2019				
Q1 2018	71.5	90.00	March 31, 2018	June 29, 2018
Q3 2018	71.5	90.00	September 30, 2018	December 3, 2018

Dividends declared and paid	Total dividends (billions of yen)	Dividends per share (yen)	Basis date	Effective date
April 1, 2019, to March 31, 2020				
Q1 2019	¥ 140.8	¥ 90.00	March 31, 2019	June 28, 2019

B. Significant Changes.

No significant change has occurred since the date of the annual financial statements.

Item 9. The Offer and Listing

A. Offer and Listing Details.

See Item 9.C of this annual report.

B. Plan of Distribution.

Not applicable.

C. Markets.

In Japan, our common stock has been listed since 1949 on the Tokyo Stock Exchange. Our common stock is also listed on the Nagoya Stock Exchange, the Fukuoka Stock Exchange and the Sapporo Securities Exchange. On each of these markets, our common stock trades under the securities identification code "4502."

ADSs, each representing 0.5 shares of our common stock, have been listed on the New York Stock Exchange since 2018 and trade under the symbol "TAK."

D. Selling Shareholders.

Not applicable.

E. Dilution.

Not applicable.

F. Expenses of the Issue.

Not applicable.

Item 10. Additional Information

A. Share Capital.

Not applicable.

B. Memorandum and Articles of Association.

We are a joint-stock corporation incorporated in Japan under the Companies Act. The rights of our shareholders are represented by shares of our common stock as described below, and shareholders' liability is limited to the amount of subscription for such shares. As of March 31, 2019, our authorized share capital consisted of 3,500,000,000 shares of common stock of which 1,565,005,908 shares were issued.

Only the holders of our common stock will be entitled to the shareholder rights described below. In order to exercise the rights described below, holders of our ADSs will be required to withdraw their ADSs in favor of shares of our common stock in order to exercise their rights as shareholders.

Company Purpose

Article 3 of our Articles of Incorporation, which are included as an exhibit hereto, set forth our objects and purposes, which are to engage in the following businesses:

- Manufacture, purchase and sale of medicines, chemicals for non-medicinal uses, quasi-medicines, medical instruments, appliances and supplies, measuring equipments, cosmetics, food products, beverages, food additives, livestock feed additives and other chemical products, and instruments, appliances and equipment relating to any of the foregoing products;
- Trucking and freight forwarding;
- Warehousing;
- Publishing;
- Management, purchase, sale and lease of real estate; and
- Business ancillary or related to any of those specified in each foregoing clause.

Book-Entry Transfer System

The Japanese book-entry transfer system for listed shares of Japanese companies under the Book-Entry Act of Japan (the "Book-Entry Act") applies to the shares of our common stock. Under this system, shares of all Japanese companies listed on any Japanese stock exchange are dematerialized. Under the book-entry transfer system, in order for any person to hold, sell or otherwise dispose of listed shares of Japanese companies, they must have an account at an account management institution unless such person has an account at Japan Securities Depository Center, Incorporated (the "JASDEC"). "Account management institutions" are financial instruments business operators (i.e., securities firms), banks, trust companies and certain other financial institutions that meet the requirements prescribed by the Book-Entry Act, and only those financial institutions that meet the further stringent requirements of the Book-Entry Act can open accounts directly at JASDEC.

The following description of the book-entry transfer system assumes that the relevant person has no account at JASDEC.

Under the Book-Entry Act, any transfer of shares is affected through book-entry, and the title to the shares passes to the transferee at the time when the transferred number of shares is recorded in the transferee's account at an account management institution. The holder of an account at an account management institution is presumed to be the legal owner of the shares held in such account.

Under the Companies Act, in order to assert shareholders' rights against us, the transferee must have its name and address registered in the register of our shareholders, except in limited circumstances. Under the book-entry transfer system, such registration is generally made upon receipt of an all shareholders notice (*soukabunushi tsuchi*) (as described in "— Register of Shareholders") from JASDEC. For this purpose, shareholders are required to file their names and addresses with our transfer agent through the account management institution and JASDEC. See "— Register of Shareholders" for more information.

Non-resident shareholders are required to appoint a standing proxy in Japan or provide a mailing address in Japan. Each such shareholder must give notice of its standing proxy or a mailing address to the relevant account management institution. Such notice will be forwarded to our transfer agent through JASDEC. Japanese securities firms and commercial banks customarily act as standing proxies and provide related services for standard fees. Notices from us to non-resident shareholders are delivered to the standing proxies or mailing addresses.

Register of Shareholders

Under the book-entry transfer system, the registration of names, addresses and other information of shareholders in the register of our shareholders will be made by us upon the receipt of an all shareholders notice (with the exception that in the event of the issuance of new shares, we will register the names, addresses and other information of our shareholders in the register of our shareholders without an all shareholders notice from JASDEC) given to us by JASDEC, which will give us such all shareholders notice based on information provided by the account management institutions. Such all shareholders notice will be made only in cases prescribed under the Book-Entry Act such as when we fix the record date and when we make a request to JASDEC with any justifiable reason. Therefore, a shareholder may not assert shareholders' rights against us immediately after such shareholder acquires our shares, unless such shareholder's name and address are registered in the register of our shareholders upon our receipt of an all shareholders notice; provided, however, that, in respect of the exercise of rights of minority shareholders as defined in the Book-Entry Act, a shareholder may exercise such rights upon giving us an individual shareholder notice (*kobetsukabunushi tsuchi*) through JASDEC only during a certain period prescribed under the Book-Entry Act.

Distribution of Surplus

Under the Companies Act, the distribution of dividends takes the form of distribution of Surplus (as defined in "—Restriction on Distribution of Surplus"), and a distribution of Surplus may be made in cash and/or in kind, with no restrictions on the timing and frequency of such distributions. The Companies Act generally requires a joint-stock corporation to make distributions of Surplus authorized by a resolution of a general meeting of shareholders. However, in accordance with the Companies Act, our Articles of Incorporation provide that the board of directors has the authority to make decisions regarding distributions of Surplus, except for limited exceptions, as provided by the Companies Act, as long as the company that has both of an independent auditor and an audit and supervisory committee satisfies the following requirements:

(a) the normal term of office of directors who are not audit and supervisory committee members expires at the close of the ordinary general meeting of shareholders held with respect to the last fiscal year ended within one year after their election (our Articles of Incorporation currently satisfies this requirement); and

(b) its non-consolidated annual financial statements and certain documents for the latest fiscal year fairly present its assets and profit or loss, as required by the ordinances of the Ministry of Justice.

A resolution of a general meeting of shareholders or the board of directors authorizing a distribution of Surplus must specify the kind and aggregate book value of the assets to be distributed, the manner of allocation of such assets to shareholders and the effective date of the distribution. If a distribution of Surplus is to be made in kind, we may, pursuant to a resolution of a general meeting of shareholders or the board of directors, grant a right to the shareholders to require us to make such distribution in cash instead of in kind. If no such right is granted to shareholders, the relevant distribution of Surplus must be approved by a special resolution of a general meeting of shareholders. See "— Voting Rights" for more details regarding a special resolution. Our Articles of Incorporation provide that we are relieved of our obligation to pay any distributions in cash that go unclaimed for three years after the date they first become payable.

Restriction on Distribution of Surplus

Under the Companies Act, we may distribute Surplus up to the excess of the aggregate of (a) and (b) below, less the aggregate of (c) through (f) below, as of the effective date of such distribution, if our net assets are not less than ¥3,000,000:

(a) the amount of Surplus, as described below;

(b) in the event that extraordinary financial statements as of, or for a period from the beginning of the fiscal year to, the specified date are approved, the aggregate amount of (i) the aggregate amount as provided for by an ordinance of the Ministry of Justice as the net profit for such period described in the statement of income constituting the extraordinary financial statements, and (ii) the amount of consideration that we received for the treasury stock that we disposed of during such period;

(c) the book value of our treasury stock;

(d) in the event that we disposed of treasury stock after the end of the previous fiscal year, the amount of consideration that we received for such treasury stock;

(e) in the event described in (b) in this paragraph, the aggregate amount as provided for by an ordinance of the Ministry of Justice as the net loss for such period described in the statement of income constituting the extraordinary financial statements; and

(f) certain other amounts set forth in the ordinances of the Ministry of Justice, including (if the sum of one-half of goodwill and the deferred assets exceeds the total of share capital, additional paid-in capital and legal earnings reserve, each such amount as it appears on the balance sheet as of the end of the previous fiscal year) all or a certain part of such excess amount as calculated in accordance with the ordinances of the Ministry of Justice.

For the purposes of this section, the amount of "Surplus" is the excess of the aggregate of (I) through (IV) below, less the aggregate of (V) through (VII) below:

(I) the aggregate of other capital surplus and other retained earnings at the end of the previous fiscal year;

(II) in the event that we disposed of treasury stock after the end of the previous fiscal year, the difference between the book value of such treasury stock and the consideration that we received for such treasury stock;

(III) in the event that we reduced our share capital after the end of the previous fiscal year, the amount of such reduction less the portion thereof that has been transferred to additional paid-in capital and/or legal earnings reserve (if any);

(IV) in the event that we reduced additional paid-in capital and/or legal earnings reserve after the end of the previous fiscal year, the amount of such reduction less the portion thereof that has been transferred to share capital (if any);

(V) in the event that we cancelled treasury stock after the end of the previous fiscal year, the book value of such treasury stock;

(VI) in the event that we distributed Surplus after the end of the previous fiscal year, the aggregate of the following amounts:

(1) the aggregate amount of the book value of the distributed assets, excluding the book value of such assets that would be distributed to shareholders but for their exercise of the right to receive dividends in cash instead of dividends in kind;

(2) the aggregate amount of cash distributed to shareholders who exercised the right to receive dividends in cash instead of dividends in kind; and

(3) the aggregate amount of cash paid to shareholders holding fewer shares than the shares that were required in order to receive dividends in kind;

(VII) the aggregate amounts of (1) through (4) below, less (5) and (6) below:

(1) in the event that the amount of Surplus was reduced and transferred to additional paid-in capital, legal earnings reserve and/or share capital after the end of the previous fiscal year, the amount so transferred;

(2) in the event that we distributed Surplus after the end of the previous fiscal year, the amount set aside in additional paid-in capital and/or legal earnings reserve;

(3) in the event that we disposed of treasury stock in the process of (x) a merger in which we acquired all rights and obligations of a company, (y) a corporate split in which we acquired all or a part of the rights and obligations of a split company or (z) a share exchange in which we acquired all shares of a company after the end of the previous fiscal year, the difference between the book value of such treasury stock and the consideration that we received for such treasury stock;

(4) in the event that the amount of Surplus was reduced in the process of a corporate split in which we transferred all or a part of our rights and obligations after the end of the previous fiscal year, the amount so reduced;

(5) in the event of (x) a merger in which we acquired all rights and obligations of a company, (y) a corporate split in which we acquired all or a part of the rights and obligations of a split company or (z) a share exchange in which we acquired all shares of a company after the end of the previous fiscal year, the aggregate amount of (i) the amount of other capital surplus after such merger, corporate split or share exchange, less the amount of other capital surplus before such merger, corporate split or share exchange, and (ii) the amount of other retained earnings after such merger, corporate split or share exchange, less the amount of other retained earnings before such merger, corporate split or share exchange; and

(6) in the event that an obligation to cover a deficiency, such as the obligation of a person who subscribed for newly issued shares with an unfair amount to be paid in, was fulfilled after the end of the previous fiscal year, the amount of other capital surplus increased by such payment.

In Japan, the "ex-dividend" date and the record date for any distribution of Surplus come before the date a company determines the amount of distribution of Surplus to be paid.

For information as to Japanese taxes on dividends, please refer to "Taxation — Japanese Taxation."

Capital and Reserves

Under the Companies Act, the paid-in amount of any newly-issued shares of stock is required to be accounted for as share capital, although we may account for an amount not exceeding one-half of such paid-in amount as additional paid-in capital. We may generally reduce additional paid-in capital and/or legal earnings reserve by resolution of a general meeting of shareholders, subject to completion of protection procedures for creditors in accordance with the Companies Act, and, if so decided by the same resolution, we may account for the whole or any part of the amount of such reduction as share capital. We may generally reduce share capital by a special resolution of a general meeting of shareholders subject to completion of protection procedures for creditors in accordance with the Companies Act, and, if so decided by the same resolution, we may account for the whole or any part of the amount of such reduction as additional paid-in capital or legal earnings reserve.

Stock Splits

Under the Companies Act, we may at any time split shares in issue into a greater number of the same class of shares by a resolution of the board of directors or by determination of an individual director to whom the authority to make such determination has been delegated by resolution of the board of directors. A company that has issued only one class of shares may amend its articles of incorporation to increase the number of the authorized shares to be issued up to a number in proportion to the stock split by resolution of the board of directors or by determination of an individual director to whom the authority to make such determination has been delegated by resolution of the board of directors, rather than a special resolution of a general meeting of shareholders, which is otherwise required for amending the articles of incorporation. When a stock split is to be made, we must give public notice of the stock split, specifying the record date therefor, at least two weeks prior to such record date.

Under the book-entry transfer system, on the effective date of the stock split, the numbers of shares recorded in all accounts held by our shareholders at account management institutions will be increased in accordance with the applicable ratio.

Gratuitous Allocations

Under the Companies Act, we may allot any class of shares to our existing shareholders without any additional contribution by resolution of the board of directors or by determination of an individual director to whom the authority to make such determination has been delegated by resolution of the board of directors; provided that although our treasury stock may be allotted to our shareholders, any allotment of shares will not accrue to shares of our treasury stock.

When a gratuitous allocation is to be made and we set a record date therefor, we must give public notice of the gratuitous allocation, specifying the record date therefor, at least two weeks prior to the record date.

Under the book-entry transfer system, on the effective date of the gratuitous allocation, the number of shares of our common stock recorded in accounts held by our shareholders at account management institutions will be increased in accordance with a notice from us to JASDEC.

Reverse Stock Split

Under the Companies Act, we may at any time consolidate our shares into a smaller number of shares by a special resolution of the general meeting of shareholders. We must disclose the reason for the reverse stock split at the general meeting of shareholders. When a reverse stock split is to be made, we must give public notice of the reverse stock split, at least two weeks (or, in certain cases where any fractions of shares are left as a result of a reverse stock split, 20 days) prior to the effective date of the reverse stock split.

Under the book-entry transfer system, on the effective date of the reverse stock split, the numbers of shares recorded in all accounts held by our shareholders at account management institutions will be decreased in accordance with the applicable ratio.

Unit Share System

General

Our Articles of Incorporation provide that 100 shares constitute one "unit" of common stock. Our board of directors or an individual director to whom the authority to make such determination has been delegated by resolution of the board of directors is permitted to reduce the number of shares that will constitute one unit or to abolish the unit share system entirely by amending our Articles of Incorporation, without shareholders' approval, with public notice without delay after the effective date of such amendment.

Transferability of Shares Constituting Less Than One Unit

Under the book-entry transfer system, shares constituting less than one unit are transferable. Under the rules of the Japanese stock exchanges, however, shares constituting less than one unit do not comprise a trading unit, except in limited circumstances, and accordingly may not be sold on the Japanese stock exchanges.

Voting Rights of a Holder of Shares Constituting Less Than One Unit

A holder of shares constituting less than one unit cannot exercise any voting rights pertaining to those shares. In calculating the quorum for various voting purposes, the aggregate number of shares constituting less than one unit will be excluded from the number of outstanding shares. A holder of shares representing one or more full units will have one vote for each full unit represented.

A holder of shares constituting less than one unit does not have any rights related to voting, such as the right to participate in a demand for the resignation of a director, the right to participate in a request for the convocation of a general meeting of shareholders and the right to join with other shareholders to propose a matter to be included in the agenda of a general meeting of shareholders.

Rights of a Holder of Shares Constituting Less Than One Unit to Require Us to Purchase Shares and to Sell Shares

Under the Companies Act, a holder of shares constituting less than one full unit may at any time request that we purchase such shares. In addition, our Articles of Incorporation provide that, pursuant to our Share Handling Regulations, a holder of shares constituting less than one full unit has the right to request that we sell to such holder such number of shares constituting less than one full unit which, when added to the shares constituting less than one full unit currently owned by such holder, will constitute one full unit.

Under the book-entry system, such a request must be made to us through the relevant account managing institution. The price at which shares of common stock constituting less than one unit will be purchased or sold by us pursuant to such a request will be equal to (a) the closing price of shares of our common stock reported by the Tokyo Stock Exchange on the day when the request is received by our transfer agent or (b) if no sale takes place on the Tokyo Stock Exchange on that day, the price at which the sale of shares of our common stock is executed on such stock exchange immediately thereafter.

General Meeting of Shareholders

Our ordinary general meeting of shareholders is usually held every June in Japan. The record date for an ordinary general meeting of shareholders is March 31 of each year. In addition, we may hold an extraordinary general meeting of shareholders whenever necessary by giving at least two weeks' advance notice to shareholders.

Notice of convocation of a general meeting of shareholders setting forth the time, place, purpose thereof and certain other matters set forth in the Companies Act and relevant ordinances must be mailed to each shareholder having voting rights (or, in the case of a non-resident shareholder, to his or her standing proxy or mailing address in Japan) at least two weeks prior to the date set for such meeting. Such notice may be given to shareholders by electronic means, subject to the consent of the relevant shareholders.

Any shareholder or group of shareholders holding at least 3% of the total number of voting rights for a period of six months or more may require, with an individual shareholder notice (as described in "— Register of Shareholders"), the convocation of a general meeting of shareholders for a particular purpose. Unless such general meeting of shareholders is convened without delay or a convocation notice of a meeting which is to be held not later than eight weeks from the day of such demand is dispatched, the requiring shareholder may, upon obtaining a court approval, convene such general meeting of shareholders.

Any shareholder or group of shareholders holding at least 300 voting rights or 1% of the total number of voting rights for a period of six months or more may propose a matter to be included in the agenda of a general meeting of shareholders, and may propose to describe such matter together with a summary of the proposal to be submitted by such shareholder in a convocation notice to our shareholders, by submitting a request to a director at least eight weeks prior to the date set for such meeting, with an individual shareholder notice (as described in "— Register of Shareholders").

The Companies Act enables a company to amend its articles of incorporation in order to loosen the requirements for the number of shares held and shareholding period, as well as the period required for dispatching a convocation notice or submission of requests, all of which are required for any shareholder or group of shareholders to request the convocation of a general meeting of shareholders or to propose a matter to be included in the agenda of a general meeting of shareholders. Our Articles of Incorporation do not provide for loosening such requirements.

Voting Rights

A shareholder of record is entitled to one vote per unit (100 shares) of common stock, except that neither we nor any corporation, partnership or other similar entity in which we hold, directly or indirectly, 25% or more of the voting rights shall exercise any voting rights in respect of shares held by us or such entity, as the case may be. Except as otherwise provided by law or by our Articles of Incorporation, a resolution can be adopted at a general meeting of shareholders by a majority of the voting rights represented at the meeting. Shareholders may also exercise their voting rights through proxies, provided that the proxy is granted to one of our shareholders having voting rights. The Companies Act and our Articles of Incorporation provide that the quorum for the election of directors is one-third of the total number of voting rights. Our Articles of Incorporation provide that the shares may not be voted cumulatively for the election of directors.

The Companies Act provides that a special resolution of the general meeting of shareholders is required for certain significant corporate transactions, including:

- any amendment to our Articles of Incorporation (except for amendments that may be made without the approval of shareholders under the Companies Act);
- a reduction of share capital, subject to certain exceptions under which a shareholders' resolution is not required, such as a reduction of share capital for the purpose of replenishing capital deficiencies;
- transfer of the whole or a part of our equity interests in any of our subsidiaries, subject to certain exceptions under which a shareholders' resolution is not required;
- a dissolution, merger or consolidation, subject to certain exceptions under which a shareholders' resolution is not required;
- the transfer of the whole or a substantial part of our business, subject to certain exceptions under which a shareholders' resolution is not required;
- the taking over of the whole of the business of any other corporation, subject to certain exceptions under which a shareholders' resolution is not required;
- a corporate split, subject to certain exceptions under which a shareholders' resolution is not required;
- a share exchange (*kabushiki kokan*) or share transfer (*kabushiki iten*) for the purpose of establishing 100% parent-subsidiary relationships, subject to certain exceptions under which a shareholders' resolution is not required;
- any issuance of new shares or transfer of existing shares held by us as treasury stock at a "specially favorable" price and any issuance of stock acquisition rights or bonds with stock acquisition rights at a "specially favorable" price or on "specially favorable" conditions to any persons other than shareholders;
- any acquisition by us of our own shares from specific persons other than our subsidiaries;
- reverse stock split; or
- the removal of directors who are audit and supervisory committee members.

Except as otherwise provided by law or in our Articles of Incorporation, a special resolution of the general meeting of shareholders requires the approval of the holders of at least two-thirds of the voting rights of all shareholders present or represented at a meeting where a quorum is present. Our Articles of Incorporation provide that a quorum exists when one-third of the total number of voting rights is present or represented.

Liquidation Rights

If we are liquidated, the assets remaining after payment of all taxes, liquidation expenses and debts will be distributed among shareholders in proportion to the number of shares they hold.

Rights to Allotment of Shares

Holders of shares of our common stock have no pre-emptive rights. Authorized but unissued shares may be issued at the times and on the terms as the board of directors or an individual director to whom the authority to make such determination has been delegated by resolution of the board of directors determines, so long as the limitations with respect to the issuance of new shares at "specially favorable" prices (as described in "— Voting Rights") are observed. Our board of directors or an individual director to whom the authority to make such determination has been delegated by resolution of the board of directors may, however, determine that shareholders shall be given rights to allotment regarding a particular issue of new shares, in which case such rights must be given on uniform terms to all holders of the shares as of a record date for which not less than two weeks' prior public notice must be given. Each shareholder to whom such rights are given must also be given notice of the expiration date thereof at least two weeks prior to the date on which such rights expire. The rights to allotment of new shares may not be transferred. However, the Companies Act enables us to allot stock acquisition rights to shareholders without consideration therefor, and such stock acquisition rights are transferable. See "— Stock Acquisition Rights" below.

In cases where a particular issuance of new shares (i) violates laws and regulations or our Articles of Incorporation, or (ii) will be performed in a manner materially unfair, and shareholders may suffer disadvantages therefrom, such shareholders may file an injunction with a court of law to enjoin such issuance.

Stock Acquisition Rights

Subject to certain conditions and to the limitations on issuances at a "specially favorable" price or on "specially favorable" conditions described in "— Voting Rights," we may issue stock acquisition rights (*shinkabu yoyakuken*) and bonds with stock acquisition rights (*shinkabu yoyakuken-tsuki shasai*) by a resolution of the board of directors or by determination of an individual director to whom the authority to make such determination has been delegated by resolution of the board of directors. Holders of stock acquisition rights may exercise their rights to acquire a certain number of shares within the exercise period as set forth in the terms of their stock acquisition rights. Upon exercise of stock acquisition rights, we will be obligated either to issue the relevant number of new shares or, alternatively, to transfer the necessary number of shares of treasury stock held by us.

Record Date

The record date for annual dividends and the determination of shareholders entitled to vote at the ordinary general meeting of our shareholders is March 31. The record date for interim dividends is September 30.

In addition, by a resolution of the board of directors or by determination of an individual director to whom the authority to make such determination has been delegated by resolution of the board of directors, we may set a record date for determining the shareholders entitled to other rights and for other purposes by giving at least two weeks' prior public notice.

Under the rules of JASDEC, we are required to give notice of each record date to JASDEC promptly after setting such record date. JASDEC is required to promptly give us notice of the names and addresses of the holders of shares of our common stock, the number of shares of our common stock held by them and other relevant information as at each record date.

Purchase of Our Own Shares

Under the Companies Act and our Articles of Incorporation, we may acquire our own shares:

- by purchase on any stock exchange on which our shares are listed or by way of tender offer, pursuant to a resolution of our board of directors subject to certain requirements;
- by purchase from a specific party other than any of our subsidiaries, pursuant to a special resolution of a general meeting of shareholders; and
- by purchase from any of our subsidiaries, pursuant to a resolution of the board of directors or determination of an individual director to whom the authority to make such determination has been delegated by resolution of the board of directors.

If we acquire our own shares from a specific party other than any of our subsidiaries as specified above at a price higher than the greater of (i) (a) the closing price of the shares at the market trading such shares on the day immediately preceding the day on which the relevant special resolution of a general meeting of shareholders is made or (b) if no sale takes place at such market on that day, the price at which the sale of the shares is effected on such market immediately thereafter and (ii) in the event that such shares are subject to a tender offer, the price set in the contract regarding such tender offer on that day, shareholders may request that we include him or her as the seller of his or her shares in the proposed purchase. Any such acquisition of shares must satisfy certain requirements, such as that we may only acquire our own shares in an aggregate amount up to the amount that we may distribute as Surplus. See "— Distribution of Surplus" above for more details regarding this amount.

Our own shares acquired by us may be held by us as treasury stock for any period or may be cancelled by resolution of the board of directors or by determination of an individual director to whom the authority to make such determination has been delegated by resolution of the board of directors. We may also transfer the shares held by us to any person, subject to a resolution of the board of directors or determination of an individual director to whom the authority to make such determination has been delegated by resolution of the board of directors, and subject also to other requirements similar to those applicable to the issuance of new shares, as described in "— Rights to Allotment of Shares" above. We may also utilize our treasury stock (x) for the purpose of transfer to any person upon exercise of stock acquisition rights or (y) for the purpose of acquiring another company by way of merger, share exchange, or corporate split through exchange of treasury stock for shares or assets of the acquired company.

Request by Controlling Shareholder to Sell All Shares

Under the Companies Act and our Articles of Incorporation, in general, a shareholder holding 90% or more of our voting rights, directly or through wholly-owned subsidiaries, shall have the right to request that all other shareholders other than us (and all other holders of stock acquisition rights other than us, as the case may be) sell all shares (and all stock acquisition rights, as the case may be) held by them with our approval, which must be made by a resolution of the board of directors or by determination of an individual director to whom the authority to make such determination has been delegated by resolution of the board of directors (*kabushiki tou uriwatashi seikyu* or a "Share Sales Request"). In order to make a Share Sales Request, such controlling shareholder will be required to issue a prior notice to us. If we approve such Share Sales Request, we will be required to make a public notice to all holders and registered pledgees of shares (and stock acquisition rights, as the case may be) not later than 20 days before the effective date of such sales.

Sale by Us of Shares Held by Shareholders Whose Addresses Are Unknown

Under the Companies Act, we are not required to send a notice to a shareholder if notices to such shareholder fail to arrive for a continuous period of five or more years at the registered address of such shareholder in the register of our shareholders or at the address otherwise notified to us.

In addition, we may sell or otherwise dispose of the shares held by a shareholder whose location is unknown. Generally, if

- notices to a shareholder fail to arrive for a continuous period of five or more years at the shareholder's registered address in the register of our shareholders or at the address otherwise notified to us, and
- the shareholder fails to receive distribution of Surplus on the shares for a continuous period of five or more years at the address registered in the register of our shareholders or at the address otherwise notified to us,

we may sell or otherwise dispose of the shareholder's shares at the market price after giving at least three months' prior public and individual notices, and hold or deposit the proceeds of such sale or disposal for the shareholder.

Reporting of Substantial Shareholdings

The Financial Instruments and Exchange Law of Japan and its related regulations require any person who has become beneficially, solely or jointly, a holder of more than 5% of total issued shares of our common stock, to file with the director of a relevant local finance bureau of the Ministry of Finance within five business days a report concerning such shareholdings. With certain exceptions, a similar report must also be filed in respect of any subsequent change of 1% or more in any such holdings or any change in material matters set out in reports previously filed. For this purpose, shares of our common stock issuable to such person upon exchange of exchangeable securities, conversion of convertible securities or exercise of warrants or stock acquisition rights (including those incorporated in bonds with stock acquisition rights) are taken into account in determining both the number of our shares held by the holder and our total issued shares.

C. Material Contracts.

TiGenix NV

In connection with our acquisition of TiGenix NV, on January 5, 2018, we entered into an Offer and Support Agreement with TiGenix NV, whereby we commenced an all cash voluntary and conditional public takeover bid for 100% of the securities with voting rights or giving access to voting rights of TiGenix NV that are not already owned by Takeda or its affiliates, at a price of €1.78 per share in cash and an equivalent price for the ADSs, warrants to acquire shares and 9% senior unsecured convertible bonds due March 6, 2018 of TiGenix NV. On July 31, 2018, we acquired all outstanding ordinary shares as well as the ADSs and warrants of TiGenix NV following the expiration of the squeeze-out period and TiGenix NV became a wholly-owned subsidiary of Takeda. Following the acquisition of all outstanding ordinary shares, ADSs and warrants of TiGenix NV, TiGenix NV was delisted from Euronext Brussels and from Nasdaq.

Shire Acquisition

In connection with the Shire Acquisition, on May 8, 2018, we entered into a Co-operation Agreement with Shire, governing certain matters leading to the closing of the Shire Acquisition. The Shire Acquisition was completed on January 8, 2019. On May 8, 2018, we entered into the Bridge Credit Agreement totaling commitments of $30.85 billion with, among others, JPMorgan Chase Bank N.A., Sumitomo Mitsui Banking Corporation and MUFG Bank, Ltd. On June 8, 2018, we entered into the Term Loan Credit Agreement for an aggregate principal amount of $7.5 billion with, among others, JPMorgan Chase Bank N.A., Sumitomo Mitsui Banking Corporation, MUFG Bank, Ltd. and Mizuho Bank, Ltd., and on the same date entered into Amendment No. 1 to the Bridge Credit Agreement to make certain technical changes thereto. On October 26, 2018, we entered into the SSTL with an aggregate commitment of ¥500.0 billion, with Sumitomo Mitsui Banking Corporation, MUFG Bank, Ltd., Mizuho Bank, Ltd., The Norinchukin Bank and Sumitomo Mitsui Trust Bank, Limited, and on the same date entered into Amendment No. 2 to the Bridge Credit Agreement to make certain technical changes thereto. On October 26, 2018, we also entered into the Subordinated Loan Agreement, with aggregate commitments of ¥500.0 billion, with Sumitomo Mitsui Banking Corporation, MUFG Bank, Ltd., Mizuho Bank, Ltd., The Norinchukin Bank and Sumitomo Mitsui Trust Bank, Limited, which may be used, at our option to refinance all or a portion of the borrowings under the SSTL following the completion of the Shire Acquisition. On November 21, 2018, we entered into a Fiscal Agency Agreement with MUFG Bank, Ltd., as Fiscal Agent, under which we issued a total aggregate principal amount of €7.5 billion of senior notes on the same day. On November 26, 2018, we entered into an Indenture with MUFG Union Bank, N.A., as Trustee (the "Indenture"), under which we issued a total aggregate principal amount of $5.5 billion of senior notes on the same day. On December 3, 2018, we entered into the JBIC Loan with the Japan Bank for International Cooperation, for an aggregate principal amount of up to $3.7 billion. On December 20, 2018 we entered into Amendment No. 1 to the Term Loan Credit Agreement to make certain technical changes thereto and entered into Amendment No. 1 to the SSTL to make certain technical changes thereto. On December 21, 2018, we cancelled in full the remaining commitments under the Bridge Credit Agreement. On December 25, we entered into Amendment No. 1 to the JBIC Loan to make certain technical changes thereto. On June 6, 2019, we issued the Hybrid Bonds with an aggregate principal amount of ¥500 billion, and we used the proceeds from the Hybrid Bonds offering to repay the SSTL. The Hybrid Bonds will mature on June 6, 2079 and, under the terms and conditions of the Hybrid Bonds, we may make an early repayment of all of the principal of the Hybrid Bonds on each interest payment date beginning October 6, 2024. Interest on the Hybrid Bonds is payable semi-annually at a rate per annum subject to revision. The Hybrid Bonds are unsecured and we are not subject to any financial covenants related to these bonds.

The Term Loan Credit Agreement and Amendment No. 1 thereto, the Fiscal Agency Agreement, the Indenture and the JBIC Loan and Amendment No. 1 thereto are filed as exhibits hereto. English-language translations of the Subordinated Loan Agreement and the terms and conditions of the Hybrid Bonds are also filed as exhibits hereto.

For a description of the agreements mentioned above as well as the effect of the Shire Acquisition on our financial condition and results of operations, see "Item 5. Operating and Financial Review and Prospects—A. Operating Results—Acquisitions."

Letter Agreement with Baxter

On January 11, 2016, Baxter International Inc. ("Baxter"), Shire and Baxalta entered into a letter agreement (the "Letter Agreement") in connection with the Shire's acquisition of Baxalta, which, among other things, addresses certain aspects of a tax matters agreement entered into between Baxter and Baxalta prior to their separation in July 2015.

Under the Letter Agreement, from and after the closing of Shire's acquisition of Baxalta (which occurred on June 3, 2016), Baxalta agreed to indemnify, and Shire agreed to guarantee such indemnity to, Baxter and each of its affiliates and each of their respective officers, directors and employees against certain tax-related losses resulting from the acquisition (other than losses resulting from any disposition of Baxalta common stock by Baxter (i) that are not attributable to the acquisition and (ii) other than in the initial distribution on July 1, 2015 and certain debt-for-equity exchanges, exchange offers, contribution of Baxalta shares to Baxter's U.S. pension fund or a dividend distribution to Baxter's stockholders (in each case as contemplated by the Letter Agreement).

The Letter Agreement is filed as an exhibit hereto.

Licensing and Collaboration Agreements

In the ordinary course of our business, we enter into agreements for licensing or collaboration in the development and commercialization of products. Our business does not materially depend on any one of these agreements. Instead, they overall form a portion of our strategy to leverage a mix of internal and external resources to develop and commercialize new products. Certain of the agreements which have led to successful commercialization to date are summarized in "Item 4. Information on the Company—B. Business Overview—Licensing and Collaboration." Our Licensing and Collaboration Agreement with Seattle Genetics, Inc. is filed as an exhibit hereto to provide investors with an example of one such agreement. We believe this agreement is representative of our licensing and collaboration agreements for marketed products in that it provides for the payment of development and commercial milestone payments and sales-based royalties and sets forth the parties' responsibilities relating to the terms of co-development, co-manufacturing and co-marketing efforts, as well as providing for geographic limitations and limitations on term for the relevant licensing and collaboration efforts. The specific terms of each of our licensing or collaboration agreements are negotiated individually. Agreements for compounds still in development may have additional terms governing, for example, equity investments or other capital relationships.

D. Exchange Controls.

The Foreign Exchange and Foreign Trade Act of Japan and related cabinet orders and ministerial ordinances, which we refer to collectively as the Foreign Exchange Regulations, govern certain aspects relating to the acquisition and holding of shares by "exchange non-residents" and by "foreign investors" (as these terms are defined below). It also applies in some cases to the acquisition and holding of ADSs representing shares of our common stock acquired and held by exchange non-residents and by foreign investors. In general, the Foreign Exchange Regulations currently in effect do not affect transactions between exchange non-residents to purchase or sell shares or ADSs outside Japan using currencies other than Japanese yen.

Exchange residents are defined in the Foreign Exchange Regulations as:

(i) individuals who reside within Japan; or

(ii) corporations whose principal offices are located within Japan.

Exchange non-residents are defined in the Foreign Exchange Regulations as:

(i) individuals who do not reside in Japan; or

(ii) corporations whose principal offices are located outside Japan.

Generally, branches and other offices of non-resident corporations located within Japan are regarded as exchange residents. Conversely, branches and other offices of Japanese corporations located outside Japan are regarded as exchange non-residents.

Foreign investors are defined in the Foreign Exchange Regulations as:

(i) individuals who do not reside in Japan;

(ii) corporations or other entities organized under the laws of foreign countries or whose principal offices are located outside Japan;

(iii) corporations of which 50% or more of the total voting rights are held, directly or indirectly, by individuals and/or corporations falling within (i) and/or (ii) above; or

(iv) corporations or other entities having a majority of either (A) directors or other persons equivalent thereto or (B) directors or other persons equivalent thereto having the power of representation who are non-resident individuals.

Acquisition of Shares

Acquisition by an exchange non-resident of shares of a Japanese corporation from an exchange resident requires post facto reporting by the exchange resident to the Minister of Finance of Japan through the Bank of Japan. No such reporting requirement is imposed, however, if:

(i) the aggregate purchase price of the relevant shares is ¥100 million or less;

(ii) the acquisition is affected through any bank, financial instruments business operator or other entity prescribed by the Foreign Exchange Regulations acting as an agent or intermediary; or

(iii) the acquisition constitutes an "inward direct investment" described below.

Inward Direct Investment in Shares of Listed Corporations

If a foreign investor acquires shares of a Japanese company that are listed on a Japanese stock exchange, such as the shares of our common stock, or that are traded on an over-the-counter market in Japan and, as a result of the acquisition, the foreign investor, in combination with any existing holdings, directly or indirectly holds 10% or more of the issued shares of the relevant company, such acquisition constitutes an "inward direct investment" and the foreign investor in general must file a report of the acquisition with the Minister of Finance and any other competent Ministers having jurisdiction over that Japanese company by the 15th day of the month immediately following the month to which the date of such acquisition belongs. In limited circumstances, such as where the foreign investor is in a country that is not listed on an exemption schedule in the Foreign Exchange Regulations, or where that Japanese company is engaged in certain businesses designated by the Foreign Exchange Regulations (including the manufacturing of biological preparations), a prior notification of the acquisition must be filed with the Minister of Finance and any other competent Ministers (including the Minister of Health, Labour and Welfare). The proposed acquisition may not be consummated until 30 days have passed from the date of filing of such notification, although this period will be shortened to two weeks unless such Ministers deem it necessary to review the proposed acquisition. The relevant Ministers may extend the screening period up to five months if they deem it necessary to review the proposed acquisition and may recommend any modification or abandonment of the proposed acquisition and, if such recommendation is not accepted, they may order the modification or abandonment of such acquisition.

Acquisition of shares by foreign investors by way of stock split is not subject to any of the foregoing notification or reporting requirements.

Dividends and Proceeds of Sale

Under the Foreign Exchange Regulations, dividends paid on, and the proceeds from sales in Japan of, shares held by exchange non-residents may generally be converted into any foreign currency and repatriated abroad.

E. Taxation.

Material U.S. Federal Income Tax Consequences

This section describes the material United States federal income tax consequences of owning ADSs. It applies to you only if you are a U.S. holder (as defined below) and you hold your ADSs as capital assets for tax purposes. This discussion addresses only United States federal income taxation and does not discuss all of the tax consequences that may be relevant to you in light of your individual circumstances, including foreign, state or local tax consequences, estate and gift tax consequences, and tax consequences arising under the Medicare contribution tax on net investment income or the alternative minimum tax. This section does not apply to you if you are a member of a special class of holders subject to special rules, including:

- a dealer in securities,
- a trader in securities that elects to use a mark-to-market method of accounting for securities holdings,
- a tax-exempt organization,
- a life insurance company,
- a person that actually or constructively owns 10% or more of the combined voting power of our voting stock or of the total value of our stock,
- a person that holds ADSs as part of a straddle or a hedging or conversion transaction,
- a person that purchases or sells ADSs as part of a wash sale for tax purposes, or
- a person whose functional currency is not the U.S. dollar.

This section is based on the Internal Revenue Code of 1986, as amended, its legislative history, existing and proposed regulations, published rulings and court decisions, all as currently in effect, as well as on the Convention Between the Government of the United States of America and the Government of Japan for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income (the "Treaty"). These

laws are subject to change, possibly on a retroactive basis. In addition, this section is based in part upon the assumption that each obligation in the deposit agreement will be performed in accordance with its terms.

If an entity or arrangement that is treated as a partnership for United States federal income tax purposes holds the ADSs, the United States federal income tax treatment of a partner will generally depend on the status of the partner and the tax treatment of the partnership. A partner in a partnership holding the ADSs should consult its tax advisor with regard to the United States federal income tax treatment of an investment in the ADSs.

You are a U.S. holder if you are a beneficial owner of ADSs and you are for United States federal income tax purposes:

- a citizen or resident of the United States,
- a domestic corporation,
- an estate whose income is subject to United States federal income tax regardless of its source, or
- a trust if a United States court can exercise primary supervision over the trust's administration and one or more United States persons are authorized to control all substantial decisions of the trust.

You should consult your own tax advisor regarding the United States federal, state and local tax consequences of owning and disposing of ADSs in your particular circumstances.

In general, and taking into account the earlier assumptions, for United States federal income tax purposes, if you hold ADRs evidencing ADSs, you will be treated as the owner of the shares represented by those ADRs. Exchanges of shares for ADRs, and ADRs for shares, generally will not be subject to United States federal income tax.

The tax treatment of your ADSs will depend in part on whether or not we are classified as a passive foreign investment company, or PFIC, for United States federal income tax purposes. Except as discussed below under "—PFIC Rules", this discussion assumes that we are not classified as PFIC for United States federal income tax purposes.

Distributions. Under the United States federal income tax laws, if you are a U.S. holder, the gross amount of any distribution we pay out of our current or accumulated earnings and profits (as determined for United States federal income tax purposes), other than certain pro-rata distributions of our shares, will be treated as a dividend that is subject to United States federal income taxation. If you are a noncorporate U.S. holder, dividends that constitute qualified dividend income will be taxable to you at the preferential rates applicable to long-term capital gains provided that you hold the ADSs for more than 60 days during the 121-day period beginning 60 days before the ex-dividend date and meet other holding period requirements. Dividends that we distribute with respect to the ADSs will be qualified dividend income if the ADSs are readily tradable on an established securities market in the United States in the year that we distribute the dividend. Our ADSs will be listed on the NYSE, in which case the ADSs will be treated as readily tradable on an established securities market in the United States. We therefore expect that dividends that we distribute on our ADSs will be qualified dividend income.

You must include any Japanese tax withheld from the dividend payment in this gross amount even though you do not in fact receive it. The dividend is taxable to you when the depositary receives the dividend, actually or constructively. The dividend will not be eligible for the dividends-received deduction generally allowed to United States corporations in respect of dividends received from other United States corporations. The amount of the dividend distribution that you must include in income will be the U.S. dollar value of the yen payments made, determined at the spot yen/U.S. dollar rate on the date the depositary actually or constructively receives the dividend, even if the depositary (a) converts the yen into U.S. dollars at a different rate or (b) does not convert the dividend payment into U.S. dollars. If the depositary converts the yen into U.S. dollars at a different rate, then you will recognize U.S. source ordinary income (that would not be treated as qualified dividends) or loss equal to the difference between the U.S. dollars that you receive and the U.S. dollar amount that you included as dividend income. If the depositary does not convert the dividend payment into U.S. dollars, then you will recognize U.S. source ordinary income (that would not be treated as qualified dividends) or loss upon a conversion of the yen into U.S. dollars equal to the difference between the U.S. dollars that you receive in the conversion and the U.S. dollar amount that you included as dividend income.

Distributions in excess of current and accumulated earnings and profits, as determined for United States federal income tax purposes, will be treated as a non-taxable return of capital to the extent of your basis in the ADSs and thereafter as capital gain. However, we do not expect to calculate earnings and profits in accordance with United States federal income tax principles. Accordingly, you should expect to generally treat distributions we make as dividends.

Subject to certain limitations, the Japanese tax withheld in accordance with the Treaty and paid over to Japan will be creditable or deductible against your United States federal income tax liability. Special rules apply in determining the foreign tax credit limitation with respect to dividends that are subject to the preferential tax rates. To the extent a reduction or refund of the tax withheld is available to you under Japanese law or under the Treaty, the amount of tax withheld that could have been reduced or that is refundable will not be eligible for credit against your United States federal income tax liability.

Dividends will generally be income from sources outside the United States and will generally be "passive" income for purposes of computing the foreign tax credit allowable to you. However, if (a) we are 50% or more owned, by vote or value, by United States persons and (b) at least 10% of our earnings and profits are attributable to sources within the United States, then for foreign tax credit purposes, a portion of our dividends would be

treated as derived from sources within the United States. With respect to any dividend paid for any taxable year, the United States source ratio of our dividends for foreign tax credit purposes would be equal to the portion of our earnings and profits from sources within the United States for such taxable year, divided by the total amount of our earnings and profits for such taxable year.

Distributions of additional shares to you with respect to ADSs that are made as part of a pro rata distribution to all of our shareholders generally will not be subject to United States federal income tax.

Capital Gains. If you are a U.S. holder and you sell or otherwise dispose of your ADSs, you will recognize capital gain or loss for United States federal income tax purposes equal to the difference between the U.S. dollar value of the amount that you realize and your tax basis, determined in U.S. dollars, in your ADSs. Capital gain of a noncorporate U.S. holder is generally taxed at preferential rates where the property is held for more than one year. The gain or loss will generally be income or loss from sources within the United States for foreign tax credit limitation purposes.

PFIC Rules. We believe that ADSs should not currently be treated as stock of a PFIC for United States federal income tax purposes and we do not expect to become a PFIC in the foreseeable future. However, this conclusion is a factual determination that is made annually and thus may be subject to change. It is therefore possible that we could become a PFIC in a future taxable year.

In general, if you are a U.S. holder, we will be a PFIC with respect to you if for any taxable year in which you held our ADSs:

- at least 75% of our gross income for the taxable year is passive income or
- at least 50% of the value, determined on the basis of a quarterly average, of our assets is attributable to assets that produce or are held for the production of passive income.

"Passive income" generally includes dividends, interest, gains from the sale or exchange of investment property, rents and royalties (other than certain rents and royalties derived in the active conduct of a trade or business) and certain other specified categories of income. If a foreign corporation owns at least 25% by value of the stock of another corporation, the foreign corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation, and as receiving directly its proportionate share of the other corporation's income.

If we are treated as a PFIC, and you are a U.S. holder that did not make a mark-to-market election, as described below, you will generally be subject to special rules with respect to:

- any gain you realize on the sale or other disposition of your ADSs and
- any excess distribution that we make to you (generally, any distributions to you during a single taxable year, other than the taxable year in which your holding period in the ADSs begins, that are greater than 125% of the average annual distributions received by you in respect of the ADSs during the three preceding taxable years or, if shorter, your holding period for the ADSs that preceded the taxable year in which you receive the distribution).

Under these rules:

- the gain or excess distribution will be allocated ratably over your holding period for the ADSs,
- the amount allocated to the taxable year in which you realized the gain or excess distribution or to prior years before the first year in which we were a PFIC with respect to you will be taxed as ordinary income,
- the amount allocated to each other prior year will be taxed at the highest tax rate in effect for that year, and
- the interest charge generally applicable to underpayments of tax will be imposed in respect of the tax attributable to each such year.

Special rules apply for calculating the amount of the foreign tax credit with respect to excess distributions by a PFIC.

If we are a PFIC in a taxable year and our ADSs are treated as "marketable stock" in such year, you may make a mark-to-market election with respect to your ADSs. If you make this election, you will not be subject to the PFIC rules described above. Instead, in general, you will include as ordinary income each year the excess, if any, of the fair market value of your ADSs at the end of the taxable year over your adjusted basis in your ADSs. You will also be allowed to take an ordinary loss in respect of the excess, if any, of the adjusted basis of your ADSs over their fair market value at the end of the taxable year (but only to the extent of the net amount of previously included income as a result of the mark-to-market election). Your basis in the ADSs will be adjusted to reflect any such income or loss amounts. Any gain that you recognize on the sale or other disposition of your ADSs would be ordinary income and any loss would be an ordinary loss to the extent of the net amount of previously included income as a result of the mark-to-market election and, thereafter, a capital loss.

Your ADSs will generally be treated as stock in a PFIC if we were a PFIC at any time during your holding period in your ADSs, even if we are not currently a PFIC.

In addition, notwithstanding any election you make with regard to the ADSs, dividends that you receive from us will not constitute qualified dividend income to you if we are a PFIC (or are treated as a PFIC with respect to you) either in the taxable year of the distribution or the preceding taxable year. Dividends that you receive that do not constitute qualified dividend income are not eligible for taxation at the preferential rates applicable

to qualified dividend income. Instead, you must include the gross amount of any such dividend paid by us out of our accumulated earnings and profits (as determined for United States federal income tax purposes) in your gross income, and it will be subject to tax at rates applicable to ordinary income.

If you own ADSs during any year that we are a PFIC with respect to you, you may be required to file Internal Revenue Service ("IRS") Form 8621.

Japanese Taxation

The following is a general summary of the principal Japanese tax consequences (limited to national tax) to owners of shares of our common stock, in the form of shares or ADSs, who are non-resident individuals of Japan or who are non-Japanese corporations without a permanent establishment in Japan, collectively referred to in this section as non-resident holders. The statements below regarding Japanese tax laws are based on the laws and treaties in force and as interpreted by the Japanese tax authorities as of the date of this annual report, and are subject to changes in applicable Japanese laws, tax treaties, conventions or agreements, or in the interpretation of them, occurring after that date. This summary is not exhaustive of all possible tax considerations that may apply to a particular investor, and potential investors are advised to satisfy themselves as to the overall tax consequences of the acquisition, ownership and disposition of shares of our common stock, including, specifically, the tax consequences under Japanese law, under the laws of the jurisdiction of which they are resident and under any tax treaty, convention or agreement between Japan and their country of residence, by consulting their own tax advisors.

For the purpose of Japanese tax law and the tax treaty between the United States and Japan, a U.S. holder of ADSs will generally be treated as the owner of the shares underlying the ADSs evidenced by the ADRs.

Generally, a non-resident holder of shares or ADSs will be subject to Japanese income tax collected by way of withholding on dividends (meaning in this section distributions made from our retained earnings for the Companies Act purposes) we pay with respect to shares of our common stock and such tax will be withheld prior to payment of dividends. Stock splits generally are not subject to Japanese income or corporation taxes.

In the absence of any applicable tax treaty, convention or agreement reducing the maximum rate of Japanese withholding tax or allowing exemption from Japanese withholding tax, the rate of the Japanese withholding tax applicable to dividends paid by Japanese corporations on their shares of stock to non-resident holders is generally 20.42% (or 20% for dividends due and payable on or after January 1, 2038) under Japanese tax law. However, with respect to dividends paid on listed shares issued by a Japanese corporation (such as shares or ADSs) to non-resident holders, other than any individual shareholder who holds 3% or more of the total number of shares issued by the relevant Japanese corporation (to whom the aforementioned withholding tax rate will still apply), the aforementioned withholding tax rate is reduced to (i) 15.315% for dividends due and payable up to and including December 31, 2037 and (ii) 15% for dividends due and payable on or after January 1, 2038. The withholding tax rates described above include the special reconstruction surtax (2.1% multiplied by the original applicable withholding tax rate, i.e., 15% or 20%, as the case may be), which is imposed during the period from and including January 1, 2013 to and including December 31, 2037, to fund the reconstruction from the Great East Japan Earthquake.

If distributions were made from our capital surplus, rather than retained earnings, for the Companies Act purposes, the portion of such distributions in excess of the amount corresponding to a pro rata portion of return of capital as determined under Japanese tax laws would be deemed dividends for Japanese tax purposes, while the rest would be treated as return of capital for Japanese tax purposes. The deemed dividend portion, if any, would generally be subject to the same tax treatment as dividends as described above, and the return of capital portion would generally be treated as proceeds derived from the sale of shares and subject to the same tax treatment as sale of shares of our common stock as described below. Distributions made in consideration of repurchase by us of our own shares or in connection with certain reorganization transactions will be treated substantially in the same manner.

Japan has income tax treaties whereby the withholding tax rate (including the special reconstruction surtax) may be reduced, generally to 15%, for portfolio investors, with, among others, Canada, Denmark, Finland, Germany, Ireland, Italy, Luxembourg, New Zealand, Norway, Singapore and Spain, while the income tax treaties with, among others, Australia, Belgium, France, Hong Kong, the Netherlands, Portugal, Sweden, Switzerland, the United Arab Emirates, the United Kingdom and the United States generally reduce the withholding tax rate to 10% for portfolio investors. In addition, under the income tax treaty between Japan and the United States, dividends paid to pension funds which are qualified U.S. residents eligible to enjoy treaty benefits are exempt from Japanese income taxation by way of withholding or otherwise unless the dividends are derived from the carrying on of a business, directly or indirectly, by the pension funds. Similar treatment is applicable to dividends paid to pension funds under the income tax treaties between Japan and the Netherlands, Switzerland and the United Kingdom. Under Japanese tax law, any reduced maximum rate applicable under a tax treaty shall be available when such maximum rate is below the rate otherwise applicable under the Japanese tax law referred to in the second preceding paragraph with respect to the dividends to be paid by us on our shares or ADSs.

Non-resident holders of our shares who are entitled under an applicable tax treaty to a reduced rate of, or exemption from, Japanese withholding tax on any dividends on our shares, in general, are required to submit, through the withholding agent to the relevant tax authority prior to the payment of dividends, an Application Form for Income Tax Convention regarding Relief from Japanese Income Tax and Special Income Tax for Reconstruction on Dividends together with any required forms and documents. A standing proxy for a non-resident holder of shares of our common stock or ADSs may be used in order to submit the application on a non-resident holder's behalf. In this regard, a certain simplified special filing procedure is available for non-resident holders to claim treaty benefits of reduction of or exemption from Japanese withholding tax, by submitting a Special Application Form for Income Tax Convention regarding Relief from Japanese Income Tax and Special Income Tax for Reconstruction on Dividends of Listed Stock, together with any required forms or documents. If the depositary needs investigation to identify whether any non-resident holders of ADSs are entitled to claim treaty benefits of exemption from or reduction of Japanese withholding tax, the depositary or its agent submits an application form before payment of dividends so that the withholding cannot be made in connection with such holders for eight months after the record date concerning such payment of dividends. If it is proved that such holders are entitled to claim treaty benefits of exemption from or reduction of Japanese withholding tax within the

foregoing eight-month period, the depositary or its agent submits another application form together with certain other documents so that such holder can be subject to exemption from or reduction of Japanese withholding tax. To claim this reduced rate or exemption, such non-resident holder of ADSs will be required to file a proof of taxpayer status, residence and beneficial ownership, as applicable, and to provide other information or documents as may be required by the depositary. Non-resident holders who are entitled, under any applicable tax treaty, to a reduced rate of Japanese withholding tax below the rate otherwise applicable under Japanese tax law, or exemption therefrom, as the case may be, but fail to submit the required application in advance may nevertheless be entitled to claim a refund from the relevant Japanese tax authority of withholding taxes withheld in excess of the rate under an applicable tax treaty (if such non-resident holders are entitled to a reduced treaty rate under the applicable tax treaty) or the full amount of tax withheld (if such non-resident holders are entitled to an exemption under the applicable tax treaty), as the case may be, by complying with a certain subsequent filing procedure. We do not assume any responsibility to ensure withholding at the reduced treaty rate, or exemption therefrom, for shareholders who would be eligible under an applicable tax treaty but who do not follow the required procedures as stated above.

Gains derived from the sale of our shares or ADSs outside Japan by a non-resident holder that is a portfolio investor will generally not be subject to Japanese income or corporation taxes. Japanese inheritance and gift taxes, at progressive rates, may be payable by an individual who has acquired from another individual our shares or ADSs as a legatee, heir or done, even if none of the acquiring individual, the decedent or the donor is a Japanese resident.

F. Dividends and Paying Agents.

Not applicable.

G. Statement by Experts.

Not applicable.

H. Documents on Display.

We have filed this annual report with the SEC under the Exchange Act with respect to the ADSs. We are subject to the information requirements of the Exchange Act and, in accordance therewith, we are required to file annual reports on Form 20-F and furnish other reports and information on Form 6-K with the SEC.

You may review a copy of our filings without charge at the SEC's web site at www.sec.gov that contains reports and other information regarding registrants that file electronically with the SEC. You can also view such filings on our web site at https://www.takeda.com/investors/reports/sec-filings/. As a foreign private issuer, we are exempt from the rules under the Exchange Act prescribing the furnishing and content of proxy statements to shareholders.

I. Subsidiary Information.

Not applicable.

Item 11. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risks primarily from changes in foreign currency exchange rates, interest rate changes and changes in the value of our investment securities. The information required under this Item 11 is set forth in Note 27 to our audited consolidated financial statements included in this annual report.

Item 12. Description of Securities Other Than Equity Securities

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

Each ADS represents one-half of one share of our common stock deposited with our depositary's (The Bank of New York Mellon) custodian (Sumitomo Mitsui Banking Corporation) in Japan. Each ADS will also represent any other securities, cash or other property which may be held by the depositary from time to time. The deposited shares of our common stock, together with any other securities, cash or other property held by the depositary are referred to as the "deposited securities."

Fees and Expenses

Persons depositing or withdrawing shares of our common stock or ADS holders must pay:	***For:***
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	Issue of ADSs, including issues resulting from a distribution of shares of our common stock or rights or other property Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
$0.05 (or less) per ADS	Any cash distribution to ADS holders
A fee equivalent to the fee that would be payable if securities distributed to ADS holders had been shares of our common stock and the shares of our common stock had been deposited for issuance of ADSs	Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
$0.05 (or less) per ADS per calendar year	Depositary services
Registration or transfer fees	Transfer and registration of shares of our common stock on our share register to or from the name of the depositary or its agent when persons deposit or withdraw shares of our common stock
Expenses of the depositary	Cable and facsimile transmissions (when expressly provided in the deposit agreement) Converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares of our common stock underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes	As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares of our common stock or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

Payment of Taxes

ADS holders will be responsible for any taxes or other governmental charges payable on their ADSs or on the deposited securities represented by any of their ADSs. The depositary may refuse to register any transfer of ADSs or allow an ADS holder to withdraw the deposited securities represented by his or her ADSs until those taxes or other charges are paid. It may apply payments owed to such ADS holder or sell deposited securities represented by such ADS holder's ADSs to pay any taxes owed and such ADS holder will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.

Direct and Indirect Payments by the Depositary

Pursuant to contractual arrangements between us and the depositary in place through January 8, 2019, the depositary had previously agreed to reimburse us for certain costs and expenses generally arising out of the establishment and maintenance of the ADS program. Costs and expenses for which the depositary has agreed to reimburse us for the fiscal year ending March 31, 2019 (through January 8, 2019), were approximately $250,000.

Beginning on January 8, 2019, the depositary has agreed to make revenue sharing payments to us based on a fixed portion of the net issuance, net cancellation cash dividend and net depositary servicing fees received by it under the deposit agreement, subject to a minimum annual payment based on the total of such fees received by the depositary. No payments were received under this revenue sharing arrangement in the fiscal year ended March 31, 2019.

The depositary has also agreed to waive fees and expenses for services provided to us, to ADS holders or to their respective brokers by the depositary in connection with the establishment, administration and ongoing servicing of the ADS program. Furthermore, the depositary has agreed to waive fees for certain value-added services, including training for our staff, investor relations advisory services and access to the depositary's analytics and reporting platform. Accordingly, in the fiscal year ended March 31, 2019, the depositary waived approximately $52,000 of fees and expenses.

Item 13. Defaults, Dividend Arrearages and Delinquencies.

Not applicable.

Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds.

Not applicable.

Item 15. Controls and Procedures.

Disclosure Controls and Procedures

We have carried out an evaluation under the supervision and with the participation of our management, including our CEO and CFO, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act"), as of March 31, 2019. Disclosure controls and procedures require that information to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported as and when required, within the time periods specified in the applicable rules and forms, and that such information is accumulated and communicated to our management, including the CEO and CFO, as appropriate to allow timely decisions regarding required disclosure. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives. Based upon our evaluation, the CEO and CFO have concluded that, as of March 31, 2019, the disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

This annual report does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Attestation Report of the Registered Public Accounting Firm

This annual report does not include an attestation report of our registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal year ended March 31, 2019 that have materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

Item 16A. Audit Committee Financial Expert.

Our board of directors has determined that Mr. Koji Hatsukawa, an external director and member of our Audit and Supervisory Committee, is an "audit committee financial expert" as defined in Item 16A of Form 20-F and is "independent" as defined in the listing standards of the New York Stock Exchange as applicable through Rule 10A-3 under the Exchange Act.

Item 16B. Code of Ethics.

We have adopted the Takeda Global Code of Conduct, which applies to all of our employees, including our principal executive officer, principal financial officer, principal accounting officer and persons performing similar functions. The Takeda Global Code of Conduct is posted on our corporate website at http://www.takeda.com/who-we-are/corporate-governance/compliance. No waivers to the Global Code of Conduct were granted to our principal executive officer, principal financial officer, principal accounting officer and persons performing similar functions in the fiscal year ended March 31, 2019.

Item 16C. Principal Accountant Fees and Services.

Audit and Non-Audit Fees

The following table sets forth the fees billed to us by our independent certified public accountant, KPMG AZSA LLC (including its Japanese and non-Japanese affiliates), in the fiscal years ended March 31, 2018 and 2019:

	For the fiscal year ended March 31,	
	2018	2019
	(billions of yen)	
Audit fees [1]	¥ 1.43	¥ 3.75
Audit-related fees [2]	0.03	0.05
Tax fees [3]	0.03	0.01
Other fees	0.03	—
Total fees	¥ 1.52	¥ 3.81

Notes:
(1) Audit fees were related to the audit of our consolidated financial statements and other services provided in connection with statutory and regulatory filings or engagements.
(2) Audit-related fees were related to assurance services with respect to our debt issuances.
(3) Tax fees were related to tax compliance and other tax-related services.

Pre-Approval Policies and Procedures

Pursuant to Rule 2-01(c)(7)(i) of Regulation S-X, we have adopted policies and procedures under which all services (including permissible non-audit services) for which we or our subsidiaries engage our independent certified public accountant, KPMG AZSA LLC, and its affiliates must be approved by our Audit and Supervisory Committee prior to entering into an engagement.

All audit services are subject to the pre-approval by the Audit and Supervisory Committee in principle, regardless of monetary value. Audit services include statutory or financial statement audits for us and our subsidiaries, services associated with the audit of our management's report on internal controls over financial reporting and services associated with the review of our quarterly financial statements. On a yearly basis, our management, following a review by our Chief Financial Officer, presents the proposed audit services to our Audit and Supervisory Committee for approval, and proposes audit fees on an entity basis to the Audit and Supervisory Committee for its consent. Once such services and fees are approved or consented to, as applicable, any additional audit services must be separately presented to and approved by our Audit and Supervisory Committee.

Permissible non-audit services, which are limited to certain services permissible under applicable regulation and our internal rules, are pre-approved by the Audit and Supervisory Committee for individual services below ¥25 million annually, subject to an aggregate annual limit of up to ¥250 million for all such services. These services are subject to review by our management for compliance with our internal policies. All non-audit services exceeding the applicable monetary limits or which are not clearly within the scope of permitted non-audit services must be presented to and pre-approved by the Audit and Supervisory Committee. All services relating to tax or internal control are also subject to separate presentation to and pre-approval by the Audit and Supervisory Committee regardless of monetary value.

Item 16D. Exemptions from the Listing Standards for Audit Committees.

As of the date of this annual report, we do not rely on any of the exemptions contained in paragraph (b)(1)(iv), the general exemption contained in paragraph (c)(3) or the last sentence of paragraph (a)(3) of Rule 10A-3 under the Exchange Act ("Rule 10A-3").

Paragraph (b)(iv)(A)(2) of Rule 10A-3 permits a minority of the members of a listed issuer's audit committee to be exempt from the independence requirements under Rule 10A-3 for a period of one year from the date of effectiveness of such issuer's initial registration statement under Section 12 of the Exchange Act or the registration statement under the Securities Act covering an initial public offering of securities to be listed by such issuer. From the time of the effectiveness of our registration statement on Form 20-F on December 21, 2018 until the election of directors at of our most recent annual general meeting of shareholders held on June 27, 2019, we relied on this exemption with respect to the former membership of one of our

directors on our Audit and Supervisory Committee, which is our "audit committee" for the purposes of Rule 10A-3. Following such election of directors, each of the members of our Audit and Supervisory Committee now satisfy the independence requirements of Rule 10A-3. We do not believe that our reliance on this transitional exemption has materially affected the ability of our Audit and Supervisory Committee to act independently or satisfy any of the other requirements under Rule 10A-3.

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers.

The following table sets forth purchases of our common stock by us and our affiliated purchasers during the fiscal year ended March 31, 2019:

	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of publicly announced plans or programs	Maximum number of shares that may yet be purchased under the plans or programs
April 1 to April 30, 2018	228	¥ 5,091	—	—
May 1 to May 31, 2018	246,075	4,674	—	—
June 1 to June 30, 2018	299	4,303	245,800	—
July 1 to July 31, 2018	478	4,673	—	—
August 1 to August 31, 2018	381	4,711	—	—
September 1 to September 30, 2018	227	4,640	—	—
October 1 to October 31, 2018	517	4,674	—	—
November 1 to November 30, 2018	410	4,557	—	—
December 1 to December 31, 2018	424	3,856	—	—
January 1 to January 31, 2019	610	4,281	—	—
February 1 to February 28, 2019	484	4,403	—	—
March 1 to March 31, 2019	372	4,597	—	—
Total	250,505	¥ 4,671	245,800	—

Purchases in the above table reflect (1) purchases of shares in relation to stock-based incentive compensation plans and (2) purchases of shares constituting less than one "unit" (100 shares).

We have two stock-based incentive compensation plans for its directors and members of senior management, the Board Incentive Plan (the "BIP") and the Employee Stock Ownership Plan (the "ESOP"). See "Item 6.B. Directors, Senior Management and Employees-Compensation." For grants under the BIP, we, through a wholly-owned trust, buy shares of our common stock in the market on the grant date, and use these shares to settle awards. Grants under the ESOP have been settled using shares newly issued by us, although it is possible in the future that we will adopt a similar trust structure for the ESOP.

The wholly-owned trust purchases shares of our common stock using funds transferred to the trust by us (less trust fees and trust expenses) at the market price of the shares during the share purchase period. As the total number of shares therefore fluctuates with the market price of our shares, the total number of shares which may be purchased under the BIP is not given above.

In May 2018, we approved the transfer of approximately ¥1.09 billion to the wholly-owned trust and, in the same month, the wholly-owned trust used such funds to purchase 245,800 shares in respect of grants under the BIP. As of the date of this annual report, the transfer of a total of an additional ¥5 billion to the wholly-owned trust for the purpose of purchasing shares of our common stock at the market in order to settle grants under the BIP for the three fiscal years ending March 31, 2022 has been approved by our annual general meeting of shareholders. The wholly-owned trust is scheduled to purchase shares up to such amount, less trust fees and trust expenses, during the period from August 2, 2019 to the end of August 2019.

A total of 4,705 shares were purchased other than through publicly announced plans or programs during the fiscal year ended March 31, 2019, due to our purchase of shares constituting less than one "unit" (100 shares) from holders of shares constituting less than one unit at the current market price of those shares.

Item 16F. Change in Registrant's Certifying Accountant.

Not applicable.

Item 16G. Corporate Governance.

Our ADSs have been listed on the NYSE since 2018. NYSE-listed companies are required to comply with corporate governance standards under Section 303A of the NYSE Listed Company Manual. However, as a foreign private issuer, we are permitted to follow home country practices in lieu of certain provisions of Section 303A. Below, we provide a brief description of significant differences between the NYSE listing standards applicable to U.S. domestic issuers and our corporate governance policies pursuant to 303A.11 of the NYSE Listed Company Manual.

Composition of the Board (303A.01)

Under the NYSE listing standards, U.S. domestic issuers are required to have a majority of directors meeting the independence tests set forth in the NYSE listed company manual.

Takeda is a "company with audit and supervisory committee" as defined in the Companies Act. Companies with audit and supervisory committees are not required to have a majority of independent directors. Such companies must have a board of directors as well as an audit and supervisory committee consisting of at least three of its directors. A majority of the members of the audit and supervisory committee must be "external directors" as defined under the Companies Act, which differs from the director independence standards under the NYSE listed company manual. Additionally, under the regulations of the Tokyo Stock Exchange, we are required to have at least one director who is "independent" for the purposes of such regulations, which are more stringent than the requirements for "external directors" under the Companies Act.

Our board of directors consists of 16 directors, of which 11 are "external directors" under the Companies Act. Our Audit and Supervisory Committee is comprised of four of our directors, three of whom qualify as "external directors" under this standard. Each of our external directors also qualifies as "independent" as described under "Director Independence (303A.02)" below, and each of the members of our Audit and Supervisory Committee qualifies as "independent" for purposes of Rule 10A-3 under the Exchange Act.

Directors who are Audit and Supervisory Committee members are elected separately from our other directors. The term of office for a director who is an Audit and Supervisory Committee member is two years, whereas the term of office for other directors is one year.

Director Independence (303A.02)

We deem a director as being an "independent director" when such director also meets independence requirements stipulated in the regulations of the Tokyo Stock Exchange, on which our common stock is listed, and independence requirements established internally. These requirements differ in certain respects from the requirements under the NYSE listed company manual.

Executive Sessions (303A.03)

The NYSE listed company manual requires that non-management directors of U.S. domestic issuers meet in regularly scheduled executive sessions without management. Although not required under Japanese law or Tokyo Stock Exchange rule, our independent external directors hold regularly scheduled executive sessions without management.

Composition of Committees (303A.04, 05, 06 and 07)

The NYSE listed company manual requires that U.S. domestic issuers establish a nomination/corporate governance committee and a compensation committee, each of which much be composed entirely of independent directors. The NYSE listed company manual also requires that all listed companies, including a foreign private issuer (as defined in the Exchange Act) such as us, establish an audit committee satisfying the requirements of Rule 10A-3 under the Exchange Act. Audit committees of U.S. domestic issuers are also subject to certain additional requirements under Section 303A.07 of the NYSE listed company manual.

Although the Companies Act does not require companies with audit and supervisory committees to establish nomination committees or compensation committees, we have established such committees in order to ensure transparency. Our nomination committee consists of four directors (of which, three are independent external directors for the purposes of Japanese law and the rules of the Tokyo Stock Exchange). Director candidates nominated by our nomination committee must be approved at our general meeting of shareholders. Unlike the nomination/corporate governance committees of U.S. domestic issuers, our nomination committee is not also responsible for corporate governance policies.

Our compensation committee consists of three directors (of which, two are independent external directors for the purposes of Japanese law and the rules of the Tokyo Stock Exchange). The maximum total amount of compensation for our directors must be approved at our general meeting of shareholders, provided that the maximum total amounts for directors who are Audit and Supervisory Committee members and for other directors must be separately approved. The individual amounts of compensation for our directors (other than Audit and Supervisory Committee members) is determined in accordance with the compensation standards determined by our board of directors or a resolution of our board of directors. The individual amounts of compensation for our Audit and Supervisory Committee members are determined by discussion among the Audit and Supervisory Committee members.

Our Audit and Supervisory Committee consists of four directors (of which, three are independent external directors for the purposes of Japanese law and the rules of the Tokyo Stock Exchange), and all of whom currently satisfy the independence requirements of Rule 10A-3 under the Exchange Act. Our Audit and Supervisory Committee does not necessarily satisfy all of the additional audit committee requirements applicable to NYSE-listed U.S. domestic companies under Section 303A.07, nor is it required to under the standards applicable to foreign private issuers under Section 303A.

Equity Compensation Plans (303A.08)

U.S. domestic issuers listed on NYSE are required to obtain the approval of shareholders for equity compensation plans and any material changes thereto, subject to certain limited exceptions.

Under Japanese law and the regulations of the Tokyo Stock Exchange, the adoption of an equity compensation plan, including for directors, requires shareholder approval. Pursuant to the approval of our general meeting of shareholders, we grant certain stock-based compensation to the directors. Stock acquisition rights or shares of common stock may be granted by resolution of the board of directors, except that, if stock acquisition rights or shares of common stock are to be granted on particularly favorable conditions, a special resolution of the general meeting of shareholders is required. The passage of a special resolution of the general meeting of shareholders requires the approval of two-thirds or more of the voting rights represented at a quorate general meeting of shareholders.

Corporate Governance Guidelines (303A.09)

U.S. domestic issuers listed on the NYSE must adopt and disclose corporate governance guidelines as set forth in the NYSE listed company manual. Japanese law and the regulations of the Tokyo Stock Exchange require us to disclose our basic views on corporate governance. In accordance with these requirements, we publish our Corporate Governance Report annually, which is posted on our website and furnished to the SEC under cover of Form 6-K, although this may not necessarily cover all of the same items as contemplated by the NYSE listed company manual.

Code of Business Conduct and Ethics (303A.10)

U.S. domestic issuers listed on NYSE are required to adopt and disclose a code of business conduct and ethics for directors, officers and employees, and promptly disclose any waivers of the code for directors or executive officers. Although not required to do so under the NYSE listed company manual, we have established a global code of business conduct and ethics, known as the Takeda Global Code of Conduct, which is posted on our website. Although the Takeda Global Code of Conduct functions as a code of business conduct and ethics, it is not required to cover all of the same areas as that of a U.S. domestic issuer under the NYSE listed company manual. Pursuant to the requirements of Form 20-F, waivers, if any, to the Takeda Global Code of Conduct given to our directors or senior management are disclosed by us in our annual reports on Form 20-F.

Item 16H. Mine Safety Disclosure

Not applicable.

Item 17. Financial Statements

The Company has responded to Item 18 in lieu of this item.

Item 18. Financial Statements

The information required by this item is set forth in our consolidated financial statements included in this annual report.

Item 19. Exhibits

Exhibit No.	Exhibit
Exhibit 1.1	Articles of Incorporation of Takeda Pharmaceutical Company Limited (English Translation) (incorporated by reference to Exhibit 1.1 to Amendment No. 1 to the Registration Statement on Form 20-F of the registrant, filed on December 17, 2018).
Exhibit 1.2	Regulations of the Board of Directors of Takeda Pharmaceutical Company Limited (English Translation) (incorporated by reference to Exhibit 1.2 to Amendment No. 1 to the Registration Statement on Form 20-F of the registrant, filed on December 17, 2018).
Exhibit 1.3	Share Handling Regulations of Takeda Pharmaceutical Company Limited (English Translation) (incorporated by reference to Exhibit 1.3 to Amendment No. 1 to the Registration Statement on Form 20-F of the registrant, filed on December 17, 2018).
Exhibit 2.1	Form of Amended and Restated Deposit Agreement among the Takeda Pharmaceutical Company Limited, The Bank of New York Mellon, as Depositary, and all Owners and Holders from time to time of American Depositary Shares issued thereunder (incorporated by reference to Exhibit 2.1 to Amendment No. 1 to the Registration Statement on Form 20-F of the registrant, filed on December 17, 2018).
Exhibit 2.2	Indenture, dated as of September 23, 2016, among Shire Acquisitions Investments Ireland DAC, Shire plc, as guarantor, and Deutsche Bank Trust Company Americas, as trustee (incorporated by reference to Exhibit 4.1 of Shire plc's Current Report on Form 8-K filed on September 23, 2016).
Exhibit 2.3	First Supplemental Indenture, dated as of September 23, 2016, to the Indenture, dated as of September 23, 2016, among Shire Acquisitions Investments Ireland DAC, Shire plc, as guarantor, and Deutsche Bank Trust Company Americas, as trustee (incorporated by reference to Exhibit 4.2 of Shire plc's Current Report on Form 8-K filed on September 23, 2016).

Exhibit No.	Exhibit
Exhibit 2.4	Second Supplemental Indenture, dated as of December 1, 2016, to the Indenture dated as of September 23, 2016, among Shire Acquisitions Investments Ireland DAC, Shire plc, as guarantor, Baxalta Incorporated, as subsidiary guarantor, and Deutsche Bank Trust Company Americas, as trustee (incorporated by reference to Exhibit 4.1 of Shire plc's Current Report on Form 8-K filed on December 2, 2016).
Exhibit 2.5*	Third Supplemental Indenture, dated as of February 4, 2019, to the Indenture dated as of September 23, 2016, among Shire Acquisitions Investments Ireland DAC, Takeda Pharmaceutical Company Limited, as guarantor, Shire plc, as guarantor, Baxalta Incorporated, as subsidiary guarantor, and Deutsche Bank Trust Company Americas, as trustee.
Exhibit 2.6	Form of 1.900% Senior Notes due 2019 of Shire Acquisitions Investments Ireland DAC (incorporated by reference to Exhibit 4.1 of Shire plc's Current Report on Form 8-K filed on September 21, 2016).
Exhibit 2.7	Form of 2.400% Senior Notes due 2021 of Shire Acquisitions Investments Ireland DAC (incorporated by reference to Exhibit 4.2 of Shire plc's Current Report on Form 8-K filed on September 21, 2016).
Exhibit 2.8	Form of 2.875% Senior Notes due 2023 of Shire Acquisitions Investments Ireland DAC (incorporated by reference to Exhibit 4.3 of Shire plc's Current Report on Form 8-K filed on September 21, 2016).
Exhibit 2.9	Form of 3.200% Senior Notes due 2026 of Shire Acquisitions Investments Ireland DAC (incorporated by reference to Exhibit 4.4 of Shire plc's Current Report on Form 8-K filed on September 21, 2016).
Exhibit 2.10	Indenture between Baxalta Incorporated and The Bank of New York Mellon Trust Company, N.A., as Trustee, dated as of June 23, 2015 (incorporated by reference to Exhibit 4.1 of Baxalta Incorporated's Current Report on Form 8-K filed on June 23, 2015).
Exhibit 2.11	First Supplemental Indenture, to the Indenture dated as of June 23, 2015, between Baxalta Incorporated and The Bank of New York Mellon Trust Company, N.A., as Trustee, dated as of June 23, 2015 (incorporated by reference to Exhibit 4.2 of Baxalta Incorporated's Current Report on Form 8-K filed on June 23, 2015).
Exhibit 2.12	Second Supplemental Indenture, to the Indenture dated as of June 23, 2015, between Baxalta Incorporated, Shire plc and The Bank of New York Mellon Trust Company, N.A., as Trustee, dated as of June 3, 2016 (incorporated by reference to Exhibit 4.3 of Shire plc's Current Report on Form 8-K filed on June 3, 2016).
Exhibit 2.13*	Third Supplemental Indenture, to the Indenture dated as of June 23, 2015, between Baxalta Incorporated, Shire plc, Takeda Pharmaceutical Company Limited and The Bank of New York Mellon Trust Company, N.A., as Trustee, dated as of February 4, 2019.
Exhibit 2.14	Term Loan Credit Agreement among Takeda Pharmaceutical Company Limited, as Borrower, Various Financial Institutions, as Lenders, and JPMorgan Chase Bank, N.A., as Administrative Agent, dated as of June 8, 2018 (incorporated by reference to Exhibit 10.7 to Amendment No. 1 to the Registration Statement on Form 20-F of the registrant, filed on December 17, 2018).
Exhibit 2.15*	Amendment No. 1, dated as of December 20, 2018, to the Term Loan Credit Agreement among Takeda Pharmaceutical Company Limited, as Borrower, Various Financial Institutions, as Lenders, and JPMorgan Chase Bank, N.A., as Administrative Agent, dated as of June 8, 2018.
Exhibit 2.16	Fiscal Agency Agreement, dated as of November 21, 2018, between Takeda Pharmaceutical Company Limited and MUFG Bank, Ltd., as Fiscal Agent (incorporated by reference to Exhibit 10.11 to Amendment No. 1 to the Registration Statement on Form 20-F of the registrant, filed on December 17, 2018).
Exhibit 2.17	Indenture, dated as of November 26, 2018, between Takeda Pharmaceutical Company Limited and MUFG Union Bank, N.A., as Trustee (incorporated by reference to Exhibit 10.12 to Amendment No. 1 to the Registration Statement on Form 20-F of the registrant, filed on December 17, 2018).
Exhibit 2.18	Registration Rights Agreement, dated as of November 26, 2018, among Takeda Pharmaceutical Company Limited, J.P. Morgan Securities LLC, SMBC Nikko Securities America, Inc., Morgan Stanley MUFG Securities Co., Ltd., Mizuho Securities USA LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated, as representatives of the several initial purchasers (incorporated by reference to Exhibit 10.13 to Amendment No. 1 to the Registration Statement on Form 20-F of the registrant, filed on December 17, 2018).
Exhibit 2.19	Loan Agreement, dated December 3, 2018, between Takeda Pharmaceutical Company Limited and Japan Bank for International Cooperation (incorporated by reference to Exhibit 10.14 to Amendment No. 1 to the Registration Statement on Form 20-F of the registrant, filed on December 17, 2018).
Exhibit 2.20*	Amendment No. 1, dated as of December 25, 2018, to the Loan Agreement, dated December 3, 2018, between Takeda Pharmaceutical Company Limited and Japan Bank for International Cooperation.
Exhibit 2.21	(English Translation) Terms and Conditions of Hybrid Bonds issued by Takeda Pharmaceutical Company Limited on June 6, 2019 (incorporated by reference to Annex 1 to Exhibit 1 to the current report on Form 6-K of the Registrant furnished to the Commission on May 31, 2019).
Exhibit 2.22	A description of the rights of each class of securities that is registered under Section 12 of the Exchange Act as of the end of the period covered by this report. The information required hereby is incorporated by reference to Items 9, 10 and 12 of Amendment No. 1 to the Registration Statement on Form 20-F of the registrant, filed on December 17, 2018.
Exhibit 4.1**	Collaboration Agreement dated December 14, 2009 by and between Seattle Genetics, Inc. and Millennium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to Amendment No. 1 to the Registration Statement on Form 20-F of the registrant, filed on December 17, 2018).
Exhibit 4.2	Letter Agreement among Shire plc, Baxalta Incorporated and Baxter International Inc. dated January 11, 2016 (incorporated by reference to Exhibit 10.1 to Shire plc's Current Report on Form 8-K filed on January 11, 2016).
Exhibit 8.1	List of subsidiaries of Takeda Pharmaceutical Company Limited, as of March 31, 2019: See "Item 4. Information on the Company—C. Organizational Structure."

Exhibit No.	Exhibit
Exhibit 12.1*	Certification of the principal executive officer required by 17 C.F.R. 240. 13a-14(a).
Exhibit 12.2*	Certification of the principal financial officer required by 17 C.F.R. 240. 13a-14(a).
Exhibit 13.1*	Certification of the chief executive officer required by 18 U.S.C. Section 1350.
Exhibit 13.2*	Certification of the chief financial officer required by 18 U.S.C. Section 1350.

* Filed herewith.

** Pursuant to a request for confidential treatment, portions of this Exhibit have been redacted from the publicly filed document and have been furnished separately to the SEC as required by Rule 24b-2 under the Securities Exchange Act of 1934.

We have not included as exhibits certain instruments with respect to our long-term debt where the amount of debt authorized under each such debt instrument does not exceed 10% or our total assets. We will furnish a copy of any such instrument to the SEC upon request.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

TAKEDA PHARMACEUTICAL COMPANY LIMITED

By: /s/ Costa Saroukos

Name: Costa Saroukos

Title: Chief Financial Officer

Date: June 27, 2019

TAKEDA PHARMACEUTICAL COMPANY LIMITED AND ITS SUBSIDIARIES

Index

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors

Takeda Pharmaceutical Company Limited:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated statements of financial position of Takeda Pharmaceutical Company Limited and subsidiaries (the "Company") as of March 31, 2019 and 2018, the related consolidated statements of income, other comprehensive income, changes in equity, and cash flows for each of the years in the three-year period ended March 31, 2019, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of March 31, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the three-year period ended March 31, 2019, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG AZSA LLC

We have served as the Company's auditor since 2007.

Tokyo, Japan

June 27, 2019

TAKEDA PHARMACEUTICAL COMPANY LIMITED AND ITS SUBSIDIARIES

Consolidated Statements of Income for the Year Ended March 31,

	Note	JPY (millions, except per share data) 2017	2018	2019
Revenue	4	¥ 1,732,051	¥ 1,770,531	¥ 2,097,224
Cost of sales		(558,755)	(495,921)	(659,690)
Selling, general and administrative expenses		(619,061)	(628,106)	(717,599)
Research and development expenses		(312,303)	(325,441)	(368,298)
Amortization and impairment losses on intangible assets associated with products	12	(156,717)	(122,131)	(203,372)
Other operating income	5	143,533	169,412	159,863
Other operating expenses	5	(72,881)	(126,555)	(103,159)
Operating profit		155,867	241,789	204,969
Finance income	6	12,274	39,543	16,843
Finance expenses	6	(23,249)	(31,928)	(83,289)
Share of loss of investments accounted for using the equity method	14	(1,546)	(32,199)	(43,627)
Profit before tax		143,346	217,205	94,896
Income tax (expense) benefit	7	(27,833)	(30,497)	14,118
Net profit for the year		¥ 115,513	¥ 186,708	¥ 109,014
Attributable to:				
Owners of the Company	8	¥ 114,940	¥ 186,886	¥ 109,126
Non-controlling interests		573	(178)	(112)
Net profit for the year		¥ 115,513	¥ 186,708	¥ 109,014
Earnings per share (JPY)				
Basic earnings per share	8	¥ 147.15	¥ 239.35	¥ 113.50
Diluted earnings per share	8	146.26	237.56	112.86

See accompanying notes to consolidated financial statements.

TAKEDA PHARMACEUTICAL COMPANY LIMITED AND ITS SUBSIDIARIES

Consolidated Statements of Other Comprehensive Income for the Year Ended March 31,

	Note	JPY (millions) 2017	2018	2019
Net profit for the year		¥ 115,513	¥ 186,708	¥ 109,014
Other comprehensive income (loss)				
Items that will not be reclassified to profit or loss:				
Changes in fair value of financial assets measured at fair value through other comprehensive income	9	—	—	6,000
Remeasurement gain (loss) of defined benefit plans	9	15,554	724	(11,665)
		15,554	724	(5,665)
Items that may be reclassified subsequently to profit or loss:				
Exchange differences on translation of foreign operations	9	(51,820)	46,611	34,639
Net changes on revaluation of available-for-sale financial assets	9	9,521	4,714	—
Cash flow hedges	9	4,634	1,919	(33,793)
Hedging cost	9	(222)	1,606	(4,909)
Share of other comprehensive income (loss) of investments accounted for using the equity method	9, 14	(38)	382	(94)
		(37,925)	55,232	(4,157)
Other comprehensive income (loss) for the year, net of tax	9	(22,371)	55,956	(9,822)
Total comprehensive income for the year		¥ 93,142	¥ 242,664	¥ 99,192
Attributable to:				
Owners of the Company		¥ 93,552	¥ 242,444	¥ 99,456
Non-controlling interests		(410)	220	(264)
Total comprehensive income for the year		¥ 93,142	¥ 242,664	¥ 99,192

See accompanying notes to consolidated financial statements.

TAKEDA PHARMACEUTICAL COMPANY LIMITED AND ITS SUBSIDIARIES

Consolidated Statements of Financial Position as of March 31,

	Note	JPY (millions) 2018	2019
Assets			
Non-current assets:			
Property, plant and equipment	10	¥ 536,801	¥ 1,316,531
Goodwill	11	1,029,248	4,161,403
Intangible assets	12	1,014,264	4,860,368
Investments accounted for using the equity method	14	107,949	114,658
Other financial assets	15	196,436	192,241
Other non-current assets		77,977	87,472
Deferred tax assets	7	64,980	88,991
Total non-current assets		3,027,655	10,821,664
Current assets:			
Inventories	16	212,944	986,744
Trade and other receivables	17	420,247	741,907
Other financial assets	15	80,646	23,276
Income tax receivables		8,545	7,212
Other current assets		57,912	109,666
Cash and cash equivalents	18	294,522	702,093
Assets held for sale	19	3,992	479,760
Total current assets		1,078,808	3,050,658
Total assets		¥ 4,106,463	¥ 13,872,322

See accompanying notes to consolidated financial statements.

	Note	JPY (millions) 2018	2019
Liabilities and Equity			
Liabilities:			
Non-current liabilities:			
Bonds and loans	20	¥ 985,644	¥ 4,766,005
Other financial liabilities	21	91,223	235,786
Net defined benefit liabilities	22	87,611	156,513
Accrued income taxes		—	61,900
Provisions	23	28,042	35,364
Other non-current liabilities	24	68,300	75,174
Deferred tax liabilities	7	90,725	867,061
Total non-current liabilities		1,351,545	6,197,803
Current liabilities:			
Bonds and loans	20	18	984,946
Trade and other payables	25	240,259	327,394
Other financial liabilities	21	29,613	47,340
Accrued income taxes		67,694	119,485
Provisions	23	132,781	392,733
Other current liabilities	24	263,930	437,888
Liabilities held for sale	19	3,214	201,145
Total current liabilities		737,509	2,510,931
Total liabilities		2,089,054	8,708,734
Equity:			
Share capital		77,914	1,643,585
Share premium		90,740	1,650,232
Treasury shares		(74,373)	(57,142)
Retained earnings		1,557,307	1,569,365
Other components of equity		350,631	353,542
Other comprehensive income related to assets held for sale		(4,795)	—
Equity attributable to owners of the company		1,997,424	5,159,582
Non-controlling interests		19,985	4,006
Total equity		2,017,409	5,163,588
Total liabilities and equity		¥ 4,106,463	¥ 13,872,322

See accompanying notes to consolidated financial statements.

TAKEDA PHARMACEUTICAL COMPANY LIMITED AND ITS SUBSIDIARIES

Consolidated Statements of Changes in Equity

	JPY (millions)														
	Equity attributable to owners of the Company														
					Other components of equity										
	Share Capital	Share Premium	Treasury Shares	Retained Earnings	Exchange Differences on Translation of Foreign Operations	Changes in fair value of financial assets measured at fair value through other comprehensive income	Net Changes on Revaluation of Available-for-Sale Financial Assets	Cash Flow Hedges	Hedging Cost	Re-measurement Gain or Loss on Defined Benefit Plans	Total	Other comprehensive income related to assets held for sale	Total	Non-Controlling Interests	Total Equity
As of April 1, 2016	¥ 64,766	¥ 68,829	¥ (35,974)	¥1,523,127	¥ 272,361	¥ —	¥ 58,523	¥ (3,162)	¥ 222	¥ —	¥ 327,944	¥ —	¥1,948,692	¥ 62,511	¥ 2,011,203
Net profit for the year	—	—	—	114,940	—	—	—	—	—	—	—	—	114,940	573	115,513
Other comprehensive income (loss)	—	—	—	—	(50,811)	—	9,457	4,634	(222)	15,554	(21,388)	—	(21,388)	(983)	(22,371)
Comprehensive income (loss) for the year	—	—	—	114,940	(50,811)	—	9,457	4,634	(222)	15,554	(21,388)	—	93,552	(410)	93,142
Transactions with owners:															
Issuance of new shares	437	437	—	—	—	—	—	—	—	—	—	—	874	—	874
Acquisition of treasury shares	—	—	(23,117)	—	—	—	—	—	—	—	—	—	(23,117)	—	(23,117)
Disposal of treasury shares	—	(0)	4	—	—	—	—	—	—	—	—	—	4	—	4
Dividends (Note 26)	—	—	—	(141,804)	—	—	—	—	—	—	—	—	(141,804)	(1,910)	(143,714)
Changes in ownership	—	—	—	—	—	—	—	—	—	—	—	—	—	(5,487)	(5,487)
Transfers from other components of equity	—	—	—	15,554	—	—	—	—	—	(15,554)	(15,554)	—	—	—	—
Share-based compensation (Note 28)	—	15,322	—	—	—	—	—	—	—	—	—	—	15,322	—	15,322
Exercise of share-based awards (Note 28)	—	(9,615)	10,353	—	—	—	—	—	—	—	—	—	738	—	738
Total transactions with owners	437	6,144	(12,760)	(126,250)	—	—	—	—	—	(15,554)	(15,554)	—	(147,983)	(7,397)	(155,380)
As of March 31, 2017	¥ 65,203	¥ 74,973	¥ (48,734)	¥1,511,817	¥ 221,550	¥ —	¥ 67,980	¥ 1,472	¥ —	¥ —	¥ 291,002	¥ —	¥1,894,261	¥ 54,704	¥ 1,948,965

See accompanying notes to consolidated financial statements.

TAKEDA PHARMACEUTICAL COMPANY LIMITED AND ITS SUBSIDIARIES

Consolidated Statements of Changes in Equity

	JPY (millions)														
	Equity attributable to owners of the Company														
					Other components of equity										
	Share Capital	Share Premium	Treasury Shares	Retained Earnings	Exchange Differences on Translation of Foreign Operations	Changes in fair value of financial assets measured at fair value through other comprehensive income	Net Changes on Revaluation of Available-for-Sale Financial Assets	Cash Flow Hedges	Hedging Cost	Re-measurement Gain or Loss on Defined Benefit Plans	Total	Other comprehensive income related to assets held for sale	Total	Non-Controlling Interests	Total Equity
As of April 1, 2017	¥ 65,203	¥ 74,973	¥ (48,734)	¥ 1,511,817	¥ 221,550	¥ —	¥ 67,980	¥ 1,472	¥ —	¥ —	¥ 291,002	¥ —	¥ 1,894,261	¥ 54,704	¥ 1,948,965
Net profit for the year	—	—	—	186,886	—	—	—	—	—	—	—	—	186,886	(178)	186,708
Other comprehensive income	—	—	—	—	46,252	—	5,057	1,919	1,606	724	55,558	—	55,558	398	55,956
Comprehensive income for the year	—	—	—	186,886	46,252	—	5,057	1,919	1,606	724	55,558	—	242,444	220	242,664
Transactions with owners:															
Issuance of new shares	12,711	12,609	—	—	—	—	—	—	—	—	—	—	25,320	—	25,320
Acquisition of treasury shares	—	—	(41,545)	—	—	—	—	—	—	—	—	—	(41,545)	—	(41,545)
Disposal of treasury shares	—	0	1	—	—	—	—	—	—	—	—	—	1	—	1
Dividends (Note 26)	—	—	—	(142,120)	—	—	—	—	—	—	—	—	(142,120)	(2,189)	(144,309)
Changes in ownership	—	—	—	—	—	—	—	—	—	—	—	—	—	(32,750)	(32,750)
Transfers from other components of equity	—	—	—	724	—	—	—	—	—	(724)	(724)	—	—	—	—
Share-based compensation (Note 28)	—	18,610	—	—	—	—	—	—	—	—	—	—	18,610	—	18,610
Exercise of share-based awards (Note 28)	—	(15,452)	15,905	—	—	—	—	—	—	—	—	—	453	—	453
Transfers to other comprehensive income related to assets held for sale	—	—	—	—	4,795	—	—	—	—	—	4,795	(4,795)	—	—	—
Total transactions with owners	12,711	15,767	(25,639)	(141,396)	4,795	—	—	—	—	(724)	4,071	(4,795)	(139,281)	(34,939)	(174,220)
As of March 31, 2018	¥ 77,914	¥ 90,740	¥ (74,373)	¥ 1,557,307	¥ 272,597	¥ —	¥ 73,037	¥ 3,391	¥ 1,606	¥ —	¥ 350,631	¥ (4,795)	¥ 1,997,424	¥ 19,985	¥ 2,017,409

See accompanying notes to consolidated financial statements.

TAKEDA PHARMACEUTICAL COMPANY LIMITED AND ITS SUBSIDIARIES

Consolidated Statements of Changes in Equity

	JPY (millions)														
	Equity attributable to owners of the Company														
					Other components of equity										
	Share Capital	Share Premium	Treasury Shares	Retained Earnings	Exchange Differences on Translation of Foreign Operations	Changes in fair value of financial assets measured at fair value through other comprehensive income	Net Changes on Revaluation of Available-for-Sale Financial Assets	Cash Flow Hedges	Hedging Cost	Re-measurement Gain or Loss on Defined Benefit Plans	Total	Other comprehensive income related to assets held for sale	Total	Non-Controlling Interests	Total Equity
As of April 1, 2018	¥ 77,914	¥ 90,740	¥ (74,373)	¥1,557,307	¥ 272,597	¥ —	¥ 73,037	¥ 3,391	¥ 1,606	¥ —	¥ 350,631	¥ (4,795)	¥1,997,424	¥ 19,985	¥ 2,017,409
Cumulative effects of changes in accounting policies (Note 2)	—	—	—	15,401	—	84,672	(73,037)	(1,378)	—	—	10,257	—	25,658	(10)	25,648
Adjusted opening balance	77,914	90,740	(74,373)	1,572,708	272,597	84,672	—	2,013	1,606	—	360,888	(4,795)	2,023,082	19,975	2,043,057
Net profit for the year	—	—	—	109,126	—	—	—	—	—	—	—	—	109,126	(112)	109,014
Other comprehensive income (loss)	—	—	—	—	29,964	5,938	—	(33,793)	(4,909)	(11,665)	(14,465)	4,795	(9,670)	(152)	(9,822)
Comprehensive income (loss) for the year	—	—	—	109,126	29,964	5,938	—	(33,793)	(4,909)	(11,665)	(14,465)	4,795	99,456	(264)	99,192
Transactions with owners:															
Issuance of new shares	1,565,671	1,565,671	—	—	—	—	—	—	—	—	—	—	3,131,342	—	3,131,342
Acquisition of treasury shares	—	—	(1,172)	—	—	—	—	—	—	—	—	—	(1,172)	—	(1,172)
Disposal of treasury shares	—	(0)	3	—	—	—	—	—	—	—	—	—	3	—	3
Dividends (Note 26)	—	—	—	(142,697)	—	—	—	—	—	—	—	—	(142,697)	(169)	(142,866)
Changes in ownership	—	—	—	(2,337)	230	—	—	—	—	—	230	—	(2,107)	(15,536)	(17,643)
Transfers from other components of equity	—	—	—	32,565	—	(44,230)	—	—	—	11,665	(32,565)	—	—	—	—
Share-based compensation (Note 28)	—	20,102	—	—	—	—	—	—	—	—	—	—	20,102	—	20,102
Exercise of share-based awards (Note 28)	—	(26,281)	18,400	—	—	—	—	—	—	—	—	—	(7,881)	—	(7,881)
Basis adjustment related to acquisitions	—	—	—	—	—	—	—	34,739	4,715	—	39,454	—	39,454	—	39,454
Total transactions with owners	1,565,671	1,559,492	17,231	(112,469)	230	(44,230)	—	34,739	4,715	11,665	7,119	—	3,037,044	(15,705)	3,021,339
As of March 31, 2019	¥ 1,643,585	¥1,650,232	¥ (57,142)	¥1,569,365	¥ 302,791	¥ 46,380	¥ —	¥ 2,959	¥ 1,412	¥ —	¥ 353,542	¥ —	¥ 5,159,582	¥ 4,006	¥ 5,163,588

See accompanying notes to consolidated financial statements.

TAKEDA PHARMACEUTICAL COMPANY LIMITED AND ITS SUBSIDIARIES

Consolidated Statements of Cash Flows for the Year Ended March 31,

	Note	JPY (millions) 2017	2018	2019
Cash flows from operating activities:				
Net profit for the year		¥ 115,513	¥ 186,708	¥ 109,014
Depreciation and amortization		171,426	182,127	272,446
Impairment losses		51,361	13,544	10,120
Equity-settled share-based compensation		15,385	18,610	20,084
Gain on sales and disposal of property, plant and equipment		(129)	(434)	(45,220)
Gain on divestment of business and subsidiaries		(115,363)	(134,100)	(82,975)
Loss (gain) on liquidation of foreign operations		—	41,465	(2,669)
Change in fair value of contingent consideration liabilities		(18,441)	10,523	(5,966)
Finance (income) expenses, net		10,975	(7,615)	66,446
Share of loss of associates accounted for using the equity method		1,546	32,199	43,627
Income tax expenses (benefit)		27,833	30,497	(14,118)
Changes in assets and liabilities:				
Increase in trade and other receivables		(37,315)	(647)	(13,382)
Decrease in inventories		3,886	13,719	58,678
Increase (decrease) in trade and other payables		42,557	6,862	(16,413)
Increase (decrease) in provisions		20,547	(6,530)	47,063
Other, net		12,333	20,809	(73,347)
Cash generated from operations		302,114	407,737	373,388
Income taxes paid		(53,227)	(54,874)	(51,536)
Tax refunds and interest on tax refunds received		12,476	24,991	6,627
Net cash from operating activities		261,363	377,854	328,479
Cash flows from investing activities:				
Interest received		2,001	2,412	6,305
Dividends received		3,674	7,699	2,739
Acquisition of property, plant and equipment		(61,660)	(67,005)	(77,677)
Proceeds from sales of property, plant and equipment		2,629	2,965	50,717
Acquisition of intangible assets		(50,367)	(61,257)	(56,437)
Acquisition of investments		(12,106)	(16,883)	(17,099)
Proceeds from sales and redemption of investments		5,268	40,743	65,035
Acquisition of business, net of cash and cash equivalents acquired	31	(589,144)	(28,328)	(2,958,686)
Proceeds from sales of business, net of cash and cash equivalents divested		64,405	85,080	85,131
Payments into restricted deposits		—	(71,774)	—
Proceeds from withdrawal of restricted deposits		—	—	71,844
Payments into time deposits		(70,000)	—	—
Proceeds from withdrawal of time deposits		70,000	—	—
Other, net		(20,391)	13,006	(7,570)
Net cash used in investing activities		(655,691)	(93,342)	(2,835,698)
Cash flows from financing activities:				
Net increase (decrease) in short-term loans	27	406,971	(403,931)	367,319
Proceeds from bonds and long-term loans	27	260,226	393,453	2,795,926
Repayments of bonds and long-term loans	27	(191,763)	(140,000)	—
Purchase of treasury shares		(23,117)	(18,756)	(1,172)
Interest paid		(6,971)	(8,365)	(34,914)
Dividends paid		(141,688)	(141,893)	(142,952)
Acquisition of non-controlling interests		(4,822)	—	(2,392)
Repayments of obligations under finance lease	27	(4,013)	(2,658)	(1,741)
Facility fees paid for loan agreements		—	—	(19,507)
Other, net		(4,927)	(4,076)	(14,330)
Net cash from (used in) financing activities		289,896	(326,226)	2,946,237
Net increase (decrease) in cash and cash equivalents		(104,432)	(41,714)	439,018
Cash and cash equivalents at the beginning of the year (Consolidated statements of financial position)	18	451,426	319,455	294,522
Cash and cash equivalents reclassified back from assets held for sale	19	—	21,797	451
Cash and cash equivalents at the beginning of the year		451,426	341,252	294,973
Effects of exchange rate changes on cash and cash equivalents		(5,742)	(4,565)	(31,269)
Cash and cash equivalents at the end of the year		341,252	294,973	702,722
Cash and cash equivalents reclassified to assets held for sale	19	(21,797)	(451)	(629)
Cash and cash equivalents at the end of the year (Consolidated statements of financial position)	18	319,455	294,522	702,093

See accompanying notes to consolidated financial statements.

Notes to Consolidated Financial Statements

1. Reporting Entity

Takeda Pharmaceutical Company Limited (the "Company") is a public company incorporated in Japan. The Company and its subsidiaries (collectively, "Takeda") is a global, values-based, research and development ("R&D") driven biopharmaceutical company with an innovative portfolio, engaged primarily in the research, development, manufacturing and marketing of pharmaceutical products. Takeda's principal pharmaceutical products include medicines in the following core business areas: gastroenterology ("GI"), rare diseases, plasma-derived therapies, oncology, and neuroscience.

Takeda has grown both organically and through acquisitions, completing a series of major transactions that have brought therapeutic, geographic and pipeline growth, specifically the acquisition of Shire plc ("Shire") in January 2019 for 6,213,335 million JPY (Note 31). Shire was a leading global biotechnology company focused on serving people with rare diseases and other highly specialized conditions.

2. Basis of Preparation

Compliance with International Financial Reporting Standards

Takeda's consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board ("IASB"). The term IFRS also includes International Accounting Standards ("IASs") and the related interpretations of the interpretations committees ("SIC" and "IFRIC").

Approval of Financial Statements

The Company's consolidated financial statements as of and for the year ended March 31, 2019 were approved on June 27, 2019 by Representative Director, President & Chief Executive Officer ("CEO") Christophe Weber and Director & Chief Financial Officer ("CFO") Costa Saroukos.

Basis of Measurement

The consolidated financial statements have been prepared on a historical cost basis, except for certain assets and liabilities recorded at fair value including investments, derivatives, and contingent considerations.

Functional and Presentation Currency

The consolidated financial statements are presented in Japanese Yen **("**JPY**"),** which is the functional currency of the Company. All financial information presented in JPY has been rounded to the nearest million JPY, except when otherwise indicated.

New Accounting Standards and Interpretations Adopted

During the year ended March 31, 2019, Takeda has adopted the following new accounting standards:

IFRS 9 Financial instruments ("IFRS 9")

IFRS 9 was issued in its final form in July 2014 and has been implemented by Takeda as of April 1, 2018. IFRS 9 replaces the majority of the requirements of IAS 39 'Financial Instruments: Recognition and Measurement' ("IAS 39") and covers the recognition, classification, measurement and de-recognition of financial assets and financial liabilities; introduces a new impairment model for financial assets based on expected losses rather than incurred losses and provides a new hedge accounting model. The principal impact for Takeda was the re-measurement of certain available-for-sale financial instruments to fair value on initial application on April 1, 2018.

Takeda applied IFRS 9 with respect to classification and measurement (including impairment) without restating previous years, with the exception of hedge accounting impacts which generally have been applied prospectively. The cumulative effects of initially applying IFRS 9 were recognized in equity as of the date of initial application of IFRS 9 (April 1, 2018). As a result of the adoption on the date of initial application, the opening balance of retained earnings and other components of equity increased by 14,073 million JPY and 10,257 million JPY, respectively, while other financial assets (non-current), other financial assets (current), and deferred tax liabilities increased by 32,809 million JPY, 856 million JPY and 9,345 million JPY, respectively, and non-controlling interests decreasing by 10 million JPY. Comparative period presented for 2017 and 2018 has not been updated as a result of the adoption of IFRS 9, with the exception of hedge accounting impacts. See Note 3 for further details on the accounting policy under IAS 39 and IFRS 9.

Takeda elected to designate irrevocably all of its equity instruments as financial assets measured at fair value through other comprehensive income (FVTOCI). This designation has been made based on the Company's intent to hold these investments for the foreseeable future. Changes in the fair

value of financial assets at FVTOCI are recognized in other comprehensive income, and the cumulative amount of the other comprehensive income is transferred to retained earnings when the instruments are derecognized due to liquidation or sale.

The classification of other financial assets under IFRS 9 is generally based on the business model in which a financial asset is managed and its contractual cash flow characteristics. The determination of the business model has been made based on the facts and circumstances that existed at the date of initial application.

The impairment of financial assets measured at amortized cost is assessed using an expected credit loss (ECL) model where previously the incurred loss model was used. There was no significant impact on the impairment of receivables upon the adoption of the new standard.

Takeda has not designated any financial liabilities as at fair value through profit or loss. There are no changes in classification and measurement for Takeda's financial liabilities following the adoption of IFRS 9.

The adoption of IFRS 9 has not had a material impact on Takeda's financial liabilities and derivatives.

The new hedge accounting model introduced by the standard requires hedge accounting relationships to be based upon Takeda's own risk management objectives and strategy, and to apply a more qualitative and forward-looking approach to assessing hedge effectiveness. The model is to be discontinued only when the hedging relationships no longer qualify for hedge accounting. All hedging relationships designated under IAS 39 as of March 31, 2018 met the criteria for hedge accounting under IFRS 9 as of April 1, 2018, and are therefore regarded as continuing hedging relationships.

In addition, under IAS 39, the currency basis spread was included in cash flow hedges under other component of equity. Under IFRS 9, this basis spread and time value of the currency options are separately accounted for and presented as hedging cost under other component of equity. The hedge accounting impacts from IFRS 9 are generally applied prospectively, with the exception of certain aspects being treated retrospectively. Takeda retrospectively applied the accounting treatment of hedging cost and adjusted the comparative information. The amounts retrospectively recorded as hedging cost resulted in a 222 million JPY increase to and a 1,606 million JPY deduction from cash flow hedge reserves as of March 31, 2017 and 2018, respectively.

Classification and carrying amounts of financial assets under IAS 39 and IFRS 9 as of the date of adoption were changed as presented in the table below.

		JPY (millions)			JPY (millions)
	IAS 39	**Carrying Amount**	**IFRS 9**	**Carrying Amount**	
Cash and cash equivalents	Loans and receivables	¥ 294,522	Financial assets measured at amortized cost	¥	294,522
Derivative assets	Financial assets measured at fair value through profit or loss	762	Financial assets measured at fair value through profit or loss		762
Derivative assets to which hedge accounting is applied	Derivative assets to which hedge accounting is applied	2,527	Derivative assets to which hedge accounting is applied		2,527
Trade and other receivables, other financial assets	Loans and receivables	516,853	Financial assets measured at amortized cost		516,853
Equity instruments	Available-for-sale financial assets	169,814	Financial assets measured at fair value through other comprehensive income		203,276
Convertible notes	Loans and receivables	5,303	Financial assets measured at fair value through profit or loss		7,576
	Financial assets measured at fair value through profit or loss	2,070			
Total		**¥ 991,851**		**¥**	**1,025,516**

The following changes were made to the carrying amount of the financial assets as of the application date.

	JPY (millions)				JPY (millions)
IAS 39	Carrying Amount	Re-Classification	Re-Measurement	IFRS 9	Carrying Amount
Loans and receivables	¥ 816,678	¥ (5,303)	¥ —	Financial assets measured at amortized cost	¥ 811,375
Financial assets measured at fair value through profit or loss	2,832	5,303	203	Financial assets measured at fair value through profit or loss	8,338
Derivative assets to which hedge accounting is applied	2,527	—	—	Derivative assets to which hedge accounting is applied	2,527
Available-for-sale financial assets	169,814	—	33,462	Financial assets measured at fair value through other comprehensive income	203,276
Total	**¥ 991,851**	**¥ —**	**¥ 33,665**		**¥ 1,025,516**

IFRS 15 Revenue from Contracts with Customers ("IFRS 15")

Takeda adopted IFRS 15 on April 1, 2018. The new standard provides a single, principles-based approach to the recognition of revenue from all contracts with customers. The standard focuses on the identification of performance obligations in a contract and requires revenue to be recognized when or as those performance obligations are satisfied. The standard also has more detailed disclosure requirements. IFRS 15 did not have a material impact on the amount or timing of recognition of revenue.

The amount and timing of the recognition of sales and the basis for the estimates of sales deductions generally remained consistent as it relates to revenue derived from the sale of pharmaceutical products.

The previous revenue recognition for considerations received related to revenue received from out-licensing agreements required the transfer of ownership and related royalty income to be recognized on an accrual basis in accordance with the substance of the agreement as remaining performance obligations. The basis of allocation to the transfer of ownership and an allocation of revenue over the remaining performance obligations, and therefore timing of recognition for consideration received, has changed as a result of adoption. The impact of this change is not material.

Takeda elected the modified retrospective method upon adoption of IFRS 15, which requires the recognition of the cumulative effect of initially applying IFRS 15 in opening equity at the date of initial application. As a result of the adoption of IFRS 15, due to the difference in allocation of revenue to performance obligations for considerations received related to out-licensing agreements, other non-current liabilities, other current liabilities, and deferred tax assets decreased by 1,247 million JPY, 495 million JPY and 414 million JPY respectively, and opening retained earnings increased by 1,328 million JPY.

For the year ended March 31, 2019, the impact from adoption of IFRS 15 on the consolidated financial statements was immaterial compared to the consolidated financial statements under IAS 18.

New Accounting Standards and Interpretations Issued and Not Yet Adopted

New or amended accounting standards and interpretations that have been issued as of the date of approval of the consolidated financial statements but are not effective and have not yet been adopted by Takeda as of March 31, 2019 are discussed below:

IFRS 16 Leases ("IFRS 16")

The standard will require lease liabilities and right of use (ROU) assets to be recognized on the balance sheet for almost all leases. Of the costs from operating leases currently included within cost of sales, selling, general and administrative expenses, research and development expenses, and other operating expenses, the portion related to the financing element will be reclassified and reported as finance expenses. In the statement of cash flow, the lease payments currently included within cash outflows from operating activities will be reported within cash flows from financing activities. IFRS 16 is effective for Takeda on April 1, 2019.

As a lessee, this standard can be applied retrospectively to each prior reporting period (retrospective approach) or retrospectively with the cumulative effect of initially applying this standard recognized at the date of initial application (modified retrospective approach). Takeda has elected to apply the standard applying the modified retrospective approach. Under the modified retrospective approach, the lease liabilities will be measured at the present value of the remaining lease payments, discounted at the incremental borrowing rate as of April 1, 2019. The ROU assets will be recognized at an amount equal to the lease liability, adjusted for any prepaid or accrued lease payments, onerous lease provisions and business combination related fair value adjustments.

On April 1, 2019, Takeda expects to recognize additional lease liabilities of approximately 220 billion JPY and corresponding ROU assets of approximately 200 billion JPY excluding existing finance leases. The additional liabilities and ROU assets include the impact of the operating leases obtained as a result of the Shire Acquisition.

IFRIC 23 Uncertainty over Income Tax Treatments ("IFRIC 23")

The interpretation clarifies that if it is considered probable that a tax authority will accept an uncertain tax treatment, the tax charge should be calculated on that basis. If it is not considered probable, the effect of the uncertainty should be estimated and reflected in the tax charge. In assessing the uncertainty, it is assumed that the tax authority will have full knowledge of all information related to the matter. IFRIC 23 is effective for Takeda on April 1, 2019.

Other Standards

In addition, the following amendments and interpretations have been issued:

- Amendments to IFRS 10 and IAS 28 'Sale or Contribution of Assets between an Investor and its Associate or Joint Venture'. The IASB has deferred these amendments until a date to be determined by the IASB.
- Amendments to IFRS 9: Prepayment Features with Negative Compensation
- Amendments to IAS 19: Plan Amendment, Curtailment or Settlement
- Amendments to IAS 28: Long-term interests in associates and joint ventures
- Annual Improvements 2015-2017 Cycle (issued in December 2017) including improvements to IFRS 3 Business Combinations, IFRS 11 Joint Arrangements, IAS 12 Income Taxes and IAS 23 Borrowing Costs

The adoption of the amendments to IFRIC 23 and these additional amendments and interpretations are not expected to have a significant impact on Takeda's consolidated financial statements. For those amendments and interpretations where early adoption is permitted, Takeda does not plan to early adopt.

Use of Judgments, Estimates, and Assumptions

The preparation of consolidated financial statements in accordance with IFRS requires management to make certain judgments, estimates, and assumptions that affect the application of accounting policies and the reported amount of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities. Actual results could differ from these estimates.

These estimates and underlying assumptions are reviewed on a continuous basis. Changes in these accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

Information about judgments and estimates that have been made in the process of applying accounting policies and that have significant effects on the amounts reported in the consolidated financial statements, and information about accounting estimates and assumptions that have significant effects on the amounts reported in the consolidated financial statements, are as follows:

- Recognition and measurement of taxes based on uncertain tax positions (Note 7)
- Recoverability of deferred tax assets (Note 7)
- Impairment of property, plant and equipment; goodwill; and other intangible assets (Note 10, Note 11, and Note 12, respectively)
- Measurement of fair value of assets acquired and liabilities assumed and contingent consideration in business combinations (Note 21 and Note 31)
- Measurement of defined benefit obligations (Note 22)
- Measurement of provisions, including estimation of rebates and return reserves associated with Takeda's product sales (Note 23)
- Valuation assumptions relating to share-based compensation (Note 28)
- Probability of an outflow of resources embodying economic benefits on contingent liabilities (Note 32)

3. Significant Accounting Policies

Basis of Consolidation

The consolidated financial statements include the accounts of the Company and its subsidiaries that are directly or indirectly controlled by the Company. All significant intercompany balances and transactions have been eliminated in consolidation.

Takeda controls an entity when it is exposed or has rights to variable returns from involvement with the entity and has the ability to affect those returns using its power, which is the current ability to direct the relevant activities, over the entity. To determine whether Takeda controls an entity, status of voting rights or similar rights, contractual agreements and other specific factors are considered.

The financial statements of the subsidiaries are included in the consolidated financial statements from the date when control is obtained until the date when control is lost. The financial statements of subsidiaries have been adjusted in order to ensure consistency with the accounting policies adopted by the Company as necessary.

Changes in ownership interest in subsidiaries that do not result in loss of control are accounted for as equity transactions. Any difference between the adjustment to non-controlling interests and the fair value of consideration transferred or received, is recognized directly in equity attributable to owners of the Company. When control over a subsidiary is lost, the investment retained after the loss of control is re-measured at fair value as of the date when control is lost, and any gain or loss on such re-measurement and disposal of the interest sold is recognized in profit or loss.

Investments in Associates and Joint Arrangements

Associates are entities over which Takeda has significant influence over the decisions on financial and operating policies, but does not have control or joint control. Investments in associates are accounted for using the equity method and recognized at cost on the acquisition date. The carrying amount is subsequently increased or decreased to recognize Takeda's share of profit or loss and other comprehensive income of the affiliate. Intra-group profits on transactions with associates accounted for using the equity method are eliminated against the investment to the extent of Takeda's equity interest in the associates. Intra-group losses are eliminated in the same way as intra-group profits unless there is evidence of impairment.

Joint arrangement is an arrangement of which two or more parties have joint control. Joint control is the contractually agreed sharing of control of an arrangement, which exists only when decisions about the relevant activities require the unanimous consent of the parties sharing control. Takeda classifies joint arrangement into either joint operations or joint ventures. The classification of a joint arrangement as a joint operation or a joint venture depends upon the rights and obligations of the parties to the arrangement. Joint operation is a joint arrangement whereby the parties that have joint control of the arrangement have rights to the assets, and obligations for the liabilities, relating to the arrangement. Joint venture is a joint arrangement whereby the parties that have joint control of the arrangement have rights to the net assets of the arrangement. The assets, liabilities, revenues and expenses in joint operations are recognized in relation to Takeda's interest. The investment in joint ventures is accounted for using the equity method. At each reporting date, the Company determines whether there is objective evidence that the investment in the associate or joint venture is impaired. If there is such evidence, the Company calculates the amount of impairment as the difference between the recoverable amount of the associate or joint venture and its carrying value, and then recognizes the loss within profit or loss.

Business Combinations

Business combinations are accounted for using the acquisition method. The identifiable assets acquired and the liabilities assumed are measured at the fair values at the acquisition date. Goodwill is measured as the excess of the sum of the fair value of consideration transferred, the amount of any non-controlling interests in the acquiree and the fair value of the acquirer's previously held equity interest in the acquiree less the fair value of identifiable assets acquired, net of liabilities assumed at the acquisition date. As part of business combinations, when the acquired entity consists of foreign operations with multiple functional currencies, Takeda allocates goodwill recognized upon the acquisition to the foreign operations based on the estimated cash flows of the acquired foreign operations.

The consideration transferred for the acquisition of a subsidiary is measured as the fair value of the assets transferred, the liabilities incurred to former owners of the acquiree, and the equity interests issued by Takeda. Non-controlling interests is initially measured either at fair value or at the non-controlling interests' proportionate share of the recognized amounts of the acquiree's identifiable net assets on a transaction-by-transaction basis. The consideration for certain acquisitions includes amounts contingent upon future events, such as the achievement of development milestones and sales targets.

Any contingent consideration included in the consideration payable for a business combination is recorded at fair value at the date of acquisition. These fair values are generally based on risk-adjusted future cash flows discounted using appropriate discount rates. The fair values are reviewed at the end of each reporting period. The changes in the fair value based on the time value of money are recognized in finance expenses and the other changes are recognized in other operating income or other operating expenses in the consolidated statements of income.

Acquisition related costs are recognized as expenses in the period they are incurred. Changes in Takeda's ownership interests in subsidiaries arising from transactions between Takeda and non-controlling interests that do not result in Takeda losing control over a subsidiary are treated as equity transactions and therefore, do not result in adjustments to goodwill.

Foreign Currency Translations

Foreign Currency Transactions

Foreign currency transactions are translated into the functional currency of each entity within Takeda using the exchange rates at the dates of the transactions or rates that approximate the exchange rates at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated into the functional currency using the spot rates of exchange at the end of each reporting period. Non-monetary assets and liabilities that are measured at fair value in foreign currencies are translated using historical exchange rates at the date when the fair value was determined. Non-monetary assets and liabilities measured based on historical cost that are denominated in foreign currencies are translated at the exchange rate at the date of the initial transaction. Exchange differences arising from the translation or settlement are recognized in profit or loss except when related to financial assets measured at fair value through other comprehensive income, as well as financial instruments designated as hedges of net investments in foreign operations and cash flow hedges subsequently recognized as other comprehensive income. The gain or loss arising from translation of non-monetary items measured at fair value is treated in line with the recognition of the gain or loss on the change in fair value of the item (i.e., translation differences on items whose fair value gain or loss is recognized in other comprehensive income or profit or loss, are also recognized in other comprehensive income or profit or loss, respectively).

Foreign Operations

The assets and liabilities of foreign operations are translated using the spot exchange rates at the end of the reporting period, while income and expenses of foreign operations presented in profit or loss and other comprehensive income are translated using the exchange rates at the dates of the transactions or rates that approximate the exchange rates at the dates of the transactions.

Exchange differences arising from translation are recognized as other comprehensive income. In cases in which foreign operations are disposed of, the cumulative amount of exchange differences related to the foreign operations is recognized as part of the gain or loss on disposal.

Revenue

Revenue on sales of Takeda products and services is recognized when control of the products is passed to the customer in an amount that reflects the consideration to which we expect to be entitled in exchange for those products. Control is generally transferred at the point in time of shipment to or receipt of the products by customer, or when the services are performed. The amount of revenue to be recognized is based on the consideration Takeda expects to receive in exchange for its goods and services. If a contract contains more than one contractual promise to a customer (performance obligation), the consideration is allocated based on the standalone selling price of each performance obligation.

The consideration Takeda receives in exchange for its goods or services may be fixed or variable. Variable consideration is only recognized when it is highly probable that a significant reversal will not occur. The most common elements of variable consideration are listed below:

- Rebates and discounts granted to government agencies, wholesalers, retail pharmacies, managed healthcare organizations and other customers are estimated and recorded as a deduction from revenue at the time the related revenues are recorded. They are calculated on the basis of historical experience and the specific terms in the individual agreements.
- Cash discounts are offered to customers and are provisioned and recorded as revenue deductions at the time the related sales are recorded.
- Sales return provisions are recognized when Takeda sells a product which provides the customer a right of return. Sales return provisions are recorded as revenue deductions when there is historical experience of Takeda agreeing to customer returns and Takeda can reasonably estimate expected future returns. In doing so, the estimated rate of return is applied, determined based on historical experience of customer returns and considering any other relevant factors. The rate is multiplied by the amounts invoiced in order to estimate expected future returns.

Takeda generally receives payments from customers within 120 days after the point in time when goods are delivered to the customers. Takeda usually performs those transactions as a principal, but Takeda also sells products on behalf of others, and revenue is recognized at an amount of sales commission that Takeda expects to be entitled as an agent.

Takeda also generates revenue in the form of royalty payments, upfront payments, and milestone payments from the out-licensing of intellectual property (IP). Royalty revenue earned through a license is recognized when the underlying sales have occurred. Revenue from upfront payment is generally recognized when Takeda provides a right to use IP. Revenue from milestone payments is recognized at the point in time when it is highly probable that the respective milestone event criteria is met, and a significant reversal in the amount of revenue recognized will not occur. Revenue from other services such as research and development of compounds that are out-licensed is recognized over the service period.

Takeda generally receives payments from customers within 60 days after entering into out-licensing contracts or confirmation by customers that conditions for the milestone payments are met. Takeda licenses its own intellectual property rights to customers, and performed those transactions as a principal. Takeda also provides other services as a principal.

Government Grants

Government grants are recognized when there is reasonable assurance that Takeda will comply with the conditions attached to them and receive the grants. Government grants for the purchasing of property, plant and equipment are recognized as deferred income and then recognized as profit or loss and offset the related expenses on a systematic basis over the useful lives of the related assets.

Government grants for expenses incurred are recognized as profit or loss and offset the related expenses over the periods in which Takeda recognizes costs for which the grants are intended to compensate.

Advertising and Sales Promotion Expenses

Costs of advertising and sales promotion are expensed as incurred. Advertising and sales promotion expense was 112,842 million JPY, 115,708 million JPY, and 106,755 million JPY for the years ended March 31, 2017, 2018 and 2019, respectively.

Research and Development Expenses

Research costs are expensed in the period incurred. Internal development expenditures are capitalized when the criteria for recognizing an asset are met in accordance with IAS 38 ‘Intangible Assets,’ usually when a regulatory filing has been made in a major market and approval is considered highly probable. Where regulatory and other uncertainties are such that the criteria are not met, the expenditures are recognized in the income statement. Property, plant and equipment used for research and development is capitalized and depreciated over the estimated life of the asset.

Income Taxes

Income taxes consist of current taxes and deferred taxes. Current and deferred taxes are recognized in profit or loss, except for income taxes resulting from business combinations, and income taxes recognized in either other comprehensive income or equity related to items that are recognized, in the same or different period, outside of profit or loss.

Current Taxes

The current tax payable or receivable is based on taxable profit for the year. Taxable profit differs from reported profit because taxable profit excludes items that are either never taxable or tax deductible or items that are taxable or tax deductible in a different period. Accrued income taxes and income tax receivable, including those from prior fiscal years, are measured at the amount that is expected to be paid to or received from the taxation authorities, reflecting uncertainty related to income taxes, if any. Takeda's current taxes also include liabilities related to uncertain tax positions. Takeda's current tax assets and liabilities are calculated using tax rates that have been enacted or substantively enacted by the reporting date.

Deferred Taxes

Deferred taxes are calculated based on the temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes at the end of the reporting period. Deferred tax assets are recognized for deductible temporary differences, unused tax credits and unused tax losses to the extent that it is probable that future taxable profit will be available against which the assets can be utilized. This requires us to evaluate and assess the probability of future taxable profit and our business plan, which are inherently uncertain. Uncertainty of estimates of future taxable profit could increase due to changes in economies in which we operate, changes in market conditions, effects of currency fluctuations, or other factors. Takeda's deferred taxes also include liabilities related to uncertain tax positions. Deferred tax liabilities are generally recognized for taxable temporary differences.

Deferred tax assets and liabilities are not recognized for the following temporary differences:

- Taxable temporary differences arising on the initial recognition of goodwill
- The initial recognition of assets and liabilities in transactions that are not business combinations and affect neither accounting profit nor taxable profit (loss) at the time of the transaction
- Deductible temporary differences arising from investments in subsidiaries and associates, when it is not probable that the temporary differences will reverse in the foreseeable future and that taxable profit will be available against which the temporary differences can be utilized
- Taxable temporary differences arising from investments in subsidiaries and associates when the timing of the reversal of the temporary differences is controllable and it is not probable that they will reverse in the foreseeable future

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the periods in which the temporary differences are expected to reverse based on the tax rates and tax laws that have been enacted or substantively enacted by the end of the reporting period. Deferred tax assets and liabilities are offset when there is a legally enforceable right to offset current tax assets against current tax liabilities and the deferred tax assets and liabilities for those related to income taxes levied by the same taxation authority on the same taxable entity.

Earnings per Share

Basic earnings per share is calculated by dividing profit or loss for the year attributable to owners of ordinary shares of the Company, by the weighted-average number of ordinary shares outstanding during the reporting period, adjusted by the number of treasury shares. Diluted earnings per share is calculated by adjusting all the effects of dilutive potential ordinary shares.

Property, Plant and Equipment

Property, plant and equipment are measured using the cost model and is stated at cost less accumulated depreciation and accumulated impairment loss. Acquisition cost includes mainly the costs directly attributable to the acquisition and the initial estimated dismantlement, removal, and restoration costs associated with the asset. Except for assets that are not subject to depreciation, such as land and construction in progress, assets are depreciated mainly using the straight-line method over the estimated useful life of the asset. Leased assets are depreciated using the straight-line method over the shorter of the lease term or the estimated useful life unless it is reasonably certain that Takeda will obtain ownership by the end of the lease term. The depreciation of these assets begins when they are available for use.

The estimated useful life of major asset items is as follows:

- Buildings and structures 3 to 50 years
- Machinery and vehicles 2 to 20 years
- Tools, furniture and fixtures 2 to 20 years

Goodwill

Goodwill arising from business combinations is stated at its cost less accumulated impairment losses. Goodwill is not amortized. Goodwill is allocated to cash-generating units or groups of cash-generating units based on expected synergies and tested for impairment annually or whenever there is any indication of impairment. Impairment losses on goodwill are recognized in the consolidated statements of income and no subsequent reversal will be made.

Intangible Assets Associated with Products

Marketed Products

An intangible asset associated with a marketed product is amortized on a straight-line basis over the estimated useful life, which is based on expected exclusivity period, ranging from 3 to 20 years. Amortization of intangible assets is included in amortization and impairment losses on intangible assets associated with products in the consolidated statements of income. Amortization and impairment losses on intangible assets associated with products is separately stated in the consolidated statement of income because intangible assets associated with products have various comprehensive rights and contribute to our ability to sell, manufacture, research, market and distribute products, compounds and benefit multiple business functions.

In-Process R&D

Takeda regularly enters into collaboration and in-license agreements with third parties for products and compounds for research and development projects. Payments for collaboration agreements generally take the form of subsequent development milestone payments. Payments for in-license agreements generally take the form of up-front payments and subsequent development milestone payments.

Up-front payments for in-license agreements are capitalized upon commencement of the in-license agreements, and development milestone payments are capitalized when the milestone is triggered.

These intangible assets relating to products in development that are not yet available for use are not amortized. These intangible assets are assessed for impairment on an annual basis, or more frequently if indicators of a potential impairment exist. An impairment is recorded if the carrying value exceeds the recoverable amount of the intangible assets. Intangible assets relating to products which fail during development, or for which development ceases for any reason are written down to their recoverable amount which is typically nil.

If and when Takeda obtains approval for the commercial application of a product in development, the related in-process research and development assets will be reclassified to intangible assets associated with marketed products and amortized over its estimated useful life from marketing approval.

Intangible Assets – Software

Software is recognized at cost and amortized on a straight-line basis over the expected useful life. The useful life used for this purpose is 3 to 10 years. Amortization of intangible assets – software is included in cost of sales, selling, general and administrative expenses, and research and development expenses in the consolidated statements of income.

Leases

Leases are classified as finance leases if substantially all the risks and rewards incidental to ownership are transferred to the lessee. Leases other than finance leases are classified as operating leases.

As Lessee

At the commencement of the lease term, Takeda recognizes finance leases as assets and liabilities in the consolidated statements of financial position at amounts equal to the fair value of the leased property or, if lower, the present value of the minimum lease payments, each determined at the inception of the lease. Lease payments for operating leases are recognized as expenses on a straight-line basis over the lease term, unless another systematic basis is more representative of the time pattern of the user's benefit is available.

Impairment of Non-Financial Assets

Takeda assesses whether there is any indication of impairment for non-financial assets at the end of each reporting period, excluding inventories, deferred tax assets, assets held for sale, and assets arising from employee benefits. If any such indication exists, or in cases in which an impairment test is required to be performed each year, the recoverable amount of the asset is estimated. In cases in which the recoverable amount cannot be estimated for each asset, they are estimated at the cash-generating unit level. The recoverable amount of an asset or a cash-generating unit is determined at the higher of its fair value less costs of disposal, or its value in use. In determining the value in use, the estimated future cash flows are discounted to their present value using a discount rate that reflects the time value of money and the risks specific to the asset. If the carrying amount of the asset or cash-generating unit exceeds the recoverable amount, impairment loss is recognized in profit or loss and the carrying amount is reduced to the recoverable amount. An asset or a cash-generating unit other than goodwill, for which impairment losses were recognized in prior years, is assessed at the end of the reporting period to determine whether there is any indication that the impairment loss recognized in prior periods

may no longer exist or may have decreased. If any such indication exists, the recoverable amount of the asset or cash-generating unit is estimated. In cases in which the recoverable amount exceeds the carrying amount of the asset or cash-generating unit, the impairment loss is reversed up to the lower of the estimated recoverable amount or the carrying amount that would have been determined if no impairment loss had been recognized in prior years. The reversal of impairment loss is immediately recognized in profit or loss.

Inventories

Inventories are measured at the lower of cost and net realizable value. The cost of inventories is determined mainly using the weighted-average cost formula. The cost of inventories includes purchase costs, costs of conversion, and other costs incurred in bringing the inventories to the present location and condition. Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale. Pre-launch inventory is held as an asset when there is a high probability of regulatory approval for the product. Before that point, a provision is made against the carrying value to its recoverable amount; the provision is then reversed at the point when a high probability of regulatory approval is determined.

Cash and cash equivalents

Cash and cash equivalents consist of cash on hand, demand deposits and short-term, highly liquid investments that are readily convertible to known amounts of cash and subject to insignificant risk of change in value and due within three months from the date of acquisition.

Assets Held for Sale

An asset or disposal group for which the cash flows are expected to arise principally from sale rather than continuing use is classified as an asset held for sale when it is highly probable that the asset or disposal group will be sold within one year, the asset or disposal group is available for immediate sale in its present condition, and the management of Takeda is committed to the sale. In such cases, the asset held for sale is measured at the lower of its carrying amount and fair value less costs to sell.

Property, plant and equipment and intangible assets classified as held for sale are not depreciated or amortized. Assets and liabilities classified as held for sale are presented separately as current items in the consolidated statements of financial position.

Post-employment Benefit

Takeda sponsors lump-sum payments on retirement, pensions and other plans such as post-retirement medical care as post-employment benefit plans. They are classified into defined benefit plans and defined contribution plans.

Defined Benefit Plans

Takeda uses the projected unit credit method to determine the present value, the related current service cost, and the past service cost by each defined benefit obligation. The discount rate is determined by reference to market yields on high quality corporate bonds at the end of the reporting period. The net defined benefit liabilities (assets) in the consolidated statements of financial position are calculated by deducting the fair value of the plan assets from the present value of the defined benefit obligations. Past service cost defined as the change in the present value of the defined benefit obligation resulting from a plan amendment or curtailment is recognized in profit or loss upon occurrence of the plan amendment or curtailment.

Re-measurement of net defined benefit plans is recognized in full in other comprehensive income and transferred to retained earnings in the period in which they are recognized.

Defined Contribution Plans

The costs for defined contribution plans are recognized as expenses when the employees render the related service.

Provisions

Takeda recognizes rebates and return reserves if Takeda receives consideration from a customer and expects to refund some or all of that consideration to the customer. In addition, provisions are recognized when Takeda has present legal or constructive obligations as a result of past events, it is probable that outflows of resources embodying economic benefits will be required to settle the obligations and reliable estimates can be made of the amount of the obligations. Takeda's provisions consist primarily of rebates and return reserves, as well as provisions for litigation and restructuring.

Financial Instruments

Takeda's financial instruments include financial instruments related to lease contracts, trade and other receivables and payables, liabilities for contingent consideration under business combinations, derivative instruments, and rights and obligations under employee benefit plans, which are dealt with in specific accounting policies.

Financial Assets – Subsequent to April 1, 2018

Initial Recognition and Measurement

Financial assets are recognized in the consolidated statements of financial position when Takeda becomes a party to the contractual provisions of the instruments. Financial assets, except for investments in debt instruments recorded at fair value through profit or loss (FVTPL), are initially measured at fair value plus transaction costs that are directly attributable to the acquisition.

Investments in debt instruments recorded at amortized cost: Assets such as trade and other receivables that are held within a business model whose objective is to hold financial assets in order to collect contractual cash flows and whose contractual terms give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding are measured at amortized cost. Trade receivables are initially recognized at their invoiced amounts, including any related sales taxes less adjustments for revenue deductions such as impairment loss allowance and cash discounts.

Investments in debt instruments recorded at fair value through other comprehensive income (FVTOCI): Assets that are held within a business model objective whose objective is achieved by both collecting contractual cash flows and selling financial assets whose contractual terms give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding are measured at FVTOCI.

Investments in debt instruments recorded at fair value through profit or loss (FVTPL): Assets that do not meet the criteria for amortized cost or FVTOCI are measured at FVTPL.

Equity instruments recorded at FVTOCI: On initial recognition, Takeda made an irrevocable FVTOCI election (on an instrument-by-instrument basis) to present the subsequent changes in the fair value of equity instruments in other comprehensive income for certain equity instruments held for the long term for strategic purposes. At the reporting date, Takeda designates all of its equity instruments as financial assets at FVTOCI.

Subsequent Measurement and Derecognition

Takeda derecognizes a financial asset only when the contractual right to receive the cash flows from the asset expires or when Takeda transfers the financial asset and substantially all the risks and rewards of ownership of the asset to another entity.

Investments in debt instruments recorded at amortized cost: These assets are subsequently measured at amortized cost using the effective interest method. The amortized cost is reduced by impairment losses. Interest income, foreign exchange gains and losses and impairment are recognized in profit or loss. Any gain or loss on derecognition is recognized in profit or loss.

Investments in debt instruments recorded at FVTOCI: These assets are subsequently measured at fair value. Interest income calculated using the effective interest method, foreign exchange gains and losses and impairment are recognized in profit or loss. Other net gains and losses are recognized in OCI. Upon derecognition of the investments, the gains and losses accumulated in OCI related to the investment is reclassified to profit or loss.

Investments in debt instruments recorded at FVTPL: These assets are subsequently measured at fair value, and a gain or loss on debt instruments that is subsequently measured at FVTPL is recognized in profit or loss.

Equity instruments recorded at FVTOCI: These assets are subsequently measured at fair value. Dividends are recognized as income in profit or loss unless the dividend clearly represents a recovery of part of the cost of the investment. Other net gains and losses are recognized in OCI and are never reclassified to profit or loss. Upon derecognition of the investments, the amounts in OCI related to the investment is reclassified within equity to retained earnings.

Impairment

Loss allowances for trade receivables are established using an ECL model. The provisions are based on a forward-looking ECL, which includes possible default events on the trade receivables over the entire holding period of the trade receivables. Takeda has elected to measure provisions for trade receivables, contract assets and lease receivables at an amount equal to lifetime ECL. Takeda uses a provisions matrix based on historical loss rates adjusted for forward looking information to calculate ECL. These provisions represent the difference between the contractual amount of the trade receivables and the lease receivables in the consolidated financial statements of financial position and the estimated collectible net amount.

Financial Assets – Prior to April 1, 2018

Initial Recognition and Measurement

Financial assets are recognized in the consolidated statements of financial position when Takeda becomes a party to the contractual provisions of the instruments. Financial assets, except for financial assets at fair value through profit or loss, are initially measured at fair value plus transaction costs that are directly attributable to the acquisition.

At the initial recognition, the financial assets are classified based on the nature and purpose in accordance with the following:

- Financial assets at fair value through profit or loss: Either held-for-trading financial assets or financial assets designated as financial assets at fair value through profit or loss.
- Loans and receivables: Non-derivative financial assets with fixed or determinable payments that are not quoted in an active market.
- Available-for-sale financial assets: Non-derivative financial assets that are either designated as available-for-sale financial assets or not classified as (a) financial assets at fair value through profit or loss, or (b) loans and receivables.

Subsequent Measurement

- Financial assets at fair value through profit or loss – Financial assets at fair value through profit or loss are measured at fair value, and any gains or losses arising on re-measurement are recognized in profit or loss.
- Loans and receivables – Loans and receivables are measured at amortized cost using the effective interest method less any impairment loss. Interest income is recognized principally by applying the effective interest rate, unless the recognition of interest is immaterial as in the case of short-term receivables.
- Available-for-sale financial assets – Available-for-sale financial assets are measured at fair value as of the end of the reporting period, and the gains and losses arising from changes in fair value are recognized in other comprehensive income. Exchange differences on monetary assets are recognized in profit or loss. Dividends on available-for-sale financial assets (equity instruments) are recognized in profit or loss in the reporting period when Takeda's right to receive the dividends is established. Upon derecognition of the investments, the amounts in OCI related to the investment is reclassified to profit or loss.

Impairment

Financial assets are considered impaired when there is objective evidence that one or more events occurred after the initial recognition of the financial asset and it is reasonably anticipated to have had a negative impact on the estimated future cash flows of the asset. For available-for-sale equity instrument, a significant or prolonged decline in the fair value below its cost is considered objective evidence of impairment. Even when there is no objective evidence of impairment individually, certain categories of financial assets, such as trade receivables, are collectively assessed for impairment. For financial assets measured at amortized cost, the impairment loss is the difference between the carrying amount of the asset and the present value of the estimated future cash flows discounted at the original effective interest rate on the asset. In a subsequent period, if the amount of the impairment loss decreases and the decrease can be related objectively to an event occurring after the impairment was recognized; the previously recognized impairment loss is reversed through profit or loss. When an available-for-sale financial asset is determined to be impaired, the cumulative gain or loss that was previously accumulated in accumulated other comprehensive income (loss) is reclassified to profit or loss in the same period. In respect to available-for-sale equity investments, impairment loss previously recognized in profit or loss is not reversed through profit or loss. In respect to available-for-sale debt instruments, if the amount of the fair value increases in a subsequent period and the increase can be related objectively to an event occurring after the impairment was recognized; the previously recognized impairment loss is reversed through profit or loss.

Derecognition

Takeda derecognizes a financial asset only when the contractual right to receive the cash flows from the asset expires or when Takeda transfers the financial asset and substantially all the risks and rewards of ownership of the asset to another entity. On derecognition of a financial asset, the difference between the carrying amount and the consideration received or receivable is recognized in profit or loss, and the cumulative gain or loss that was previously accumulated in accumulated other comprehensive income (loss) is reclassified to profit or loss.

Financial Liabilities

Initial Recognition and Measurement

Financial liabilities are recognized in the consolidated statements of financial position when Takeda becomes party to contractual provisions of financial instruments. Financial liabilities are classified, at initial recognition, as financial liabilities at fair value through profit or loss, bonds and loans, or payables.

Financial liabilities, except for financial liabilities at fair value through profit or loss, are initially measured at fair value less transaction costs that are directly attributable to the issuance.

Subsequent Measurement

Financial liabilities recorded at FVTPL: Financial liabilities at fair value through profit or loss are measured at fair value, and any gains or losses arising on re-measurement are recognized in profit or loss. Financial liabilities at fair value through the profit and loss includes derivatives and contingent consideration related to business combinations.

Other financial liabilities, including bonds and loans: Other financial liabilities are measured at amortized cost mainly using the effective interest method.

Derecognition

Takeda derecognizes a financial liability only when the obligation specified in the contract is discharged, cancelled, or expires. On derecognition of a financial liability, the difference between the carrying amount and the consideration paid or payable is recognized in profit or loss.

Derivatives

Takeda hedges the risks arising mainly from their exposure to fluctuations in foreign currency exchange rates and interest rates using derivative financial instruments such as foreign exchange forward contracts, interest rate swaps, currency options, and currency swaps. Takeda does not enter into derivative transactions for trading or speculative purposes. Derivatives are measured at FVTPL unless the derivative contracts are designated as hedging instruments. The gains and losses on derivatives that are not designed as hedging instruments are recognized in profit or loss. The treatment of the change in fair value for derivatives designated as hedging instruments varies based on the type of hedge as described below.

Hedge Accounting- Subsequent to April 1, 2018

For foreign currency exposure as a result of translation risk, Takeda designates certain non-derivatives, such as foreign currency denominated debt, as net investment hedges of foreign operations. For foreign currency exposure due to foreign currency denominated transactions, Takeda designates certain derivatives, such as foreign currency forwards, as cash flow hedges of forecasted transactions. Within the designation documentation at inception, Takeda documents the risk management objective, nature of the risk being hedged, and relationship between hedging instruments and hedged risk based on the strategy for undertaking the hedging relationships. At inception and on a quarterly basis, Takeda also assesses whether the hedging instruments are highly effective in offsetting changes in the fair value or the cash flows of the hedged item.

Cash flow hedges – the effective portion of changes in the fair value of derivatives designated and qualifying as cash flow hedges is recognized in other comprehensive income. The gain or loss relating to the ineffective portion is recognized immediately in profit or loss. The cumulative gain or loss that was previously recognized in other comprehensive income is reclassified to profit or loss in the same period when the cash flows of the hedged items are recognized in profit or loss and in the same line item in the consolidated statements of income. The currency basis spread and the time value of the foreign currency options are accounted for and presented as hedging cost under other components of equity separately from cash flow hedges.

Net investment hedges – the gain or loss on hedging instruments is recognized in other comprehensive income. At the time of disposal of the foreign operations, the cumulative gain or loss recognized in other comprehensive income is reclassified to profit or loss.

Hedge accounting is discontinued when the hedging instrument expires or is sold, terminated or exercised, or when the hedge no longer qualifies for hedge accounting.

Hedge Accounting - Prior to April 1, 2018

The policy applied prior to April 1, 2018 is similar to that applied subsequent to April 1, 2018. However, for all cash flow hedges, the currency basis spread was accounted for and presented under cash flow hedges.

Transaction costs of financial liabilities

Transaction costs relating to the financial liabilities of debt issued are recorded against the corresponding debt and amortized to the consolidated statements of income over the period to the earliest redemption date of the debt, using the effective interest rate method. On extinguishment of the related debt, any unamortized deferred transaction costs are written off and charged to interest expense in the consolidated statements of income.

Share-based Payments

Takeda has implemented share-based payment programs and provides equity and cash-settled share-based payments.

Equity-settled Share-based Payments

Equity-settled share-based payments are granted based on the service performed by the employees, directors, and senior management. The service received and the corresponding increase in equity are measured at the fair value of the equity instruments at the grant date. The fair value of the equity instruments granted to employees, directors, and senior management are recognized as expense over the vesting period of the awards with a corresponding amount as an increase in equity.

Cash-settled Share-based Payments

Cash-settled share-based payments are granted based on the service performed by the employees, directors, and senior management. The service received and the corresponding liability are measured at the fair value of the corresponding liability. The fair value of the liability-classified awards granted to employees, directors, and senior management are recognized as expense over the vesting period of the awards with a corresponding amount as an increase in liability. Takeda re-measures the fair value of the liability at the end of each reporting period and at the date of settlement, and recognizes any changes in fair value in profit or loss.

Capital

Ordinary Shares

Proceeds from the issuance of ordinary shares by the Company are included in share capital and share premium.

Treasury Shares

When the Company acquires treasury shares, the consideration paid is recognized as a deduction from equity. When the Company sells the treasury shares, the difference between the carrying amount and the consideration received is recognized in share premium.

4. Operating Segment and Revenue Information

Takeda comprises a single operating segment and is engaged in the research, development, manufacturing and marketing of pharmaceutical products, over-the-counter ("OTC") medicines and quasi-drug consumer products, and other healthcare products. This is consistent with how the financial information is viewed in allocating resources, measuring performance, and forecasting future periods by the CEO who is Takeda's Chief Operating Decision Maker.

Takeda's revenue from contracts with customers is comprised of the following:

	JPY (millions) For the Year Ended March 31		
	2017	2018	2019
Sales of pharmaceutical products	¥ 1,671,911	¥ 1,693,838	¥ 2,026,273
Royalty and service income	60,140	76,693	70,951
Total	¥ 1,732,051	¥ 1,770,531	¥ 2,097,224

Geographic Information

Takeda's revenue from contracts with customers is based in the following geographic locations:

	JPY (millions) For the Year Ended March 31							
	Japan	United States	Europe and Canada	Russia/ CIS	Latin America	Asia	Other	Total
2017	¥ 655,344	¥ 520,161	¥ 279,693	¥ 57,550	¥ 72,516	¥ 112,799	¥ 33,988	¥ 1,732,051
2018	580,349	598,341	313,723	68,240	75,658	104,026	30,194	1,770,531
2019	571,016	828,985	405,641	59,741	88,115	105,411	38,315	2,097,224

Other includes the Middle East, Oceania and Africa.

Takeda's non-current assets are held in the following geographic locations:

	JPY (millions) As of March 31				
	Japan	United States	Switzerland	Other	Total
2018	¥ 413,457	¥ 1,231,051	¥ 70,175	¥ 902,226	¥ 2,616,909
2019	400,342	6,649,357	1,523,527	1,818,875	10,392,101

Non-current assets exclude financial instruments, deferred tax assets and net defined benefit assets. Goodwill recognized as a result of the Shire acquisition during the year ended March 31, 2019 was allocated to United States, Switzerland and Other.

Information Related to Major Customers

During the year ended March 31, 2017, 2018, and 2019, Medipal Holdings Corporation and its subsidiaries (collectively, "Medipal Group") represented more than 10% of Takeda's sales. The sales to the Medipal Group were 265,646 million JPY, 220,249 million JPY, and 225,962 million JPY for the years ended March 31, 2017, 2018 and 2019, respectively.

These customers represented an aggregate 49,565 million JPY and 58,965 million JPY of trade receivables as of March 31, 2018 and 2019, respectively.

Other Revenue Information

Contract Balances

	JPY (millions)	
	As of April 1, 2018	As of March 31, 2019
Receivables from contracts with customers		
Receivables included in trade and other receivables (net of impairment loss allowance) (Note 17)	¥ 360,833	¥ 657,681
Receivables included in assets held for sale (net of impairment loss allowance)	1,277	—
Contract assets		
Unbilled receivables	—	4,237
Contract liabilities		
Deferred income (Note 24)	4,321	6,819
Advance payments	541	1,101

The revenue recognized during the year ended March 31, 2019 that was included in the contract liability balance as of April 1, 2018 was 781 million JPY. The revenue recognized during the year ended March 31, 2019 from performance obligations satisfied (or partially satisfied) in previous periods was 53,931 million JPY, and primarily relates to royalty income.

Takeda's contract assets relate to the right to receive consideration where performance was completed based on the contract, and trade receivables are recognized when the right to receive consideration becomes unconditional. The change during the year was mainly due to business combinations.

Takeda's contract liabilities primarily relate to out-licensing arrangements where Takeda receives cash consideration prior to the completion of its performance obligations under the agreements.

Receivables from contracts with customers primarily increased as a result of the acquisition of Shire, upon which 304,720 million JPY of such receivables were recorded.

Transaction price allocated to the remaining performance obligations

	JPY (millions)					
	As of April 1, 2018	Changes during the period	As of March 31, 2019	Duration of the remaining performance obligations		
				Within a year	After a year but before 5 years	After 5 years
Contract liabilities	¥ 4,862	¥ 3,058	¥ 7,920	¥ 4,200	¥ 1,015	¥ 2,705

5. Other Operating Income and Expenses

	JPY (millions) For the Year Ended March 31		
	2017	2018	2019
Other operating income:			
Change in fair value of contingent consideration liabilities (Note 21)	¥ 18,441	¥ —	¥ 5,966
Gain on sales of property, plant and equipment and investment property	762	18,814	50,330
Gain on divestment of business to Teva Takeda Yakuhin (Note 14)	115,363	27,481	30,366
Gain on sale of shares of subsidiaries	—	106,337	56,625
Other	8,967	16,780	16,576
Total	¥ 143,533	¥ 169,412	¥ 159,863
Other operating expenses:			
Donations and contributions	¥ 3,763	¥ 5,603	¥ 3,627
Restructuring expense (Note 23)	54,589	44,736	82,962
Loss on liquidation of foreign operations	—	41,465	2,112
Change in fair value of contingent consideration liabilities (Note 21)	—	10,523	—
Loss on sale of shares of subsidiaries	—	—	4,016
Other	14,529	24,228	10,442
Total	¥ 72,881	¥ 126,555	¥ 103,159

For the year ended March 31, 2018, the loss on liquidation of foreign operations primarily consists of the realization of cumulative translation loss recorded in the consolidated statement of income upon the liquidation of certain foreign operations. The gain on the sale of shares of subsidiaries relates to the sale of shareholding in Wako Pure Chemical Industries, Ltd.

For the year ended March 31, 2019, the gain on sales of property, plant and equipment and investment property primarily relates to the sale of the former headquarters in Tokyo. The gain on sale of shares of subsidiaries relates to the sale of shareholding in certain real estate properties, including the former Osaka headquarters, and the gain on the sale of 100% of the shares held in Guangdong Techpool Bio-Pharma Co., Ltd.

6. Finance Income and Expenses

	JPY (millions) For the Year Ended March 31		
	2017	2018	2019
Finance Income:			
Interest income			
Interest income from financial assets measured at amortized cost			¥ 6,171
Interest income from financial assets measured at fair value through P&L			448
Total interest income	¥ 2,019	¥ 3,282	6,619
Dividend income			
Dividend income from financial assets measured at fair value through OCI and disposed of during the period			1,353
Dividend income from financial assets measured at fair value through OCI and held at end of the period			1,116
Dividend income from financial assets measured at fair value through P&L			145
Total dividend income	3,236	3,165	2,614
Gain on sales of available-for-sale financial assets	3,638	30,430	—
Gain on foreign currency exchange, net	1,897	—	7,007
Other	1,484	2,666	603
Total	¥ 12,274	¥ 39,543	¥ 16,843
Finance Expenses:			
Interest expense	¥ 7,560	¥ 10,036	¥ 48,158
Change in fair value of contingent consideration liabilities (Note 21)	3,693	2,261	3,743
Impairment of available-for-sale financial assets	3,659	6,657	—
Loss on derivative financial assets	5,428	—	11,365
Loss on foreign currency exchange, net	—	10,279	—
Financing fees for bridge loan for acquisition of Shire	—	—	16,102
Other	2,909	2,695	3,921
Total	¥ 23,249	¥ 31,928	¥ 83,289

7. Income Taxes

Income Tax Expenses (Benefit)

The composition of income tax expense (benefit) is as follows:

	JPY (millions) For the Year Ended March 31		
	2017	2018	2019
Current tax expenses	¥ 60,239	¥ 37,758	¥ 61,606
Deferred tax expenses	(32,406)	(7,261)	(75,724)
Total	¥ 27,833	¥ 30,497	¥ (14,118)

Current tax expenses include the benefits arising from previously unrecognized tax losses, tax credits, and temporary differences of prior periods. These effects decreased current tax expenses by 1,563 million JPY, 8,005 million JPY and 10,875 million JPY for the years ended March 31, 2017, 2018 and 2019, respectively.

Deferred tax expenses include the benefits arising from previously unrecognized tax losses, tax credits, and temporary differences of prior periods. These effects decreased deferred tax expenses by 10,915 million JPY, 2,998 million JPY and 6,975 million JPY for the years ended March 31, 2017, 2018 and 2019, respectively.

The Company is mainly subject to income taxes, inhabitant tax, and deductible enterprise tax in Japan. The statutory tax rate calculated based on these taxes for the years ended March 31, 2017, 2018 and 2019 were 30.8%, 30.8% and 30.6% respectively. The tax law changed during the periods presented, which resulted in the reduction in the statutory tax rate for the Company.

The following is a reconciliation from the Company's domestic (Japanese) tax rate to the effective tax rate for the year ended March 31:

	Unit: Percentage		
	2017	**2018**	**2019**
Company's domestic (Japanese) tax rate	30.8	30.8	30.6
Non-deductible expenses for tax purposes [(1)]	4.7	2.6	23.2
Changes in unrecognized deferred tax assets and deferred tax liabilities [(2)]	(5.0)	(0.6)	(61.5)
Tax credits	(6.4)	(4.7)	(13.4)
Differences in applicable tax rates of overseas subsidiaries [(3)]	(7.1)	(5.4)	8.2
Changes in tax effects of undistributed profit of overseas subsidiaries	0.5	0.1	7.9
Effect of changes in applicable tax rates	(1.8)	(12.6)	1.9
Tax contingencies [(4)]	3.7	2.7	(10.0)
Non-deductible impairment of goodwill	2.3	—	—
Changes in fair value of contingent consideration	(3.7)	1.7	(1.8)
Others	1.4	(0.6)	0.0
Effective tax rate	19.4	14.0	(14.9)

[(1)] The 23.2%, impact for the year ended March 31, 2019 includes the impact from intra territory eliminations, the pre-tax effect of which has been eliminated in arriving at the Company's consolidated income from continuing operations before income taxes as well as non-deductible transaction costs related to the Shire acquisition.
[(2)] The (61.5)% impact for the year ended March 31, 2019 is primarily driven by a capital tax loss related to restructuring of subsidiaries.
[(3)] The 8.2% impact for the year ended March 31, 2019 is primarily driven by a unitary tax on overseas subsidiaries.
[(4)] The (10.0)% impact for the year ended March 31, 2019 primarily relates to the tax benefit driven by favorable audit settlements.

In the United States, the Tax Cuts and Jobs Act ("U.S. Tax Reform") was enacted on December 22, 2017. The federal corporate tax rate was reduced from 35% to 21% beginning January 1, 2018 under the new tax law. As a consequence of U.S. Tax Reform enactment, Takeda recognized tax benefits of 27,516 million JPY during the year ended March 31, 2018, primarily from the revaluation of net deferred tax liabilities at lower future tax rates and the improved recoverability of deferred tax attributes resulting from U.S. Tax Reform enacted federal law changes.

The decrease in Takeda's effective tax rate from 19.4% to 14.0% between the years ended March 31, 2017 and 2018, was primarily due to a one-time tax benefit from the enactment of U.S. Tax Reform principally related to the revaluation of net deferred tax liability at a lower enacted tax rate and improved recoverability of deferred tax attributes resulting from U.S. Tax Reform during the year ended March 31, 2018 (in effect of changes in applicable tax rates), partially offset by tax benefit from subsidiary capital redemption (in changes in unrecognized deferred tax assets and deferred tax liabilities) during the prior year that did not occur in the current year.

The decrease in Takeda's effective tax rate from 14.0% to (14.9)% between the years ended March 31, 2018 and 2019 was primarily due to a one-time tax benefit from restructuring of subsidiaries (in changes in unrecognized deferred tax assets and deferred tax liabilities) and favorable audit settlements (in tax contingencies), partially offset by an increase in non-deductible expenses for tax purposes and differences in applicable tax rates of overseas subsidiaries and the impact of U.S. Tax Reform (in effect of changes in applicable tax rates) during the prior year that did not occur in the current year.

Deferred Taxes

Deferred tax assets and liabilities reported in the consolidated statements of financial position are as follows:

	JPY (millions) As of March 31	
	2018	**2019**
Deferred tax assets	¥ 64,980	¥ 88,991
Deferred tax liabilities	(90,725)	(867,061)
Net deferred tax liabilities	¥ (25,745)	¥ (778,070)

The major items and changes in deferred tax assets and liabilities are as follows:

	JPY (millions)					
	As of April 1, 2017	Recognized in Profit or (Loss)	Recognized in Other Comprehensive Income	Acquisitions through Business Combinations	Others[1]	As of March 31, 2018
Research and development expenses	¥ 52,595	¥ (34,007)	¥ —	¥ —	¥ (225)	¥ 18,363
Inventories	38,452	(6,561)	—	—	18	31,909
Property, plant and equipment	(33,574)	656	—	—	(111)	(33,029)
Intangible assets	(254,908)	84,254	—	—	1,696	(168,958)
Available-for-sale financial assets	(28,241)	—	4,074	—	89	(24,078)
Accrued expenses and provisions	80,266	(10,373)	—	—	(1,560)	68,333
Defined benefit plans	4,815	(3,032)	(432)	—	1,027	2,378
Deferred income	17,562	709	—	—	(503)	17,768
Unused tax losses	62,886	(16,114)	—	—	915	47,687
Tax credits	29,563	9,314	—	—	(2,456)	36,421
Investments in subsidiaries and associates	(35,461)	6,762	—	—	89	(28,610)
Other	31,617	(24,347)	(1,570)	—	371	6,071
Total	¥ (34,428)	¥ 7,261	¥ 2,072	¥ —	¥ (650)	¥ (25,745)

	JPY (millions)					
	As of April 1, 2018	Recognized in Profit or (Loss)	Recognized in Other Comprehensive Income	Acquisitions through Business Combinations	Others[1]	As of March 31, 2019
Research and development expenses	¥ 18,363	¥ (5,512)	¥ —	¥ 17,605	¥ 650	¥ 31,106
Inventories	31,909	19,628	—	(39,308)	(5,965)	6,264
Property, plant and equipment	(33,029)	4,514	—	(52,036)	(3,289)	(83,840)
Intangible assets	(168,958)	47,320	—	(733,472)	(9,728)	(864,838)
Available-for-sale financial assets	(24,078)	—	—	—	24,078	—
Financial assets measured at FVTOCI	—	—	(1,202)	15	(28,095)	(29,282)
Accrued expenses and provisions	68,333	(3,528)	—	37,472	1,958	104,235
Defined benefit plans	2,378	303	3,241	10,314	448	16,684
Deferred income	17,768	283	—	6	(519)	17,538
Unused tax losses	47,687	30,418	—	52,705	(3,467)	127,343
Tax credits	36,421	(335)	—	38,562	(979)	73,669
Investments in subsidiaries and associates	(28,610)	(20,353)	—	(113,900)	(1,210)	(164,073)
Other	6,071	2,986	720	(20,989)	(1,664)	(12,876)
Total	¥ (25,745)	¥ 75,724	¥ 2,759	¥ (803,026)	¥ (27,782)	¥ (778,070)

[1] Other consists primarily of foreign currency translation differences, reclassification of deferred tax assets and liabilities classified as held for sale and the tax impact of items recorded directly to equity. There was no amount of deferred tax recorded directly to equity for the period ended March 31, 2018. The aggregate amount of deferred tax related to items recorded directly to equity for the period ended March 31, 2019 caused a reduction in equity of 1,992 million JPY.

Takeda considers the probability that a portion, or all of the future deductible temporary differences, unused tax losses, or unused tax credits can be utilized against future taxable profits upon recognition of deferred tax assets. In assessing the recoverability of deferred tax assets, Takeda considers the scheduled reversal of taxable temporary differences, projected future taxable profits, and tax planning strategies.

Based on the level of historical taxable profits and projected future taxable profits during the periods in which the temporary differences become deductible, Takeda determined that it is probable that the tax benefits can be utilized.

The unused tax losses, deductible temporary differences, and unused tax credits for which deferred tax assets were not recognized are as follows:

	JPY (millions) As of March 31	
	2018	2019
Unused tax losses	¥ 36,878	¥ 840,867
Deductible temporary differences	11,593	45,135
Unused tax credits	7,954	6,054

The unused tax losses and unused tax credits for which deferred tax assets were not recognized will expire as follows:

	JPY (millions) As of March 31	
Unused tax losses	2018	2019
1st year	¥ —	¥ —
2nd year	92	1
3rd year	8,901	22,690
4th year	505	163
5th year	301	615
After 5th year	25,189	741,044
Indefinite	1,890	76,354
Total	¥ 36,878	¥ 840,867

	JPY (millions) As of March 31	
Unused tax credits	2018	2019
Less than 5 years	¥ 3,201	¥ 1,200
5 years or more	4,383	4,460
Indefinite	370	394
Total	¥ 7,954	¥ 6,054

The aggregate amounts of temporary differences associated with investments in subsidiaries for which deferred tax assets were not recognized were 140,647 million JPY and 1,728,537 million JPY as of March 31, 2018 and 2019, respectively.

The aggregate amounts of temporary differences associated with investments in subsidiaries for which deferred tax liabilities were not recognized were 157,656 million JPY and 2,462,928 million JPY as of March 31, 2018 and 2019, respectively.

8. Earnings per Share

The basis for calculating basic and diluted earnings per share ("EPS") (attributable to owners) is as follows:

	As of March 31		
	2017	2018	2019
Net profit for the year attributable to owners of the Company:			
Net profit for the year attributable to owners of the Company JPY (millions)	¥ 114,940	¥ 186,886	¥ 109,126
Net profit used for calculation of earnings per share JPY (millions)	¥ 114,940	¥ 186,886	¥ 109,126
Weighted-average number of ordinary shares outstanding during the year (thousands of shares) [basic]	781,096	780,812	961,477
Dilutive effect (thousands of shares)	4,792	5,895	5,420
Weighted-average number of ordinary shares outstanding during the year (thousands of shares) [diluted]	785,888	786,707	966,897
Earnings per share			
Basic (JPY)	147.15	239.35	113.50
Diluted (JPY)	146.26	237.56	112.86

Basic EPS is calculated by dividing the net profit for the year attributable to owners of the Company, with the weighted average number of ordinary shares outstanding during the year. This calculation excludes the average number of treasury shares. Diluted EPS is calculated by dividing the net profit for the year attributable to owners of the Company, with the weighted-average number of ordinary shares outstanding during the year plus the weighted-average number of ordinary shares that would be issued upon conversion of all the dilutive ordinary shares into ordinary shares.

There were 901 thousand shares, such as stock options that are anti-dilutive, not included in the calculation of diluted earnings per share for the year ended March 31, 2017, and 814 thousand such anti-dilutive shares not included for the year ended March 31, 2019. There were no anti-dilutive shares for the years ended March 31, 2018.

9. Other Comprehensive Income (Loss)

Amounts arising during the year, reclassification adjustments to profit or loss, and tax effects for each component of other comprehensive income (loss) are as follows:

	JPY (millions) For the Year Ended March 31		
	2017	2018	2019
Re-measurement gain or (loss) on defined benefit plans:			
Amounts arising during the year	¥ 23,242	¥ 1,156	¥ (14,906)
Tax effects	(7,688)	(432)	3,241
Re-measurement gain or (loss) on defined benefit plans	¥ 15,554	¥ 724	¥ (11,665)
Exchange differences on translation of foreign operations:			
Amounts arising during the year	¥ (51,252)	¥ 8,125	¥ 42,939
Reclassification adjustments to profit or (loss)	22	39,964	(3,134)
Before tax effects	(51,230)	48,089	39,805
Tax effects	(590)	(1,478)	(5,166)
Exchange differences on translation of foreign operations	¥ (51,820)	¥ 46,611	¥ 34,639
Net changes on revaluation of available-for-sale financial assets			
Amounts arising during the year	¥ 12,485	¥ 24,413	¥ —
Reclassification adjustments to profit or (loss)	22	(23,773)	—
Before tax effects	12,507	640	—
Tax effects	(2,986)	4,074	—
Net changes on revaluation of available-for-sale financial assets	¥ 9,521	¥ 4,714	¥ —

Changes in fair value of financial assets measured at fair value through OCI:			
Amounts arising during the year	¥ —	¥ —	¥ 7,202
Tax effects	—	—	(1,202)
Changes in fair value of financial assets measured at fair value through OCI	¥ —	¥ —	¥ 6,000
Cash flow hedges:			
Amounts arising during the year	¥ 7,254	¥ (1,460)	¥ (28,063)
Reclassification adjustments to profit or (loss)	(418)	4,240	(6,363)
Before tax effects	6,836	2,780	(34,426)
Tax effects	(2,202)	(861)	633
Cash flow hedges	¥ 4,634	¥ 1,919	¥ (33,793)
Hedging cost:			
Amounts arising during the year	¥ (321)	¥ 3,130	¥ (4,088)
Reclassification adjustments to profit or (loss)	—	(815)	(908)
Before tax effects	(321)	2,315	(4,996)
Tax effects	99	(709)	87
Hedging cost	¥ (222)	¥ 1,606	¥ (4,909)
Share of other comprehensive income of investments accounted for using the equity method:			
Amounts arising during the year	¥ (38)	¥ 295	¥ (101)
Reclassification adjustments to profit or (loss)	—	87	7
Before tax effects	(38)	382	(94)
Tax effects	—	—	—
Share of other comprehensive income of investments accounted for using the equity method	¥ (38)	¥ 382	¥ (94)
Total other comprehensive income (loss) for the year	¥ (22,371)	¥ 55,956	¥ (9,822)

10. Property, Plant and Equipment

	JPY (millions)					
Acquisition cost	**Buildings and structures**	**Machinery and vehicles**	**Tools, furniture, and fixtures**	**Land**	**Construction in progress**	**Total**
As of April 1, 2017	¥515,202	¥ 384,184	¥ 107,408	¥ 69,586	¥ 58,052	¥ 1,134,432
Additions	19,778	11,327	6,288	63	37,071	74,527
Acquisitions through business combinations	—	—	—	—	—	—
Transfers	15,741	19,184	1,615	72	(37,382)	(770)
Disposals and other decreases	(864)	(8,459)	(9,564)	(77)	(376)	(19,340)
Reclassification to assets held for sale (Note 19)	(1,830)	(2,066)	(276)	(94)	—	(4,266)
Foreign currency translation differences	630	5,020	767	541	626	7,584
Other	(328)	(445)	313	(2)	(307)	(769)
As of March 31, 2018	¥ 548,329	¥ 408,745	¥ 106,551	¥ 70,089	¥ 57,684	¥ 1,191,398
Additions	123,099	12,974	7,374	383	44,564	188,394
Acquisitions through business combinations	267,871	244,277	26,909	46,117	100,724	685,898
Transfers	42,353	9,511	3,055	(11,519)	(55,388)	(11,988)
Disposals and other decreases	(35,073)	(23,933)	(10,132)	(3,397)	(374)	(72,909)
Reclassification to assets held for sale (Note 19)	(2,272)	(167)	(9,784)	(69)	—	(12,292)
Foreign currency translation differences	1,596	(2,611)	(1,271)	125	(3,841)	(6,002)
Other	(4,418)	(1,698)	(624)	2	(809)	(7,547)
As of March 31, 2019	¥ 941,485	¥ 647,098	¥ 122,078	¥ 101,731	¥ 142,560	¥ 1,954,952
Accumulated depreciation and accumulated impairment losses						
As of April 1, 2017	¥ (222,794)	¥ (292,117)	¥ (89,197)	¥ (361)	¥ (2,619)	¥ (607,088)
Depreciation expenses	(19,480)	(21,357)	(6,670)	—	—	(47,507)
Impairment losses	(13,620)	(454)	(9)	—	(137)	(14,220)
Transfers	637	5	90	—	—	732
Disposals and other decreases	701	7,126	9,268	—	—	17,095
Reclassification to assets held for sale (Note 19)	525	846	171	—	—	1,542
Foreign currency translation differences	(774)	(3,829)	(533)	(34)	—	(5,170)
Other	106	21	(108)	—	—	19
As of March 31, 2018	¥ (254,699)	¥ (309,759)	¥ (86,988)	¥ (395)	¥ (2,756)	¥ (654,597)
Depreciation expenses	(24,261)	(29,888)	(9,169)	—	—	(63,318)
Impairment losses	(355)	(151)	(72)	—	(43)	(621)
Transfers	(1,269)	374	895	—	—	—
Disposals and other decreases	27,045	23,225	9,953	—	—	60,223
Reclassification to assets held for sale (Note 19)	1,109	168	9,342	—	—	10,619
Foreign currency translation differences	1,203	3,535	831	21	9	5,599
Other	2,249	1,179	246	—	—	3,674
As of March 31, 2019	¥ (248,978)	¥ (311,317)	¥ (74,962)	¥ (374)	¥ (2,790)	¥ (638,421)

Carrying amount	JPY (millions)					
	Buildings and structures	Machinery and vehicles	Tools, furniture, and fixtures	Land	Construction in progress	Total
As of April 1, 2017	¥ 292,408	¥ 92,067	¥ 18,211	¥ 69,225	¥ 55,433	¥ 527,344
As of March 31, 2018	293,630	98,986	19,563	69,694	54,928	536,801
As of March 31, 2019	692,507	335,781	47,116	101,357	139,770	1,316,531

Property, plant and equipment includes assets held under finance leases. The carrying amounts of these assets are as follows:

	JPY (millions)		
	Buildings and structures	Machinery and vehicles	Tools, furniture and fixtures
As of April 1, 2017	¥ 61,375	¥ 2,702	¥ 494
As of March 31, 2018	55,941	1,523	330
As of March 31, 2019	179,668	1,331	220

Takeda recognized the following impairment losses, which are reflected as follows, in the consolidated statements of income:

	JPY (millions) For the Year Ended March 31		
	2017	2018	2019
Cost of sales	¥ (1,079)	¥ (365)	¥ (35)
Selling, general and administrative expenses	—	—	(354)
Research and development expenses	(678)	—	(41)
Other operating expenses	(4,091)	(13,855)	(191)
Total	¥ (5,848)	¥ (14,220)	¥ (621)

Impairment loss for the year ended March 31, 2017 was primarily due to the impairment of construction in progress relating to construction of a facility that was terminated following the decision to discontinue a product to be manufactured at this facility.

Impairment loss for the year ended March 31, 2018 was related primarily to buildings and structures in research equipment which were deemed as underutilized assets, related to the R&D transformation strategy.

Impairment loss for the year ended March 31, 2019 resulted primarily from facilities for administrative and sales activities in Japan that were divested in the year ended March 31, 2019.

The carrying amounts of the impaired assets were reduced to the recoverable amounts, which were measured at the fair value less costs of disposal using values, such as expected sales amounts. This fair value is classified as Level 3 in the fair value hierarchy.

11. Goodwill

	JPY (millions)	
	2018	2019
Acquisition cost		
As of beginning of the year	¥ 1,020,471	¥ 1,029,291
Acquisitions (Note 31)	3,256	3,105,512
Deconsolidation	(899)	(3,899)
Foreign currency translation differences	6,512	30,499
Reclassification to assets held for sale (Note 19)	(49)	—
As of end of the year	¥ 1,029,291	¥ 4,161,403
Accumulated impairment losses		
As of beginning of the year	¥ (897)	¥ (43)
Deconsolidation	899	40
Foreign currency translation differences	(45)	3
As of end of the year	¥ (43)	¥ —
Carrying amount		
As of beginning of the year	¥ 1,019,574	¥ 1,029,248
As of end of the year	1,029,248	4,161,403

Goodwill is allocated to the following groups of cash-generating units ("CGU"):

	JPY (millions) As of March 31	
	2018	2019
Prescription drugs sold worldwide	¥ 527,481	¥ 3,685,352
Prescription drugs sold outside of the United States and Japan	429,363	403,474
Other	72,404	72,577
Total	¥ 1,029,248	¥ 4,161,403

Impairment loss for goodwill is recognized if the recoverable amount of goodwill is less than the carrying amount. The recoverable amount is the greater of fair value less costs to sell, or value in use. Value in use is calculated by discounting the estimated future cash flows based on a three-year projection approved by management using an appropriate growth rate and a discount rate. The projection includes assumptions about product launches, competition from rival products and pricing policy as well as the possibility of generics entering the market and loss of exclusivity. In setting these assumptions, Takeda considers past experience, external sources of information, knowledge of competitor activity, and industry trends.

The significant assumptions used to calculate the recoverable amount (value in use) are as follows:

	Growth Rate	Discount Rate (Post-tax)	Discount Rate (Pre-tax)
	Based on country/market specific long-term average growth rate for the CGU	Based on country/market specific weighted average cost of capital	Based on country/market specific weighted average cost of capital
March 31, 2017	1.5% – 2.7%	4.9% – 13.5%	7.0% – 16.9%
March 31, 2018	1.5% – 3.2%	5.6% – 14.4%	8.0% – 18.0%
March 31, 2019	1.3% – 2.8%	6.1% – 11.8%	8.8% – 15.5%

The value in use exceeded the relevant carrying amount in each group of CGUs, and a reasonable change in the assumptions would not result in an impairment.

12. Intangible Assets

	JPY (millions)			
Acquisition cost	**Software**	**Intangible Assets Associated with Products**	**Other**	**Total**
As of April 1, 2017	¥ 69,154	¥ 1,977,596	¥ 23,337	¥ 2,070,087
Additions	16,934	32,594	1	49,529
Acquisitions through business combinations (Note 31)	—	41,764	—	41,764
Disposals and other decreases	(1,975)	(4,517)	(8)	(6,500)
Reclassification to assets held for sale (Note 19)	(158)	(2,655)	—	(2,813)
Deconsolidation	—	(2,356)	—	(2,356)
Foreign currency translation differences	830	(21,565)	(1,126)	(21,861)
As of March 31, 2018	¥ 84,785	¥ 2,020,861	¥ 22,204	¥ 2,127,850
Additions	26,188	29,857	141	56,186
Acquisitions through business combinations (Note 31)	51,722	3,910,997	—	3,962,719
Disposals and other decreases	(2,522)	(131)	(11)	(2,664)
Reclassification to assets held for sale (Note 19)	(120)	—	—	(120)
Deconsolidation	(220)	(28,794)	(4)	(29,018)
Foreign currency translation differences	404	63,581	3	63,988
As of March 31, 2019	¥ 160,237	¥ 5,996,371	¥ 22,333	¥ 6,178,941
Accumulated amortization and accumulated impairment losses				
As of April 1, 2017	¥ (45,011)	¥ (951,122)	¥ (10,917)	¥ (1,007,050)
Amortization	(8,045)	(126,108)	(41)	(134,194)
Impairment losses	(88)	(19,080)	—	(19,168)
Reversal of impairment losses	—	23,057	—	23,057
Disposals and other decreases	1,242	2,397	6	3,645
Reclassification to assets held for sale (Note 19)	118	2,079	—	2,197
Deconsolidation	—	2,356	—	2,356
Foreign currency translation differences	13	15,557	1	15,571
As of March 31, 2018	¥ (51,771)	¥ (1,050,864)	¥ (10,951)	¥ (1,113,586)
Amortization	(13,774)	(194,727)	(61)	(208,562)
Impairment losses	(53)	(8,645)	—	(8,698)
Disposals and other decreases	2,388	22	6	2,416
Reclassification to assets held for sale (Note 19)	59	—	—	59
Deconsolidation	153	17,888	4	18,045
Foreign currency translation differences	55	(8,325)	23	(8,247)
As of March 31, 2019	¥ (62,943)	¥ (1,244,651)	¥ (10,979)	¥ (1,318,573)
Carrying amount				
As of April 1, 2017	¥ 24,143	¥ 1,026,474	¥ 12,420	¥ 1,063,037
As of March 31, 2018	33,014	969,997	11,253	1,014,264
As of March 31, 2019	97,294	4,751,720	11,354	4,860,368

There were no material internally generated intangible assets recorded in the consolidated statements of financial position.
The intangible assets associated with products are comprised of the following:

	JPY (millions)		
	Marketed Products	In-Process R&D	Carrying amount
As of April 1, 2017	¥ 645,449	¥ 381,025	¥ 1,026,474
As of March 31, 2018	698,329	271,668	969,997
As of March 31, 2019	4,248,285	503,435	4,751,720

Marketed products mainly represent license rights associated with commercialized products. These include, but are not limited to, intangible assets associated with *PANTOPRAZOLE* acquired through the acquisition of Nycomed, which represent 318,281 million JPY and 253,272 million JPY as of March 31, 2018 and 2019, respectively, intangible assets associated with ALUNBRIG and ICLUSIG acquired through the acquisition of ARIAD Pharmaceuticals, Inc., which represent 204,378 million JPY and 192,200 million JPY as of March 31, 2018 and 2019, respectively and *TAKHZYRO*, *VYVANSE*, *GAMMAGARD*, *ADVATE, ADYNOVATE*, and *REPLAGAL*, acquired through the acquisition of Shire, which represent 2,497,460 million JPY as of March 31, 2019.

The remaining amortization period is 3 to 8 years as of March 31, 2019 for the assets acquired through the acquisition of Nycomed, 8 to 12 years for the assets acquired through the acquisition of ARIAD Pharmaceuticals, Inc. and 1 to 20 years for the assets acquired through the acquisition of Shire.

In-process R&D mainly represents products in development and license rights obtained in connection with Takeda's in-licensing and collaboration agreements. These agreements relate to the right to sell products that are being developed (Note 13). These intangible assets are not subject to amortization. These include intangible assets associated mainly with ALUNBRIG acquired through the acquisition of ARIAD Pharmaceuticals, Inc., which represent 182,002 million JPY and 189,184 million JPY as of March 31, 2018 and 2019, respectively and with SHP621 budesonide and SHP620 Maribavir acquired through the acquisition of Shire, which represents 70,796 million JPY as of March 31, 2019.

Impairment

Takeda's impairment assessment for intangible assets requires a number of significant judgments to be made by management to estimate the recoverable amount, including the estimated pricing and costs, likelihood of regulatory approval, and the estimated market and Takeda's share of the market. The most significant assumption for intangible assets associated with marketed products is the product market share of the therapeutic area and estimated pricing, whereas the most significant assumption with pre-marketed products and in-process R&D is the probability of regulatory approval. A change in these assumptions may have a significant impact on the amount, if any, of an impairment charge recorded during a period. For example, negative results from a clinical trial may change the assumption and result in an impairment. Products in development may be fully impaired when a trial is unsuccessful and there is no alternative use for the development asset.

Takeda recorded impairment losses of 44,609 million JPY, a reversal of impairment losses 3,889 million JPY (net of impairment losses), and impairment losses of 8,698 million JPY during the years ended March 31, 2017, 2018, and 2019, respectively. These losses are primarily recognized in amortization and impairment losses on intangible assets associated with products in the consolidated statement of income.

During the year ended March 31, 2017, Takeda recorded impairment losses of 44,609 million JPY primarily resulting from a decision to terminate development of certain products and competitive product launches. The recoverable amount of the impaired assets amounted to 45,275 million JPY. Specifically, during the year ended March 31, 2017, Takeda recorded an impairment loss of 16,003 million JPY due to a decline in expected profitability of COLCRYS, an impairment loss of 7,889 million JPY due to the termination of development of an oncology product, and an impairment loss of 3,359 million JPY due to the termination of development of a vaccine product.

During the year ended March 31, 2018, Takeda recorded reversal of a previously recorded impairment losses of 23,057 million JPY mainly related to COLCRYS based on more favorable sales performance. The recoverable amount of the assets related to the reversal was 49,113 million JPY. This was offset by impairment losses of 19,168 million JPY primarily resulting from a decision to terminate development of certain products. The recoverable amount of the impaired assets amounted to 3,185 million JPY.

During the year ended March 31, 2019, Takeda recorded impairment losses of 8,698 million JPY. The recoverable amount of the combined impaired assets amounted to 29,667 million JPY. The impairment losses primarily resulted from the decision to terminate a collaboration agreement on development of oncology products (Note 13).

Impairment losses were calculated by deducting the recoverable amount from the carrying amount.

The significant assumptions used to calculate the recoverable amount (value in use) are as follows:

	Discount Rate (Post-tax)	Discount Rate (Pre-tax)
March 31, 2017	5.7% - 13.5%	8.3% - 16.9%
March 31, 2018	6.5% - 14.4%	9.4% - 18.5%
March 31, 2019	11.0%	14.2%

A part of the recoverable amount was measured at the fair value less costs of disposal (the amount that was expected to be received by selling the assets). This fair value is classified as Level 3 in the fair value hierarchy.

13. Collaborations and Licensing Arrangements

Takeda is party to certain collaborations, in-licensing agreements and out-licensing arrangements.

Out-licensing agreements

Takeda has entered into various licensing arrangements where it has licensed certain product or intellectual property rights for consideration such as up-front payments, equity interest of partners, development milestones, sales milestones and/or sales-based royalty payments. The receipt of the variable considerations related to these substantive milestones is uncertain and contingent on the achievement of certain development milestones or the achievement of a specified level of annual net sales by the licensee.

Collaborations and in-licensing arrangements

These agreements generally provide for commercialization rights to a product or products being developed by the counterparty, and, in exchange, often resulted in an up-front payment being paid upon execution of the agreement and resulting an obligation that may require Takeda to make future development, regulatory approval, or commercial milestone payments as well as sales-based royalty payments. In some of these arrangements, Takeda and the licensee are both actively involved in the development and commercialization of the licensed product, and have exposure to risks and rewards that are dependent on its commercial success.

Under the terms of these collaboration and licensing arrangements, Takeda made the following payments during the years ended March 31:

	JPY (millions)		
	2017	2018	2019
Initial up-front and milestone payments	¥ 62,282	¥ 32,594	¥ 29,857
Acquisition of shares of collaboration and in- licensing partners	2,480	15,074	5,994

The following is a description of Takeda's significant collaborations and in-licensing agreements.

Mersana Therapeutics ("Mersana")

In March 2014, Takeda entered into an agreement with Mersana related to the development of antibody drug conjugates, which was expanded in January 2015 and again in February 2016. In January 2019, Takeda and Mersana terminated the partnership. Accordingly, Takeda recognized impairment loss on intangible assets associated with products of 7,237 million JPY during the year ended March 31, 2019.

GlaxoSmithKline plc. ("GSK")

In July 2017, Takeda entered into an exclusive licensing agreement with TESARO, Inc. ("TESARO") for the commercialization and clinical development of Niraparib, a novel poly ADP-ribose polymerase inhibitor. TESARO was acquired by GSK during the year ended March 31, 2019. The collaboration agreement grants Takeda the right to develop and commercialize all indications in Japan and all indications, except prostate cancer, in South Korea, Taiwan, Russia and Australia. Under the terms of this agreement, Takeda has made an up-front payment and is required to make additional milestone payments upon the achievement of certain regulatory and commercial goals. GSK will also be eligible to receive from Takeda tiered royalties based on a double-digit percentage of net product sales.

Denali Therapeutics ("Denali")

In January 2018, Takeda entered into a collaboration agreement with Denali to develop and commercialize up to three specified therapeutic product candidates for neurodegenerative diseases. Each program is directed to a genetically validated target for neurodegenerative disorders, including Alzheimer's disease and other indications, and incorporates Denali's Antibody Transport Vehicle platform for increased exposure of biotherapeutic products in the brain. Under the terms of the agreement, Takeda made an up-front payment in exchange for certain option rights and the purchase of Denali equity. In addition, Denali is eligible to receive development and commercial milestone payments. Denali will be responsible for all development activities and costs prior to Investigational New Drug filing for each of the three programs. Takeda has the option to co-develop and co-commercialize each of the three programs. If Takeda exercises the option, the parties will then jointly conduct clinical development and share all costs equally. Denali will lead early clinical development activities and Takeda will lead late-stage clinical development activities. Takeda and Denali will jointly commercialize the products in the United States and China, and Takeda will have exclusive commercialization rights in all other markets. The parties will share global profits equally.

Wave Life Sciences Ltd. ("Wave")

In February 2018, Takeda entered into an agreement with Wave to discover, develop and commercialize nucleic acid therapies for disorders of the central nervous system ("CNS"). Under the agreement, Takeda has the option to co-develop and co-commercialize programs in areas of Huntington's disease (HD), amyotrophic lateral sclerosis (ALS), frontotemporal dementia (FTD) and spinocerebellar ataxia type 3 (SCA3). In addition, Takeda has the right to license multiple preclinical programs targeting CNS disorders, including Alzheimer's disease and Parkinson's disease. Takeda made an upfront payment and investment in Wave and has the potential to make future payments related to development and commercial milestone payments.

Rani Therapeutics LLC ("Rani")

In January 2019, Takeda acquired a collaboration agreement with Rani to conduct research on the use of the RANI PILL technology for oral delivery of Factor VIII (FVIII) therapy for patients with hemophilia A. This collaboration agreement was acquired through the acquisition of Shire. The agreement provides Takeda an exclusive option to negotiate a license to develop and commercialize the technology for delivery of FVIII therapy following completion of feasibility studies and a 0.84% equity ownership in Rani.

Novimmune S.A. ("Novimmune")

In January 2019, Takeda acquired a licensing agreement with Novimmune through its acquisition of Shire. The agreement provides Takeda a license to the exclusive worldwide rights to develop and commercialize a bi-specific antibody for the treatment of hemophilia A and hemophilia A patients with inhibitors. Under the terms of the agreement, Takeda will develop, and if approved, commercialize the product. Novimmune will be entitled to receive additional potential milestone payments based on clinical, regulatory and commercial milestones and single-digit royalties.

AB Biosciences Inc. ("AB Biosciences")

In January 2019, Takeda acquired a licensing agreement with AB Biosciences through its acquisition of Shire. The agreement grants Takeda a license to exclusive worldwide rights to develop and commercialize a recombinant immunoglobulin product candidate and an exclusive, worldwide license to AB Bioscience's intellectual property relating to its pan receptor interacting molecule program. AB Biosciences is eligible to receive contingent research, development, and commercialization milestone payments and tiered royalty payments.

14. Investments Accounted for Using the Equity Method

Teva Takeda Pharma

Teva Takeda Pharma Ltd. ("Teva Takeda Pharma") is a business venture of Takeda and Teva Pharmaceutical Industries Ltd. ("Teva") headquartered in Israel.

On April 1, 2016, Takeda sold its off-patented and long-listed products business in Japan to Teva Takeda Yakuhin Ltd. ("Teva Takeda Yakuhin"), a subsidiary of Teva Takeda Pharma, and received 49.0% of shares of Teva Takeda Pharma as consideration for the business. The remainder of Teva Takeda Pharma is owned by a subsidiary of Teva. The long-listed products business had a book value of 3,755 million JPY on the date of disposal. Takeda has significant influence over Teva Takeda Pharma and has applied the equity method. Takeda accounted for the transaction based on IAS 28 'Investments in Associates and Joint Ventures'. Under this accounting, Takeda recognized a gain for the difference between the fair value consideration received (shares of Teva Takeda Pharma) and the carrying value of the business to the extent it had disposed of the business and it deferred the remainder of the gain (49)%. The gain on transfer of business recorded in other operating income for the year ended March 31, 2017 was 115,363 million JPY, which included the gain of 102,899 million JPY recognized at the date of disposal. The remainder of the gain was deferred and is amortized over 15 years, which is the same period as the intangible assets identified in the purchase price allocation. The amortization of the gain is recorded in other operating income.

Teva Takeda Pharma, which continues its generics business, and Teva Takeda Yakuhin, which operates the long-listed products business and its generics business, are jointly engaged in business in Japan. Takeda recognizes revenue for product sales of goods related to its supply of the long-listed products, to Teva Takeda Yakuhin and service revenue for its distribution using its channel to deliver products including generic products of Teva Takeda Pharma and Teva Takeda Yakuhin, to healthcare providers.

The summarized consolidated financial information of Teva Takeda Pharma and Teva Takeda Yakuhin is as follows:

	JPY (millions) For the Year Ended March 31		
	2017	2018	2019
Revenue	¥ 105,547	¥ 103,719	¥ 89,686
Net loss for the year	(4,132)	(66,301)	(87,106)
Other comprehensive income (loss)	—	—	—
Total comprehensive loss for the year	(4,132)	(66,301)	(87,106)
Total comprehensive loss for the year (49.0%)	(2,025)	(32,487)	(42,682)
Other	(120)	(137)	211
Takeda's share of loss for the year	¥ (2,145)	¥ (32,624)	¥ (42,471)

	JPY (millions) As of March 31	
	2018	2019
Non-current assets	¥ 163,979	¥ 111,379
Current assets	97,865	108,423
Non-current liabilities	(31,901)	(15,615)
Current liabilities	(20,119)	(18,695)
Equity	¥ 209,824	¥ 185,492
Takeda's share of equity (49.0%)	¥ 102,814	¥ 90,891
Goodwill	66,094	32,921
Deferred gain	(73,554)	(39,881)
Carrying amount of investments accounted for using the equity method	¥ 95,354	¥ 83,931

The results of Teva Takeda Pharma and Teva Takeda Yakuhin for the year ended March 31, 2018 included an impairment loss of 104,753 million JPY of which, 35,725 million JPY represents Takeda's share. The results for the year ended March 31, 2019 included an impairment loss of 117,890 million JPY, of which 50,183 million JPY represents Takeda's share. These impairments relate to changes in the business environment such as the revision of the pharmaceutical pricing system in Japan.

Takeda received dividends of 4,159 million JPY from Teva Takeda Pharma for the year ended March 31, 2018. There were no dividends received from Teva Takeda Pharma for the year ended March 31, 2019. Teva Takeda Pharma cannot distribute its profits without the consent from the two venture partners.

Associates that are individually immaterial to Takeda

Financial information for associates, which are individually immaterial to Takeda, is as follows: These amounts are based on the shareholding ratio of Takeda.

	JPY (millions) For the Year Ended March 31		
	2017	2018	2019
Net profit (loss) for the year	¥ 599	¥ 425	¥ (1,156)
Other comprehensive income (loss)	(38)	382	(94)
Total comprehensive income (loss) for the year	¥ 561	¥ 807	¥ (1,250)

The carrying amount of the investments in associates, which are individually immaterial to Takeda, is as follows:

	JPY (millions) As of March 31	
	2018	2019
Carrying amount of investments accounted for using the equity method	¥ 12,595	¥ 30,727

15. Other Financial Assets

	JPY (millions) As of March 31	
	2018	2019
Derivative assets	¥ 3,289	¥ 8,315
Investment in convertible notes at FVTPL	—	9,865
Investment in debt securities at FVTPL	—	1,608
Investment in equity instruments at FVTOCI	—	168,732
Available-for-sale financial assets	169,814	—
Restricted deposits	87,381	15,577
Other	16,598	11,420
Total	¥ 277,082	¥ 215,517
Non-current	¥ 196,436	¥ 192,241
Current	¥ 80,646	¥ 23,276

As of March 31, 2018, available-for-sale financial assets included 163,030 million JPY of investments in public companies. As of March 31, 2019, equity instruments included 119,907 million JPY of investments in public companies. These are considered Level 1 in the fair value hierarchy as defined in Note 27. The remainder of the equity instruments primarily relates to investments acquired in connection with collaborations and licensing agreements (Note 13) and are considered Level 3 investments in the fair value hierarchy.

As of March 31, 2018, the restricted deposits mainly represent cash restricted for the acquisition of TiGenix NV (Note 31). These amounts were subsequently released following the completion of the acquisition. As of March 31, 2019, the restricted deposits mainly represent amounts related to Takeda's business combinations.

16. Inventories

	JPY (millions) As of March 31	
	2018	2019
Finished products and merchandise	¥ 86,254	¥ 280,738
Work-in-process	63,145	544,411
Raw materials and supplies	63,545	161,595
Total	¥ 212,944	¥ 986,744

The amount of inventory write-offs recognized was 11,621 million JPY, 10,292 million JPY, and 9,321 million JPY for the years ended March 31, 2017, 2018 and 2019 respectively, and were included within cost of sales. Inventory as of March 31, 2019 increased due to the recording of the acquired inventory at fair value upon the acquisition of Shire (Note 31).

17. Trade and Other Receivables

	JPY (millions) As of March 31	
	2018	2019
Trade receivables	¥ 369,652	¥ 660,999
Other receivables	59,414	84,226
Impairment loss allowance	(8,819)	(3,318)
Total	¥ 420,247	¥ 741,907

18. Cash and Cash Equivalents

	JPY (millions) As of March 31	
	2018	2019
Cash and deposits	¥ 243,324	¥ 462,890
Short-term investments	51,198	239,203
Total	¥ 294,522	¥ 702,093

19. Assets and Disposal Groups Held for Sale

Takeda has classified certain assets as held for sale in the consolidated statement of financial position. Non-current assets and disposal groups are transferred to assets held for sale when it is expected that their carrying amounts will be recovered principally through a sale and the sale is considered highly probable. The non-current assets and disposal groups held for sale are held at the lower of carrying amount or fair value less costs to sell.

Gains or losses recognized from measuring the disposal groups classified as held for sale at the lower of their carrying amounts or fair value less costs to sell when assets or disposal groups are classified to held for sale, are recorded as other operating income or expense.

Assets Held for Sale

	JPY (millions) As of March 31	
	2018	2019
Buildings and structures	¥ 98	¥ —
Land	65	—
Investments accounted for using the equity method	18	450
Total	¥ 181	¥ 450

The assets held for sale as of March 31, 2018 primarily represent buildings and structures that were classified as held for sale during the year then ended based on management decision to sell this property. No impairment was recorded upon classification of the building as held for sale. These items were sold during the year ended March 31, 2019. The fair value of the assets is based on valuations by independent appraisers who hold recognized and relevant professional qualifications in the respective location of assets held for sale. The valuations, which conform to the standards of the location, are based on market evidence of transaction prices for similar assets.

The assets held for sale as of March 31, 2019 primarily represent an investment accounted for using the equity method in PRA Health Sciences that were classified as held for sale based on management decision to sell the investment. No impairment was recorded upon classification of the investments as held for sale. This investment was sold in May 2019. The fair value of the assets is based on expected sales price less costs of disposal.

The fair value of assets held for sale is classified as Level 3 in the fair value hierarchy.

Disposal Groups Held for Sale

	JPY (millions) As of March 31	
	2018	2019
Property, plant and equipment	¥ —	¥ 451
Intangible assets	—	58
Inventories	1,202	—
Trade and other receivables	1,466	179
Cash and cash equivalents	451	629
Other	692	1,379
Total assets	¥ 3,811	¥ 2,696
Net defined benefit liabilities	¥ —	¥ 383
Provisions	1,066	—
Trade and other payables	165	210
Other	1,983	959
Total liabilities	¥ 3,214	¥ 1,552

The disposal groups held for sale as of March 31, 2018, consisted mainly of a group of assets, liabilities, and other comprehensive income related to Takeda's consolidated subsidiary, Multilab Indústria e Comércio de Produtos Farmacêuticos Ltda., and reclassified as held for sale. The shares of the subsidiary were sold in July 2018. The fair value of the disposal group is based on the publicly announced sales price less costs of disposal and is classified as Level 2 in the fair value hierarchy as of March 31, 2018.

The disposal groups held for sales as of March 31, 2019, consisted mainly of a group of assets and liabilities related to Takeda's consolidated subsidiary, Axcelead Drug Discovery Partners, Inc., and reclassified as held for sale following management decision to sell the subsidiary. The shares of the subsidiary were sold in April 2019. The fair value of the disposal group is based on the agreed upon sales price with the third party less costs of disposal and is classified as Level 3 in the fair value hierarchy as of March 31, 2019.

Takeda recorded a loss of 3,213 million JPY on the classification of the disposal group as held for sale for the year ended March 31, 2018. No loss on the classification was recorded for the year ended March 31, 2019.

Items classified as held for sale at acquisition

There were certain asset and disposal groups that were acquired from Shire with the intention to be sold that were classified as held for sale at the acquisition date. These relate to the Xiidra® (lifitegrast ophthalmic solution) product which Takeda has subsequently announced a sale agreement for, as included in Note 33. These also include the research and development program referred to as SHP647 that the European Union had required to be disposed as a condition to the acquisition of Shire by Takeda.

	JPY (millions) As of March 31
	2019
Intangible assets	¥ 455,340
Inventories	13,682
Deferred tax assets	7,592
Total assets	¥ 476,614
Deferred tax liabilities	¥ 102,947
Provisions	78,836
Other financial liabilities	17,810
Total liabilities	¥ 199,593

20. Bonds and Loans

	JPY (millions) As of March 31	
	2018	2019
Bonds	¥ 172,889	¥ 3,196,365
Short-term loans	18	500,002
Long-term loans	812,755	2,054,584
Total	¥ 985,662	¥ 5,750,951
Non-current	¥ 985,644	¥ 4,766,005
Current	¥ 18	¥ 984,946

The composition of bonds is as follows:

Instrument	Principal Amount in contractual currency (millions)	JPY (millions) Carrying value As of March 31, 2018	JPY (millions) Carrying value As of March 31, 2019	Interest Rate (%)	Maturity
14th Unsecured Straight Bonds	60,000 JPY	¥ 59,967	¥ 59,992	0.540%	Jul 2019
15th Unsecured Straight Bonds	60,000 JPY	59,944	59,968	0.704%	Jul 2020
USD Unsecured Senior Notes	500 USD	52,978	55,129	2.450%	Jan 2022
2018 EUR Unsecured Senior Notes – variable rate	1,750 EUR	—	216,717	3 month EURIBOR + margin (0.550-1.100%)	Nov 2020 - Nov 2022
2018 EUR Unsecured Senior Notes – fixed rate	5,750 EUR	—	708,860	0.375-3.000%	Nov 2020 - Nov 2030
2018 USD Unsecured Senior Notes – fixed rate	5,500 USD	—	605,261	3.800-5.000%	Nov 2020 - Nov 2028
Unsecured Senior Notes Assumed in Shire Acquisition	12,100 USD	—	1,278,490	1.900-3.200%	Sep 2019 - Sep 2026
Unsecured Senior Notes Assumed in Shire Acquisition	1,925 USD	—	211,948	2.875%-5.250%	Jun 2020 - Jun 2045
Total		¥ 172,889	¥ 3,196,365		

The composition of loans is as follows:

Instrument	Principal Amount in contractual currency (millions)	JPY (millions) Carrying value As of March 31, 2018	JPY (millions) Carrying value As of March 31, 2019	Interest Rate (%)	Maturity
Syndicated Loans 2013	120,000 JPY	¥ 120,000	¥ 120,000	3 month LIBOR + 0.010%	Jul 2019 - Jul 2020
Syndicated Loans 2016	200,000 JPY	200,000	200,000	0.200–0.300%	Apr 2023 - Apr 2026
Syndicated Loans 2017	113,500 JPY	113,500	113,500	0.350%	Apr 2027
USD Syndicated Loans 2017	1,500 USD	159,255	165,599	6 month LIBOR + 0.500%	Apr 2027
Syndicated Loans 2019	500,000 JPY	—	500,000	1 month TIBOR + 0.100%	Jul 2019
USD Syndicated Loans 2019	7,500 USD	—	819,482	LIBOR + variable margin (0.750-1.500%)	Jan 2024
USD Japan Bank for International Cooperation 2019	3,700 USD	—	409,346	6 month LIBOR + 0.600%	Dec 2025
Other		220,018	226,659		
Total		¥ 812,773	¥ 2,554,586		

The bonds and loans incurred by Takeda to fund a portion of the Shire Acquisition comprised of the following:

- 2018 EUR Unsecured Notes - variable rate comprised of 1,000 million EUR at 3 month EURIBOR + 0.550% interest maturing in 2020, 750 million EUR at 3 month EURIBOR + 1.100% interest maturing in 2022.

- 2018 EUR Unsecured Notes - fixed rate comprised of 1,250 million EUR at 0.375% interest maturing in 2020, 1,500 million EUR at 1.125% interest maturing in 2022, 1,500 million EUR at 2.250% interest maturing in 2026, and 1,500 million EUR at 3.000% interest maturing in 2030.
- 2018 USD Unsecured Notes - fixed rate comprised of 1,000 million USD at 3.800% annual interest maturing in 2020, 1,250 million USD at 4.000% annual interest maturing in 2021, 1,500 million USD at 4.400% annual interest maturing in 2023, and 1,750 million USD at 5.000% annual interest maturing in 2028.
- Syndicated Loans 2019 comprised of a Senior Short-Term Loan Facility agreement with aggregate principal amounts up to 500,000 million JPY at 1 month TIBOR + 0.100% interest maturing in July 2019.
- USD Syndicated Loans 2019 comprised of a Term Loan Credit Agreement with aggregate principal amounts up to 7,500 million USD, out of which 3,500 million USD was made available in Euros. These syndicated loans mature in 2024, and have an interest rate of LIBOR plus a variable margin based on the public debt rating. As of March 31, 2019, the principal amounts in USD and EUR were 4,000 million USD and 3,057 million EUR, respectively.
- Loan Agreement with the Japan Bank for International Cooperation (the "JBIC Loan") with aggregate principal amount of up to 3,700 million USD. The JBIC loan has interest of 6 month LIBOR + 0.600% interest, and matures in 2025.

The bonds and loans assumed from Shire with the acquisition are mainly comprised of the following:

- Shire Unsecured Senior Notes, guaranteed by Takeda Pharmaceuticals Company Limited, comprised of 3,300 million USD at 1.900% interest maturing in 2019, 3,300 million USD at 2.400% interest maturing in 2021, 2,500 million USD at 2.875% interest maturing in 2023, 3,000 million USD at 3.200% interest maturing in 2026.
- Shire Unsecured Senior Notes, guaranteed by Takeda Pharmaceuticals Company Limited, comprised of 405 million USD at 2.875% interest maturing in 2020, 220 million USD at 3.600% interest maturing in 2022, 800 million USD at 4.000% interest maturing in 2025, and 500 million USD at 5.250% interest maturing in 2045.
- Shire Revolving Credit Facilities Agreement – On December 12, 2014, Shire entered into a 2,100 million USD revolving credit facilities agreement with a number of financial institutions. This agreement was terminated in February 2019.

At their respective times of issuance, Takeda entered into a currency and interest rate swap agreement to hedge the JPY amount for 200 million USD of the USD Unsecured Senior Notes and 925 million USD of the USD Syndicated Loans 2017. Takeda entered into an interest rate swap agreement to fix the interest rate for 120,000 million JPY of the Syndicated Loans 2013 and 575 million USD of the USD Syndicated Loans 2017.

As of March 31, 2019, Takeda had borrowing availability of 300,000 million JPY.

The 2018 USD Senior Notes have registration rights that, among other things, require Takeda to file a registration statement with the US Securities and Exchange Commission for an offer to exchange the 2018 USD Senior Notes for registered notes prior to August 23, 2019. To the extent that this is not accomplished, Takeda will be required to pay penalty interest until remedied. There are long-term financing agreements that contain various financial covenants which require Takeda to maintain certain financial ratios and other restrictions including the level of the company's borrowings. The most restrictive of these covenants is that profit before tax must not be negative for two consecutive years. Takeda was in compliance with all such covenants as of March 31, 2019.

21. Other Financial Liabilities

	JPY (millions) As of March 31	
	2018	2019
Derivative liabilities	¥ 8,871	¥ 8,745
Finance lease obligations	53,149	179,411
Contingent consideration liabilities arising from business combinations	30,569	71,062
Other	28,247	23,908
Total	¥ 120,836	¥ 283,126
Non-current	¥ 91,223	¥ 235,786
Current	¥ 29,613	¥ 47,340

Finance lease obligations

The future minimum payments related to the finance lease obligations are as follows:

	JPY (millions) As of March 31			
	Minimum Lease Payments		Present Value of Minimum Lease Payments	
	2018	2019	2018	2019
Within one year	¥ 4,808	¥ 6,925	¥ 2,127	¥ 2,145
Between one year and five years	14,335	37,738	4,704	9,634
More than five years	80,018	288,470	46,318	167,632
Total	¥ 99,161	¥ 333,133	¥ 53,149	¥ 179,411
Less: Future finance charges	46,012	153,722		
Present value of minimum lease payments	¥ 53,149	¥ 179,411		
Non-current	¥ 51,022	¥ 177,266		
Current	¥ 2,127	¥ 2,145		

Financial liabilities associated with contingent consideration arrangements

Financial liabilities associated with contingent consideration arrangements represent consideration related to business combinations or license agreements that is payable only upon future events such as the achievement of development milestones and sales targets, including pre-existing contingent consideration arrangements of the companies that are acquired by Takeda. At each reporting date, the fair value of contingent consideration is re-measured based on risk-adjusted future cash flows discounted using appropriate discount rate.

As of the year ended March 31, 2018, financial liabilities associated with contingent consideration arrangements primarily consists of contingent consideration related to the performance of the COLCRYS business which was acquired in the acquisition of URL Pharma. Inc. in June 2012.

As of the year ended March 31, 2019, the balance primarily relates to pre-existing contingent consideration arrangements from Shire's historical acquisitions.

The pre-existing contingent consideration acquired from Shire through Shire's historical acquisitions is due upon the achievement of certain milestones related to the development, regulatory, first commercial sale and other sales milestones of products at various stages of development and marketing, which could total up to 83,802 million JPY of undiscounted payments over a period of over 20 years. The fair value of the contingent consideration payable could increase or decrease due to changes in certain assumptions which underpin the fair value measurements. The assumptions include probability of milestones being achieved.

The fair value of financial liabilities associated with contingent consideration arrangements are classified as Level 3 in the fair value hierarchy.

	JPY (millions) For the Year Ended March 31	
	2018	2019
As of the beginning of the year	¥ 28,976	¥ 30,569
Additions arising from business combinations (Note 31)	3,164	52,046
Changes in the fair value during the period	12,784	(2,223)
Settled and paid during the period	(12,606)	(7,734)
Settled during the period and reclassified to other payables	—	(1,648)
Foreign currency translation differences	(1,243)	175
Other	(506)	(123)
As of the end of the year	¥ 30,569	¥ 71,062

	JPY (millions) As of March 31	
	2018	2019
Payment term (undiscounted)		
Within one year	¥ 10,620	¥ 17,604
Between one and three years	18,584	19,470
Between three and five years	4,641	10,885
More than five years	2,831	54,536

The following sensitivity analysis represents effect on the fair value of financial liabilities associated with contingent consideration arrangements from changes in major assumptions:

		JPY (millions) As of March 31	
		2018	2019
Probability of technical milestones being achieved for Shire's historical contingent consideration arrangements	Increase by 5%	¥ —	¥ 3,204
	Decrease by 5%	—	(3,204)
Discount rate	Increase by 0.5%	(257)	(1,626)
	Decrease by 0.5%	256	1,626

22. Employee Benefits

Defined Benefit Plans

The Company and some of its subsidiaries have various defined benefit plans such as lump-sum retirement payments plans and defined benefit pension plans, which define the amount of benefits that an employee will receive on or after retirement, usually based on one or more factors, such as age, years of employment, compensation, classes, and service.

The Company's defined benefit plans account for the majority of Takeda's defined benefit obligations and plan assets.

Defined benefit pension plans

Japan

The Company's corporate defined benefit pension plan in Japan is a funded defined benefit pension plan, which is regulated by the Defined-Benefit Corporate Pension Act, one of the Japanese pension laws. Benefits are paid in exchange for services rendered by employees who worked for more than a specified period, typically three years, considering their years of service and the degree of their contribution to the Company.
The Company's pension fund (the "Fund") is an independent entity established in accordance with the Japanese pension laws, and Takeda has an obligation to make contributions. The Director(s) of the Fund has the fiduciary duty to comply with laws; the directives by the Minister of Health, Labor and Welfare, and the Director-Generals of Regional Bureaus of Health and Welfare made pursuant to those laws; and the by-laws of the Fund

and the decisions made by the Board of Representatives of the Fund. Contributions are also regularly reviewed and adjusted as necessary to the extent permitted by laws and regulations.

Foreign

Other types of defined benefit pension plans operated by Takeda are generally established and operated in the same manner as described above and in accordance with local laws and regulations where applicable.

The present value of the defined benefit obligation is calculated annually based on actuarial valuations that are dependent upon a number of assumptions, including discount rates and future salary (benefit) increases, in accordance with IAS 19 'Employee Benefits'. Service costs charged to operating expense related to defined benefit plans represent the increase in the defined benefit liability arising from pension benefits earned by active participants in the current period. Takeda is exposed to investment and other experience risks and may need to make additional contributions where it is estimated that the benefits will not be met from regular contributions, expected investment income, and assets held.

The amounts recognized in the consolidated statements of income and the consolidated statements of financial position are as follows:

Consolidated statements of income

	JPY (millions) For the Year Ended March 31		
	2017	2018	2019
Japan	¥ 6,779	¥ 4,582	¥ 4,621
Foreign	5,210	5,772	6,786
Defined benefit costs	¥ 11,989	¥ 10,354	¥ 11,407

Consolidated statements of financial position

	JPY (millions) As of March 31, 2018		
	Japan	Foreign	Total
Present value of defined benefit obligations	¥ 198,686	¥ 99,174	¥ 297,860
Fair value of plan assets	230,421	21,207	251,628
Net defined benefit liabilities (assets)	¥ (31,735)	¥ 77,967	¥ 46,232
Consolidated statement of financial position			
Net defined benefit liabilities	¥ 9,604	¥ 78,007	¥ 87,611
Net defined benefit assets	41,339	40	41,379
Net amount of liabilities (assets) recognized in the consolidated statement of financial position	¥ (31,735)	¥ 77,967	¥ 46,232

	JPY (millions) As of March 31, 2019		
	Japan	Foreign	Total
Present value of defined benefit obligations	¥ 198,293	¥ 227,975	¥ 426,268
Fair value of plan assets	223,191	80,625	303,816
Net defined benefit liabilities (assets)	¥ (24,898)	¥ 147,350	¥ 122,452
Consolidated statement of financial position			
Net defined benefit liabilities	¥ 9,461	¥ 147,435	¥ 156,896
Net defined benefit assets	34,359	85	34,444
Net amount of liabilities (assets) recognized in the consolidated statement of financial position	¥ (24,898)	¥ 147,350	¥ 122,452

Net defined benefit assets were included in other non-current assets on the consolidated statements of financial position. Net defined benefit assets included 771 million JPY in assets held for sale, and net defined benefit liabilities included 383 million JPY in liabilities held for sale as of March 31, 2019, related to disposal groups held for sale (Note 19).

Defined benefit obligations

A summary of changes in present value of the defined benefit obligations for the periods presented is as follows:

	JPY (millions) For the Year Ended March 31, 2018		
	Japan	Foreign	Total
At beginning of the year	¥ 217,026	¥ 90,424	¥ 307,450
Current service cost	4,866	4,295	9,161
Interest cost	1,424	1,713	3,137
Re-measurement gains and losses of defined benefit plans			
From changes in demographic assumptions	3,294	(1,179)	2,115
From changes in financial assumptions	(3)	782	779
Experience adjustments	466	297	763
Past service cost	11	5	16
Settlement	(2,515)	2,346	(169)
Benefits paid	(13,134)	(3,093)	(16,227)
Effect of business combinations and disposals	(12,749)	81	(12,668)
Foreign currency translation differences	—	3,503	3,503
At end of the year	¥ 198,686	¥ 99,174	¥ 297,860

	JPY (millions) For the Year Ended March 31, 2019		
	Japan	Foreign	Total
At beginning of year	¥ 198,686	¥ 99,174	¥ 297,860
Current service cost	4,774	5,041	9,815
Interest cost	1,390	2,356	3,746
Re-measurement gains and losses of defined benefit plans			
From changes in demographic assumptions	1,499	(44)	1,455
From changes in financial assumptions	2,577	13,101	15,678
Experience adjustments	301	(1,301)	(1,000)
Past service cost	71	—	71
Settlement	(262)	—	(262)
Benefits paid	(11,784)	(5,156)	(16,940)
Effect of business combinations and disposals	1,041	116,060	117,101
Foreign currency translation differences	—	(1,256)	(1,256)
At end of the year	¥ 198,293	¥ 227,975	¥ 426,268

The remaining weighted average duration of the defined benefit obligations was 14.4 years and 15.2 years as of March 31, 2018 and 2019, respectively.

Significant actuarial assumptions used to determine the present value are as follows:

	Discount Rate	Future Salary Increases
2018		
Japan	0.7%	0.2%
Foreign	1.7%	2.7%
2019		
Japan	0.6%	0.2%
Foreign	1.7%	2.2%

A 0.5% change in these actuarial assumptions would affect the present value of defined benefit obligations at the end of the reporting period, while holding all other assumptions constant, by the amounts shown below:

	JPY (millions)			
	Discount Rate		Future Salary Increases	
	Change in assumption	Impact	Change in assumption	Impact
2018				
Japan	+0.50 %	¥ (12,250)	+0.50 %	¥ 517
	-0.50 %	13,778	-0.50 %	(477)
Foreign	+0.50 %	(7,371)	+0.50 %	479
	-0.50 %	8,247	-0.50 %	(665)
2019				
Japan	+0.50 %	(12,608)	+0.50 %	499
	-0.50 %	14,193	-0.50 %	(470)
Foreign	+0.50 %	(19,158)	+0.50 %	2,745
	-0.50 %	17,699	-0.50 %	(3,995)

Plan assets

The defined benefit plans are independent of Takeda and funded only by contributions from Takeda. Takeda's investment policies are designed to secure the necessary returns in the long-term within acceptable risk levels to ensure payments of pension benefits to eligible participants, including future participants. The acceptable risk level in the return rate on the plan assets is derived from a detailed study considering the mid- to long-term trends and the changes in income such as contributions and payments. Based on policies and studies, after consideration of issues such as the expected rate of return and risks, Takeda formulates a basic asset mix which aims at an optimal portfolio on a long-term basis with the selection of appropriate investment assets.

A summary of changes in fair value of plan assets for the periods presented is as follows:

	JPY (millions) For the Year Ended March 31,	
	2018	2019
Balance at beginning of the year	¥ 265,031	¥ 251,628
Interest income on plan assets	1,959	2,225
Re-measurement of defined benefit plans Return on plan assets	4,813	468
Contributions by the employer	4,753	5,706
Settlement	(3,564)	—
Benefits paid	(11,507)	(12,923)
Effect of business combinations and disposals	(11,225)	55,133
Foreign currency translation differences	1,368	1,579
Balance at end of the year	¥ 251,628	¥ 303,816

Takeda expects to contribute 7,770 million JPY to the defined benefit plans for the year ending March 31, 2020.

The breakdown of fair value by asset class is as follows:

	JPY (millions) As of March 31			
	2018		2019	
	With Quoted Prices in Active Markets	No Quoted Prices in Active Markets	With Quoted Prices in Active Markets	No Quoted Prices in Active Markets
Equities:				
Japan	¥ 15,494	¥ 2,804	¥ 15,025	¥ 3,444
Foreign	6,396	58,286	20,680	74,309
Bonds:				
Japan	1,568	19,157	1,040	16,523
Foreign	2,278	38,716	12,011	34,250
Life insurance company general accounts	—	68,551	—	88,178
Cash and cash equivalent	8,452	—	9,663	—
Investments in trusts	—	—	—	18,683
Others	514	29,412	404	9,606
Total plan assets	¥ 34,702	¥ 216,926	¥ 58,823	¥ 244,993

Equities and bonds with no quoted prices in active markets includes pooled funds that are primarily invested in listed securities on active markets. Life insurance company general accounts are accounts with guaranteed capital and minimum interest rate, in which life insurance companies manage funds on a contractual basis.

Defined Contribution Plans

The Company and some of the Company's subsidiaries offer defined contribution benefit plans.

Benefits of defined contribution plans are linked to contributions paid, the performance of each participant's chosen investments, and the form in which participants choose to redeem their benefits. Contributions made into these plans are generally paid into an independently administered fund.

Contributions payable by Takeda for these plans are charged to operating expenses. Takeda has no exposure to investment risks and other experience risks with regard to defined contribution plans.

The amount of defined contribution costs was 20,897 million JPY, 19,525 million JPY, and 21,068 million JPY for the years ended March 31, 2017, 2018 and 2019, respectively. These amounts include contributions to publicly provided plans.

Other Employee Benefit Expenses

Major employee benefit expenses other than retirement benefits for each fiscal year are as follows:

	JPY (millions) For the Year Ended March 31		
	2017	2018	2019
Salary	¥ 226,985	¥ 215,256	¥ 272,930
Bonuses	68,935	70,708	89,439
Other	75,949	81,616	93,711

The above table does not include severance expenses.

23. Provisions

The movements in the provisions are as follows:

	JPY (millions)				
	Litigation (Note 32)	Restructuring	Rebates and Return Reserves	Other	Total
As of April 1, 2017	¥ 33,446	¥ 27,118	¥ 90,870	¥ 22,470	¥ 173,904
Increases	3,692	5,935	310,070	14,009	333,706
Decreases (utilized)	(12,372)	(19,183)	(284,164)	(11,579)	(327,298)
Decreases (reversed)	(286)	(128)	(9,557)	(2,045)	(12,016)
Decreases from deconsolidation	—	(133)	—	(107)	(240)
Reclassification to liabilities held for sale	(676)	—	—	(390)	(1,066)
Foreign currency translation differences	(622)	(993)	(5,378)	826	(6,167)
As of March 31, 2018	¥ 23,182	¥ 12,616	¥ 101,841	¥ 23,184	¥ 160,823
Increases	10,382	30,547	441,188	13,198	495,315
Acquisitions through business combinations	29,570	14,506	217,002	17,912	278,990
Decreases (utilized)	(11,426)	(8,594)	(462,335)	(10,836)	(493,191)
Decreases (reversed)	(3,146)	(679)	(11,447)	(3,335)	(18,607)
Decreases from deconsolidation	(1,032)	—	(994)	(295)	(2,321)
Foreign currency translation differences	(755)	1,285	8,107	(1,549)	7,088
As of March 31, 2019	¥ 46,775	¥ 49,681	¥ 293,362	¥ 38,279	¥ 428,097

The current portion of the provision is 135,796 million JPY, 132,781 million JPY, and 392,733 million JPY as of April 1, 2017, March 31, 2018 and 2019, respectively. The non-current portion of the provision is 38,108 million JPY, 28,042 million JPY and 35,364 million JPY, as of April 1, 2017, March 31, 2018 and 2019, respectively.

Restructuring

Takeda has various restructuring efforts in place during the years ended March 31, 2017, 2018 and 2019, in connection with the following:

- Transform its R&D function – Takeda has commenced various restructuring efforts during the years ended March 31, 2017, 2018 and 2019, in connection with efforts to transform its R&D function and to improve the efficiency of its operations. These initiatives included consolidation of sites and functions and reduction in workforce.
- Integration of Shire - In the year ended March 31, 2019, Takeda commenced various restructuring efforts following the acquisition of Shire. The integration of Shire includes initiatives to consolidate systems, sites, and functions, and to optimize the workforce.
- Acquired restructuring programs – Takeda acquired various restructuring programs in connection with the Shire Acquisition. These include Shire program related to completing the integration of Baxalta, Inc., which was acquired by Shire in June 2016.
- Various other efforts to improve the efficiency of its operations and related facilities

A restructuring provision is recorded when Takeda has a detailed formal plan for the restructuring. Takeda records the provision and associated expenses based on estimated costs associated with the plan. The ultimate cost and the timing of any payments under the plan will be impacted by the actual timing of the actions and the actions of employees impacted by the restructuring activities. The payments for non-current restructuring provision are expected to be made within approximately 3 years.

Restructuring expenses recorded are as follows:

	JPY (millions) For the Year Ended March 31		
	2017	2018	2019
Cash:			
Severance	¥ 32,290	¥ 6,397	¥ 17,574
Consulting fees	7,271	7,205	19,040
Other	11,611	16,528	44,906
Total	¥ 51,172	¥ 30,130	¥ 81,520
Non-Cash:			
Depreciation and impairment	¥ 3,417	¥ 14,606	¥ 1,442
Total	¥ 54,589	¥ 44,736	¥ 82,962

The other restructuring costs mainly relate to retention and contract termination costs. The other restructuring costs for the year ending March 31, 2019 includes personnel costs of 20,754 million JPY mainly related to retention bonus and salary of employees fully dedicated to restructuring programs.

Rebates and Returns

Takeda has recognized a provision related mainly to sales rebates and returns for products and merchandises, which include sales-linked rebates such as government health programs in the US. These are expected to be paid out generally within one year. Sales rebates and sales returns are reviewed and updated monthly or when there is a significant change in its amount.

Other

Other provisions are primarily related to asset retirement obligations, contract termination fees and onerous contracts.

24. Other Liabilities

	JPY (millions) As of March 31	
	2018	2019
Accrued expenses	¥ 231,497	¥ 406,956
Deferred income	52,527	45,431
Other	48,206	60,675
Total	¥ 332,230	¥ 513,062
Non-current	¥ 68,300	¥ 75,174
Current	¥ 263,930	¥ 437,888

Accrued expenses include accrued labor cost of 108,766 million JPY and 163,241 million JPY as of March 31, 2018 and 2019, respectively.

Deferred income includes government grants for the purchase of property, plant and equipment. The grants received were 23,937 million JPY and 21,145 million JPY during the years ended March 31, 2018 and 2019, respectively. The primary government grants relate to funding a portion of Takeda's investment in the development and production of new influenza vaccines. Takeda was reimbursed for investments it made in facilities. The grant income is recognized over the life of the associated assets and is recorded as an offset to the depreciation expense (included in cost of sales, selling, general, and administrative expenses, and research and development expenses). Deferred income also includes unearned co-promotion fees received in advance of 21,656 million JPY and 16,756 million JPY as of March 31, 2018 and 2019, respectively. When the co-promotion fees are recognized, they will offset selling, general and administrative expenses.

25. Trade and Other Payables

	JPY (millions) As of March 31	
	2018	2019
Trade payables	¥ 133,705	¥ 212,348
Other payables	106,554	115,046
Total	¥ 240,259	¥ 327,394

Trade payables relate to expenditures associated with Takeda's manufacturing and other payables relate to other expenditures associated with its day-to-day operations.

26. Equity and Other Equity Items

	(Thousands of Shares)	
	2018	2019
Authorized shares as of April 1	3,500,000	3,500,000
Outstanding shares:		
At April 1	790,521	794,688
Exercise of stock options	617	15
Issuance of shares (Note 31)	3,550	770,303
At March 31	794,688	1,565,006

The shares issued by the Company are ordinary shares with no par value that have no restrictions on any rights. The number of treasury shares included in the above outstanding shares was 9,680 thousand shares, 13,379 thousand shares, and 10,226 thousand shares as of April 1, 2017, March 31, 2018, and 2019, respectively. The number of treasury shares as of March 31, 2018 and March 31, 2019 includes 13,133 thousand shares and 9,976 thousand shares, respectively, held by the Employee Stock Ownership Plan ("ESOP") Trust and the Board Incentive Plan ("BIP") Trust. The ESOP and BIP Trust acquired 246 thousand shares and sold 3,403 thousand shares during the year ended March 31, 2019.

During the year ended March 31, 2018, the Company issued 3,550 thousand shares through third- party allotment to the Master Trust Bank of Japan, Ltd., which is the trust account for Takeda's ESOP subsidiary. The issuance of these shares resulted in an increase in share capital of 11,388 million JPY and share premium of 11,286 million JPY. The Master Trust Bank of Japan is a co-trustee of the ESOP. This issuance was approved by the resolution of our Board of Directors. These shares were reacquired by the Company from the ESOP trust for distribution of share based compensation awards. The reacquisition of the shares resulted in an increase in treasury shares of 22,773 million JPY.

During the year ended March 31, 2019, the Company issued 770,303 thousand ordinary shares to fund the acquisition of Shire (Note 31).

Dividends Declared and Paid	JPY (millions) Total Dividends	Dividends Per Share JPY	Basis Date	Effective Date
April 1, 2016, to March 31, 2017				
Q1 2016	¥ 71,112	¥ 90.00	March 31, 2016	June 30, 2016
Q3 2016	71,122	90.00	September 30, 2016	December 1, 2016
April 1, 2017, to March 31, 2018				
Q1 2017	71,133	90.00	March 31, 2017	June 29, 2017
Q3 2017	71,165	90.00	September 30, 2017	December 1, 2017
April 1, 2018, to March 31, 2019				
Q1 2018	71,507	90.00	March 31, 2018	June 29, 2018
Q3 2018	71,509	90.00	September 30, 2018	December 3, 2018

Dividends declared for which the effective date falls in the following fiscal year are as follows:

Dividends Declared	JPY (millions) Total Dividends	Dividends Per Share JPY	Basis Date	Effective Date
April 1, 2019, to March 31, 2020				
Q1 2019	¥ 140,836	¥ 90.00	March 31, 2019	June 28, 2019

27. Financial Instruments

Takeda promotes risk management to reduce the financial risks arising from business operations. The principal risks to which Takeda is exposed include market risk, counterparty credit risk, and liquidity risk caused by changes in the market environment such as fluctuations in the price of foreign currency, interest rates and market prices of commodities and other financial holdings. Each of these risks are managed in accordance with Takeda's policies.

Financial Assets and Liabilities

	JPY (millions) As of March 31, 2018					
	Loans and Receivables	Available-for-sale financial assets	Derivative hedging instruments	Measured at fair value through profit or loss	Other Financial Liabilities	Total
Financial Assets Measured at Fair Value						
Other financial assets -						
Available-for-sale financial assets	¥ —	¥ 169,814	¥ —	¥ —	¥ —	¥ 169,814
Derivative financial instruments	—	—	2,527	762	—	3,289
Other	—	—	—	2,070	—	2,070
Total	¥ —	¥ 169,814	¥ 2,527	¥ 2,832	¥ —	¥ 175,173
Financial Assets Not Measured at Fair Value						
Other financial assets -						
Restricted deposits	¥ 87,381	¥ —	¥ —	¥ —	¥ —	¥ 87,381
Other	14,528	—	—	—	—	14,528
Trade and Other Receivables	420,247	—	—	—	—	420,247
Cash and cash equivalents	294,522	—	—	—	—	294,522
Total	¥ 816,678	¥ —	¥ —	¥ —	¥ —	¥ 816,678
Financial Liabilities Measured at Fair Value						
Other financial liabilities -						
Contingent considerations	¥ —	¥ —	¥ —	¥ 30,569	¥ —	¥ 30,569
Derivative financial instruments	—	—	3,498	5,373	—	8,871
Total	¥ —	¥ —	¥ 3,498	¥ 35,942	¥ —	¥ 39,440
Financial Liabilities Not Measured at Fair Value						
Other financial liabilities -						
Finance leases	¥ —	¥ —	¥ —	¥ —	¥ 53,149	¥ 53,149
Other	—	—	—	—	28,247	28,247
Trade and Other Payables	—	—	—	—	240,259	240,259
Bonds and Loans	—	—	—	—	985,662	985,662
Total	¥ —	¥ —	¥ —	¥ —	¥ 1,307,317	¥ 1,307,317

	JPY (millions) As of March 31, 2019					
	Measured at amortized cost	Measured at fair value through other comprehensive income	Measured at fair value through profit or loss	Derivative hedging instruments	Other Financial Liabilities	Total
Financial Assets Measured at Fair Value						
Other financial assets -						
Equity instruments	¥ —	¥ 168,732	¥ —	¥ —	¥ —	¥ 168,732
Derivative financial instruments	—	—	4,590	3,725	—	8,315
Investments in convertible notes	—	—	9,865	—	—	9,865
Investments in debt securities	—	—	1,608	—	—	1,608
Other	—	—	504	—	—	504
Total	¥ —	¥ 168,732	¥ 16,567	¥ 3,725	¥ —	¥ 189,024
Financial Assets Not Measured at Fair Value						
Other financial assets -						
Others	¥ 26,493	¥ —	¥ —	¥ —	¥ —	¥ 26,493
Trade and Other Receivables	741,907	—	—	—	—	741,907
Cash and cash equivalents	702,093	—	—	—	—	702,093
Total	¥ 1,470,493	¥ —	¥ —	¥ —	¥ —	¥ 1,470,493
Financial Liabilities Measured at Fair Value						
Other financial liabilities -						
Contingent considerations	¥ —	¥ —	¥ 71,062	¥ —	¥ —	¥ 71,062
Derivative financial instruments	—	—	7,120	1,625	—	8,745
Total	¥ —	¥ —	¥ 78,182	¥ 1,625	¥ —	¥ 79,807
Financial Liabilities Not Measured at Fair Value						
Other financial liabilities -						
Finance leases	¥ —	¥ —	¥ —	¥ —	¥ 179,411	¥ 179,411
Other	—	—	—	—	23,908	23,908
Trade and Other Payables	—	—	—	—	327,394	327,394
Bonds and Loans	—	—	—	—	5,750,951	5,750,951
Total	¥ —	¥ —	¥ —	¥ —	¥ 6,281,664	¥ 6,281,664

Fair Value Measurement

Derivative and non-derivative financial instruments measured at fair value are categorized in the following three-tier fair value hierarchy that reflects the significance of the inputs in making the measurements. Level 1 is defined as observable inputs, such as quoted prices in active markets for an identical asset or liability. Level 2 is defined as inputs other than quoted prices in active markets within Level 1 that are directly or indirectly observable. Level 3 is defined as unobservable inputs. Fair value information is not provided for financial instruments, if the carrying amount is a reasonable estimate of fair value due to the relatively short period of maturity of these instruments.

	JPY (millions) For the Year Ended March 31, 2018			
	Level 1	Level 2	Level 3	Total
Assets:				
Financial assets measured at fair value through profit or loss				
Derivatives	¥ —	¥ 762	¥ —	¥ 762
Derivatives for which hedge accounting is applied	—	2,527	—	2,527
Available-for-sale financial assets	163,030	34	—	163,064
Total	¥ 163,030	¥ 3,323	¥ —	¥ 166,353
Liabilities:				
Financial liabilities measured at fair value through profit or loss				
Derivatives	¥ —	¥ 5,373	¥ —	¥ 5,373
Contingent considerations arising from business combinations	—	—	30,569	30,569
Derivatives for which hedge accounting is applied	—	3,498	—	3,498
Total	¥ —	¥ 8,871	¥ 30,569	¥ 39,440

	JPY (millions) For the Year Ended March 31, 2019			
	Level 1	Level 2	Level 3	Total
Assets:				
Financial assets measured at fair value through profit or loss				
Derivatives	¥ —	¥ 4,590	¥ —	¥ 4,590
Investment in convertible notes	—	—	9,865	9,865
Investment in debt securities	—	—	1,608	1,608
Other	—	—	504	504
Derivatives for which hedge accounting is applied	—	3,725	—	3,725
Financial assets measured at fair value through OCI				
Equity instruments	119,907	—	48,825	168,732
Total	¥ 119,907	¥ 8,315	¥ 60,802	¥ 189,024
Liabilities:				
Financial liabilities measured at fair value through profit or loss				
Derivatives	¥ —	¥ 7,120	¥ —	¥ 7,120
Contingent considerations arising from business combinations	—	—	71,062	71,062
Derivative for which hedge accounting is applied	—	1,625	—	1,625
Total	¥ —	¥ 8,745	¥ 71,062	¥ 79,807

For the year ended March 31, 2018, available-for-sale financial assets and other financial assets for which it was difficult to reliably measure the fair value are excluded from the table. The carrying amounts of such assets as of March 31, 2018 were 6,750 million JPY and 2,070 million JPY respectively. These assets were primarily unlisted equity investments and the fair value of the investments was difficult to reliably measure as they are not traded on stock markets.

Valuation Techniques

The fair value of derivatives is measured at quoted prices or quotes obtained from financial institutions, whose significant inputs to the valuation model used are based on observable market data.

The fair value of the investment in convertible notes is measured using techniques such as the discounted cash flow and option pricing models.

Equity investments and investments in debt securities are not held for trading. If equity instruments or investments in debt securities are quoted in an active market, the fair value is based on price quotations at the period-end-date. If equity instruments or investments in debt securities are not quoted

in an active market, the fair value is calculated utilizing a net asset-book value method or multiples of EBITDA approach based on available information as of each period-end-date and company comparable. The principle input that is not observable and utilized for the calculation of the fair value of equity instruments and investments in debt securities classified as Level 3 is the EBITDA rate used for the EBITDA multiples approach, which ranges from 4.6 times to 11.1 times. During the year ended March 31, 2019, a cumulative gain on equity investments of 44,230 million JPY was reclassified from other comprehensive income to retained earnings upon the disposal of certain equity investments in publicly traded companies. The fair value of these investments on the dates of disposal was 65,035 million JPY. The investments were disposed of after management's assessment of these investments relative to the investment strategy.

Contingent consideration, resulting from business combinations, is valued at fair value at the acquisition date as part of the business combination. When the contingent consideration meets the definition of a financial liability, it is subsequently re-measured to fair value at each reporting date. The determination of the fair value is based on models such as scenario-based methods and discounted cash flows. The key assumptions take into consideration the probability of meeting each performance target, forecasted revenue projections, and the discount factor. The fair value measurement of contingent considerations arising from business combinations is discussed in Note 21.

The joint venture net written option, included in other Level 3 assets for the year ended March 31, 2019 above is valued at fair value, and subsequently re-measured to fair value at each reporting date. The determination of the fair value is based on the Monte Carlo Simulation model. The key assumptions include probability weighting, estimated earnings and assumed market participant discount rates that taken into account for the fair value.

Transfers between levels

Takeda recognizes transfers between levels of the fair value hierarchy, at the end of the reporting period during which the change has occurred. There were no transfers among Level 1, Level 2, and Level 3 except transfers from Level 3 to Level 1 recorded in 2018 and 2019. These transfers resulted from the investments in the companies whose shares were previously not listed on an equity or stock exchange and had no recent observable active trades in the shares. During the years ended March 31, 2018 and 2019, the companies listed its equity shares on an exchange and are currently actively traded in the market. As the equity shares have a published price quotation in an active market, the fair value measurement was transferred from Level 3 to Level 1 on the fair value hierarchy during the years ended March 31, 2018 and March 31, 2019, respectively.

Level 3 fair values

The following table shows a reconciliation from the opening balances to the closing balances for Level 3 financial asset fair values for the year ended March 31, 2019. There were no Level 3 financial assets reflected in the consolidated financial statements of Takeda for the years ended March 31, 2017 and 2018. The disclosure related to the Level 3 financial liabilities, which are related to contingent considerations arising from business combinations, are included in Note 21.

	JPY (millions)
Balance as of March 31, 2018	¥ —
Adoption of IFRS 9	47,789
Balance as of April 1, 2018	47,789
Additions arising from business combinations	6,183
Gain recognized as finance income	587
Loss recognized as changes in fair value of financial assets measured at fair value through OCI and exchange differences on translation of foreign operations	(4,060)
Purchases	12,253
Sales	(1,844)
Transfers to Level 1	(111)
Other	5
As of March 31, 2019	¥ 60,802

Financial instruments not recorded at fair value

The carrying amount and fair value of financial instruments that are not recorded at fair value in the consolidated statements of financial position are as follows:

	JPY (millions) As of March 31			
	2018		2019	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
Bonds	¥ 172,889	¥ 172,872	¥ 3,196,365	¥ 3,323,592
Long-term loans	812,755	815,865	2,054,584	2,058,929
Finance leases	53,149	53,690	179,411	181,776

Long-term debt is recognized at its amortized cost. The fair value of bonds is measured at quotes obtained from financial institutions whose significant inputs to the valuation model used are based on observable market data. The fair value of loans and finance leases is measured at the present value of future cash flows discounted using the applicable market rate on the loans with consideration of the credit risk by each group classified in a specified period. The fair value of bonds, long-term loans, and finance leases are classified as Level 2 in the fair value hierarchy.

Market Risk

Major market risks to which Takeda is exposed are 1) foreign currency risk, 2) interest rate risk and 3) price fluctuation risk. Financial instruments affected by market risk include loans and borrowings, deposits, equity investments and derivative financial instruments.

Foreign Currency Risk

Takeda's exposure to the risk of changes in foreign exchange rates primarily relates to its operations (when revenue or expense is denominated in a foreign currency) and the Company's net investments in foreign subsidiaries. The Company manages foreign currency risks in a centralized manner using derivative financial instruments. The Company's policy does not permit the use of speculative foreign currency financial instruments or derivatives, and Takeda does not enter into derivative contracts or financial instruments to manage its exposure currency translation risk.

Takeda uses forward exchange contracts, currency swaps, and currency options to hedge individually significant foreign currency transactions. Takeda has also designated loans and bonds denominated in the US dollar and Euro, including the US dollar and Euro debt instruments used to fund the Shire Acquisition, as hedges of net investments in foreign operations. As of March 31, 2018, the total fair value of the foreign currency denominated loans and foreign currency denominated bonds was 61,200 million JPY and 31,930 million JPY, respectively. As of March 31, 2019, the total fair value of the foreign currency denominated loans and foreign currency denominated bonds was 1,404,031 million JPY and 3,203,040 million JPY, respectively.

Takeda is exposed mainly to foreign currency risks of the US dollar and Euro. A depreciation of the JPY by 5% against the US dollar and Euro would impact profit or loss by 5,156 million JPY, 12,533 million JPY, and 19,530 million JPY as of March 31, 2017, 2018 and 2019, respectively. These amounts do not include the effects of foreign currency translation on financial instruments in the functional currency or on assets, liabilities, revenue, and expenses of foreign operations. This analysis assumes that all other variables, in particular interest rates, remain constant. Takeda's exposure to foreign currency changes for all other currencies is not material.

	JPY (millions) For the Year Ended March 31, 2018		
	Contract Amount	Contract amount to be settled in more than one year	Fair Value
Forward exchange contracts:			
Selling:			
Euro	¥ 98,198	¥ —	¥ (894)
United States Dollar	39,799	—	100
Chinese Yuan	20,528	—	(1,211)
Other	1,854	—	(1)
Buying:			
Euro	173,627	—	(964)
United States Dollar	9,585	—	(19)
Other	5,105	—	95
Currency swaps:			
Buying:			
United States Dollar	124,028	123,993	(1,773)

	JPY (millions) For the Year Ended March 31, 2019		
	Contract Amount	Contract amount to be settled in more than one year	Fair Value
Forward exchange contracts:			
Selling:			
Euro	¥ 219,580	¥ —	¥ 544
United States Dollar	200,571	—	(2,145)
Other	722	—	(2)
Buying:			
Euro	357,550	—	(4,156)
United States Dollar	227,262	—	3,254
Currency swaps:			
Buying:			
United States Dollar	123,993	123,959	2,621
Currency collar options:			
Russian Ruble	11,463	—	(9)
Brazilian Real	13,507	—	(15)

The above currency swaps were related to bonds and loans denominated in foreign currency, which the Company designated as hedging instruments in a cash flow hedges. The cash flow hedge reserve related to the currency swaps were reclassified to profit or loss in the same period as the hedged expected future cash flows occur.

Interest Rate Risk

Takeda's exposure to the risk of changes in benchmark interest rates and foreign exchange rate relates primarily to the outstanding borrowings with floating interest rates. Takeda may use interest and currency swaps that fix the amount of future payments to manage interest and foreign exchange rate risks through cash flow hedge strategies. The following summarizes interest and cross currency interest rate swaps designated as cash flow hedges for the periods ended March 31:

	JPY (millions) For the Year Ended March 31		
	Notional Amount	More than One Year	Fair Value
2018	¥ 300,938	¥ 300,938	¥ (970)
2019	308,078	248,078	2,100

The above swaps are related to the borrowings which the Company designated as hedging instruments in a cash flow hedge.

The following represents interest rate sensitivity analysis for the periods presented. This analysis assumes that all other variables, in particular foreign currency exchange rates, remain constant.

	JPY (millions)			
	As of March 31, 2018 Interest rate		As of March 31, 2019 Interest rate	
	+1%	-1%	+1%	-1%
Impact on net profit or loss before tax	¥ —	¥ —	¥ (4,632)	¥ 4,632
Impact on other comprehensive income (before tax effects)	16,543	(16,543)	14,840	(14,840)

For the year ended March 31, 2018, there is an immaterial impact on net profit or loss because the amount of interest payments from all the outstanding borrowings with floating rates are fixed using interest rate swaps. The ineffective portion of the hedges was immaterial.

Price Fluctuation Risk Management

Commodity Price Risk

For its business operations, Takeda is exposed to risks from commodity price fluctuations. Takeda manages this risk primarily by utilizing fixed price contracts, but may also use financial instruments to lock in a fixed price.

Market Price Risk

Market pricing and valuations of Takeda's fixed-income financial assets and liabilities are impacted by changes in currency rates, interest rates and credit spreads, which are managed as described above.

For equity instruments, the Company manages the risk of price fluctuations in the instruments by regularly reviewing share prices and financial positions of the issuers. The analysis shows that if the market price of equity instruments held by Takeda and investments in trusts which hold equity instruments on behalf of Takeda had increased by 10%, the hypothetical impact on other comprehensive income (before tax effect) would have been 16,303 million JPY and 11,991 million JPY as of March 31, 2018 and 2019 respectively. This analysis assumes that all other variables, in particular interest rates and foreign currency exchange rates, remain constant.

Derivative Financial Instruments

As described above, Takeda is exposed to effects related to foreign exchange fluctuations in connection with our international business activities that are denominated in various currencies and Takeda entities that have different functional currencies. Takeda is also exposed to currency and interest rate fluctuations on our borrowings that we use to finance our business operations and our acquisitions. These borrowings are denominated in various currencies and may bear interest at variable rates, resulting in the risk related to the currency and interest rate movements.

In order to manage the risk of currency exchange rate and interest rate fluctuations, Takeda may enter into derivative contracts with highly rated financial institutions. Takeda enters into derivative contracts based our risk management policies, which determine the authority for entering into such transactions and the transaction limits. The policy, which has been consistently followed, is that financial derivatives be used only for hedging foreign currency and interest rate exposure and not for speculative purposes.

Takeda generally designates its derivatives as hedges for accounting purposes. In certain instances, Takeda enters into derivative contracts that do not qualify for hedge accounting but are utilized to manage the underlying risk (''economic hedges''). Takeda does not use financial instruments for trading purposes. The Company established guidelines for risk assessment procedures and controls for the use of financial instruments. They include a clear segregation of duties with regard to execution on one side and administration, accounting and controlling on the other.

Summary of Financial Position and Financial Performance for Derivative and Hedging Activities

The following table details the items designated as hedging instruments as of March 31, 2019:

		JPY (millions)			
	Notional	Carrying Amount – Assets	Carrying Amount – Liabilities	Line Item in the Statement of Financial Position where Hedging Instrument is included	Average Rate Used for the Fair Value of the Hedging
Cash Flow Hedges					
Interest risk					
Interest rate swaps	120,000 million JPY	¥ —	¥ 917	Other financial liabilities	0.66%
	575 million USD	396	—	Other financial assets	2.83%
Currency and interest risk					
Currency and interest rate swaps	1,125 million USD	3,329	708	Other financial assets / liabilities	109.97 JPY 0.03%
Net Investment Hedges					
Foreign currency denominated bonds and loans	12,881 million USD	—	1,425,116	Bonds and loans	
	10,540 million EUR	—	1,308,686	Bonds and loans	

The following table details the amounts within other components of equity related to items designated as hedged items as of March 31, 2019:

	JPY (millions)	
	Balance in cash flow hedges and exchange differences on translation	Balance in hedge cost
Cash Flow Hedges		
Interest risk		
Interest rate swaps	¥ (362)	¥ —
Forward interest rate	33	—
Currency and interest risk		
Currency and interest rate swaps	(109)	1,412
Currency risk		
Hedge related to acquisition	3,397	—
Net Investment Hedges		
Foreign currency denominated bonds and loans	7,969	—

The following table details the amounts of changes in fair value of hedging instruments recorded in other comprehensive income and the amounts reclassified from the hedging reserve to profit or loss as of March 31, 2019:

	JPY (millions)						
	Amounts recognized in OCI		Amounts reclassified to Goodwill		Amount reclassified to profit or loss		
	Change in Fair Value of Hedges	Hedging Costs	Cash Flow Hedge	Hedging Costs	Cash Flow Hedge	Hedging Costs	Line item in which reclassification adjustment is included
Cash Flow Hedges							
Interest risk							
Interest rate swaps	¥ (2,177)	¥ —	¥ —	¥ —	¥ 845	¥ —	Financial expenses
Forward interest rate	—	—	—	—	53	—	Financial expenses
Currency and interest risk							
Currency and interest rate swaps	7,204	627	—	—	(7,261)	(908)	Financial income and Financial expenses
Currency risk							
Hedge related to acquisition	(33,090)	(4,715)	35,773	4,715	—	—	
Net Investment Hedges							
Foreign currency denominated bonds and loans	(8,488)	—	—	—	—	—	

The amount relating to the ineffectiveness recorded in profit or loss was immaterial for the years ended March 31, 2018 and 2019. The amount of hedging gains/losses recorded in other comprehensive income and reclassified to profit or loss as hedged future cash flows were no longer expected to occur was immaterial for the years ended March 31, 2018 and 2019.

Capital Management

The capital structure of Takeda consists of shareholders' equity (Note 26), bonds and loans (Note 20), and cash and cash equivalents (Note 18). The fundamental principles of Takeda's capital risk management are to build and maintain a steady financial base for the purpose of maintaining soundness and efficiency of operations and achieving sustainable growth. According to these principles, Takeda conducts capital investment, profit distribution such as dividends, and repayment of loans based on steady operating cash flows through the development and sale of competitive products. Takeda balances and monitors its capital structure between debt and equity and adheres to a conservative financial discipline.

Credit Risk

Takeda is exposed to credit risk from its operating activities (primarily trade receivables) and from its financing activities, including deposits with banks and financial institutions, foreign exchange transactions, and other financial instruments. The maximum exposure to credit risk, without taking into

account of any collateral held at the end of the reporting period, is represented by the carrying amount of the financial instruments which is exposed to credit risk on the consolidated statement of financial position.

Customer Credit Risk

Trade and other receivables are exposed to customer credit risk. Takeda monitors the status of overdue balances, reviews outstanding balances for each customer and regularly examines the credibility of major customers in accordance with Takeda's policies for credit management to facilitate the early evaluation and the reduction of potential credit risks. If necessary, Takeda obtains rights to collateral or guarantees on the receivables.

The following represents the age of trade receivables that are past due but not impaired:

	JPY (millions) Amount Past Due					
	Total	Within 30 Days	Over 30 Days but within 60 Days	Over 60 Days but within 90 Days	Over 90 Days but within One Year	Over One Year
As of March 31, 2018	¥ 16,222	¥ 6,453	¥ 2,243	¥ 782	¥ 5,042	¥ 1,702

The amounts in the above table are net of allowances for doubtful receivables. Takeda has provided loss allowances on trade receivables and other receivables not past due based on an analysis of credit histories. Takeda establishes loss allowances that represent an estimate of expected losses at the end of the reporting period.

The following represents the carrying amount of the trade receivables categorized by due date and the analysis of impairment loss allowance as of March 31, 2019:

	JPY (millions) except for percentage						
		Amount Past Due					
	Current	Within 30 Days	Over 30 Days but within 60 Days	Over 60 Days but within 90 Days	Over 90 Days but within One Year	Over One Year	Total
Gross carrying amount	¥ 613,062	¥ 17,244	¥ 7,441	¥ 5,968	¥ 14,336	¥ 2,948	¥ 660,999
Impairment loss allowance	(2,350)	(27)	(24)	(99)	(477)	(341)	(3,318)
Net carrying amount	610,712	17,217	7,417	5,869	13,859	2,607	657,681
Weighted average loss rate	0.4%	0.2%	0.3%	1.7%	3.3%	11.6%	0.5%

Management believes that the unimpaired amounts that are past due are still collectible in full, based on historical payment behavior and extensive analysis of customer credit risk.

As of March 31, 2019, Takeda has provided loss allowance on trade receivables and other receivables not past due based on an analysis of credit histories. Loss allowance for trade receivables are measured based on expected credit losses on a collective basis using the simplified approach. However, when events that have a detrimental impact on the estimated future cash flows such as customers' deterioration of financial conditions or failure of payment overdue have occurred, expected credit losses are measured on an individual basis as credit-impaired financial assets. Takeda considers a financial asset to be in default when the customer is unlikely to pay the obligation in full, without recourse by Takeda to take actions such as realizing collaterals, if any.

The following is a summary of the change in the loss allowance for trade receivables and other assets for the years ended March 31, 2017 and 2018. The loss allowance recognized for other than trade receivables is immaterial. Comparative amounts for 2017 and 2018 represent the allowance account for impairment losses under IAS 39.

	JPY (millions)	
	2017	2018
At beginning of the year	¥ 9,165	¥ 9,733
Increases	2,438	1,946
Decreases (written off)	(1,185)	(1,941)
Decreases (reversed)	(712)	(1,130)
Reclassification to assets held for sale	(40)	(45)
Foreign currency translation differences	67	262
At end of the year	¥ 9,733	¥ 8,825

The following is a summary of the change in the impairment loss allowance for trade receivables for the year ended March 31, 2019. The impairment loss allowance recognized for other than trade receivables is immaterial.

	JPY (millions)		
	Bad debt provision calculated by simplified approach	Bad debt provision recognized to credit-impaired financial asset	Total
At beginning of the year	¥ 3,661	¥ 5,158	¥ 8,819
Increases	1,305	2,243	3,548
Decreases (written off)	(2,716)	(5,257)	(7,973)
Decreases (reversed)	(942)	(208)	(1,150)
Reclassification to assets held for sale	(36)	—	(36)
Foreign currency translation differences	119	(9)	110
At end of the year	¥ 1,391	¥ 1,927	¥ 3,318

Other Counterparty Credit Risk

Cash reserves of the subsidiaries are concentrated mostly with the Company and entities acting as the cash pool leader in the United States and Europe. These cash reserves are primarily managed exclusively by investments in highly rated short-term bank deposits and bonds of highly rated issuers within the investment limits determined by reviewing the investment ratings and terms under Takeda's policies for fund management, resulting in limited credit risk. Cash reserves, other than those subject to the group cash pooling system, are managed by each consolidated subsidiary in accordance with the Company's fund management policies.

For derivatives, Takeda enters into trading contracts only with financial counterparties rated investment grade or higher in order to minimize counterparty risk.

Liquidity Risk

The Company manages liquidity risk and establishes an adequate management framework for liquidity risk to secure stable short-, mid-, and long-term funds and sufficient liquidity for operations. Takeda manages liquidity risk by monitoring forecasted cash flows and actual cash flows. In addition, Takeda has commitment lines with some counterparty financial institutions to manage liquidity risk (Note 20). Takeda strives to maximize the available liquidity with a combination of liquid short-term investments and committed credit lines with strong rated counterparties. The objective is to maintain levels in excess of project cash needs to mitigate the risk of contingencies.

The table below presents the balances of financial liabilities by maturity. The total contract amount below reflects cash flows presented on an undiscounted cash flow basis, including interest expense. The amounts disclosed as of March 31, 2018 and 2019 are undiscounted cash flows using the respective spot foreign exchange rates as of March 31, 2018 and 2019.

	JPY (millions)							
	Carrying Amount	Total	Within One Year	Between One and Two Years	Between Two and Three	Between Three and Four Years	Between Four and Five Years	More than Five Years
As of March 31, 2018								
Bonds and loans								
Bonds	¥ 172,889	¥ 179,567	¥ 2,050	¥ 61,824	¥ 61,429	¥ 54,264	¥ —	¥ —
Loans	812,773	872,738	5,556	66,611	76,879	6,881	81,882	634,929
Trade and other payables	240,259	240,259	240,259	—	—	—	—	—
Finance leases	53,149	99,161	4,808	5,410	3,495	2,709	2,721	80,018
Derivative liabilities	8,871	6,364	5,639	40	(336)	1,021	—	—
Derivative assets	(3,289)	(33,590)	(3,049)	(3,383)	(3,729)	(3,698)	(3,699)	(16,032)
As of March 31, 2019								
Bonds and loans								
Bonds	¥ 3,196,365	¥ 3,790,239	¥ 507,158	¥ 572,336	¥ 625,401	¥ 358,700	¥ 490,302	¥ 1,236,342
Loans	2,554,586	2,780,332	603,589	152,453	75,627	190,754	787,720	970,189
Trade and other payables	327,394	327,394	327,394	—	—	—	—	—
Finance leases	179,411	333,133	6,925	8,996	9,360	9,575	9,807	288,470
Derivative liabilities	8,745	7,106	7,246	(301)	161	—	—	—
Derivative assets	(8,315)	(30,902)	(8,090)	(2,983)	(2,576)	(2,633)	(2,816)	(11,804)

Reconciliation of liabilities arising from financing activities

	JPY (millions)						
	Bonds	Long-term Loans	Short-term Loans	Finance Lease Obligations	Derivative Assets Used for Hedge of Debts	Derivative Liabilities Used for Hedge of Debts	Total
As of April 1, 2017	¥ 179,836	¥ 560,000	¥ 405,054	¥ 58,811	¥ —	¥ —	¥ 1,203,701
Cash flows from financing activities							
Net increase (decrease) in short-term loans	—	—	(403,931)	—	—	—	(403,931)
Proceeds from long-term loans	—	337,955	—	—	—	(801)	337,154
Repayments of long-term loans	—	(80,000)	—	—	—	—	(80,000)
Proceeds from bonds	55,951	—	—	—	348	—	56,299
Repayments of bonds	(60,000)	—	—	—	—	—	(60,000)
Repayments of obligations under finance lease	—	—	—	(2,658)	—	—	(2,658)
Interest paid	—	—	—	(2,855)	—	—	(2,855)
Non-cash items							
Foreign exchange movement	(3,019)	(5,244)	(1,105)	(2,610)	—	—	(11,978)
Change in fair value	—	—	—	—	(528)	2,754	2,226
New and amended finance leases	—	—	—	375	—	—	375
Others	121	44	—	2,086	—	—	2,251
As of March 31, 2018	¥ 172,889	¥ 812,755	¥ 18	¥ 53,149	¥ (180)	¥ 1,953	¥ 1,040,584

	JPY (millions)						
	Bonds	Long-term Loans	Short-term Loans	Finance Lease Obligations	Derivative Assets Used for Hedge of Debts	Derivative Liabilities Used for Hedge of Debts	Total
As of April 1, 2018	172,889	812,755	18	53,149	(180)	1,953	1,040,584
Cash flows from financing activities							
Net increase (decrease) in short-term loans	—	—	367,319	—	—	—	367,319
Proceeds from long-term loans	—	1,215,526	—	—	—	—	1,215,526
Proceeds from bonds	1,580,400	—	—	—	—	—	1,580,400
Repayments of obligations under finance lease	—	—	—	(1,741)	—	—	(1,741)
Interest paid	—	—	—	(4,643)	—	—	(4,643)
Acquisitions through business combinations	1,461,627	4,170	138,674	8,685	—	—	1,613,156
Non-cash items							
Foreign exchange movement	(23,562)	21,955	(6,009)	1,281	—	—	(6,335)
Change in fair value	—	—	—	—	(3,149)	(1,245)	(4,394)
New and amended finance leases	—	—	—	118,037	—	—	118,037
Others	5,011	178	—	4,643	—	—	9,832
As of March 31, 2019	¥ 3,196,365	¥ 2,054,584	¥ 500,002	¥ 179,411	¥ (3,329)	¥ 708	¥ 5,927,741

Others includes increase in debts due to application of amortized cost method.

28. Share-based Payments

Takeda maintains certain share-based compensation payment plans for the benefit of its directors and certain of its employees. Takeda recorded total compensation expense related to its share-based payment plans of 17,414 million JPY, 22,172 million JPY, and 18,787 million JPY for the years ended March 31, 2017, 2018 and 2019, respectively, in its consolidated statements of income.

Equity-settled Plans

Stock Options

Takeda had maintained a stock option plan under which it granted awards to members of the board, corporate officer, and senior management through the year ended March 31, 2014. There were no stock options granted during the years presented in these financial statements and all previously granted awards are fully vested. These awards generally vested three years after the grant date. The stock options are exercisable for 10 years after the grant date for options held by directors and 20 years for options held by corporate officers and senior management. The individual must be either a director of the Company or an employee of Takeda to exercise the options, unless the individual retired due to the expiration of their term of office, mandatory retirement or other acceptable reasons.

The total compensation expense recognized related to the stock option was 63 million JPY during the year ended March 31, 2017. There was no compensation expense during the years ended March 31, 2018 or 2019 as all awards were fully vested.

The following table summarizes the stock option activities:

	For the Year Ended March 31					
	2017		2018		2019	
	Number of options (shares)	Weighted average exercise price (JPY)	Number of options (shares)	Weighted average exercise price (JPY)	Number of options (shares)	Weighted average exercise price (JPY)
As of beginning of the year	4,258,000	¥ 3,920	4,020,900	¥ 4,026	3,403,800	¥ 4,054
Exercised	(237,100)	2,121	(617,100)	3,876	(14,600)	3,721
As of end of the year	4,020,900	4,026	3,403,800	4,054	3,389,200	4,055

All of the stock options were exercisable as of March 31, 2017, 2018, and 2019.

The weighted-average share price at the date of exercise was 4,939 JPY, 5,965 JPY and 4,679 JPY during the year ended March 31, 2017, 2018 and 2019, respectively. The weighted-average exercise price and weighted-average remaining contractual life of the share options outstanding were 4,026 JPY and 15 years, 4,054 JPY and 14 years, and 4,055 JPY and 13 years, as of March 31, 2017, 2018 and 2019, respectively.

Stock Incentive Plans

Takeda has two stock-based incentive compensation plans for its directors and members of senior management, including the following:

Board incentive plan (BIP) -The BIP is a stock-based incentive plan for directors of the Company whereby Restricted Share and Performance Share awards are granted to the directors. Each award is settled in a single share of stock of the Company. Under the BIP, Restricted Shares vest one third each year over a three-year period and Performance Shares vest three years from the date of grant. The settlement of the awards is based on stock price, foreign exchange rates (in countries other than Japan), and company dividends. Performance shares are also based on the achievement of certain performance criteria, which are established at the grant date, including, among others, accumulated revenue, operating free cash flow, earnings per share and R&D goals, which are transparent and objective indicators. Takeda, through a wholly owned trust, buys shares of the Company in the market on the grant date, and uses these shares to settle the awards. The number of shares the individual receives (either through physical settlement or cash) is based on the achievement of the performance criteria and vesting of the award. The trust settles the awards through the issuance of shares to individuals in Japan. For individuals outside of Japan the trust sells the share the individual is eligible to receive and pays the cash to the individual.

Employee Stock Ownership Plan (ESOP) - The ESOP is a stock-based incentive plan for senior management whereby awards are granted to the employees. Each award is settled in a single share of stock of the Company. The vesting of the awards under this plan is the same as the BIP for certain members of senior management with the remainder of the employees' awards vesting one third each year over a three-year period. The settlement of the awards is based on stock price, foreign exchange rates (in countries other than Japan), and company dividends. Performance shares, are also based on the achievement of certain performance criteria, which are established at the grant date including, among others, accumulated revenue, operating free cash flow, earnings per share and targeted R&D goals, which are transparent and objective indicators. Takeda, through wholly owned trust, buys shares of the Company in the market on the grant date and uses these shares to settle the awards. The number of shares the individual receives (either through physical settlement or cash) is based on the achievement of the performance criteria and vesting of the award. The trust settles the awards through the issuance of shares to individuals in Japan. For individuals outside of Japan the trust sells the share the individual is eligible to receive and pays cash to the individual.

The total compensation expense recognized related to these plans was 15,322 million JPY, 18,610 million JPY and 20,084 million JPY during the years ended March 31, 2017, 2018 and 2019, respectively.

The weighted average fair value of the awards at the grant date is as follows (in JPY):

	For the Year Ended March 31		
	2017	2018	2019
BIP:			
Weighted average fair value at grant date	¥ 4,664	¥ 5,709	¥ 4,631
ESOP:			
Weighted average fair value at grant date	4,438	5,709	4,678

The grant date fair value was calculated using the Company's share price on the grant date as it was determined to be approximately the same as the fair value of the awards.

The following table summarizes the award activity related to the stock incentive plans (number of awards):

	For the Year Ended March 31					
	2017		2018		2019	
	ESOP	BIP	ESOP	BIP	ESOP	BIP
At beginning of the year	4,809,442	281,154	6,471,104	414,933	6,891,762	433,260
Granted	4,328,364	192,818	3,944,938	188,695	5,021,627	252,647
Forfeited/expired before vesting	(849,886)	—	(602,245)	—	(781,033)	(17,832)
Settled	(1,816,816)	(59,039)	(2,922,035)	(170,368)	(3,192,681)	(182,843)
At end of the year	6,471,104	414,933	6,891,762	433,260	7,939,675	485,232

There were no exercisable shares as of March 31, 2017, 2018, and 2019. The weighted average remaining contractual life of the outstanding awards was one year as of each year end for both the BIP and the ESOP plans.

Liability Settled Awards

Takeda has a phantom stock appreciation rights (PSARs) plan and a restricted stock units (RSUs) plan for certain of its employees. The value of these awards is linked to share price of the Company and are settled in cash. The total compensation expense recorded associated with these plans was 2,029 million JPY and 3,562 million JPY during the years ended March 31, 2017 and 2018. A reversal of total compensation expense of 1,297 million JPY was recorded during the year ended March 31, 2019. The total liability reflected in the consolidated statements of financial position as of March 31, 2018 and 2019, is 4,872 million JPY and 2,597 million JPY, respectively.

Phantom stock appreciation rights (PSARs)

The PSARs vest one third each year over a three-year period from the end of the fiscal year during which the awards were granted and can be exercised for a period of ten years from the end of the fiscal year during which the awards were granted. The awards are settled through a cash payment to the holder based on the difference between the share price of the Company at the date of exercise, and the share price at the date of grant.

The following table summarizes the award activity related to the PSARs:

	For the Year Ended March 31					
	2017		2018		2019	
	Number of PSARs	Weighted Average Exercise Price (JPY)	Number of PSARs	Weighted Average Exercise Price (JPY)	Number of PSARs	Weighted Average Exercise Price (JPY)
As of beginning of the year	10,257,155	¥ 5,063	9,282,080	¥ 5,017	4,584,937	¥ 4,650
Granted	—	—	—	—	—	—
Forfeited before vesting	—	—	—	—	—	—
Exercised	(618,494)	4,706	(4,335,961)	5,072	(214,296)	4,428
Forfeited/expired after vesting	(356,581)	5,012	(361,182)	5,505	(195,294)	4,940
As of end of the year	9,282,080	5,017	4,584,937	4,650	4,175,347	4,849

All PSARs were exercisable as of March 31, 2017, 2018, and 2019.

Restricted stock units (RSUs)

The RSUs vest one third each year over a three-year period from the end of the fiscal year during which the awards were granted. The RSUs are settled upon vesting based on the share price at the vesting date plus any dividends paid on shares during the vesting period. There is no exercise price payable by the holder.

The following table summarizes the award activity related to the RSUs (number of RSUs):

	For the Year Ended March 31		
	2017	2018	2019
As of the beginning of the year	1,220,234	448,286	398,479
Granted	255,116	254,710	279,436
Forfeited/expired before vesting	(148,502)	(82,388)	(92,829)
Settled	(878,562)	(222,129)	(183,933)
As of the end of the year	448,286	398,479	401,153

There are no exercisable balances as of March 31, 2017, 2018, and 2019. The total intrinsic value of vested cash-settled share-based payments was 2,442 million JPY as of March 31, 2018. There was no intrinsic value of vested cash-settled share-based payments as of March 31, 2019.

29. Subsidiaries and Associates

The number of consolidated subsidiaries increased by 240 in the year ended March 31, 2019, primarily due to acquisition of Shire and Tigenix and decreased by 13 primarily due to divestitures including Guangdong Techpool Bio-Pharma Co., Ltd. The number of associates accounted for using the equity method increased by 7 primarily due to the acquisition of Shire and decreased by 3 primarily due to divestitures.

The following is a listing of the Company's consolidated subsidiaries as of March 31, 2019:

Company Name	Country	Voting Share Capital Hd
Takeda Austria GmbH	Austria	100.0%
Baxter AG	Austria	100.0%
Baxalta Innovations GmbH	Austria	100.0%
Takeda Distribuidora Ltda.	Brazil	100.0%
Shire Pharma Canada ULC	Canada	100.0%
Takeda (China) Holdings Co., Ltd.	China	100.0%
Shire BioScience (Shanghai) Co. Ltd	China	100.0%
Takeda Pharmaceutical (China) Company Limited	China	100.0%
Takeda Pharma A/S	Denmark	100.0%
Takeda France S.A.S.	France	100.0%
Shire France S.A.S	France	100.0%
Takeda GmbH	Germany	100.0%
Shire Deutschland GmbH	Germany	100.0%
Takeda Ireland Limited	Ireland	100.0%
Shire Pharmaceutical Holdings Ireland Limited	Ireland	100.0%
Shire Pharmaceuticals International Unlimited Company	Ireland	100.0%
Shire Pharmaceuticals Ireland Limited	Ireland	100.0%
Shire Acquisitions Investments Ireland Designated Activity Company	Ireland	100.0%
Shire Ireland Finance Trading Limited	Ireland	100.0%
Takeda Italia S.p.A.	Italy	100.0%
Shire Italia S.p.A.	Italy	100.0%
Takeda Consumer Healthcare Company Limited	Japan	100.0%
Nihon Pharmaceutical Co., Ltd.	Japan	87.3%
Shire Japan KK	Japan	100.0%
Shire plc	Jersey	100.0%
Takeda Pharmaceuticals Korea Co., Ltd.	Korea	100.0%
Takeda AS	Norway	100.0%
Takeda Pharmaceuticals Limited Liability Company	Russia	100.0%
Takeda Development Center Asia, Pte. Ltd.	Singapore	100.0%
Takeda Vaccines Pte. Ltd.	Singapore	100.0%
Shire Pharmaceuticals Iberica S.L.U.	Spain	100.0%
Takeda Pharmaceuticals International AG	Switzerland	100.0%
Baxalta GmbH	Switzerland	100.0%
Baxalta Manufacturing S.à r.l.	Switzerland	100.0%
Baxalta Recombinant S.à r.l	Switzerland	100.0%
Shire International GmbH	Switzerland	100.0%
Takeda UK Limited	U.K	100.0%
Takeda Development Centre Europe Ltd.	U.K	100.0%
Shire Pharmaceuticals Limited	U.K.	100.0%
Shire Pharmaceutical Development Limited	U.K.	100.0%
Takeda Pharmaceuticals International, Inc.	U.S.A.	100.0%
Takeda Pharmaceuticals U.S.A., Inc.	U.S.A.	100.0%
Millennium Pharmaceuticals, Inc.	U.S.A.	100.0%
ARIAD Pharmaceutical, Inc.	U.S.A.	100.0%
Takeda California, Inc.	U.S.A.	100.0%
Takeda Vaccines, Inc.	U.S.A.	100.0%
Takeda Development Center Americas, Inc.	U.S.A.	100.0%

Company Name	Country	Voting Share Capital Hd
Baxalta Incorporated	U.S.A.	100.0%
Baxalta US Inc.	U.S.A.	100.0%
Shire Human Genetic Therapies Inc	U.S.A.	100.0%
Shire ViroPharma Incorporated	U.S.A.	100.0%
Shire-NPS Pharmaceuticals, Inc.	U.S.A.	100.0%
Dyax Corp.	U.S.A.	100.0%
Meritage Pharma, Inc.	U.S.A.	100.0%
Shire Development LLC	U.S.A.	100.0%
Shire North American Group Inc.	U.S.A.	100.0%
301 immaterial subsidiaries		

The following is a listing of the Company's associates accounted for using the equity method as of March 31, 2019:

Company Name	Country	Voting Share Capital Hd
Cerevance, LLC	U.S.A.	27.8%
Teva Takeda Pharma Ltd.	Japan	49.0%
Amato Pharmaceutical Products, Ltd.	Japan	30.0%
16 immaterial associates		

30. Related Party Transactions

Transactions with Affiliates

Takeda has one major affiliate, Teva Takeda Pharma, to which Takeda sells products and acts as a sales agent. Total transactions with Teva Takeda Pharma for the years ended March 31, 2018 and 2019 were 18,166 million JPY and 10,380 million JPY, respectively. Balances of receivables and payables are as follows:

	JPY (millions) As of March 31	
	2018	2019
Trade receivables	¥ 4,187	¥ 2,885
Other receivables	1,507	1,892
Other payables	30,066	26,844

The terms and conditions of the related party transactions are entered into on terms consistent with third-party transactions and considering market prices. In addition, the receivables and payables are settled in cash and consistent with terms of third-party settlements.

There is no outstanding balance of collateral or guarantee. Impairment loss allowances are not recognized for the receivables.

Compensation for Key Management Personnel

Key management personnel are defined as members of the Board and the Chief Financial Officer. The compensation for key management personnel is as follows:

	JPY (millions) For the Year Ended March 31		
	2017	2018	2019
Basic compensation and bonuses	¥ 1,478	¥ 1,332	2,226
Share-based compensation (expensed amount)	948	1,176	1,305
Retirement benefits	38	26	73
Total	¥ 2,464	¥ 2,534	3,604

31. Business Combinations

Acquisitions during the Year Ended March 31, 2019

Shire plc

On January 8, 2019, Takeda completed the acquisition of 100% of the outstanding shares of Shire plc in a cash and equity transaction valued at 6,213,335 million JPY. Takeda paid $30.33 in cash for each Shire ordinary share and issued either 0.839 of a new share (a "New Takeda Share") or 1.678 American Depositary Shares ("ADSs") in Takeda (one ADS equals 0.5 New Takeda Share). Takeda incurred 23,750 million JPY of acquisition related costs, which were expensed as incurred and recorded in selling, general and administrative expenses. Takeda has entered into several borrowing agreements to fund the cash portion of the acquisition price (Note 20). Shire was a leading global biotechnology company focused on serving people with rare diseases. This acquisition creates a global R&D driven biopharmaceutical with an attractive geographic footprint as well as strengthens Takeda's core therapeutic areas, bringing together complementary positions in gastroenterology (GI) and neuroscience. Some of the Shire's marketed products include *GAMMAGARD*, *HYQVIA* and *TAKHZYRO* for Immunology, *ADVATE, ADYNOVATE*, *VONVENDI* and *FEIBA* for Hematology, *VYVANSE* and *ADDERALL XR* for Neuroscience, *LIALDA/MEZAVANT* and *PENTASA* for Internal Medicine, *ELAPRASE* and *REPLAGAL* for Genetic Diseases. Shire's R&D focused on rare diseases.

The total consideration transferred was comprised of the following:

	JPY (millions) Amount
Cash	¥ 3,029,431
Takeda equity (770,303,013 shares)	3,131,282
Cash for cash settled awards	52,622
Total	¥ 6,213,335

The Company issued 770,303,013 ordinary shares allocated to the former shareholders of Shire as part of the purchase consideration. The issue price was 4,065 JPY per share, of which 2,032.50 JPY per share is recorded as share capital and the remainder is recorded as share premium. The total increase in equity was 3,131,282 million JPY, of which 1,565,641 million JPY is recorded as share capital and the remainder is recorded as share premium. The fair value of the Takeda shares issued as part of the consideration paid was determined based on the trading price of Takeda shares at the opening of the Tokyo Stock Exchange on the date of acquisition.

The total cash outflow was 2,891,937 million JPY, which represents the initial cash consideration transferred of 3,082,053 million JPY and basis adjustment of 37,107 million JPY, less cash acquired of 227,223 million JPY.

The following represents the preliminary estimate of the fair value of assets acquired and liabilities assumed:

	JPY (millions) Amount
Cash and cash equivalents	¥ 227,223
Trade and other receivables	326,154
Inventories	825,985
Property, plant & equipment	684,487
Intangible assets	3,899,298
Assets held for sale	463,526
Other assets	103,283
Trade and other payables	(61,382)
Provisions	(342,202)
Bonds and loans	(1,603,199)
Deferred tax liabilities	(809,667)
Liabilities held for sale	(196,294)
Other liabilities	(354,139)
Basis adjustments	(37,107)
Goodwill	3,087,369
Net assets acquired	¥ 6,213,335

Goodwill is calculated as the excess of the consideration transferred over the net assets recognized and represents the expected revenue and cost synergies of the combined Takeda/Shire group. Goodwill recognized as a result of the acquisition is not deductible for tax purposes (Note 11).

Provisions include 29,570 million JPY associated with amounts payable related to legal proceedings (Note 32). Other liabilities also include pre-existing contingent consideration related to Shire's historical acquisitions. The assumed pre-existing contingent consideration is payable mainly upon the achievement of certain milestones, and the fair value of the potential payments Takeda could be required to make is 52,046 million JPY (Note 21).

The estimated fair values primarily consisting of intangible assets, deferred tax liabilities and goodwill noted above are preliminary and are subject to change. As Takeda finalizes the fair value of assets acquired and liabilities assumed, additional purchase price adjustments will be recorded during the measurement period during fiscal year 2019. Fair value estimates are based on a complex series of judgments about future events and uncertainties and rely heavily on estimates and assumptions. The judgments used to determine the estimated fair value assigned to each class of assets acquired and liabilities assumed, as well as asset lives, can materially impact the Takeda's results of operations. The finalization of the purchase accounting assessment will result in a change in the valuation of assets acquired and liabilities assumed, and may have a material impact on Takeda's results of operations and financial position.

Takeda held foreign currency denominated deposits and entered into foreign currency options to hedge foreign currency risks for the acquisition of Shire, and Takeda applied the hedge accounting to the instruments. Basis adjustment represents accumulated change in fair value of the hedging instruments recorded in other comprehensive income of 37,107 million JPY that was added to the amount of goodwill at the acquisition date.

Takeda recorded 309,198 million JPY of revenue and 126,068 million JPY of net loss related to the operating results of Shire between the acquisition date and March 31, 2019.

Pro forma information

The following pro forma financial information presents the combined results of the operations of Takeda and Shire as if the acquisition of Shire had occurred as of April 1, 2018. The pro forma financial information is not necessarily indicative of what the consolidated results of operations would have been had the respective acquisitions been completed on April 1, 2018. In addition, the pro forma financial information does not purport to project the future results of operations of the combined Company.

	JPY (millions) For the Year Ended March 31, 2019
Revenues	¥ 3,412,468
Net loss	(90,581)

For the purpose of the pro forma financial information, Shire's historical financial information has been conformed from U.S. Generally Accepted Accounting Principles to IFRS, and to Takeda's accounting policies for material accounting policy differences.

TiGenix NV ("TiGenix")

On April 30, 2018, Takeda made an all cash voluntary public takeover bid for the entire issued ordinary shares, warrants, and ADSs (collectively the "Securities") of TiGenix not already owned by Takeda. On June 8, 2018, the Company acquired the Securities tendered in the first acceptance period for 470.2 million EUR. In response to the takeover bid with the Securities already owned by Takeda, Takeda acquired 90.8% of the voting rights. Takeda incurred 767 million JPY of acquisition related costs, which were expensed as incurred and recorded in selling, general and administrative expenses.

TiGenix is a biopharmaceutical company which develops novel stem cell therapies for treatment of medical conditions. This acquisition will expand Takeda's late stage gastroenterology (GI) pipeline with the U.S. rights to Cx601 (darvadstrocel), a suspension of allogeneic expanded adipose-derived stem cells (eASC) under investigation for the treatment of complex perianal fistulas in patients with non-active/mildly active luminal Crohn's disease (CD). Following the 2nd Takeover bid and a squeeze-out ended in July 2018, TiGenix became a wholly owned subsidiary of Takeda.

The total consideration transferred was comprised of the following:

	JPY (millions) Amount
Cash	¥ 67,319
The ordinary shares of TiGenix already owned by Takeda immediately prior to the acquisition date	2,684
Total	¥ 70,003

The total cash outflow was 66,749 million JPY, which represents the initial cash consideration transferred of 67,319 million JPY and basis adjustment of 3,381 million JPY, less cash acquired of 3,951 million JPY.

The following represents provisional fair value of assets acquired and liabilities assumed:

	JPY (millions) Amount
Intangible assets	¥ 63,421
Other assets	5,541
Deferred tax liabilities	(8,043)
Other liabilities	(5,678)
Basis adjustments	(3,381)
Goodwill	18,143
Net assets acquired	¥ 70,003

Goodwill comprises increased earnings expected from the future business development. Goodwill is not deductible for tax purposes.

The fair value primarily consisting of intangible assets, deferred tax liabilities and goodwill assumed as of the acquisition date have been recorded provisionally based on the information available as of March 31, 2019. These amounts are subject to change as the Company is in the process of reviewing further details of the basis for the fair value measurement. For the year ended March 31, 2019, goodwill at the acquisition date decreased by 1,831 million JPY as a result of the adjustment to the provisional fair value, while other assets and deferred tax liabilities decreased by 253 million JPY and 2,084 million JPY, respectively.

Takeda entered into a forward exchange contract to hedge foreign currency risks for the acquisition of TiGenix, and applied the hedge accounting to the contract. Basis adjustment represents a fair value of the hedging instrument of 3,381 million JPY that was added to the amount of goodwill at the acquisition date.

No gains or losses were recognized as a result of remeasurement of fair value of the ordinary shares of TiGenix already owned by Takeda immediately prior to the acquisition date.

The revenue and net profit of TiGenix for the post-acquisition period, which were recognized in the consolidated financial statements for the year ended March 31, 2019 were immaterial.

The impact on Takeda’s revenue and net profit for the year ended March 31, 2019 assuming the acquisitions date of TiGenix had been April 1, 2018 was immaterial.

Acquisitions during the Years ended March 31, 2018

During the year ended March 31, 2018, Takeda acquired a business for 28,328 million JPY, which was fully paid in cash.

Acquisitions during the Year Ended March 31, 2017

ARIAD Pharmaceuticals, Inc.

On February 16, 2017, Takeda acquired ARIAD Pharmaceuticals, Inc. (hereinafter referred to as “ARIAD") through a tender offer to purchase all issued and outstanding shares of common stock in cash. ARIAD was focused on discovering, developing and commercializing precision therapies for patients with rare cancers. The acquisition of ARIAD is a highly strategic deal as it transforms Takeda’s global oncology portfolio and pipeline by expanding into solid tumors and reinforcing the existing strength in hematology. Brigatinib (US product name: ALUNBRIG) is a small molecule ALK (anaplastic lymphoma kinase) inhibitor for non-small cell lung cancer. After the acquisition, Brigatinib was granted marketing authorization by the US Food and Drug Administration (FDA) in April 2017. ICLUSIG, a treatment for CML (chronic myeloid leukemia) and Philadelphia chromosome positive ALL (acute lymphoblastic leukemia), is commercialized globally (marketing rights of the product are out-licensed in some certain markets other than the US). These two targeted and innovative medicines, with cost synergies, are expected to be value drivers for Takeda's oncology business. Additionally, ARIAD has a robust early stage pipeline, and Takeda will leverage ARIAD's R&D capabilities and platform to generate immediate and long-term growth in the pharmaceutical business.

The following represents fair value of assets acquired, liabilities assumed, purchase consideration transferred:

	JPY (millions) Amount
Intangible assets	¥ 433,047
Other assets	43,490
Deferred tax liabilities	(92,419)
Other liabilities	(38,852)
Goodwill	273,627
Net Assets Acquired	¥ 618,893

The consideration transferred was comprised of the following:

	JPY (millions) Amount
Cash	¥ 531,918
Debt assumed	59,155
Assumption of share-based payment liabilities	27,820
Total	¥ 618,893
Reduced by:	
Cash acquired	(29,869)
Deferred consideration	(1,509)
Proceeds from cash flow hedge	(4,411)
Net consideration paid	¥ 583,104

Goodwill comprises higher earnings expected from the future business development. Goodwill is not deductible for tax purposes.

The fair value of the assets acquired and the liabilities assumed, as of March 31, 2017, was booked provisionally, and allocation of the purchase price was completed during the year ended March 31, 2018. The purchase price allocation above reflects the fair value, and has been updated from the provisional amounts. As a result of the adjustments to the provisional fair value, goodwill at the acquisition date decreased by 3,198 million JPY while other liabilities increased by 2,827 million JPY and intangible assets, other assets and deferred tax liabilities decreased by 2,853 million JPY, 3,114 million JPY and 11,992 million JPY, respectively.

Acquisition-related costs of 3,194 million JPY, which includes agent fee and legal fee arising from the acquisition, were expensed as incurred and recorded in selling, general and administrative expenses.

Net revenue and net loss of ARIAD during the post-acquisition period, which were recognized in the consolidated statement of income for the year ended March 31, 2017, were immaterial. The impact on Takeda's revenue and net profit of ARIAD for the period ended March 31, 2017 assuming the acquisition date had been as of the beginning of the annual reporting period was immaterial.

In addition to the acquisition of ARIAD, Takeda acquired another business during the year for 6,040 million JPY. The aggregate net cash paid for acquisitions during the year ended March 31, 2017 was 589,144 million JPY.

32. Commitments and Contingent Liabilities

Operating Lease

Takeda is the lessee under several operating leases, primarily for office and other facilities, and certain office equipment. Future minimum lease payments by maturity under non-cancellable operating leases that have initial or remaining lease terms in excess of one year are as follows:

	JPY (millions) As of March 31	
	2018	2019
Within one year	¥ 12,053	¥ 31,172
Between one and five years	31,278	91,105
More than five years	33,720	111,301
Total	¥ 77,051	¥ 233,578

Total future minimum sublease payments expected to be received under non-cancellable subleases as of March 31, 2018 and 2019 were 34,482 million JPY and 13,140 million JPY, respectively.

Rent expense for operating lease contracts and sublease income recognized in profit or loss are as follows:

	JPY (millions) For the Year Ended March 31		
	2017	2018	2019
Rent expense	¥ 11,758	¥ 21,384	¥ 27,444
Sublease income	(109)	(2,493)	(3,579)
Total	¥ 11,649	¥ 18,891	¥ 23,865

Purchase commitments

The amount of contractual commitments for the acquisition of property, plant and equipment was 14,078 million JPY and 33,991 million JPY as of March 31, 2018 and 2019, respectively.

Irish Revenue Authority assessment

Shire received a tax assessment from the Irish Revenue Authority on November 28, 2018 for 398 million EUR. This assessment relates to a potential taxable gain from a 1,635 million USD break fee Shire received from AbbVie, Inc. ("AbbVie") in connection with the terminated offer to acquire Shire made by AbbVie in 2014. Takeda is currently in the appeal process with regards to this assessment as it does not believe a tax liability should arise from the break fee.

Milestone Payments

As discussed in Note 13, Takeda has certain contractual agreements related to the acquisition of intangible assets that require it to make payments of up to 517,017 million JPY and 655,531 million JPY as of March 31, 2018 and 2019, respectively. These commitments include development milestone payments in relation to R&D programs under development and expected maximum commercial milestone payments in relation to launched products. As for the programs under development, the possibility to meet certain conditions for commercial milestone payments is uncertain and the related commercial milestone payments were not included in the commitments.

Guarantees

The amount of contingent liabilities related to guarantees was 186 million JPY and 99 million JPY as of March 31, 2018 and 2019, respectively. These are all related to transactions with financial institutions and are not recognized as financial liabilities in the consolidated statement of financial position because the possibility of loss from contingent liabilities was remote.

Litigation

Takeda is involved in various legal and administrative proceedings. The most significant matters are described below.

Takeda may become involved in significant legal proceedings for which it is not possible to make a reliable estimate of the expected financial effect, if any, which may result from ultimate resolution of the proceedings. In these cases, appropriate disclosures about such cases would be included in this note, but no provision would be made for the cases.

With respect to each of the legal proceedings described below, other than those for which a provision has been made, Takeda is unable to make a reliable estimate of the expected financial effect at this stage. This is due to a number of factors, including, but not limited to, the stage of proceedings, the entitlement of parties to appeal a decision, if any, and lack of clarity as to the merits of theories of liability, the merits of Takeda's defenses, the amount and recoverability of damages and/or governing law. The Company does not believe that information about the amount sought by the plaintiffs, if that is known, is, by itself, meaningful in every instance with respect to the outcome of those legal proceedings.

Legal expenses incurred and charges related to legal claims are recorded in selling, general and administrative expenses. Provisions are recorded, after taking appropriate legal and other specialist advice, where an outflow of resources is considered probable and a reliable estimate can be made of the likely outcome of the dispute. For certain product liability claims, Takeda will record a provision where there is sufficient history of claims made and settlements to enable management to make a reliable estimate of the provision required to cover unasserted claims. As of March 31, 2019, Takeda's aggregate provisions for legal and other disputes were 46,775 million JPY. The ultimate liability for legal claims may vary from the amounts provided and is dependent upon the outcome of litigation proceedings, investigations and possible settlement negotiations. Unless otherwise stated below, Takeda is unable to predict the outcome or duration of these matters at this time.

Takeda's position could change over time, and, therefore, there can be no assurance that any losses that result from the outcome of any legal proceedings will not exceed, by a material amount, the amount of the provisions reported in these consolidated financial statement.

Certain of the matters discussed below were originally brought against Shire or its subsidiaries prior to Takeda's acquisition of Shire. Refer to Note 31 on Business Combination for discussion of Takeda's purchase accounting for the acquisition of Shire.

Product Liability and Related Claims

Pre-clinical and clinical trials are conducted during the development of potential products to determine the safety and efficacy of products for use by humans following approval by regulatory bodies. Notwithstanding these efforts, when drugs and vaccines are introduced into the marketplace, unanticipated safety issues may become, or be claimed by some to be, evident. Takeda is currently a defendant in a number of product liability lawsuits related to its products. For the product liability lawsuits and related claims, other than those for which a provision has been made, Takeda is unable to make a reliable estimate of the expected financial effect at this stage.

The Company's principal pending legal and other proceedings are disclosed below. The outcomes of these proceedings are not always predictable and can be affected by various factors. For those legal and other proceedings for which it is considered at least reasonably possible that a loss has been incurred, the Company discloses the possible loss or range of possible loss in excess of the recorded loss contingency provision, if any, where such excess is both material and estimable.

ACTOS

Takeda has been named as a defendant in lawsuits in U.S. federal and state courts in which plaintiffs allege to have developed bladder cancer or other injuries as a result of taking products containing type 2 diabetes treatment pioglitazone (U.S. brand name ACTOS). Eli Lilly and Company ("Lilly"), which co-promoted ACTOS in the United States for a period of time, also has been named as a defendant in many of these lawsuits. Under the parties' co-promotion agreement, Takeda has agreed to defend and indemnify Lilly in the U.S. matters. Outside the U.S., lawsuits and claims have also been brought by persons claiming similar injuries.

In April 2015, Takeda reached an agreement with the lead plaintiffs' lawyers that resolved the vast majority of ACTOS product liability lawsuits pending against Takeda and Lilly in the U.S. The settlement covered all bladder cancer claims pending in any U.S. court as of the date of settlement. Claimants with unfiled claims in the U.S. represented by counsel as of the date of settlement and within three days thereafter were also eligible to participate. The settlement became effective when 95% of litigants and claimants opted-in. In connection with this broad settlement, Takeda has paid 2.4 billion USD (approximately 288 billion JPY) into a qualified settlement fund. Takeda received insurance proceeds totaling approximately 58 billion JPY under various policies covering product liability claims against Takeda. Takeda also established provisions for the remaining ACTOS claims and lawsuits.

In addition to remaining product liability claims, the following lawsuits have been filed against Takeda by public and private third-party payors, as well as consumers, seeking damages for alleged economic losses:

A purported nation-wide class action lawsuit has been filed in federal court in California—the Painters' Fund case—on behalf of third-party payors and consumers seeking, among other things, reimbursement of monies spent on ACTOS. In April 2018, the court dismissed the Painters' Fund case. Plaintiffs appealed.

A purported California class action has been filed in federal court in California asserting claims similar to the Painters' Fund case.

The States of Mississippi and Louisiana have filed lawsuits against Takeda and Lilly alleging that defendants did not warn about bladder cancer and other risks of ACTOS. The lawsuits seek reimbursement of the cost of ACTOS, paid by the states on behalf of patients through programs such as Medicaid, and for medical treatment of patients allegedly injured by ACTOS, attorneys' fees and expenses, and punitive damages. The court granted Takeda's motion to dismiss the Louisiana case. The decision has been appealed. In November 2018, Takeda and Lilly agreed to settle the lawsuit brought by the State of Mississippi. The lawsuit brought by the State of Louisiana remains pending.

Proton Pump Inhibitor ("PPI") Related Claims

As of June 10, 2019 approximately 6,000 product liability lawsuits involving PREVACID and DEXILANT have been filed against Takeda in U.S. federal and state courts. The federal lawsuits are consolidated for pre-trial proceedings in a multi-district litigation in federal court in New Jersey. The plaintiffs in these cases allege they developed kidney injuries as a result of taking PREVACID and/or DEXILANT, and that Takeda failed to adequately warn them of this potential risk. It remains unclear how many of the plaintiffs actually took PREVACID and/or DEXILANT. Similar cases are pending against other manufacturers of drugs in the same PPI class as Takeda's products, including AstraZeneca plc ("AstraZeneca"), Procter & Gamble Company ("Procter & Gamble") and Pfizer Inc. ("Pfizer"). Outside the U.S., three proposed class actions have been filed in three provinces in Canada (Quebec, Ontario, and Saskatchewan). The defendants in these actions include Takeda, AstraZeneca, Janssen Pharmaceutical Companies ("Janssen") and several generic manufacturers. It is unclear how many additional actions, if any, may be filed against Takeda in the U.S., Canada or elsewhere.

ELAPRASE

In 2014, Shire's Brazilian affiliate, Shire Farmaceutica Brasil Ltda, was served with a lawsuit brought by the State of Sao Paulo where the Brazilian Public Attorney's office has intervened alleging that Shire would be obligated to supply ELAPRASE for an indefinite period at no cost to patients who participated in ELAPRASE clinical trials in Brazil, and seeking recoupment to the Brazilian government for amounts paid on behalf of these patients to date, and moral damages associated with these claims.

On May 6, 2016, the trial court judge ruled on the case and dismissed all the claims under the class action, which was appealed. On February 20, 2017, the Court of Appeals in Sao Paulo issued a decision upholding the decision rendered by the lower court judge, dismissing, therefore, all the claims under the class action. On July 12, 2017, the Public Prosecutor filed an appeal addressed to the Supreme Court. On October 10, 2017, the State of Sao Paulo filed appeals addressed to the Superior Court of Justice and to the Supreme Court. On November 13, 2017, Shire submitted its answers to the aforementioned appeals. On July 3, 2018 the President of Sao Paulo Court of Appeals issued a decision denying the remittance of all appeals to the Superior Courts. Against such decision, both the State (on August 23, 2018) and the Public Prosecutor (on October 3, 2018) filed an appeal. By virtue of such appeal, the case records were remitted to the Superior Court of Justice on February 27, 2019. Takeda is currently waiting the assignment of the case to one of the Justices of the Superior Court of Justice.

Intellectual property

Intellectual property claims include challenges to the validity and enforceability of Takeda's patents on various products or processes as well as assertions of non-infringement of those patents. A loss in any of these cases could result in loss of patent protection for the product at issue. The consequences of any such loss could be a significant decrease in sales of that product and could materially affect future results of operations for Takeda.

PREVACID

In January 2018, Takeda received notice from Zydus Pharmaceuticals (USA) Inc. ("Zydus") that it has amended its application for a generic version of SoluTab. In response, Takeda filed a patent infringement lawsuit against Zydus and in response, Zydus filed a counterclaim asserting that Takeda's challenge of Zydus' abbreviated new drug application ("ANDA") product violates antitrust laws. Takeda believes the counterclaim is without merit.

In June 2009, Apotex Pharmaceuticals Inc. ("Apotex") filed a lawsuit in Toronto, Canada, against Takeda and Abbott Laboratories ("Abbott") seeking alleged damages for delayed market entry of its generic lansoprazole capsules due to a prior patent infringement lawsuit against Apotex. Previously, Abbott and Takeda filed a patent infringement lawsuit against Apotex in response to Apotex's regulatory submission to the Canadian Minister of Health seeking permission to market generic lansoprazole capsules before the expiration of various Canadian patents relating to this drug. In January 2019, the parties settled the lawsuit.

PANTOPRAZOLE

On January 15, 2016, Mylan Inc. ("Mylan") filed a suit at the Federal Court against Takeda claiming damages as a result of the dismissal of Takeda´s previous PM(NOC) proceeding against Mylan. Mylan claimed damages due to being held-off the market with its generic pantoprazole magnesium product during the time period of June 27, 2013 until June 15, 2015. The parties settled the lawsuit in May 2018.

AMITIZA

In March 2017, Sucampo Pharmaceuticals, Inc. ("Sucampo") (Takeda's licensor) received a paragraph IV certification directed to AMITIZA from Amneal Pharmaceuticals, and in August 2017 received a paragraph IV certification directed to AMITIZA from Teva Pharmaceutical Industries Ltd. ("Teva"). These parties contend that the patents listed in FDA's Orange Book for AMITIZA are invalid and/or not infringed by their ANDA product. In response, Sucampo and Takeda filed a patent infringement lawsuit against the parties. Patent litigation against other ANDA filers for AMITIZA were previously settled, and patent litigation against Amneal Pharmaceuticals and Teva was settled in June 2018.

TRINTELLIX

Takeda has received notices from sixteen generic pharmaceutical companies that they have submitted ANDAs with paragraph IV certifications seeking to sell generic versions of TRINTELLIX. To date, at least four generic companies are challenging the patents covering the compound, vortioxetine, which expire in 2026. Takeda filed patent infringement lawsuits against the ANDA filers in federal court in Delaware.

ENTYVIO

F. Hoffmann-La Roche, Ltd. ("Roche") has filed patent infringement lawsuits against Takeda in Germany and Italy alleging that ENTYVIO infringes a Roche patent issued in Germany and Italy. Takeda is vigorously defending these lawsuits. Additionally, Takeda has filed a lawsuit in the U.K. seeking nullification of Roche's patent in the U.K.

MYDAYIS

On October 12, 2017, Shire was notified that Teva Pharmaceuticals USA, Inc. had submitted an ANDA to the FDA seeking permission to market a generic version of MYDAYIS. Within the requisite 45-day period, Shire filed a lawsuit in the U.S. District Court for the District of Delaware against Teva Pharmaceuticals USA, Inc., Actavis Laboratories, Inc. and Teva Pharmaceutical Industries Limited (collectively the "Teva entities"). A Markman hearing took place on January 23, 2019. A trial is scheduled to begin on December 9, 2019.

On March 8, 2018, Shire was notified that Impax Laboratories, Inc. ("Impax") had submitted an ANDA to the FDA seeking permission to market a generic version of MYDAYIS. Within the requisite 45-day period, Shire filed a lawsuit in the U.S. District Court for the District of Delaware against Impax. A Markman hearing took place on January 23, 2019. A trial is scheduled to begin on December 9, 2019.

On April 19, 2018, Shire was notified that SpecGX LLC ("SpecGX") had submitted an ANDA to the FDA seeking permission to market a generic version of MYDAYIS. Within the requisite 45-day period, Shire filed a lawsuit in the U.S. District Court for the District of Delaware against SpecGx. Shire and SpecGx settled the lawsuit on January 28, 2019.

Petitions to institute inter partes reviews ("IPRs") against U.S. Patent numbers 8,846,100 and 9,173,857 were filed by KVK Tech in January 2018 and the petitions were granted in July 2018. Both of these patents are listed in the Orange Book as covering MYDAYIS and are among the patents-in-suit in the infringement action brought against the Teva entities and Impax as noted above. A decision on the merits is expected on or before July 10, 2019.

ADYNOVATE

On December 5, 2016, Bayer Healthcare LLC ("Bayer") filed a lawsuit in the US District Court for the District of Delaware against Baxalta Incorporated and Baxalta US Inc. (collectively "Baxalta"), which are direct or indirect wholly owned subsidiaries of Shire, and Nektar Therapeutics ("Nektar") filed alleging infringement of U.S. Patent No. 9,364,520 in connection with the sales of ADYNOVATE [antihemophilic factor (recombinant), PEGylated]. The case was tried before a jury beginning on January 28, 2019. The jury found in favor of Bayer determining that the patent is infringed. The jury further awarded damages in the amount of 155.2 million USD. Takeda is considering its further options. Takeda established a provision against this case in purchase accounting (Note 31).

On September 15, 2017, Baxalta and Nektar filed a lawsuit in the US District Court for the District of Delaware against Bayer alleging infringement of US Patent Nos. 7,199,223; 7,863,421; 8,143,378; 8,247,536; 8,519,102; 8,618,259; 8,889,831: This case was consolidated on December 7, 2018 with Baxalta's and Nektar's lawsuit filed on August 31, 2018 alleging infringement of 7,026,440; 7,872,072; 8,273,833; 8,809,453; and 9,187,569 in connection with the BAY-94 (subsequently approved and marketed as Jivi® (antihemophilic factor (recombinant PEGylated-aucl)). On July 2, 2018, an amended complaint was filed adding US Patent No. 9,999,657. Markman hearings are scheduled to take place on June 21, 2019 and August 20, 2019. A trial is scheduled to begin on April 27, 2020.

Other

In addition to the individual patent litigation cases described above, Takeda is party to a number of cases where Takeda has received notices that companies have submitted ANDAs with paragraph IV certifications to sell generic versions of other Takeda products. These include other Takeda products including Alogliptin. Takeda has filed patent infringement lawsuits against parties involved in these situations.

Sales, Marketing, and Regulation

Takeda has other litigations related to its products and its activities, the most significant of which are describe below.

ACTOS

There have been purported class action lawsuits filed in federal court in New York by several end payors and wholesalers against Takeda alleging anticompetitive conduct to delay generic competition for ACTOS. In September 2015, the court granted defendants' motions to dismiss the antitrust claims asserted by the end payors. The end payors appealed this decision to the Federal 2nd Circuit Court of Appeals. The wholesalers' lawsuit had been stayed pending the appellate court's decision in the end payors' lawsuit. In February 2017, the appellate court reversed in part the dismissal of the end payors' case and allowed one of plaintiffs' antitrust theories to proceed in the trial court. Specifically, the court ruled that plaintiffs sufficiently alleged that Takeda's characterizations of two patents in the FDA Orange Book were false, and that this resulted in delaying Teva's launch of generic ACTOS. Takeda disagrees with these allegations and believes the Orange Book listings were correct. The court, however, affirmed the trial court's dismissal of other antitrust theories. The end payors' case, along with the wholesalers' case, is proceeding in the trial court, where Takeda has filed a motion to dismiss the remaining legal theory.

VANCOCIN

On April 6, 2012, ViroPharma Incorporated ("ViroPharma") received a notification that the United States Federal Trade Commission ("FTC") was conducting an investigation into whether ViroPharma had engaged in unfair methods of competition with respect to VANCOCIN, which Shire acquired in January 2014. Following its divestiture of VANCOCIN in August 2014, Shire retained certain liabilities including any potential liabilities related to the VANCOCIN citizen petition.

On August 3, 2012, and September 8, 2014, ViroPharma and Shire respectively received Civil Investigative Demands from the FTC requesting additional information related to this matter. Shire has fully cooperated with the FTC's investigation.

On February 7, 2017, the FTC filed a complaint against Shire alleging that ViroPharma engaged in conduct in violation of U.S. antitrust laws arising from a citizen petition ViroPharma filed in 2006 related to FDA's policy for evaluating bioequivalence for generic versions of VANCOCIN. The complaint seeks equitable relief, including an injunction and disgorgement. Shire filed a motion to dismiss on April 10, 2017. On March 20, 2018, the court granted Shire's motion. On April 11, 2018, the FTC filed a Notice of Appeal. On February 25, 2019, the Court of Appeals for the Third Circuit affirmed the dismissal of the FTC's complaint.

At this time, Takeda is unable to predict the outcome or duration of this case.

Investigation of Patient Assistance Programs

In November 2016, the U.S. Department of Justice (through the U.S. Attorneys' Office in Boston) issued a subpoena to ARIAD, which was acquired by Takeda during the year ended March 31, 2017, seeking information from January 2010 to the present relating to ARIAD's donations to 501(c) (3) co-payment foundations, financial assistance programs, and free drug programs available to Medicare beneficiaries and the relationship between these co-payment foundations and specialty pharmacies, hubs or case management programs. ARIAD is cooperating in the investigation.

In June 2019, the U.S. Department of Justice (through the U.S. Attorney's Office in Boston, Massachusetts) issued a subpoena to Shire Pharmaceuticals LLC, which was acquired by Takeda during the year ended March 31, 2019 (through Takeda's acquisition of Shire plc). The subpoena generally seeks information about Shire's interactions with 501(c)(3) organizations that provide financial assistance to Medicare patients taking Shire drugs, including the hereditary angioedema medications Firazyr and Cinryze. Shire is cooperating with the investigation.

33. Subsequent Events

On May 9, 2019, Takeda announced the sale of Xiidra® (lifitegrast ophthalmic solution), which was obtained as part of the Shire acquisition, to buyer Novartis. Xiidra® is currently marketed in the United States and Canada. Under the terms of the agreement, Takeda will receive total consideration of up to 5.3 billion USD (approximately 590.0 billion JPY), including 3.4 billion USD in cash at closing and up to 1.9 billion USD in contingent payments. The contingent payments become payable to Takeda at specified milestones based on sales of Xiidra® or a comparable generic product. Xiidra® was recorded as held for sale at the date of the Shire acquisition, as Takeda intended to dispose of Xiidra®. The disposal group including Xiidra® was recorded at the acquisition date based on the estimated consideration to be received in the transaction. The deal is expected to be closed in the second quarter ended September 30, 2019.

On May 9, 2019, Takeda announced the sale of TachoSil™ (Fibrin Sealant Patch) to buyer Ethicon for 400 million EUR (approximately 50 billion JPY). In addition, Takeda entered in a long-term manufacturing services agreement with the buyer. The transaction includes the sale of product rights and transfer of related workforce. The deal is expected to be closed in the second quarter ended September 30, 2019.

On May 14, 2019, Takeda announced the issuance of 11,350 thousand shares at an issuance price of 4,318 JPY per share through third- party allotment to The Master Trust Bank of Japan, Ltd., which is the trust account for Takeda's ESOP subsidiary. This issuance was approved by the resolution of the Board of Directors. These shares are issued with the intention to be reacquired by Takeda from the ESOP trust for distribution of share-based compensation awards.

On June 6, 2019, Takeda issued hybrid bonds (subordinated bonds) ("Hybrid Bonds") with an aggregate principal amount of 500 billion JPY. The proceeds from this Hybrid Bonds offering were used to repay the existing syndicated loans comprised of the senior short-term loan facility that was utilized to finance the acquisition of Shire. The Hybrid Bonds will mature on June 6, 2079. Under the terms and conditions of the Hybrid Bonds, Takeda may make an early repayment of all of the principal of the Hybrid Bonds on each interest payment date beginning October 6, 2024. Interest is payable semi-annually at a rate per annum subject to revision. The Hybrid Bonds are unsecured, and Takeda is not subject to any financial covenants related to these bonds.