



FORM 20-F FY2020

TAKEDA PHARMACEUTICAL COMPANY LIMITED



As filed with the Securities and Exchange Commission on June 29, 2021

**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, 2021

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

(Jurisdiction of incorporation or organization)

1-1, Nihonbashi-Honcho 2-Chome

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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 Common Stock, no par value*	TAK	New York Stock Exchange
0.750% Senior Notes due 2027	TAK27	New York Stock Exchange
1.000% Senior Notes due 2029	TAK29	New York Stock Exchange
1.375% Senior Notes due 2032	TAK32	New York Stock Exchange
2.000% Senior Notes due 2040	TAK40A	New York Stock Exchange

* 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.

157,132,028 ADSs outstanding as of March 31, 2021

1,563,358,159 shares of common stock as of March 31, 2021

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 whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

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, 2020 and 2021 and for the fiscal years ended March 31, 2019, 2020 and 2021. 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 (“SIC”) and International Financial Reporting Interpretations Committee (“IFRIC”).

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.”) 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.” “Notes” refers to the series of notes issued by us and registered under Section 12(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) listed on the cover page of this annual report. References to “our securities” refer to collectively to our ADSs, the shares of our common stock and the notes.

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 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;
- the ability to achieve the expected benefits of businesses we may acquire, including our acquisition of Shire plc (including, except as the context otherwise requires, its consolidated subsidiaries “Shire”);
- developments regarding or the outcome of any litigation or other legal, administrative, regulatory or governmental proceedings;
- information regarding competition within our industry;
- the impact of the COVID-19 pandemic; 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 fiscal years ended March 31, 2017, 2018, 2019, 2020, and 2021 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,				
	2017	2018	2019	2020	2021
(billions of yen, except share and per share data and where designated as U.S. dollar)					
Selected Statements of Operations Data:					
Revenue	¥ 1,732.1	¥ 1,770.5	¥ 2,097.2	¥ 3,291.2	¥ 3,197.8
Operating profit	155.9	241.8	237.7	100.4	509.3
Share of profit (loss) of investments accounted for using the equity method	(1.5)	(32.2)	(43.6)	(24.0)	0.1
Profit (loss) before tax	143.3	217.2	127.6	(60.8)	366.2
Net profit for the year	115.5	186.7	135.1	44.3	376.2
Net profit attributable to owners of the Company	114.9	186.9	135.2	44.2	376.0
Per share amounts					
Basic earnings	¥ 147.15	¥ 239.35	¥ 140.61	¥ 28.41	¥ 240.72
Diluted earnings	146.26	237.56	139.82	28.25	238.96
Annual cash dividends	180.00	180.00	180.00	180.00	180.00
Cash dividends in U.S. dollars ⁽¹⁾	\$ 1.62	\$ 1.69	\$ 1.63	\$ 1.67	\$ 1.63
Selected Statements of Financial Position Data:					
Cash and cash equivalents	¥ 319.5	¥ 294.5	¥ 702.1	¥ 637.6	¥ 966.2
Total assets	4,346.8	4,106.5	13,792.8	12,821.1	12,912.3
Total bonds and loans	1,144.9	985.7	5,751.0	5,093.3	4,635.4
Total liabilities	2,397.8	2,089.1	8,606.8	8,093.6	7,735.1
Total equity	1,949.0	2,017.4	5,186.0	4,727.5	5,177.2
Share capital	65.2	77.9	1,643.6	1,668.1	1,668.1
Other Data:					
Number of shares issued at end of period (in thousands)	790,521	794,688	1,565,006	1,576,374	1,576,388

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 securities 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 securities. If any of the following risks actually occur, it could have a material adverse effect on our business, financial condition, results of operations, future prospects, and the market value of our securities.

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 securities.

Risks Relating to Development, Production and Marketing of Pharmaceutical Products

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 offset the effects of losses of exclusivity in our existing products and 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. We discuss regulatory considerations below under “—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 biopharmaceutical product also requires us to attract and retain sufficient numbers of highly-skilled employees and can often take more than ten years from discovery to commercial launch. 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 unfavorable results or indications of safety concerns regarding a new compound; difficulty or delays in enrolling patients or administering in clinical trials; delays in completing formulation and other testing and work necessary to support an application for regulatory approval; insufficient clinical trial data to support the safety or efficacy of the product candidate; 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 or the inability to manufacture sufficient quantities of a product candidate for development or commercialization activities in a timely or cost-efficient manner. Moreover, 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. Activities described above become more difficult during pandemics, such as the COVID-19 pandemic, which may result in more serious obstacles to advance research and development efforts.

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”), the Pharmaceuticals and Medical Devices Agency (the “PMDA”) in Japan and National Medical Products Administration (the “NMPA”) for China 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-marketing commitments, including continual review, risk evaluations, comparative effectiveness studies and, in some cases, requirements to conduct post-marketing 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, specialized organizations, health professionals or patients regarding the use of products. For example, such recommendations could include a request to limit the patient population of a drug’s indication, the imposition of marketing restrictions, including changes in package insert or labeling, or the suspension or withdrawal of the product. Any such recommendation, whether implemented or not, could 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 have been subject to increasing supervision by governmental authorities, and we believe that this trend will continue.

In the U.S., 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 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 our operations, 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 consumers 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 U.S., there has been increasing pricing pressure from managed care groups and institutional and governmental purchasers. 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 legislative and regulatory environment, in the U.S. we continue to experience heightened pricing pressure on, and limitations on access to, our branded pharmaceutical products sold in the U.S. 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, expand the Affordable Care Act, and lower the overall spending by the government on prescription medicines. The future of 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 U.S. will continue to be subject to increased 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”), 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 previously subject to revisions based on the actual prices at which the pharmaceutical products are purchased by medical institutions in Japan after discounts and rebates from the listed price, and 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. As part of these initiatives, the annual NHI price list revision was introduced in April 2021, which could lead to more frequent

downward price revisions. The government is also addressing the efficient use of drugs, including the further promotion of generic use that slightly falls short of a target of 80% penetration by volume by September 2020 with respect to products for which market exclusivity has expired. In addition, a cost-effectiveness evaluation has been officially introduced by the MHLW since 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 the outcome of this review.

In Europe, as in the U.S., 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 including China. We expect such pricing pressures to continue as we expand our business in those regions and 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 U.S., 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 U.S. 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 April 2021 announced its intention to raise generic drug penetration with respect to products for which market exclusivity has expired, to 80% by volume in all prefectures (regions) by the end of the fiscal year-ending 2023. Legislation has also been passed in the U.S. 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 products of ours 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 covering bortezomib, the active ingredient in *VELCADE*, one of our largest selling products in the U.S., a competing bortezomib-containing product has been introduced. Although the market share impact to date has not been large due to the limitations of the competing product's formulation, further entry of competing products, particularly with a subcutaneous administration route, could result in an acceleration of revenue declines. Such decreases may accelerate further following the scheduled expiration of patent protection covering the formulation of *VELCADE* in 2022. Patent protections covering *VYVANSE*, are scheduled to expire in the U.S. in 2023, which we anticipate will lead to declines in sales. Based on current data and marketing exclusivities, the period of regulatory exclusivity for *ENTYVIO*, which is currently our top selling product, may continue until, at the earliest, 2024 in the EU and 2026 in the U.S. and Japan, and we expect to see decreased sales of *ENTYVIO* in the long term as a result. There are also patents for *ENTYVIO* that expire in 2032, and therefore the exact timing of biosimilar entry is uncertain at this time.

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, if the generic manufacturer is able to design around our patents, or if the manufacturer obtains approval of their product and launches it at risk (i.e. prior to a judicial determination). If such a launch occurred prior to completion of court proceedings, a court may decline to grant a preliminary injunction. 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 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, partnerships 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, 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 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. Certain 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. Furthermore, 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.

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

In Japan, the steady introduction of drugs already marketed outside Japan by overseas competitors has led to increased competition. 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 or biosimilars of our products, as well as those 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.

Furthermore, sales of the rare disease portfolio 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 maintain the competitiveness of our products.

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

We expect that we will continue to collaborate with 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 consolidated statement of financial position, any termination of the relevant partnership could require us to recognize an impairment loss up to the full value of such assets;
- 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 or partner may attempt to terminate its license or partnership agreement with us or elect not to renew it to pursue other marketing opportunities. Our licensors or partners also could merge with or be acquired by another company or experience financial or other setbacks unrelated to our alliance 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 use of third parties for the performance of certain key business functions, particularly product manufacture and commercialization, heightens the risks faced by our business.

We commonly use suppliers, vendors and partners, including alliances with other pharmaceutical companies, for certain key aspects of our business, including manufacturing 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 regulations, 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. 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 certain final drug products. Sources of some materials may be limited to a single supplier, and if such a 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 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 the Good Manufacturing Practice (the “GMP”) and other applicable regulations and quality assurance guidelines, which could lead to manufacturing shutdowns, product shortages, delays in product manufacturing and /or administrative, enforcement or other actions by regulatory authorities if regulatory authorities deem our products to be adulterated or otherwise in violation of applicable laws; 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; the inability to obtain sufficient components or raw materials on a timely basis or at a cost-effective price due to public health crises, medical epidemics or pandemics such as the COVID-19 pandemic; 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.

In addition, despite efforts at compliance, from time to time we or our partners may receive notices of manufacturing, quality-related, or other observations following inspections by regulatory authorities around the world, as well as official agency correspondence regarding compliance. For example, on June 9, 2020 the FDA issued a warning letter related to our manufacturing plant in Hikari, Yamaguchi, Japan which included several technical observations, including observations about procedures, personnel, records, investigations, training, equipment, and oversight. We responded to the warning letter within the required timeframe and the Hikari plant is currently working under the comprehensive corrective action/preventative action plan. The issues raised as part of the inspection are being addressed within the context of those activities. The corrective actions resulted in a temporary supply shortage of Leuprorelin, a product which we supply to AbbVie, Inc. (“AbbVie”) pursuant to a supply agreement. AbbVie has since filed a lawsuit against us on November 6, 2020 specifying an alleged breach of contract. We or our partners may receive additional or similar observations, correspondence and claims in the future, whether regarding the Hikari plant or otherwise. If we are unable to resolve these observations and address regulator concerns and claims from partners in a timely fashion, our business, financial condition and results of operations could be

materially affected. See “—*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*” for further discussion on risks associated with litigation and lawsuits relating to our operations.

The development and manufacture of biologics and stem cell therapies 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.

Furthermore, sourcing and transportation of plasma and production and distribution of plasma-derived products is complex, capital intensive and subject to extensive regulation. Efforts to increase the collection of plasma may require strengthening acquisition and third-party contracting capacities and successful regulatory approval of additional plasma collection facilities and plasma fractionation facilities. Further development of such capacities and facilities involve a lengthy regulatory process and is highly capital intensive. In addition, access to and transport and use of plasma may be subject to restrictions by governmental agencies. If we are unable to manage these inherent risks and challenges, 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.

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

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.

Risks Relating to Our Business Strategies

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 4,635.4 billion JPY as of March 31, 2021, the majority of which was incurred in connection with the acquisition of 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”) or represents the related indebtedness of Shire that is included in our consolidated statements of financial position, some of which was refinanced in the financial year. This significant amount of aggregate debt and the substantial amount of cash required for payments of interest and principal could adversely affect our liquidity. 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, cash flows, business and results of operations. Furthermore, we may desire to or be required from time to time to incur additional borrowings, including in relation to the repayment or refinancing of any of our currently outstanding indebtedness. Our ability to arrange new financing, or a re-financing and the terms thereof 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.

While we have disposed of significant non-core assets since the Shire Acquisition and have primarily deployed the proceeds thereof toward deleveraging, such disposals may affect our business, financial condition or results of operations adversely, leading to larger-than-expected decreases in earnings.

Credit rating agencies routinely evaluate our business, and their ratings are based on a number of factors, including our leverage, ability to generate cash flows, overall financial strength and diversification, as well as other factors beyond our control, such as the state of the global economy and our industry generally. For example, we have announced our goals to reduce the extent of our leverage. 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. While our credit ratings remain investment grade, each rating agency reviews its ratings periodically, and there is no assurance that the current credit ratings assigned to us will not be downgraded. A downgrade of our credit rating may materially and adversely affect the market prices of our equity and debt securities, including the notes, the interest rates at which our borrowings are made and debt securities are issued, and fees charged to us by current or future lenders. This could make it significantly more costly for us to borrow money, to issue debt securities and to raise certain other types of capital and/or complete additional financings. Such negative credit rating actions and the underlying reasons for such actions could materially and adversely affect our cash flows, results of operations and financial condition and the market price of, and our ability to pay the principal and interest on our debt securities.

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 plc. The ultimate 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. 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, in connection with the Shire Acquisition, we recorded significant intangible assets and, as a result, significant amortization expense in the fiscal years ended March 31, 2019, 2020 and 2021, and we expect to continue to record significant amounts of amortization expense in future fiscal years. We also 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 years ended March 31, 2019, 2020 and 2021; we expect to record a certain level of these expenses in the fiscal years ending March 31, 2022 and 2023. In addition, we recorded significant amounts of goodwill, and, if we are unable to achieve the anticipated benefits of the 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. See "*—We may have to recognize additional charges on our statements of profit or loss due to impairment of goodwill, other intangible assets and equity method investments.*" for further discussion on risks associated with impairments.

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 several 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 have significant operations across the world, including emerging markets, and continued expansion into new and developing markets is a key strategy, 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 difficulties in monitoring and coordinating research and development, marketing, supply-chain and other operations in a large number of jurisdictions; risks related to 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 U.S., 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 global, regional or local economies, or the overall political, economic or social climate, including inter-country relationships; acts of terrorism, war, global climate change, extreme weather events, medical epidemics or pandemics such as the recent COVID-19 pandemic, 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, 2021, regions outside of Japan accounted for 82.5% of our consolidated revenue, with the U.S. in particular contributing 49.0% of consolidated revenue. We expect that markets outside Japan, particularly the U.S. and also Europe and Canada, will continue to be increasingly important to our business and results of operations, increasing the likelihood that any of these risks is realized. We have also 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 404.0 billion JPY (or 12.6% of our total revenue) for the fiscal year ended March 31, 2021, and we intend to pursue further growth in such emerging markets. In particular, we believe that there is an attractive opportunity to grow our business in China.

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. Moreover, we may face additional legal and regulatory barriers to achieving growth, such as restrictions on the import of raw materials or other trade regulations (for example, on the import of plasma into China) that will require us to expend additional resources to achieve our goals.

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

We may experience difficulty implementing sustainability-related measures, particularly those relating to the environment, or in meeting the expectations of stakeholders.

Governmental and regulatory authorities, counterparties such as vendors and suppliers, investors, the public at large and others have increasingly focused on sustainability and social responsibility-related issues, particularly as they relate to the environment. Moreover, we have established a company-wide sustainability program, and as part of this program, we have committed to reducing our carbon footprint, decreasing the waste created by our business and enhancing our water stewardship, and expect our vendors and suppliers to cooperate in these initiatives. Particularly, we announced that we would become carbon neutral and implement a long-term strategy to reduce companywide emissions to zero by 2040. However, we may be unable to meet such standards or achieve our goals, and our efforts to do so may for example impose significant additional costs on us, require us to seek alternative vendors or suppliers or impair our ability to procure or use certain materials. Conversely, if we are unable to meet such standards, we may not be able to continue to administer our manufacturing, research and development or other aspects of our business as we desire. Moreover, to the extent that we are unable to meet the expectations of stakeholders, including governmental and regulatory authorities, counterparties, investors, or the public, our reputation may be harmed, we may face increased compliance or other costs and demand for securities issued by us and our ability to participate in the debt and equity markets may decrease. Furthermore, such standards and expectations are subject to ongoing change and refinement, and may shift in unexpected and potentially significant ways, which we may struggle to accommodate.

Our digital transformation initiatives may be unsuccessful, and our profitability may be hurt or our business otherwise might be adversely affected.

We have made and plan to continue to make significant investments in digital transformation initiatives, with the goal of modernizing our platforms, accelerating data services, enhancing our ability to innovate and equipping our employees with new skills and ways of working. These types of activities are complex and are dependent on a number of factors, including entering into successful partnerships and alliances with technology companies, as well as developing and deploying technology architecture successfully. If we do not successfully manage our digitalization initiatives, or any other related activities that we may take in the future, any expected efficiencies and benefits might be delayed or not realized, and our operations and business could be disrupted. If we fail to adequately integrate digitalization into our business, we may lose patients and market share. Even if our efforts are successful, our competitors, including established competitors or new entrants with specialized expertise, may be better able to achieve digitalization and realize its benefits, giving them a competitive advantage over us, displace any technology that we may develop or implement or make them obsolete. In addition, the costs associated with implementing these initiatives might exceed expectations, which could result in additional future charges, and we may be exposed to increased cybersecurity or related risks. The occurrence of any of these risks could have a material adverse effect on our business, financial position 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. We also increasingly seek to develop and collaborate on technology-based digital health products, such as mobile applications that aim to improve patient welfare in a variety of ways, which could lead us to store and transfer personal information about individual patients, customers and others. The size, age and complexity of our information technology systems make them potentially vulnerable to service interruptions, malicious intrusions and random attacks. Cyber-attacks are increasing in frequency, sophistication and intensity, and opportunistically in response to, for example, the spread of COVID-19 and implementation of remote working arrangements. These and other cyber-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, hackers, 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.

Although we have not, to date, detected any material breaches of our information technology systems, data systems or personal information, the risk of such breaches remains and cannot be completely negated. 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, employees or the patients we serve is misappropriated, our reputation with our customers, employees and patients may be injured resulting in loss of business and/or morale, and we may incur costs to remediate possible injury to those individuals 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.

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 talent 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.

Legal and Regulatory Risks

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, intellectual property and commercial disputes, as well as claims related 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.

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 liabilities 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, 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 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 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.

We are subject to evolving and complex tax and related risks, which may have a material adverse effect on our business, financial position and results of operations.

We are subject to evolving and complex tax laws in the jurisdictions in which we operate, and routinely obtain advice on tax-related matters, including in connection with the Shire Acquisition, where we assumed certain tax related risks related to the legacy Shire business, including the tax treatment of the break fee of 1.635 billion USD that Shire received in connection with the terminated offer to acquire Shire made by AbbVie, Inc. in 2014. The Revenue Commissioners in Ireland issued an assessment in November 2018 for 398 million EUR in respect of this fee, which is currently under appeal. See Note 32 to our audited consolidated financial statements included in this annual report. Shire also agreed to indemnify Baxter International Inc. and related parties 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 from tax counsel that the merger will not cause such prior transactions to fail to qualify as tax-free, such an opinion is not binding on the tax authorities and the potential tax indemnification obligations are not limited in amount.

Significant judgment is required in determining our tax liabilities, and our tax returns are periodically examined by various tax authorities. We regularly assess the likelihood of outcomes resulting from these examinations to determine the adequacy of its accrual for tax contingencies; however, due to the complexity of tax matters, the ultimate resolution of any tax matters may result in payments greater or less than the amounts accrued. In addition, we may be affected by changes in tax laws, including tax rate changes, new tax laws, and revised tax law interpretations in domestic and foreign jurisdictions and between jurisdictions, including by the EU, which could materially adversely affect our tax expense and/or tax balances, and changes in tax policies could materially adversely impact our business. The occurrence of any of these risks could have a material adverse effect on our business, financial position and results of operations.

Changes in data privacy and protection laws and regulations, particularly in Europe but increasingly in other jurisdictions as well, 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") imposes significant data protection obligations on companies regarding the handling of personal data and provides individuals with heightened privacy rights. Since GDPR became effective on May 25, 2018, other countries have enacted or are in the process of drafting GDPR style laws, such as California and other states in the U.S., Canada, India, Japan and Singapore. The EU is also moving towards higher restrictions and obligations regarding the transfer of personal data outside the EU on account of a major Court of Justice of the European Union ruling in July 2020 (Schrems II). Moreover, significant regulatory fines may be imposed on us for violation of these laws, particularly in the case of the GDPR, which are set at a maximum of the higher of 20 million EUR or 4% of annual global turnover for the most serious breaches. The increased use of digital technologies involving personal data, such as mobile health apps, wearables, digitalization of clinical trials or artificial intelligence tools deployed on personal data pose additional risks for our company both in terms of the larger volume of personal data we handle but also in terms of potential security threats of such technology and our ability to assess the deployment of each technology because

of the sheer volume and speed at which they are being developed. Compliance with existing, proposed and recently enacted laws (including implementation of the privacy and process enhancements called for under the 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, legal proceedings against us by governmental entities or others or damage to our reputation and credibility and could also have a negative impact on our results of operations.

We may incur claims relating to our use, manufacture, handling, storage or disposal of hazardous materials.

Our research and development and manufacturing processes require the transportation, storage and use of hazardous materials, including chemicals and radioactive and biological materials, and may result in the generation of 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, transportation 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 eliminate the risk of industrial accidents that may lead to discharges or releases of hazardous materials and any resultant injury, property damage or environmental contamination 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 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. Examples of new or evolving regulatory requirements include REACH, Classification, Labelling, and Packaging of substances and mixtures (“CLP”)/Globally Harmonized System of Classification and Labelling of Chemicals (“GHS”), producer responsibility frameworks, and regulations related to addressing climate change or other emerging environmental areas. Increased environment, health and safety laws, regulations and enforcement could result in substantial costs and liabilities to us and could subject our use, manufacture, handling, storage, transportation, and disposal of hazardous materials to additional constraints. Consequently, compliance with these laws could result in capital expenditures as well as other costs and liabilities, thereby adversely affecting our operations or financials.

Risks Relating to the Operating Environment

The COVID-19 pandemic may continue to negatively affect our business, operating results and financial condition.

The COVID-19 pandemic continues to affect our business activities, operations, financial condition and results of operations to varying degrees. We have taken a number of actions in response to the spread of COVID-19, including implementing remote work arrangements where possible, canceling non-essential business travel and decreasing in-person meetings between our sales representatives and prescribers.

In the early stages of the global pandemic, we placed a general pause on the initiation of new studies, as well as new patient enrollment for ongoing studies with a small number of exceptions. While most of those temporary pauses on clinical trials were lifted and resumed, we do anticipate a certain level of delays on some clinical studies due to the disruption. We have also seen limited impact on demand for our products to date as many of our medicines are for severe chronic or life-threatening diseases, without the requirement of a hospital elective procedure. However, an adverse effect due to the spread of COVID-19 was observed in certain therapeutic areas, especially in Neuroscience in the first several months of the outbreak, for reasons such as less frequent visits by patients to medical care providers, on the other hand, an expansion of certain products with a more convenient administration profile was observed in the early phase of the outbreak, although these trends recently normalized to pre-COVID-19 levels.

Further outbreaks and preventative or protective actions that governments, corporations or individuals may take in the future to contain the spread of COVID-19 may result in a period of further reduced operations, decreased product demand including due to reduced numbers of in-person meetings with prescribers, patient visits with physicians, vaccinations and elective surgeries, further delays in the start of clinical trials or other research and development efforts, business disruption for us and our suppliers, subcontractors, customers and other third parties with which we do business and potential delays or disruptions related to regulatory approvals. Further outbreaks and related actions may also prevent our suppliers, vendors or subcontractors from meeting their obligations to us, including the supply of plasma, which has no substitute, which could also impair our ability to meet our supply obligations or execute our business plans in a timely manner or at all, or require us to incur significant additional costs. Any costs associated with the COVID-19 outbreak may not be fully recoverable or adequately covered by insurance. Further outbreaks and related actions may also result in reduced customer demand or limit the ability of customers, including governments or government agencies, to perform their obligations to us, including in making timely payments to us. Any of these factors, depending on the severity and duration of the outbreak and its effects, could have a material adverse effect on our business, results of operations and financial condition.

Although the impacts of COVID-19 to our financial condition and results of operations were relatively limited and we currently do not anticipate material liquidity and funding issues, we are unable to accurately predict future impacts to our business, operations, financial condition, results of operations, cash flow and our share price, given the dynamically and rapidly changing uncertain environment under COVID-19. If countermeasures by governments, corporations and individuals against COVID-19, including vaccinations, are unsuccessful and the COVID-19 pandemic spreads or there is a resurgence of the existing virus or a mutation thereof and the disruption to various aspects of business operations is prolonged, our financial condition, results of operations and cash flow may be adversely affected.

Further, to the extent COVID-19 adversely affects our operations and global economic conditions more generally, many of the other risks described in this “Risk Factors” section may materialize or be amplified, which could adversely affect our business, operating results and financial condition.

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, 2021, 82.5% of our sales were in markets outside Japan. 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 business may be adversely affected by climate change, extreme weather events, earthquakes, civil or political unrest, terrorism or other catastrophic events.

We are exposed to both physical and transition risks (financial and regulatory driven risks) associated with climate change. In recent years, extreme weather events and changing weather patterns such as storms, flooding, droughts and temperature changes have become more common. As a result, we are potentially exposed to various natural disasters or extreme weather risks such as hurricanes, tornadoes, droughts or floods, typhoons, tidal waves, wildfires or other events that may result from the impact of climate change on the environment.

Climate change may also result in new or more stringent regulatory requirements globally. Climate related regulations may require companies to accelerate and/or increase investment in technology to reduce energy consumption, water consumption and greenhouse gas emissions beyond current plans. Climate related regulations could also lead to mandatory carbon pricing or climate risk disclosures. The net impact of these climate related transition risks could increase our operational expenses or that of our suppliers.

In addition, Japan, the U.S. and other regions in the world where we operate are subject to the risk of natural disasters such as earthquakes, tsunamis and/or volcanic eruptions. Other events outside our control, such as war, civil or political unrest, deliberate acts of sabotage, terrorism 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, terrorism, 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 insurance policies to cover all potential losses and therefore our insurance policies may not be adequate to cover all possible losses and expenses. For instance, we do not maintain earthquake insurance in Japan.

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 to communicate about pharmaceutical products and the diseases they are intended to treat, and may use other, newer technologies in a similar way in the future. 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.

Other Risks Affecting Our Business

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, 2021, there were two wholesale distributors, AmerisourceBergen Corporation and McKesson Corporation, that each individually accounted for over ten percent of Takeda's total revenue. If one of our significant wholesale distributors encounters financial or other difficulties, such a 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 may have to recognize additional charges on our statements of profit or loss due to impairment of goodwill, other intangible assets and equity method investments.

We carry significant amounts of goodwill and intangible assets on our consolidated statements of financial position as a result of past acquisitions, including the Shire Acquisition. As of March 31, 2021, we had goodwill of 4,033.9 billion JPY and intangible assets of 3,909.1 billion JPY. Goodwill and intangible assets recorded in relation to acquisitions are recognized on our consolidated statements of financial position on the acquisition date. Under IFRS, we are required to examine such assets for impairment annually or 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 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, 2021, the carrying amount of investments accounted for using the equity method was 112.5 billion JPY. 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.

We are subject to additional risk due to uncertainty relating to the calculation of London Interbank Offered Rate (“LIBOR”) and other reference rates and their potential discontinuance.

The loan from Japan Bank for International Cooperation (“JBIC Loan”) is subject to a floating interest rate calculated in reference to the LIBOR. LIBOR rates that are currently produced in seven tenors across various currencies will cease to be in use for most of the currencies and tenors by the end of 2021, except for certain USD LIBOR tenors, including the 6-month LIBOR used for the JBIC Loan, which will continue until June 30, 2023. A number of alternatives to LIBOR have been proposed and 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 adversely affect our remaining interest payments under the JBIC Loan.

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 depository 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 depository, through its custodian agents, is the record holder of the shares underlying the ADSs, only the depository can exercise those rights in connection with the deposited shares. Pursuant to the deposit agreement, the depository 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 depository 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 depository 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 a 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 depository.

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 U.S., and a large portion of our assets and the assets of these persons are located in Japan and elsewhere outside the U.S. It may not be possible, therefore, for U.S. investors to effect service of process within the U.S. 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 U.S. 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 U.S.

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 depository in Japanese yen and then converted by the depository 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 depository 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 depository 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 depository 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 U.S. 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 depository in connection with matters arising under the deposit agreement or the ADSs, including claims under federal securities laws, such a 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 depository. If a lawsuit is brought against us or the depository 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 depository 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

Takeda is a global, values-based, research and development (“R&D”) driven biopharmaceutical company, headquartered in Japan. We are committed to discovering, developing and delivering life-transforming treatments, guided by our commitment to patients, our people and the planet. Takeda focuses its R&D efforts on four therapeutic areas: oncology, rare genetics and hematology, neuroscience, and gastroenterology (“GI”). We also make targeted R&D investments in plasma-derived therapies (“PDT”) and vaccines. We are focusing on developing highly innovative medicines that contribute to making a difference in people’s lives by advancing the frontier of new treatment options and leveraging our enhanced collaborative R&D engine and capabilities to create a robust, modality-diverse pipeline. Our employees are committed to improving quality of life for patients and to working with our partners in health care in approximately 80 countries and regions.

We are also committed to our five corporate imperatives, which are to:

- responsibly translate science into highly innovative life-changing medicines and vaccines,
- accelerate access to improve lives worldwide,
- create an exceptional people experience,
- protect our planet, and
- unleash the power of data and digital.

Our 240-year history started in 1781, when Chobei Takeda began selling traditional Japanese and Chinese herbal 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 discover 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 U.S. and Europe.

In 2008, we acquired a leading U.S. biopharmaceutical company in Millennium Pharmaceuticals, Inc. We leveraged the complementary strengths of Millennium and Takeda, with Millennium’s innovative product, pipeline and expertise in oncology. Takeda also acquired Nycomed in 2011, with a strong presence in Europe and emerging markets. This allowed Takeda to expand to over 70 markets and enhance its global sales structure in order to deliver pharmaceutical products to more patients around the world. These two large acquisitions within a short time span allowed Takeda to accelerate its globalization.

Since 2014, our efforts have been focused on enhancements to our R&D capabilities, successful cross-border acquisition activities and post-acquisition integration. Specifically, Takeda implemented an R&D transformation process to diversify modalities in our research, actively engage with innovative ecosystems around the world in the form of partnerships, and focus on our core therapeutic areas of oncology, rare genetic and hematology, neuroscience, and GI. As examples of cross-border acquisitions, in February 2017, we acquired ARIAD Pharmaceuticals, Inc., a commercial-stage biotechnology company, to obtain late stage assets for the treatment of cancer, and in June 2018, we acquired TiGenix NV, an advanced biopharmaceutical company developing therapies for patients with gastrointestinal disorders.

In January 2019, we completed the acquisition of Shire and have essentially completed the integration. This was a major step in our development to create a global, values-based, R&D-driven biopharmaceutical company. Specifically, the Shire Acquisition strengthened our core therapeutic areas, bringing together Takeda and Shire’s complementary positions in GI and neuroscience to establish leading positions in rare diseases and PDT to complement Takeda’s previously existing strength in oncology and focused efforts in vaccines. It also contributed to a highly complementary, robust, modality-diverse pipeline and a strengthened R&D engine focused on innovation.

During the three fiscal years ended March 31, 2021, we also divested from several businesses and assets in non-core areas. See Item 5. Operating and Financial Review and Prospects—A. Operating Results-Divestitures for further details on divested businesses and assets.

Our principal capital expenditures during the three fiscal years ended March 31, 2021 consisted of additions to property, plant and equipment and additions to intangible assets. In the fiscal years ended March 31, 2019, 2020 and 2021, excluding acquisitions, we made capital expenditures (consisting of the additions to property, plant and equipment and intangible assets recorded on our consolidated statements of financial position) of 244.6 billion JPY, 246.3 billion JPY and 330.7 billion JPY, respectively, including the following highlights:

- In the fiscal year ended March 31, 2019, we entered into 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 the renewal option that we are reasonably certain to exercise is 88.8 billion JPY as of March 31, 2019.
- In the fiscal year ended March 31, 2020, we opened the dengue vaccine candidate manufacturing plant in Singen, Germany. We also invested in expanding our plasma collection center network, with the addition of 32 new centers in the U.S. and Europe. In

addition, we entered into an exclusive license agreement and research agreement of CAR NK with the University of Texas MD Anderson Cancer Center.

- In the fiscal year ended March 31, 2021, we invested in a 24,000 square-foot cell therapy manufacturing facility allowing for the production of clinical-grade material to enable clinical development through pivotal phase 2b trials. We continued to invest in our dengue vaccine candidate manufacturing plant in Singen, Germany, and our oncology and gastroenterology manufacturing site in Tianjin, China, as well as expanding our plasma collection center network, with the addition of 26 new centers in the U.S. and Europe to bring Takeda's total footprint to 181 centers. We also executed several in-licensing deals to strengthen the pipeline, including TAK-999 from Arrowhead Pharmaceuticals Inc., and soticlestat from Ovid Therapeutics Inc.

We currently have various capital expenditures projects in process, including the continued expansion of production capacity of our plasma manufacturing network.

The address of our global head office is 1-1, Nihonbashi-Honcho 2-Chome, Chuo-ku, Tokyo, 103-8668, Japan; telephone number: 81-3-3278-2111. Takeda's agent in the U.S. in connection with this annual report is Takeda Pharmaceuticals U.S.A. Inc., 99 Hayden Avenue, 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 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, R&D-driven biopharmaceutical company with an innovative portfolio, engaged primarily in the research, development, production and global commercialization of pharmaceutical products. Our intent is to translate science into highly innovative life transforming medicines. We have built an R&D engine focused on four therapy areas, leveraging internal research and external partners in order to have access to different modalities like biologicals or cell therapy. We have a geographically diversified global business base and our prescription drugs are marketed in major countries worldwide.

We have approximately 47,000 employees worldwide dedicated to our purpose of striving towards better health for people and a brighter future for the world through leading innovation in medicine. Our culture is based on our values of Takeda-ism which incorporate Integrity, Fairness, Honesty, and Perseverance, with Integrity at the core. They are brought to life through actions based on Patient-Trust-Reputation-Business, in that order.

Our commercial efforts are focused on five key business areas of GI, rare diseases, PDT, oncology, and neuroscience, which in the fiscal year ended March 31, 2021 accounted for 82.0% of our total revenue. We believe these five business areas will drive our future revenue growth, and we will continue to make the necessary investments to maximize our portfolios in these areas. Our key growth driver products in our key business areas include the following 14 global brands: *ENTYVIO*, *GATTEX/REVESTIVE*, *ALOFISEL*, *TAKHZYRO*, *ADYNOVATE/ADYNOVI*, *ELAPRASE*, *VPRIV*, *NATPARA/NATPAR*, *GAMMAGARD LIQUID/KIOVIG*, *HYQVIA*, *CUVITRU*, *ALBUMIN/FLEXBUMIN*, *NINLARO*, and *ALUNBRIG*. We have also been making targeted acquisitions and divestitures to further increase our level of focus on these key business areas, and plan to continue to refine our portfolio going forward.

Our R&D engine is focused on translating science into highly innovative, life-changing medicines that make a critical difference to patients. We support dedicated R&D efforts across three areas: Innovative Biopharma, Plasma-Derived Therapies (PDT) and Vaccines. The R&D engine for Innovative Biopharma is the largest component of our R&D investment and has produced exciting new molecular entities (NMEs) that represent potential best-in-class and/or first-in-class medicines in areas of high unmet medical need across our core Therapeutic Areas (oncology, rare genetics and hematology, neuroscience, and gastroenterology (GI)). Over the past several years, and more recently bolstered by our acquisition of Shire, we have also harnessed the potential of cell and gene therapies by investing in new capabilities and next-generation platforms internally and through a network of partnerships.

We are also focused on optimizing our financial strength, driving margin expansion and generating cash flows to invest in the business, to deleverage and to return cash to shareholders.

The following is a summary of our principal products by key business area.

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 the U.S. and Europe in 2014 to become our top selling product in the fiscal year ended March 31, 2021. *ENTYVIO* is now approved in 72 countries worldwide. We strive to maximize its potential by seeking approval in additional countries, examining use in further indications, while also pursuing a subcutaneously administered formulation. In the fiscal year ended March 31, 2021, our revenue from *ENTYVIO* was 429.3 billion JPY.

- *TAKECAB* (vonoprazan fumarate), a treatment for acid-related diseases. *TAKECAB* was launched in Japan in 2015 and has achieved significant growth driven by its efficacy in reflux esophagitis and the prevention of recurrence of gastric and duodenal ulcers during low-dose aspirin administration. In the fiscal year ended March 31, 2021, our revenue from *TAKECAB* was 84.8 billion JPY.
- *GATTEX/REVESTIVE* (teduglutide[rDNA origin]), a treatment for patients with short bowel syndrome (“SBS”) who are dependent on parenteral support. In 2019, the FDA approved extending the indication of *GATTEX* to include children 1 year of age and older with SBS. In the fiscal year ended March 31, 2021, our revenue from *GATTEX/REVESTIVE* was 64.6 billion JPY.
- *ALOFISEL* (darvadstrocel), 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 Europe in 2018, becoming the first allogeneic stem cell therapy to receive central marketing authorization approval in Europe. In the fiscal year ended March 31, 2021, our revenue from *ALOFISEL* was 0.8 billion JPY.

In rare diseases, our principal products are:

- *TAKHZYRO* (lanadelumab-flyo), for the prevention of hereditary angioedema (“HAE”) attacks. *TAKHZYRO* is a fully human monoclonal antibody that specifically binds and decreases plasma kallikrein, an enzyme which is chronically uncontrolled in people with HAE. *TAKHZYRO* was approved in both the U.S. and Europe in 2018, and in China in 2020, and we are working to expand into further geographic areas. In the fiscal year ended March 31, 2021, our revenue from *TAKHZYRO* was 86.7 billion JPY.
- *ADYNOVATE/ADYNOVI* (antihemophilic factor (recombinant) [PEGylated]), an extended half-life recombinant factor VIII treatment for hemophilia A. *ADYNOVATE/ADYNOVI* uses the same manufacturing process as the standard half-life recombinant factor VIII therapy *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. In the fiscal year ended March 31, 2021, our revenue from *ADYNOVATE/ADYNOVI* was 58.1 billion JPY.
- *NATPARA/NATPAR* (parathyroid hormone), a treatment for adult patients with chronic hypoparathyroidism (“HPT”) who cannot be adequately controlled with standard therapy of calcium and vitamin D alone. HPT is a rare condition in which the parathyroid glands fail to produce sufficient amounts of parathyroid hormone (“PTH”) or where the PTH lacks biological activity. In September 2019, Takeda issued a recall in the U.S. for all doses of *NATPARA* after discussions with the FDA due to a potential issue related to rubber particulates originating from the rubber septum of the *NATPARA* cartridge. Takeda is working closely with the FDA to resolve the issue and resume supply as soon as possible, although we do not expect to record revenue from *NATPARA* in the U.S. in the fiscal year ending March 31, 2022. *NATPARA/NATPAR* continues to be available in markets outside of the U.S. In the fiscal year ended March 31, 2021, our revenue from *NATPARA/NATPAR* was 3.6 billion JPY.
- *ELAPRASE* (idursulfase), an enzyme replacement therapy for the treatment of Hunter syndrome (also known as Mucopolysaccharidosis Type II or MPS II). In the fiscal year ended March 31, 2021, our revenue from *ELAPRASE* was 68.8 billion JPY.
- *REPLAGAL* (agalsidase alfa), an enzyme replacement therapy for the treatment of Fabry disease, marketed outside of the U.S., and also approved in China in 2020. 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. In the fiscal year ended March 31, 2021, our revenue from *REPLAGAL* was 51.8 billion JPY.
- *VPRIV* (velaglucerase alfa), an enzyme replacement therapy for the treatment for type 1 Gaucher disease. In the fiscal year ended March 31, 2021, our revenue from *VPRIV* was 38.5 billion JPY.

In PDT immunology, our principal products are:

- *GAMMAGARD LIQUID/KIOVIG* (Immune Globulin Intravenous (Human) 10%), a liquid formulation of the antibody replacement therapy immunoglobulin (“IG”), for the treatment of adult and pediatric patients two years of age or older with primary immunodeficiencies (“PID”) (administered either intravenously or subcutaneously), and 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 patients with PID and certain secondary immunodeficiencies, and for adults with MMN.
- *GAMMAGARD S/D* (Immune Globulin Intravenous (Human)) (IgA less than 1 µg/mL in a 5% solution), for the treatment of PID in patients two years of age and older. *GAMMAGARD S/D* is also indicated for the prevention of bacterial infections in hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell chronic lymphocytic leukemia (“CLL”), the treatment of adult patients with chronic idiopathic thrombocytopenic purpura (“ITP”) to increase platelet count and to prevent and/or control bleeding, and the prevention of coronary artery aneurysms associated with Kawasaki Syndrome in pediatric patients. *GAMMAGARD S/D* is an option for patients who require a low IgA content in their intravenous treatment (IgA less than 1 µg/mL in a 5% solution).
- *HYQVIA* (Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase), 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 that requires only one infusion up to once per month and one injection site per infusion to deliver a full therapeutic dose of IG. *HYQVIA* is approved in the U.S. for adults with PID, and in Europe for patients with PID syndromes and myeloma or CLL with severe secondary hypogammaglobulinemia and recurrent infections.

- *CUVITRU* (Immune Globulin Subcutaneous (Human), 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 Europe 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.

In the fiscal year ended March 31, 2021, the total revenue from our PDT immunology portfolio, including *GAMMAGARD LIQUID/KIOVIG*, *GAMMAGARD S/D*, *HYQVIA*, and *CUVITRU*, was 334.9 billion JPY.

- *FLEXBUMIN* (Human Albumin in a bag) and Human Albumin (glass), available as 5% and 25% solutions, 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”). In the fiscal year ended March 31, 2021, the total revenue from our albumin portfolio, including *FLEXBUMIN* and Human Albumin (glass) was 57.6 billion JPY.

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 U.S. in 2015 for relapsed/refractory MM and has also been approved in Europe in 2016, in Japan in 2017, and in China in 2018. We are currently examining *NINLARO* in MM maintenance settings, with the potential to expand the eligible patient population. In the fiscal year ended March 31, 2021, revenue from *NINLARO* was 87.4 billion JPY.
- *ADCETRIS* (brentuximab vedotin), an anti-cancer agent used to treat Hodgkin lymphoma (“HL”) and systemic anaplastic large cell lymphoma (“sALCL”). *ADCETRIS* has received marketing authorization by regulatory authorities in more than 70 countries worldwide and was approved in China in May 2020. We jointly develop *ADCETRIS* with Seagen Inc. and have commercialization rights in countries outside the U.S. and Canada. In the fiscal year ended March 31, 2021, our revenue from *ADCETRIS* was 59.4 billion JPY.
- *ALUNBRIG* (brigatinib), an orally administered small molecule anaplastic lymphoma kinase (“ALK”) inhibitor used to treat ALK-positive non-small cell lung cancer (“NSCLC”). *ALUNBRIG* was granted accelerated approval in the U.S. in 2017, and the European Commission granted the product marketing authorization in 2018. The indication of *ALUNBRIG* was expanded to include newly diagnosed ALK-positive NSCLC patients in May 2020. In the fiscal year ended March 31, 2021, our revenue from *ALUNBRIG* was 8.8 billion JPY.

In neuroscience, our principal products are:

- *VYVANSE* (lisdexamfetamine dimesylate), a stimulant medication indicated for the treatment of attention deficit hyperactivity disorder (“ADHD”) in patients aged six and above, and for the treatment of moderate to severe binge eating disorder in adults. In the fiscal year ended March 31, 2021, our revenue from *VYVANSE* was 271.5 billion JPY.
- *TRINTELLIX* (vortioxetine), an antidepressant indicated for the treatment of major depressive disorder in adults. *TRINTELLIX* was co-developed with H. Lundbeck A/S, and Takeda has commercialization rights in the U.S., where it was launched in 2014 and in Japan, where it was launched in 2019. In the fiscal year ended March 31, 2021, our revenue from *TRINTELLIX* was 68.9 billion JPY.

For a breakdown of revenues by geographic region, see Note 4 to our audited consolidated financial statements.

Impact of the Spread of the Novel Coronavirus Infectious Disease (COVID-19) and Takeda’s Initiatives in Response

(i) Impact of COVID-19 on Takeda’s Operations and Financial Condition

It has been more than a year since the COVID-19 pandemic began, and Takeda continues to respond and provide industry support in a number of ways. While vaccines are becoming more broadly available, we continue to strictly adhere to local public health guidance across our geographies in addition to the existing protocols we have had in place over the past year, and monitor any potential impacts of effects of COVID-19 on our business activities.

In monitoring demand for our products, we have seen limited impact to date as many of our medicines are for severe chronic or life-threatening diseases, without the requirement of a hospital elective procedure. In terms of our global supply chain, based on current assessments, we have not yet seen, nor do we anticipate, any material potential supply distribution issues due to the COVID-19 outbreak.

During the year, we have continued voluntary suspensions of certain business activities, including business travel, attending industry events, and holding company-sponsored events.

In the early stages of the global pandemic, we placed a temporary pause on the initiation of new clinical trial studies, with the exception of CoVIG-19, the investigational plasma-derived therapy for COVID-19. At the same time, for studies already ongoing, we

temporarily paused the activation of new study sites and new patient enrollment with a small number of exceptions. This was a short-term action and we have now resumed most of our trial activities.

While we do anticipate some delays on some studies, we anticipate that we will regain this time as studies restart. We are closely monitoring the situation on a per-study level, down to each country and site in the event that we need to temporarily pause studies again due to the impact of COVID-19.

As we continue to monitor developments in the financial markets, we currently do not anticipate any material liquidity or funding-related issues.

(ii) Takeda's Initiatives to Mitigate the Impact of COVID-19

Guided by our values, Takeda's response to COVID-19 continues to focus on protecting the health and safety of our employees, our ability to ensure our medicines are available to patients who rely on them and playing our part to reduce transmission and support the communities where our employees live and work.

In order to address the issues relating to COVID-19, in January 2020 we activated a Global Crisis Management Committee (GCMC), who along with the support of internal and external experts has guided Takeda's response to the pandemic. This includes the development of employee guidance, support resources, and implementing enhanced infection control and workplace case management protocols across our essential operations. The GCMC have also developed comprehensive workplace readiness checklists to support a safe and gradual return to office workplaces where this is possible.

With regards to measures to safeguard employees, we continue to enforce work from home policies and provide enhanced technology to support such initiatives. We have applied our telework guidance broadly to our global employees including as many of our customer-facing employees as possible, especially those who interact with health care professionals. For our employees who are required to continue to work on-site in our manufacturing, laboratory, and BioLife plasma donation facilities, we have implemented enhanced safety measures to mitigate the spread of the virus.

Our GCMC and a dedicated Return to the Workplace Team developed guidance on how to configure our "new workplace" to limit the introduction and transmission of the COVID-19 virus while maintaining and even strengthening our operations. Plans have been tailored to each country and are based on the science, epidemiology, and relevant local public health context, but also follow common principles and requirements such as compliance with local government and public health regulations; workplace readiness including necessary infection prevention measures like face coverings and physical distancing; reduced population density; enhanced infection control protocols; employee-specific circumstances; and a careful, stepwise approach.

In terms of our post-COVID workplace strategy, we do not intend to have one single strategy or policy. Instead, we have created core principles, designed guidance and toolkits to help Takeda leaders determine and implement the best working environment strategy for their teams.

We have continued to suspend all non-essential international travel and large external meetings until further notice, while monitoring the situation on an ongoing basis.

Our field forces are resuming a small number of face-to-face engagements with customers, with the majority of all interactions still virtual. Where we are engaging face-to-face, it is only with the agreement of healthcare providers and employees following strict infection prevention protocols set out by both Takeda and any additional public health and customer requirements.

Takeda has aided the COVID-19 response through donations, including approximately 25 million USD to non-profit organizations including the Red Cross and United Nations-led organizations (World Food Programme (WFP), United Nations Population Fund (UNFPA), and International Atomic Energy Agency (IAEA)), while also providing in-kind donations and matching employee donations.

In order to maintain business continuity, we are managing levels of inventory, including assessing alternative suppliers for the production of our medicines, to secure product supply continuity for patients. This strategy is generally applied across our global supply chain for key starting materials, excipients, raw materials, APIs, and finished products. We are tracking the situation as it evolves and will take all necessary actions in an effort to ensure supply continuity for the people we serve.

In R&D, where possible, Takeda has implemented solutions such as direct-to-patient delivery of study medicines and the re-evaluation of trial design to account for potential disruptions. We continue to assess and build out digital technologies to enable remote monitoring of patients enrolled in clinical trials.

The CoVig-19 Plasma Alliance is one example of Takeda's initiatives to develop potential therapies to combat COVID-19. In April 2020, Takeda and CSL Behring co-founded the Alliance with other leading global and regional manufacturers of plasma-derived therapies. Together, the Alliance members collaborated to develop and manufacture an investigational non-branded plasma-derived hyperimmune globulin (H-Ig) medicine, referred to as CoVig-19 for adults hospitalized with COVID-19 at risk for serious complications. The H-Ig was evaluated in a

multi-national Phase 3 clinical trial funded by the National Institute of Allergy and Infectious Disease (NIAID) of the U.S. National Institutes of Health (NIH) that was completed in March 2021. While the clinical trial did not meet its endpoints, the program may contribute to a growing understanding of this challenging virus and strategies for patient care. Following the outcome of the trial, the CoVig-19 Plasma Alliance's work has now concluded.

In addition to the CoVig-19 Plasma Alliance, Takeda has undertaken a number of efforts to help the world respond to COVID-19, including the evaluation of a number of our marketed products and pipeline compounds for efficacy against the COVID-19 virus and participation in global research collaborations.

Takeda has also announced two partnerships to bring COVID-19 vaccines to Japan. The first partnership is with Novavax, for the development, manufacturing and commercialization of its COVID-19 vaccine candidate NVX-CoV2373 (development code in Japan: TAK-019) in Japan. The second partnership is with Moderna and the Government of Japan's Ministry of Health Labour & Welfare (MHLW) to import and distribute its COVID-19 vaccine candidate mRNA-1273 (development code in Japan: TAK-919) in Japan. In May 2021, Takeda obtained approval from the MHLW for TAK-919 following positive interim results in Takeda's Phase 1/2 immunogenicity and safety clinical trial, and has since commenced distribution in Japan. Additionally, Takeda has also announced a mutual agreement with IDT Biologika GmbH (IDT) to utilize capacity at IDT previously reserved for Takeda's dengue vaccine candidate to manufacture the single-shot COVID-19 vaccine developed by Janssen Pharmaceutical Companies of Johnson & Johnson.

Research and Development

The research and development (R&D) of pharmaceutical products is a lengthy and expensive process that can span more than 10 years. The process includes multiple studies to evaluate a product's efficacy and safety, followed by submission to regulatory authorities who review the data and decide whether to grant marketing approval. Only a small number of compounds pass such rigorous investigation and become available for use in clinical treatment. Once approved, there is ongoing R&D support for marketed products, including medical affairs and other investments.

Clinical trials, which must comply with regional and international regulatory guidelines, generally take five to seven years or longer, and require substantial expenditures. In general, clinical trials are performed in accordance with the guidelines set by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. The relevant regional regulatory authorities are the Ministry of Health, Labour and Welfare (MHLW) for Japan, the Food and Drug Administration (FDA) for the United States, the European Medicines Agency (EMA) for the EU and National Medical Products Administration (NMPA) for China.

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

Phase 1 ("P-1") 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 2 ("P-2") clinical trials

Conducted using a small group of patient volunteers in order to evaluate safety, efficacy, dosage and administration methods. P-2 clinical trials may be divided into two sub-categories, P-2a and P-2b. P-2a are usually pilot studies designed to demonstrate clinical efficacy or biological activity. P-2b studies look to find the optimum dose at which the drug shows biological activity with minimal side-effects.

Phase 3 ("P-3") 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 3 requires the largest expenditures and thus the decision to proceed with Phase 3 testing is a critical business decision in the drug development process. For those drug candidates that pass Phase 3 clinical trials, a New Drug Application ("NDA"), Biologics License Application ("BLA") or a Marketing Authorization Application ("MAA") is submitted to the relevant governmental authorities for approval, which if granted permits the subsequent launch of the drug. The preparation of an NDA, BLA or MAA submission 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.

Takeda's R&D engine is focused on translating science into highly innovative, life-changing medicines that make a critical difference to patients. Takeda supports dedicated R&D efforts across three areas: Innovative Biopharma, Plasma-Derived Therapies (PDT) and Vaccines. The R&D engine for Innovative Biopharma is the largest component of our R&D investment and has produced exciting new molecular entities (NMEs) that represent potential best-in-class and/or first-in-class medicines in areas of high unmet medical need across our core Therapeutic Areas (oncology, rare genetics and hematology, neuroscience, and gastroenterology (GI)). Over the past several years, and more recently bolstered by our acquisition of Shire, we have also harnessed the potential of cell and gene therapies by investing in new capabilities and next-generation platforms internally and through a network of partnerships.

In addition to our concentrated efforts to increase our in-house R&D capabilities, external partnerships with third-party partners are a key component of our strategy for enhancing our R&D pipeline. 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 R&D collaborations.

Our key in-house R&D 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 to enhance scientific innovation and establish a life science ecosystem with diverse external parties. To attract more diverse partners and to further the success of the Shonan iPark, in April 2020 Takeda transferred ownership rights of Shonan iPark to a trustee and Takeda, as a flagship tenant, has signed a 20-year lease agreement with the trustee and is committed to invigorating life science research in Japan.
- *Greater Boston Area Research and Development Site*: Our Boston R&D site is located in Cambridge, Massachusetts in the United States. It is the center of our global oncology, gastroenterology (GI), and rare genetics and hematology R&D, and also supports R&D in other areas including plasma-derived therapies and vaccines, as well as research in immunomodulation and biologics. The site is home to the Takeda Cell Therapy engine with a recently opened state-of-the-art cell therapy manufacturing facility.
- *San Diego Research and Development Site*: Our R&D site located in San Diego, California in the United States supports R&D in the GI and neuroscience areas. The San Diego research center operates as a "biotech-like" site and leverages internal capabilities such as structural biology and biophysics to catalyze research internally and externally.
- *Vienna, Austria Research and Development Site*: Our R&D sites, located in Vienna and nearby Orth, Austria, support R&D in PDT and Gene Therapy. The research centers contain manufacturing sites for plasma derived products and gene therapy products which have the opportunity to develop innovative drugs for patients around the world.

The following summarizes our R&D 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, Takeda endeavors to deliver novel medicines to patients with cancer worldwide through a commitment to breakthrough innovation and a passion for improving the lives of patients. Takeda focuses on three key areas in oncology: (1) building on its 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, Myelodysplastic Syndromes, and other blood cancers; (2) further developing its portfolio in lung cancer with the marketed product ALUNBRIG and development programs in targeted lung cancer populations; 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 11, 2021 (the date of our annual earnings release), along with notes for major subsequent developments thereafter, is as follows:

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Stage	
SGN-35 ⁽¹⁾ <brentuximab vedotin> ADCETRIS (EU, Japan, China)	CD30 monoclonal antibody-drug conjugate (injection)	Biologic and other	Previously untreated systemic Anaplastic Large Cell Lymphoma	EU	Approved (May 2020)
			Relapsed / refractory Hodgkin Lymphoma	China	Approved (May 2020)
			Relapsed / refractory systemic Anaplastic Large Cell Lymphoma	China	Approved (May 2020)
			Cutaneous T cell lymphoma	China	Approved (Apr 2021)
<brigatinib> ALUNBRIG (Global)	ALK inhibitor (oral)	Small molecule	1L ALK-positive Non-Small Cell Lung Cancer	U.S.	Approved (May 2020)
			1L ALK-positive Non-Small Cell Lung Cancer	Japan	Approved (Jan 2021)
			2L ALK-positive Non-Small Cell Lung Cancer in patients previously treated with ALK inhibitors	Japan	Approved (Jan 2021)
			1L & 2L ALK-positive Non-Small Cell Lung Cancer	China	Filed (Dec 2020)
			2L ALK-positive Non-Small Cell Lung Cancer (head-to-head with alectinib)	Global	P-III

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Stage	
MLN9708 <ixazomib> NINLARO (Global)	Proteasome inhibitor (oral)	Small molecule	Maintenance therapy in patients with newly diagnosed Multiple Myeloma not treated with stem cell transplant	Japan U.S. EU China	Filed (May 2020) ⁽¹²⁾ P-III P-III P-III
			Maintenance therapy in patients with newly diagnosed Multiple Myeloma following autologous stem cell transplant	U.S. EU	P-III P-III
<cabozantinib> ⁽²⁾ CABOMETYX (Japan)	Multi-targeted kinase inhibitor (oral)	Small molecule	2L Hepatocellular carcinoma	Japan	Approved (Nov 2020)
			1L Renal cell carcinoma in combination with nivolumab	Japan	Filed (October 2020)
			2L metastatic Non-Small Cell Lung Cancer in combination with atezolizumab ⁽³⁾	Japan	P-III
			Metastatic Castration-Resistant Prostate Cancer in combination with atezolizumab ⁽⁴⁾	Japan	P-III
<niraparib> ⁽⁵⁾ ZEJULA (Japan)	PARP1/2 inhibitor (oral)	Small molecule	Ovarian cancer maintenance following 1L or 2L, salvage	Japan	Approved (Sep 2020)
<ponatinib> ICLUSIG (U.S.)	BCR-ABL inhibitor (oral)	Small molecule	Label update for the treatment of patients with Chronic Myeloid Leukemia and Philadelphia chromosome-positive Acute Lymphoblastic Leukemia based on the interim analysis of the OPTIC trial in CML patients and adjudicated data from PACE trial in CML and Ph+ ALL patients	U.S.	Approved (Dec 2020)
			Front line Philadelphia chromosome-positive Acute Lymphoblastic Leukemia	U.S.	P-III
TAK-924 <pevonedistat>	NEDD 8 activating enzyme inhibitor (injection)	Small molecule	High-risk Myelodysplastic Syndrome	Global	P-III
			Unfit Acute Myelogenous Leukemia	Global	P-III
TAK-788 <mobocertinib>	EGFR/HER2 exon 20 inhibitor (oral)	Small molecule	Treatment Naïve Non-Small Cell Lung Cancer with Exon-20 insertion	Global	P-III
			Previously treated Non-Small Cell Lung Cancer with Exon-20 insertion	U.S. Japan EU China	Filed (Apr 2021) P-III P-III P-III
TAK-385 <relugolix>	LH-RH antagonist (oral)	Small molecule	Prostate cancer	Japan China	P-III P-III
TAK-007 ⁽⁶⁾	CD19 CAR-NK (injection)	Cell and gene therapy	Relapsed/refractory B-cell malignancies	-	P-I/II
TAK-102 ⁽⁷⁾	GPC3 CAR-T (injection)	Cell and gene therapy	Solid tumors	-	P-I
TAK-573 ⁽⁸⁾	CD38-targeted IgG4 genetically fused with an attenuated IFN α (injection)	Biologic and other	Relapsed/refractory Multiple Myeloma	-	P-I
TAK-605 ⁽⁹⁾	Oncolytic virus (intra-tumoral administration)	Biologic and other	Solid tumors	-	P-I
TAK-676	STING agonist (injection)	Small molecule	Solid tumors	-	P-I
TAK-940 ⁽¹⁰⁾	CD19 1XX CAR-T (injection)	Cell and gene therapy	Relapsed/refractory B-cell malignancies	-	P-I
TAK-981	SUMO inhibitor (injection)	Small molecule	Multiple cancers	-	P-I

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Stage	
TAK-252 / SL-279252 ⁽¹¹⁾	PD-1-Fc-OX40L (injection)	Biologic and other	Solid tumors or lymphomas	-	P-I
TAK-186	T-Cell Engager	Biologic and other	EGFR expressing solid tumors	-	P-I

Notes:

- (1) Partnership with Seagen, Inc.
- (2) Partnership with Exelixis, Inc.
- (3) Partnership with Chugai Pharmaceutical. Chugai operates Phase 3 development
- (4) Partnership with Chugai Pharmaceutical. Takeda operates Phase 3 development
- (5) Partnership with GlaxoSmithKline
- (6) Partnership with The University of Texas MD Anderson Cancer Center
- (7) Partnership with Noile-Immune Biotech, Inc.
- (8) Partnership with Teva Pharmaceutical Industries Ltd.
- (9) Partnership with Turnstone Biologics
- (10) Partnership with Memorial Sloan Kettering Cancer Center
- (11) Partnership with Shattuck Labs, Inc.
- (12) Subsequently approved in May 2021.

Rare Genetic & Hematology

In rare genetics & hematology, Takeda focuses on hereditary angioedema to transform the treatment paradigm including through recently launched TAKHZYRO; going forward the focus will be on rare hematology and rare metabolic diseases, with the aim to deliver functional cures in a select group of diseases using novel modalities and platforms.

Our rare genetic and hematology pipeline as of May 11, 2021 (the date of our annual earnings release), along with notes for major subsequent developments thereafter, is as follows:

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Stage	
TAK-743 <lanadelumab> TAKHZYRO (U.S., EU, China)	Plasma kallikrein inhibitor (injection)	Biologic and other	Hereditary Angioedema	China	Approved (Dec 2020)
			Hereditary Angioedema	Japan	Filed (Mar 2021)
			Pediatric Hereditary Angioedema	Global	P-III
			Bradykinin-Mediated Angioedema	Global	P-III
TAK-577 VONVENDI (U.S., Japan), VEYVONDI (EU)	von Willebrand factor [recombinant] (injection)	Biologic and other	Adult prophylactic treatment of von Willebrand disease	U.S. Japan EU China	Submission on track P-III P-III P-III
			Pediatric on-demand and surgery treatment of von Willebrand disease	Global	P-III
TAK-660 ADYNOVATE (U.S., Japan), ADYNOVI (EU)	Antihemophilic factor [recombinant], PEGylated (injection)	Biologic and other	Pediatric Hemophilia A	EU	P-III
TAK-755 ⁽¹⁾	Replacement of the deficient- ADAMTS13 enzyme (injection)	Biologic and other	Congenital Thrombotic Thrombocytopenic Purpura	U.S. EU	P-III P-III
			Immune Thrombotic Thrombocytopenic Purpura	U.S. EU	P-II P-II
			Sickle cell disease	U.S.	P-I/II
TAK-620 ⁽²⁾ <maribavir>	Benzimidazole riboside inhibitor (oral)	Small molecule	Cytomegalovirus infection in transplant patients	U.S. EU	Submission on track ⁽⁵⁾ P-III
TAK-607	Insulin-like Growth Factor / IGF Binding Protein (injection)	Biologic and other	Complications of prematurity	-	P-II

TAK-609	Recombinant human iduronate-2-sulfatase for intrathecal administration (injection)	Biologic and other	Hunter syndrome CNS	U.S. EU	P-II P-II
TAK-611	Recombinant human arylsulfatase A for intrathecal administration (injection)	Biologic and other	Metachromatic leukodystrophy	-	P-II
TAK-079 ⁽³⁾ <mezagitamab>	Anti-CD38 monoclonal antibody (injection)	Biologic and other	Myasthenia gravis	-	P-II
			Immune thrombocytopenic purpura	-	P-II
			Systemic lupus erythematosus	-	P-I/II
TAK-834 <i>NATPARA</i> (U.S.), <i>NATPAR</i> (EU)	Parathyroid hormone (injection)	Biologic and other	Hypoparathyroidism	Japan	P-I ⁽⁴⁾

Notes:

- (1) Partnership with KM Biologics for coexclusive license for commercialization in Japan only
- (2) Partnership with GlaxoSmithKline
- (3) Relapsed/refractory Multiple Myeloma will continue until trial completion.
- (4) P-I study in Japan completed; P-III study start timing under review.
- (5) Subsequently the FDA accepted the filing in May 2021.

Neuroscience

In neuroscience, Takeda is focusing its R&D investments on potentially transformative treatments for neurological and neuromuscular diseases of high unmet need, and building its pipeline through a combination of in-house expertise and partnerships. By harnessing advances in disease biology understanding, translational tools, and innovative modalities, Takeda is primarily focusing on rare neurology (e.g., narcolepsy, Amyotrophic Lateral Sclerosis, Huntington’s disease and other ataxias), as well as making targeted investments to potentially address well-defined segments of neurodegenerative diseases (e.g., Parkinson’s Disease).

Our neuroscience pipeline as of May 11, 2021 (the date of our annual earnings release), along with notes for major subsequent developments thereafter, is as follows:

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Stage	
TAK-815 <midazolam> <i>BUCCOLUAM</i> (JP)	GABA Allosteric Modulator (oromucosal)	Small molecule	Status epilepticus (seizures)	Japan	Approved (Sep 2020)
TAK-935 <soticlestat>	CH24H inhibitor (oral)	Small molecule	Dravet Syndrome, Lennox-Gastaut syndrome	-	P-II
			15q duplication syndrome, CDKL5 deficiency disorder	-	P-II
TAK-994	Orexin 2R agonist (oral)	Small molecule	Narcolepsy	-	P-II
TAK-831 ⁽¹⁾ <luvadaxistat>	D-amino acid oxidase (DAAO) inhibitor (oral)	Small molecule	Negative symptoms and/or cognitive impairment associated with schizophrenia	-	P-II(a)
TAK-071	M1 positive allosteric modulator (M1PAM) (oral)	Small molecule	Parkinson’s disease	-	P-II
TAK-041 ⁽²⁾	GPR139 agonist (oral)	Small molecule	Anhedonia in major depressive disorder (MDD)	-	P-I
TAK-341/ MED11341 ⁽³⁾	Alpha-synuclein antibody (injection)	Biologic and other	Parkinson’s disease	-	P-I
TAK-653 ⁽²⁾	AMPA receptor potentiator (oral)	Small molecule	Treatment resistant depression	-	P-I

TAK-861	Orexin 2R agonist (oral)	Small molecule	Narcolepsy	-	P-I
TAK-925	Orexin 2R agonist (injection)	Small molecule	Narcolepsy, other sleep disorders	-	P-I

Notes:

- (1) 50:50 co-development and co-commercialization option with Neurocrine Biosciences
- (2) 50:50 co-development and co-commercialization with Neurocrine Biosciences
- (3) Partnership with AstraZeneca. AstraZeneca operates Phase 1 development

Gastroenterology (GI)

In GI, Takeda focuses on delivering innovative, life-changing therapeutics for patients with GI and liver diseases. Takeda is maximizing the potential of our inflammatory bowel disease (IBD) franchise around ENTYVIO and ALOFISEL, expanding our position in specialty GI with GATTEX / REVESTIVE and progressing a pipeline built through partnerships exploring opportunities in motility disorders, celiac disease, and select liver diseases.

Our GI pipeline as of May 11, 2021 (the date of our annual earnings release), along with notes for major subsequent developments thereafter, is as follows:

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Stage	
MLN0002 <vedolizumab> ENTYVIO (Global)	Humanized monoclonal antibody against $\alpha 4\beta 7$ integrin (injection)	Biologic and other	Subcutaneous formulation for ulcerative colitis	U.S. Japan	CRL received (Dec 2019) ⁽¹⁰⁾ Filed (Aug 2019)
			Subcutaneous formulation for Crohn's disease	U.S. Japan	P-III P-III
			Graft-versus-Host Disease prophylaxis in patients undergoing allogeneic hematopoietic stem cell transplantation	EU Japan	P-III P-III
			Pediatrics Study (ulcerative colitis, Crohn's disease)	Global	P-II
TAK-438 <vonoprazan> TAKECAB (Japan) VOCINTI (China)	Potassium-competitive acid blocker (oral)	Small molecule	Acid related diseases (Reflex Esophagitis Maintenance)	China	Filed (Mar 2020)
			Acid related diseases (Duodenal Ulcer)	China	Filed (Apr 2020)
			Oral disintegrated tablet formulation	Japan	Filed (Mar 2021)
			Acid related diseases (adjunct to Helicobacter pylori eradication)	China	P-III
TAK-633 <teduglutide> GATTEX (U.S.) REVESTIVE (EU)	GLP-2 analogue (injection)	Peptide/ Oligo-nucleotide	Short bowel syndrome (pediatric indication)	Japan	Filed (Oct 2020)
			Short bowel syndrome (in adults)	Japan	Filed (Oct 2020)
TAK-721 ⁽¹⁾ <budesonide>	Glucocorticosteroid (oral)	Small molecule	Eosinophilic esophagitis	U.S.	Filed (Dec 2020)
Cx601 <darvadstrocel> ALOFISEL (EU)	A suspension of allogeneic expanded adipose-derived stem cells (injection)	Biologic and other	Refractory complex perianal fistulas in patients with Crohn's disease	U.S. Japan	P-III Filed (Feb 2021)
TAK-906	Dopamine D2/D3 receptor antagonist (oral)	Small molecule	Gastroparesis	-	P-II (b)
TAK-954 ⁽²⁾	5-HT ₄ - hydroxytryptamine receptor agonist (injection)	Small molecule	Post-operative gastrointestinal dysfunction	-	P-II (b)

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Stage	
				U.S. EU	
TAK-999 ⁽³⁾	GalNAc based RNA interference (RNAi) (injection)	Peptide/ Oligo-nucleotide	Alpha-1 antitrypsin-associated liver disease	U.S. EU	P-II (b) P-II (b)
TAK-101 ⁽⁴⁾	Tolerizing Immune Modifying nanoParticle (TIMP) (injection)	Biologic and other	Celiac disease	-	P-II (a)
TAK-018/EB8018 ⁽⁵⁾ <sibofimloc>	FimH antagonist (oral)	Small molecule	Crohn's disease (post-operative and ileitis)	-	P-II (a)
TAK-951	Peptide agonist (sub-cutaneous)	Peptide/ Oligo-nucleotide	Nausea and vomiting	-	P-II
TAK-510	Peptide agonist (sub-cutaneous)	Peptide/ Oligo-nucleotide	Nausea and vomiting	-	P-I
TAK-671 ⁽⁶⁾	Protease inhibitor (injection)	Biologic and other	Acute pancreatitis	-	P-I
TAK-062 ⁽⁷⁾	Glutenase (oral)	Biologic and other	Celiac disease	-	P-I
TAK-039 ⁽⁸⁾	Bacterial consortium (oral)	Microbio me	Clostridium difficile infections ⁽⁹⁾	-	P-I

Notes:

- (1) Partnership with the University of California San Diego and Fortis Advisors
- (2) Partnership with Theravance Biopharma, Inc.
- (3) Partnership with Arrowhead Pharmaceuticals, Inc.
- (4) Acquired development and commercialization license for TAK-101 from Cour Pharmaceutical Development Company. Previously known as TIMP-GLIA.
- (5) Partnership with Enterome Bioscience SA
- (6) Partnership with Samsung Bioepis
- (7) Acquired Pvp Biologics, Inc. including TAK-062. Previously known as Kuma062.
- (8) Partnership with NuBiyota
- (9) Phase 1 study in clostridium difficile infections completed; strategic intention is to take the program forward in hepatic encephalopathy.
- (10) Complete Response Letter (CRL) is unrelated to the clinical safety and efficacy data, and included queries related to the design and labelling of the SC device. In August 2020, Takeda had a meeting with the FDA to review the Company's latest data and to seek guidance on additional data needs required to support the approval of vedolizumab SC. During the meeting, Takeda gained clarity on data needs for the device, and is moving forward to address them. Continued testing of the device will take time, and as a result, Takeda expects to potentially launch vedolizumab SC for moderate to severe ulcerative colitis in the U.S. in 2022, pending FDA approval.

Plasma-Derived Therapy (PDT)

Takeda created a dedicated PDT business unit with a focus to manage the business end-to-end, from plasma collection to manufacturing and commercialization. In PDT, we maximize the therapeutic value of PDT for patients with rare and complex diseases through innovation across the product life cycle. The dedicated R&D organization in PDT is charged with identifying new targeted therapies and optimizing efficiencies of current product manufacturing. PDT focuses 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 PDT pipeline as of May 11, 2021 (the date of our annual earnings release), along with notes for major subsequent developments thereafter, is as follows:

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Stage	
TAK-664 <i>CUVITRU</i> (U.S., EU)	Immunoglobulin 20% [human] (subcutaneous)	Biologic and other	Primary immunodeficiencies	Japan	P-III
TAK-771 ⁽¹⁾ <IG Infusion 10% (Human) w/ Recombinant Human Hyaluronidase> <i>HYQVIA</i> (U.S., EU)	Immunoglobulin (IgG) + recombinant hyaluronidase replacement therapy (injection)	Biologic and other	Secondary immunodeficiencies	EU	Approved (Sep 2020)
			Pediatric indication for primary immunodeficiency	U.S.	P-III
			Chronic inflammatory demyelinating polyradiculoneuropathy	U.S. EU	P-III P-III

Notes:

- (1) Partnership with Halozyme

Vaccines

In vaccines, Takeda is applying innovation to tackle some of the world's most challenging infectious diseases such as dengue, COVID-19, zika, and norovirus. To support the expansion of our pipeline and the development of our programs, we have entered into partnerships with government organizations in Japan and the U.S., and leading global institutions. Such partnerships have been essential in building the critical capabilities that will be necessary to deliver on our programs and realize their full potential.

Our vaccines pipeline as of May 11, 2021 (the date of our annual earnings release), along with notes for major subsequent developments thereafter, is as follows:

Development code Brand name (country/region)	Type of vaccine (administration route)	Modality	Indications / additional formulations	Stage	
TAK-003	Tetavalent dengue vaccine (injection)	Biologic and other	For the prevention of dengue fever of any severity, due to any serotype, in individuals aged 4 up to 60 years of age	EU and EU- M4all -	Filed (Mar 2021) ⁽⁴⁾ P-III
TAK-919/ mRNA-1273 ⁽¹⁾	COVID-19 vaccine (injection)	Biologic and other	Active immunization for the prevention of COVID-19	Japan	Filed (Mar 2021) ⁽⁵⁾
TAK-019/ NVX-CoV2373 ⁽²⁾	COVID-19 vaccine (injection)	Biologic and other	Active immunization for the prevention of COVID-19	Japan	P-I/II
TAK-214	Norovirus vaccine (injection)	Biologic and other	Active immunization for the prevention of acute gastroenteritis caused by norovirus	-	P-II (b)
TAK-426 ⁽³⁾	Zika vaccine (injection)	Biologic and other	Active immunization for the prevention of disease caused by Zika virus	-	P-I

Notes:

- (1) Partnership with Moderna and MHLW to bring Moderna's COVID-19 vaccine candidate to Japan
(2) Partnership with Novavax, Inc. to bring Novavax' COVID-19 vaccine candidate to Japan with funding from the Government of Japan's Ministry of Health, Labour and Welfare (MHLW) and Agency for Medical Research and Development (AMED)
(3) Partnership with The Biomedical Advanced Research and Development Authority (BARDA) - U.S. Government
(4) In addition to filing in the EU and through the EU-M4all (previously Article 58) procedure for countries outside of the EU, filings began in dengue endemic countries in Latin America and Asia that are not participating in the EU-M4all procedure.
(5) Subsequently approved in May 2021.

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 certain 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 healthy individuals to donate human plasma to develop and manufacture our plasma-derived therapies. We own and operate plasma donation facilities, principally in the U.S., Austria, Hungary and the Czech Republic, and we also maintain relationships with other plasma suppliers for external sourcing to meet our planned supply commitments to patients.

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 or 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 strategic products, we have decided to make significant long-term capital investments to build internal manufacturing capacity and secure dual sources to reduce the dependency on outsourced manufacturing relationships with third-party suppliers.

Manufacturing

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

We manufacture a certain number of our products in our own facilities within our global manufacturing network. In addition, we source certain other products from third-party contract manufacturers. We have a network of over 130 contract manufacturers which provide varying services such as the manufacture of active pharmaceutical ingredients, bulk drug product, aseptic fill finish and final packaging. In cases where we utilize contract manufacturers, we are often dual sourced with an internal manufacturing site. In cases where we are not dual sourced, we manage the risks associated with the reliance on a single source of production by carrying additional inventories.

Sales and Marketing

Our primary sales and marketing activities are organized around regional business units focused on the U.S., Japan, Europe and Canada, and Growth and Emerging Markets. These business units make focused investments that support the growth potential of our portfolios in each market.

The U.S. is the largest pharmaceutical market in the world, and is also Takeda's largest region by revenue. The United States Business Unit ("USBU") is focused on the successful uptake of recently approved products such as *TAKHZYRO*, as well as continuing to grow core promoted brands such as *ENTYVIO*, *TRINTELLIX*, *VYVANSE*, *GATTEX* and Immunoglobulin products. These and other principal products are supported by significant investment in marketing and sales force promotion.

The Japan Pharma Business Unit ("JPBU") is focused on retaining Takeda's position as one of the leading pharmaceutical companies in our home market of Japan. Although we continue to promote our strong primary care portfolio, with the Japanese government driving stricter control of drug prices and promoting the penetration of generics, our strategy is to shift focus more towards the uptake of our highly innovative and differentiated specialty medicines such as *ENTYVIO*, *ADCETRIS*, and *NINLARO*.

The Europe and Canada ("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 clear differentiation in order for products to be reimbursed.

The Growth and Emerging Markets business unit focuses on maximizing growth potential in areas across the Asia Pacific, Greater China, Latin America, Near East, Middle East and Africa and Russia/CIS. In particular, China is a key focus market for us in the medium-term.

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 R&D 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 R&D 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 to 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 U.S., patents generally expire 20 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 U.S. 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 ethical combination 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. While the term of a patent granted by the EPO or a European country office may be extended or adjusted, it 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 the EPO and EU level, respectively, due to different national implementation they may not always lead to the same result, for example, if challenged in 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 R&D 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”) (U.S. 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”), 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 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⁾
Gastroenterology (GI):			
<i>ENTYVIO</i>	Patent: - RP: July 2026 ⁽²⁾	Patent: September 2021 RDP: May 2026 ⁽⁸⁾	Patent: August 2017 (Extended expiry of August 2022 in certain countries) RDP: May 2024 ⁽⁸⁾
<i>DEXILANT</i>	Not commercialized	Patent: -	Patent: -
<i>PANTOLOC /CONTROLO (PANTOPRAZOLE)</i>	Not commercialized	Patent: -	Patent: -
<i>TAKECAB⁽³⁾</i>	Patent: August 2031 RP: December 2022 ⁽²⁾	Patent: - ⁽³⁾	Patent: - ⁽³⁾
<i>GATTEX/REVESTIVE</i>	Not commercialized	Patent: - ⁽⁵⁾	Patent: - RDP: September 2024
<i>PENTASA⁽⁴⁾</i>	Patent: - ⁽⁴⁾	Patent: -	Patent: - ⁽⁴⁾
<i>LIALDA/MEZAVANT⁽³⁾</i>	Patent: - ⁽³⁾ RP: September 2022 ⁽²⁾	Patent: -	Patent: -
<i>AMITIZA⁽⁴⁾</i>	Patent: - ⁽⁴⁾	Patent: May 2021 ⁽⁶⁾	Not commercialized
<i>RESOLOR/MOTEGRITY</i>	Not commercialized	Patent: - RDP: December 2023	Patent: -

Our product	Japan expiry dates ⁽¹⁾⁽²⁾	U.S. expiry dates ⁽¹⁾	EU expiry dates ⁽¹⁾
Rare Metabolic:			
<i>ELAPRASE</i> ⁽³⁾	Patent: - ⁽³⁾	Patent: -	Patent: -
<i>REPLAGAL</i>	Patent: -	Not commercialized	Patent: -
<i>VPRIV</i>	Patent: -	Patent: -	Patent: -
	RP: July 2024 ⁽²⁾		RDP: August 2022
<i>NATPARA/NATPAR</i>	Not commercialized	Patent: -	Patent: -
		RDP: January 2027	RDP: April 2029
Rare Hematology:			
<i>ADVATE</i>	Patent: -	Patent: -	Patent: -
<i>ADYNOVATE/ADYNOVI</i>	Patent: January 2026	Patent: February 2026	Patent: January 2028 if granted
	RP: March 2024 ⁽²⁾	RDP: November 2027	RDP: January 2028
<i>FEIBA</i> ⁽⁷⁾	Patent: -	Patent: -	Patent: -
<i>HEMOFIL</i> ⁽⁷⁾	Not commercialized	Patent: -	Not commercialized
<i>IMMUNATE</i> ⁽⁷⁾	Not commercialized	Not commercialized	Patent: -
<i>IMMUNINE</i> ⁽⁷⁾	Not commercialized	Not commercialized	Patent: -
<i>BEBULIN</i> ⁽⁷⁾	Not commercialized	Patent: -	Not commercialized
<i>PROTHROMPLEX</i> ⁽⁷⁾	Not commercialized	Not commercialized	Patent: -
<i>FACTOR VII</i> ⁽⁷⁾	Not commercialized	Not commercialized	Patent: -
<i>VONVENDI</i>	Patent: -	Patent: December 2030	Patent: -
	RP: March 2030 ⁽²⁾	RDP: December 2027	RDP: August 2028
<i>OBIZUR</i>	Not commercialized	Patent: -	Patent: February 2026
		RDP: October 2026	RDP: November 2025
<i>RIXUBIS</i>	Patent: -	Patent: -	Patent: -
	RP: December 2022 ⁽²⁾		
<i>AGRYLIN/XAGRID</i>	Patent: -	Patent: -	Patent: -
	RP: September 2024 ⁽²⁾		
<i>RECOMBINATE</i>	Not commercialized	Patent: -	Not commercialized
Hereditary Angioedema:			
<i>FIRAZYR</i>	Patent: -	Patent: -	Patent: -
	RP: September 2028 ⁽²⁾		
<i>TAKHZYRO</i>	Patent: January 2031	Patent: December 2031, February 2032, March 2032	Patent: January 2031 (Extended expiry of November 2033 in some countries)
	Extended expiry of September 2035 if PTE granted	Extended expiry of August 2032 if PTE granted	RDP: November 2028
		RDP: August 2030	
<i>KALBITOR</i>	Not commercialized	Patent: December 2023	Not commercialized
<i>CINRYZE</i> ⁽⁷⁾	Not commercialized	Patent: -	Patent: -
Plasma-Derived Therapies (PDT) Immunology:			
<i>GAMMAGARD LIQUID</i> ⁽⁷⁾	Not commercialized	Patent: -	Patent: -
		Patent: -	Patent: -
<i>HYQVIA</i> ⁽⁷⁾	Not commercialized	RDP: September 2026	RDP: May 2024
		Patent: -	Patent: -
<i>CUVITRU</i> ⁽⁷⁾	Not commercialized	RDP: September 2028	RDP: July 2027
<i>FLEXBUMIN</i> ⁽⁷⁾	Not commercialized	Patent: -	Patent: -
<i>HUMANALBUMIN</i> ⁽⁷⁾	Not commercialized	Not commercialized	Patent: -
<i>GLASSIA</i> ⁽⁷⁾	Patent: - ⁽⁴⁾	Patent: -	Patent: - ⁽⁴⁾
		RDP: July 2022	

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Our product	Japan expiry dates⁽¹⁾⁽²⁾	U.S. expiry dates⁽¹⁾	EU expiry dates⁽¹⁾
<i>ARALAST⁽⁷⁾</i>	Not commercialized	Patent: -	Not commercialized
<i>CEPROTIN⁽⁷⁾</i>	Not commercialized	Patent: -	Patent: -
<i>ANTITHROMBIN III⁽⁷⁾</i>	Not commercialized	Not commercialized	Patent: -
<i>KENKETU-GLOVENIN-I⁽⁷⁾</i>	Patent: -	Not commercialized	Not commercialized
<i>KENKETU-NONTHRON⁽⁷⁾</i>	Patent: -	Not commercialized	Not commercialized
<i>KENKETU-ALUBMIN⁽⁷⁾</i>	Patent: -	Not commercialized	Not commercialized
Oncology:			
<i>VELCADE⁽³⁾</i>	Patent: - ⁽³⁾	Patent: -	Patent: - ⁽³⁾
<i>LEUPLIN/ENANTONE</i>	Patent: -	Patent: -	Patent: -
<i>NINLARO</i>	Patent: July 2031	Patent: November 2029	Patent: November 2031
	RP: March 2027 ⁽²⁾	RDP: November 2022	RDP: November 2026
<i>ADCETRIS⁽⁴⁾</i>	Patent: April 2026	Patent: - ⁽⁴⁾	Patent: October 2027
	RP: January 2024 ⁽²⁾		RDP: October 2023, January 2028
<i>ICLUSIG⁽³⁾</i>	Patent: - ⁽³⁾	Patent: January 2027	Patent: - ⁽³⁾
<i>ALUNBRIG</i>	Patent: November 2032	Patent: July 2030	Patent: May 2029
	RP: January 2029	Extended expiry of April 2031 if PTE granted	Extended expiry of November 2033 if SPC granted
		RDP: April 2024	RDP: November 2028
<i>VECTIBIX⁽⁴⁾</i>	Patent: August 2022	Patent: - ⁽⁴⁾	Patent: - ⁽⁴⁾
<i>CABOMETYX⁽⁴⁾</i>	Patent: September 2024	Patent: - ⁽⁴⁾	Patent: - ⁽⁴⁾
	Extended expiry of September 2029 of PTE granted		
Neuroscience:			
<i>VYVANSE/ELVANSE</i>	Patent: June 2029	Patent: February 2023	Patent: June 2024 (Extended expiry of February 2028 or March 2029 in certain countries)
	RP: March 2027 ⁽²⁾		
<i>TRINTELLIX⁽⁴⁾</i>	Patent: October 2027	Patent: December 2026	
	RP: September 2027 ⁽²⁾	Extended expiry of December 2026 if pediatric exclusivity (PED) granted	Patent: - ⁽⁴⁾
<i>ADDERALL XR</i>	Not commercialized	Patent: -	Not commercialized
<i>ROZEREM</i>	Patent: March 2022	Patent: -	Not commercialized
<i>REMINYL</i>	Patent: -	Patent: - ⁽⁴⁾	Patent: -
<i>INTUNIV</i>	Patent: -	Patent: -	Patent: -
	RP: March 2025 ⁽²⁾		RDP: September 2025
<i>COPAXONE⁽⁴⁾</i>	Patent: -	Patent: - ⁽⁴⁾	Patent: - ⁽⁴⁾
	RP: September 2025 ⁽²⁾		
<i>AZILECT⁽⁴⁾</i>	Patent: -	Patent: - ⁽⁴⁾	Patent: - ⁽⁴⁾
	RP: March 2026 ⁽²⁾		
<i>MYDAYIS</i>	Not commercialized	Patent: -	Not commercialized
<i>EQUASYM</i>	Not commercialized	Patent: - ⁽³⁾	Patent: -
<i>CARBATROL</i>	Not commercialized	Patent: -	Not commercialized

Our product	Japan expiry dates ⁽¹⁾⁽²⁾	U.S. expiry dates ⁽¹⁾	EU expiry dates ⁽¹⁾
Other:			
<i>AZILVA-F</i>	Patent: - RP: October 2021 ⁽²⁾	Not commercialized	Not commercialized
<i>NESINA/VIPIDIA-F</i>	Patent: - ⁽³⁾	Patent: June 2028	Patent: September 2028
<i>ULORIC</i> ⁽⁴⁾	Patent: - ⁽⁴⁾	Patent: -	Patent: - ⁽⁴⁾
<i>COLCRYS</i>	Not commercialized	Patent: -	Not commercialized
<i>LOTTRIGA</i> ⁽⁴⁾	Patent: -	Patent: - ⁽⁴⁾	Patent: - ⁽⁴⁾

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 “—Licensing and Collaboration” for further information on the licensing agreements.
- (5) Generic may be introduced after March 2023 based on a settlement with an ANDA filer.
- (6) Generic may be introduced after January 2021 (or earlier under certain circumstances) based on a settlement with an ANDA filer.
- (7) Relates to plasma-derived therapies products.
- (8) There are other patents for ENTYVIO that expire in 2032, and therefore the exact timing of biosimilar entry is uncertain.

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 have led to successful commercialization to date are summarized below:

- *ADCETRIS*: We entered into a Collaboration Agreement with Seagen, Inc. (formerly Seattle Genetics, Inc.) (“Seagen”) 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 Seagen). 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 Seagen 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 Seagen 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, 2021, there are no further incremental potential commercial milestone payments remaining under the *ADCETRIS* collaboration.
- *TRINTELLIX*: We entered into a License, Development, Supply and Commercialization Agreement with H. Lundbeck A/S in 2007 for the exclusive co-development and co-commercialization in the U.S. and Japan of several compounds in Lundbeck’s pipeline for the treatment of mood and anxiety disorders. Under the agreement, both partners commercialize *TRINTELLIX* in the U.S. and Japan and have agreed to jointly develop the relevant compounds, with most of development funding provided by us. Revenues for *TRINTELLIX* are booked by us, and we pay Lundbeck a portion of net sales, as well as tiered royalties ranging from the low to mid-teens on the portion of sales retained by us. We have also agreed to pay 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, 2021, there are no further incremental potential commercial milestone payments remaining under the *TRINTELLIX* collaboration.
- *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 in the teens, resetting each year. On January 1, 2021, we began sharing 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, 2021, there are no further incremental potential commercial milestone payments remaining under the *AMITIZA* collaboration.

Our other R&D licensing and collaboration arrangements pipeline include, but are not limited to, the following:

Partner	Country	Description of collaboration
Oncology:		
Adimab	U.S.	Agreement for the discovery, development and commercialization of three mAbs and three CD3 Bi-Specific antibodies for oncology indications.
Centre d'Immunologie de Marseille-Luminy	France	Collaboration agreement to bring together expertise and knowledge in innate biology with Takeda's BacTrap capabilities to identify novel targets and pathways in myeloid cells.
ASKA Pharmaceutical Co., Ltd	Japan	Takeda granted 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).
Crescendo Biologics	U.K.	Collaboration and licensing agreement for the discovery, development and commercialization of Humabody®-based therapeutics for cancer indications.
Egle Therapeutics	France	Identify novel tumor-specific regulatory T-cell targets and develop unique anti-suppressor-based immunotherapies.
Exelixis, Inc.	U.S.	Exclusive licensing agreement to commercialize and develop novel cancer therapy cabozantinib and all potential future cabozantinib indications in Japan, including advanced renal cell carcinoma and hepatocellular carcinoma.
GammaDelta Therapeutics	U.K.	Collaboration agreement to discover and develop new immunotherapies in oncology using GammaDelta Therapeutics' novel T cell platform based on the unique properties of gamma delta T cells derived from human tissues.
GlaxoSmithKline	U.K.	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.
Heidelberg Pharma	Germany	Antibody-Drug-Conjugate (ADC) research collaboration on 2 targets and licensing agreement (α -amanitin payload and proprietary linker).
KSQ Therapeutics	U.S.	Strategic collaboration to research, develop and commercialize novel immune-based therapies for cancer using KSQ's CRISPRomics® technology
MD Anderson Cancer Center	U.S.	Exclusive license and research agreement to develop cord blood-derived chimeric antigen receptor-directed natural killer (CAR NK)-cell therapies, 'armored' with IL-15, for the treatment of B-cell malignancies and other cancers
Memorial Sloan Kettering Cancer Center	U.S.	Strategic research collaboration and license to develop novel chimeric antigen receptor T-cell (CAR-T) products for the treatment of multiple myeloma, acute myeloid leukemia and additional solid tumor indications. The collaboration is co-led by Michel Sadelain, who is currently head of the Center for Cell Engineering at Memorial Sloan Kettering
Molecular Templates	U.S.	Molecular Templates will continue to develop TAK-169 and Takeda will maintain its equity stake in Molecular Templates.
Myovant Sciences	Switzerland	Takeda 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).
National Cancer Center of Japan	Japan	Partnership agreement 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.
Noile-Immune Biotech	Japan	Collaboration agreement for the development of next generation CAR-T cell therapy, developed by Professor Koji Tamada at Yamaguchi University. Takeda has exclusive options to obtain licensing rights for the development and commercialization of Noile-Immune Biotech's pipeline and products resulting from this partnership. Due to the success of the collaboration, Takeda licensed NIB-102 and NIB-103.
Presage Biosciences	U.S.	Research collaboration and license for multiple programs using Presage's proprietary platform CIVO to evaluate patients' unique responses to microdoses of cancer drugs.
Shattuck Labs	U.S.	Collaboration agreement to explore and develop checkpoint fusion proteins utilizing Shattuck's unique Agonist Redirected Checkpoint (ARC) TM platform which enables combination immunotherapy with a single product. Takeda will have the option to take an exclusive license to further develop and commercialize TAK-252/SL-279252
Teva	Israel	Agreement for worldwide License to TEV-48573 (TAK-573) (CD38-Attenukine) and multi-target discovery collaboration accessing Teva's attenukine platform.
Turnstone Biologics	U.S.	Collaboration to co-develop TAK-605 (RIVAL-01) (novel oncolytic virus expressing aCTLA4, IL12-mb, flt3L) via a worldwide partnership and also conduct collaborative discovery efforts to identify additional novel product candidates based on a Turnstone's vaccinia virus platform.

Partner	Country	Description of collaboration
Rare genetics and hematology:		
Asklepios Biopharmaceuticals	U.S.	Agreement for multiple research and development collaborations using FVIII Gene Therapy for the treatment of Hemophilia A and B.
BioMarin	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).
Carmine Therapeutics	Singapore	Research collaboration agreement to discover, develop and commercialize transformative non-viral gene therapies for two rare disease targets using Carmine's REGENT(TM) technology, based on red blood cell extracellular vesicles.
Codexis, Inc.	U.S.	Strategic collaboration and license for the research and development of novel gene therapies for certain disease indications, including the treatment of lysosomal storage disorders and blood factor deficiencies.
Ensoma	U.S.	Research collaboration and license provides Takeda with an exclusive worldwide license to Ensoma's Engenius™ vectors for up to five rare disease indication,
Evox Therapeutics	U.K.	Collaboration for developing novel protein replacement and mRNA therapies and targeted delivery using Evox's proprietary exosome technology. Partnership for up to five rare disease targets with Takeda assuming responsibility for its clinical development
GlaxoSmithKline	U.K.	In-license agreement between GSK and University of Michigan for TAK-620 (maribavir) in the treatment of human cytomegalovirus.
IPSEN	France	Purchase agreement for the development of 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	Japan	Agreement for the development collaboration of TAK-755 to overcome the ADAMTS13 deficiency in TTP.
Rani Therapeutics	U.S.	Research collaboration agreement to evaluate a micro tablet pill technology for oral delivery of FVIII therapy in hemophilia
Xenetic Biosciences	U.S.	Exclusive R&D license agreement for PolyXen delivery technology for hemophilia factors VII, VIII, IX, X.
Neuroscience:		
Anima Biotech	U.S.	Strategic collaboration to discover and develop mRNA translation modulators for genetically-defined neurological diseases
AstraZeneca	UK	Agreement for the joint development and commercialization of MEDI1341, an alpha-synuclein antibody currently in development as a potential treatment for Parkinson's disease.
Bridgene	U.S.	Research collaboration to discover small molecule drugs for "undruggable" targets using Bridgene's chemoproteomics platform
Denali Therapeutics	U.S.	Strategic option and collaboration agreement to develop and commercialize up to three specified therapeutic product candidates for neurodegenerative diseases, incorporating Denali's ATV platform for increased exposure of biotherapeutic products in the brain.
Neurocrine Biosciences	U.S.	Collaboration to develop and commercialize compounds in Takeda's early-to-mid stage neuroscience pipeline, including TAK-041, TAK-653 and TAK-831. Takeda will be entitled to certain development milestones, commercial milestones and royalties on net sales. At certain development events, Takeda may elect to opt in or out of a 50:50 profit share on all clinical programs on an asset-by-asset basis. For any asset in which Takeda is participating in a 50:50 profit share arrangement, Takeda will not be eligible to receive development or commercial milestones.
PeptiDream	Japan	Collaborative research and exclusive license agreement to create peptide-drug conjugates (PDCs) for neuromuscular diseases
Skyhawk Therapeutics	U.S.	Collaboration and licensing agreement to develop and commercialize RNA modulation therapies targeting neurodegenerative diseases.
StrideBio	U.S.	Collaboration and license agreement to develop in vivo AAV based therapies for Friedreich's Ataxia (FA) and two additional undisclosed targets.
Wave Life Sciences	Singapore	Research, development and commercial collaboration and multi-program option agreement to develop antisense oligonucleotides for a range of neurological diseases.

Partner	Country	Description of collaboration
Gastroenterology (GI):		
Ambys Medicines	U.S.	Collaboration agreement for the application of novel modalities, including cell and gene therapy and gain-of-function drug therapy, to meet the urgent need for treatments that restore liver function and prevent the progression to liver failure across multiple liver diseases. Under the terms of the agreement, Takeda has an option to ex-U.S. commercialization rights for the first 4 products that reach an investigational new drug application.
Arcturus	U.S.	Collaboration agreement to develop RNA-based therapeutics for the treatment of non-alcoholic steatohepatitis and other gastrointestinal related disorders using Arcturus' wholly-owned LUNAR™ lipid-mediated delivery systems and UNA Oligomer chemistry.
Arrowhead Pharmaceuticals	U.S.	Collaboration and licensing agreement to develop TAK-999 (ARO-AAT), a Phase 2 investigational RNA interference (RNAi) therapy in development to treat alpha-1 antitrypsin-associated liver disease (AATLD). ARO-AAT is a potential first-in-class therapy designed to reduce the production of mutant alpha-1 antitrypsin protein, the cause of AATLD progression.
Beacon Discovery	U.S.	Collaboration agreement for the G-protein coupled receptor drug discovery and development program to identify drug candidates for a range of gastrointestinal disorders. The agreement grants Takeda worldwide rights to develop, manufacture and commercialize products resulting from the collaboration.
Cerevance	U.S.	Multi-year research alliance to identify novel target proteins expressed in the central nervous system and to develop new therapies against them for certain GI disorders. Goal of the collaboration is to select, confirm and validate targets from gene expression data sets generated by Cerevance's NETSeq technology.
Cour Pharmaceutical Development Company	U.S.	Takeda has acquired an exclusive global license to develop and commercialize the investigational medicine TIMP-GLIA (TAK-101), an immune modifying nanoparticle containing gliadin proteins.
Engitix	U.K.	Collaboration and licensing agreement to utilize Engitix's liver fibrosis platform to conduct research activities and to nominate, confirm, and validate potential targets against which Takeda may advance new therapeutic programs.
Enterome	France	Collaboration agreement to research and develop microbiome targets thought to play crucial roles in gastrointestinal disorders, including inflammatory bowel diseases (e.g. ulcerative colitis). The agreement includes a global license and co-development of EB8018/TAK-018 in Crohn's disease.
Finch Therapeutics	U.S.	Global agreement to develop FIN-524, a live biotherapeutic product composed of cultured bacterial strains linked to favorable clinical outcomes in studies of microbiota transplantations in inflammatory bowel disease. Under the terms of the agreement, Takeda obtains the exclusive worldwide rights to develop and commercialize FIN-524 and rights to follow-on products in inflammatory bowel diseases.
Genevant Sciences Corporation	U.S.	Collaboration and License Agreement to leverage Genevant's hepatic stellate cell-partitioning LNP platform to deliver Takeda-designed RNAi oligonucleotides intended to halt or reverse the progression of liver fibrosis.
Hemoshear Therapeutics	U.S.	Collaboration agreement for novel target and therapeutic development for liver diseases, using Hemoshear's proprietary REVEAL-Tx drug discovery platform.
NuBiyota	Canada	Agreement for the development of Microbial Ecosystem Therapeutic products for gastroenterology indications.
Phathom Pharmaceuticals	U.S.	Takeda has granted a license to Phathom Pharmaceuticals for the development and exclusive commercialization rights to vonoprazan in the U.S., Europe and Canada in exchange for upfront cash and equity, as well as future cash milestones and royalties on net sales.
Samsung Bioepis	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.
Silence Therapeutics	U.K.	Technology Evaluation Agreement with Silence Therapeutics to access their GalNAc-siRNA technology platform. The objective of the evaluation is to identify a GalNAc-conjugated siRNA that inhibits expression of a proprietary Takeda target.
Theravance Biopharma	U.S.	Global license, development and commercialization agreement for TAK-954, a selective 5-HT4 receptor agonist for motility disorders.
UCSD/Fortis Advisors	U.S.	Technology license for the development of oral budesonide formulation (TAK-721) for treatment of eosinophilic esophagitis.
Plasma-Derived Therapies (PDT):		
Halozyme	U.S.	Agreement for the in-license of Halozyme's proprietary ENHANZE™ platform technology to increase dispersion and absorption of HyQvia. Ongoing development work for a U.S. pediatric indication to treat primary immunodeficiencies and a Phase 3 indication in Chronic Inflammatory Demyelinating Polyradiculoneuropathy.
Kamada	Israel	In-license agreement to develop and commercialize IV Alpha-1 proteinase inhibitor (Glassia); Exclusive supply and distribution of Glassia in the U.S., Canada, Australia and New Zealand; work on post market commitments ongoing.
ProThera Biologics	U.S.	Global licensing agreement to develop a novel plasma-derived Inter-alpha Inhibitor Proteins (IAIP) therapy for the treatment of acute inflammatory conditions.

Partner	Country	Description of collaboration
Vaccines:		
Biological E. Limited	India	Takeda 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 TAK-426, a Zika vaccine candidate, for the U.S. with the option to use data generated for filing also in affected regions around the world.
Novavax	U.S.	Partnership for the development, manufacturing and commercialization of over 250 million doses per year of TAK-019 (NVX-CoV2373), Novavax' COVID-19 vaccine candidate, in Japan, which is being funded by the Government of Japan's Ministry of Health, Labour and Welfare.(MHLW) and Agency for Medical Research and Development (AMED).
Moderna	U.S.	Three-way agreement with Moderna and the Government of Japan's Ministry of Health Labour & Welfare (MHLW) to import and distribute 50 million doses of TAK-919 (mRNA-1273) Moderna's COVID-19 vaccine candidate, in Japan from the first half of 2021.
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. Bridge Medicines will give financial, operational and managerial support to move projects seamlessly from a validating, proof-of-concept study to an in-human clinical trial.
Center for iPS Cell Research Application, Kyoto University (CiRA)	Japan	Collaboration agreement for clinical applications of iPS cells in Takeda strategic areas including applications in neurosciences, oncology and GI as well as discovery efforts in additional areas of compelling iPSC translational science.
Charles River Laboratories	U.S.	Collaboration on multiple integrated programs across Takeda's core therapeutic areas using Charles River Laboratories' end-to-end drug discovery and safety assessment platform to progress these programs towards candidate status.
Evotec GT	Germany	Research alliance to support Takeda's growing number of research stage gene therapy discovery programs.
HiFiBio	U.S.	Collaboration agreement 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.
Massachusetts Institute of Technology	U.S.	MIT-Takeda Program to fuel the development and application of artificial intelligence (AI) capabilities to benefit human health and drug development. Centered within the Abdul Latif Jameel Clinic for Machine Learning in Health (J-Clinic), the new program will leverage the combined expertise of both organizations, and is supported by Takeda's three-year investment (with the potential for a two-year extension).
Portal Instruments	U.S.	Agreement for the development and commercialization of Portal's jet injector drug delivery device for potential use with Takeda's investigational or approved biologic medicines.
Schrödinger	U.S.	Agreement for the multi-target research collaboration combining Schrödinger's in silico platform-driven drug discovery capabilities with Takeda's deep therapeutic area knowledge and expertise in structural biology.
Seattle Collaboration	U.S.	Agreement for SPRInT (Seattle Partnership for Research on Innovative Therapies) to accelerate the translation of Fred Hutchinson Cancer Research Center's and University of Washington's cutting-edge discoveries into treatments for human disease (focusing on Oncology, GI and Neuroscience).
Stanford University	U.S.	Collaboration agreement with Stanford University to form the Stanford Alliance for Innovative Medicines to more effectively develop innovative treatments and therapies.
Tri-Institutional Therapeutics Discovery Institute (Tri-I TDI)	U.S.	Agreement for the collaboration of academic institutions and industry to more effectively develop innovative treatments and therapies.
Twist Bioscience	U.S.	Agreement and license for Takeda to access Tiwst's "Library of Libraries," a panel of synthetic antibody phage display libraries derived only from sequences that exist in the human body. Together, the companies will work to discover, validate and optimize new antibody candidates.

Competition

Competition in each market where we conduct business is based on, among other things, product safety, efficacy, convenience of dosing, reliability, availability and pricing. Our competitors include large international companies whose capabilities cover the entire product creation process from R&D to manufacturing and marketing, as well as biopharmaceutical companies with a focus on specific therapeutic areas.

We also face competition from generic drugs and biosimilars 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 the introduction of our own new products that treat similar diseases as our older products.

The competition we face often differs by product and geographic market, and competitors may emerge and fall away over time due to advances in innovation, 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:		
<i>DEXILANT, PANTOPRAZOLE (Protonix)</i>	generic lansoprazole, esomeprazole	—
<i>ENTYVIO</i>	<i>Remicade</i> <i>Humira</i> <i>Simponi</i> <i>Stelara</i> <i>Cimzia</i> generic infliximab	Janssen Biotech Abbvie Janssen Biotech Janssen Biotech UCB —
<i>TAKECAB</i>	<i>Nexium</i> generic lansoprazole, omeprazole	AstraZeneca —
<i>GATTEX/REVESTIVE</i>	<i>Zorbtive</i> <i>Nutrestore</i>	EMD/Serono Emmaus LifeSciences
<i>ALOFISEL</i>	<i>Autologous tissue, chronic seton usage</i> <i>Remicade</i> generic infliximab	— Janssen Biotech —
Rare Diseases:		
<i>ADVATE and ADYNOVATE</i>	<i>Xyntha/Refacto AF</i> <i>Kogenate</i> <i>Helixate</i> <i>Kovaltry</i> <i>Iblias</i> <i>Eloctate/Elocta</i> <i>Novoeight</i> <i>Nuwiq</i> <i>Afstyla</i> <i>Hemlibra</i>	Pfizer and Sobi Bayer CSL Bayer CSL Sanofi and Sobi Novo Nordisk Octapharma CSL Roche
<i>TAKHZYRO</i>	<i>Ruconest</i> <i>Generic Icatibant</i> <i>Haegarda</i> <i>Beriner</i> <i>Orladeyo</i>	Pharming — CSL CSL BioCryst
<i>REPLAGAL</i>	<i>Fabrazyme</i> <i>Galafold</i> <i>Fabagal</i>	Genzyme Amicus Isu Abaxis
<i>VPRIV</i>	<i>Cerezyme</i> <i>Ellyso/uplyso</i> <i>Zavesca</i> <i>Cerdelga</i> <i>Abcertin</i>	Sanofi Genzyme Pfizer/Protalix Actelion [Janssen] Sanofi Genzyme Isu Abaxis
<i>Elaprase</i>	<i>Hunterase</i> <i>IZCARGO</i>	Korean Green Cross JCR Pharmaceuticals

Our product	Principal competing product	Primary manufacturer or distributor
PDT		
GAMMAGARD LIQUID/KIOVIG, GAMMAGARD S/D	Privigen	CSL
	Carimune	CSL
	Gamunex-C	Grifols
	Flebogamma	Grifols
	Bivigam	ADMA
	Gammaked	Kendrion
	Gammaplex	BPL
	Octagam	Octapharma
	Panzya	Octapharma
GAMMAGARD LIQUID, HYQVIA, CUVITRU	Hizentra	CSL
	Gamunex-C	Grifols
	Cutaquig/Gammanorm	Octapharma
FLEXBUMIN and HUMAN ALBUMIN	Alburex/AlbuRx	CSL
	Albuminar, Albumex	CSL
	Plasbumin	Grifols
	Albutein	Grifols
	Albunorm	Octapharma
	Kedbumin, Albuked	Kendrion
Oncology:		
ADCETRIS	Keytruda	Merck/MSD
	Opdivo	Bristol-Myers Squibb
ALUNBRIG	Xalkori	Pfizer
	Zykadia	Novartis
	Alecensa	Roche
	Lorbrena	Pfizer
ICLUSIG	Gleevec	Novartis
	Tasigna	Novartis
	Sprycel	Bristol-Myers Squibb
	Bosulif	Pfizer
LEUPRORELIN (LEUPLIN)	Zoladex generic leuprorelin	AstraZeneca —
NINLARO, VELCADE	Revlimid	Bristol-Myers Squibb
	Pomalyst/Imnovid	Bristol-Myers Squibb
	Kyprolis	Amgen
	Darzalex	Janssen Biotech
	Empliciti	Bristol-Myers Squibb
	Xpovio	Karyopharm
	Sarclisa	Sanofi
	Papexto	Oncopeptide
Abecma	Bristol-Myers Squibb	
Neuroscience:		
TRINTELLIX	Viibryd Fetzima Generics: Amitriptyline, amoxapine, bupropion, citalopram, clomipramine, desipramine, desvenlafaxine, doxepin, duloxetine, esketamine, escitalopram, fluoxetine, flvoxamine, imipramine, maprotiline, mirtazapine, nefazodone, nomifensine, nortriptyline, nefazodone, paroxetine, protriptyline, sertraline, trazodone, trimipramine, venlafaxine	AbbVie AbbVie Various

Our product	Principal competing product	Primary manufacturer or distributor
<i>VYVANSE</i>	generic mixed salts of a single-entity amphetamine product: – Adderall IR	Various
	generic mixed salts of a single-entity amphetamine product, extended release: – Adderall XR	Various
	generic methylphenidate, extended release: – Concerta – Jornay PM – Adhansia XR	Various Ironshore Pharmaceuticals Adlon Therapeutics
	Non-stimulants: – Stratterra (atomoxetine) – Intuniv (guanfacine) – Kapvay (clonidine)	Various
	Other:	
<i>AZILVA</i>	generic candesartan, olmesartan	—
<i>NESINA</i>	<i>Januvia</i>	Merck Co., Inc.
	generic pioglitazone	—

Regulation

The pharmaceutical industry is subject to extensive global regulation by regional, national, state and local agencies. The regulatory agencies 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 U.S., 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 introducing a new product to market. 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 U.S., 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 Biologics License Application (“sBLA”) 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 sBLA 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 (“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 Amendments addresses the development and approval of generic drugs, the Biologics Price Competition and Innovation Act of 2009 (the “BPCIA”), enacted in the Affordable Care Act (the “ACA”) amended the Public Health Service Act (the “PHS Act”) to create an abbreviated licensure pathway for biological products that are demonstrated to be “biosimilar” to, or “interchangeable”, with an FDA-licensed reference product. BPCIA allows for approval of a biosimilar if it is “highly similar” and has no clinically meaningful differences from its 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. In general, this meant that CMS grouped biosimilar products that were licensed with a common reference product with the same payment limit and HCPCS code. However, effective January 1, 2018 under the 2018 Physician Fee Schedule Final Rule, newly approved biosimilar biological products with a common reference product were no longer grouped into the same billing code. Instead, biosimilars are separately coded and paid for under Medicare Part B.

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 MHLW 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 (“Pharmaceutical and Medical Device Act” or the “PMD Act”). Under the PMD Act, the relevant licenses must be obtained from the MHLW 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 clinical trial result data and other pertinent data must be attached to the 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 experts on 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 with which a manufacturing and distribution business license for the type of drug concerned has been obtained, and to confirm that the product has been manufactured in a plant compliant with the GMP.

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, in addition to post marketing surveillance including Early Post-marketing Phase Vigilance (“EPPV”) based on the risk management plan (“RMP”) for all new medications. 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 PMD 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 PMD Act, the Minister may take various measures to supervise manufacturing and marketing license holders of Designated Products. The Minister has the 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 holder 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 an 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, 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 U.S. our sales are subject to various voluntary and mandatory rebates, which vary depending on the type of coverage and can have a significant impact on our results. The most significant of these are rebates associated with commercial managed care, Medicaid, Medicare and other government programs. In general, the details of these rebates are not disclosed publicly.

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 specialty 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. This includes a mandatory minimum rebate, additional rebates if commercial discounts are greater than the mandatory minimum rebate and an inflation penalty if our prices have increased above inflation. These rebates guarantee that any patient in the Medicaid program can have access to Takeda's products, although there could be significant utilization management imposed by the state. In addition to the mandatory rebates, Takeda may also choose to offer supplemental rebates to a state or Medicaid managed care organization to ensure Takeda's drugs are on the preferred drug list (which is similar to a formulary for Medicaid programs). 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

Medicare is a federally run program that provides healthcare to persons aged 65 and over, and certain persons under the age of 65 who have a long-term disability and meet certain eligibility requirements. Drugs are primarily covered under two different benefits for Medicare beneficiaries, Medicare Part B and Medicare Part D. Medicare Part B covers outpatient health and medical services, which includes some drugs under the medical benefit. These drugs tend to be the most biologically complex and are generally administered in a doctor's office or hospital outpatient setting. Medicare Part D is a voluntary drug offering available to Medicare beneficiaries through private health insurance plans that contract with the government to deliver this benefit.

Part B covers drugs that are administered by infusion or injection in a doctor's office or hospital outpatient setting, as well as certain drugs furnished by suppliers. Medicare pays physicians and outpatient hospitals for most separately payable Part B-covered drugs they furnish to beneficiaries at a rate of 106 percent of the manufacturer-reported ASP before sequestration. A product's ASP reflects the average price realized by the manufacturer for sales to all purchasers net of rebates, discounts, and price concessions with certain exceptions. There are no rebates for drugs reimbursed under Part B. Takeda must also calculate and report specific prices to government agencies, including the ASP used by the Medicare Part B program. The required calculations are complex, and a misrepresentation in the reported pricing may expose Takeda to penalties.

Part D covers most of the other outpatient prescription drugs. Rather than Medicare setting prices administratively, Medicare pays Part D plan sponsors (health plans offering the benefit) that, through their pharmacy benefit managers (the "PBMs"), contract with pharmacies over payment rates for each prescription filled by an enrollee and negotiate with drug manufacturers for prices and post-sale rebates. Takeda may offer a rebate as part of the negotiation between plan sponsors and manufacturers to ensure that our products are on the formulary. In addition, the Part D program also has an additional mandatory rebate during part of the year, when beneficiaries are in the Medicare Part D coverage gap. Pharmaceutical manufacturers are required to provide a discount of 70% on brand drugs used during that portion of the benefit.

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 (the "PHS") pharmaceutical pricing program ("340B") and the Federal Supply Schedule (the "FSS").

The 340B program was designed to assist safety net hospitals that serve a disproportionate share of indigent patients by requiring manufacturers, as a stipulation of participation in the Medicaid Drug Rebate Program, to provide deep discounts on covered outpatient drugs. The discounts adhere to a statutory formula, per product, that requires manufacturers to charge no more than a certain price. Entities that may apply to participate in the 340B program include qualifying hospitals, federal grantees, the Centers for Disease Control and Prevention, and the Indian Health Service.

The FSS is a list of contracts and prices for frequently used supplies and services available for purchase by federal agencies and other entities such as the U.S. territories and tribal governments. Although there are no statutory ceilings on prices, the government often uses a favored price as a starting point in negotiations to obtain below-market prices.

Health Care System Reform

For the past few years, there has been an increased focus and downward pressure on pricing which we expect to continue for a variety of circumstantial reasons. There are a number of legislative and regulatory proposals under consideration that would impact how drugs are reimbursed in the U.S., could restrict patient access, and have financial implications for manufacturers.

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 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 previously subject to revisions based on the actual prices at which the pharmaceutical products are purchased by medical institutions in Japan after discounts and rebates from the listed price, and 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. As part of these initiatives, the annual NHI price list revision was introduced in April 2021, which could lead to more frequent downward price revisions. The government is also addressing the efficient use of drugs, including the further promotion of generic use that slightly falls short of a target of 80% penetration by volume by September 2020 with respect to products for which market exclusivity has expired. In addition, a cost-effectiveness evaluation has been officially introduced by the MHLW since 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 the 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.

The EU 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.

Furthermore, certain European countries also utilize tendering to secure prescription drugs at controlled price level. Takeda often participates in tendering in these regions, which usually results in a significant price discount.

Other

Many other countries around the world are also taking steps to control prescription drug prices. For example, in 2017, China - one of the most important markets in our Growth and Emerging Markets business - 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. Furthermore, certain other countries also utilize a tendering process to control prescription drugs, in which Takeda often participates.

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 our 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, 2021, the net book values of the buildings and structures, machinery and vehicles, tools, furniture and fixtures and land we owned were 866.7 billion JPY, 311.3 billion JPY, 41.0 billion JPY and 94.8 billion JPY, respectively. We own the majority of our facilities, none of which are subject to any material encumbrances.

The following table describes our major facilities as of March 31, 2021:

<u>Group company</u>	<u>Location</u>	<u>Use of facility</u>	<u>Land Area (in square meter)</u>
Takeda Pharmaceutical Company Limited	Chuo-ku, Tokyo, Japan	Global Headquarters (Administrative and sales)	13,102
Takeda Pharmaceutical Company Limited	Chuo-ku, Osaka, Japan	Head Office ⁽¹⁾ (Administrative and sales)	443,441
Takeda Pharmaceutical Company Limited	Hikari-shi, Yamaguchi, Japan	Production, research and development	1,011,061
Takeda Pharmaceutical Company Limited	Fujisawa-shi, Kanagawa, Japan	Research and development	22,749
Millennium Pharmaceuticals, Inc.	Cambridge, MA, U.S.	Research and development, others	144,675
Takeda Ireland Limited	Kilruddery, Ireland	Production, others	202,679
Baxalta US Inc.	Covington, GA, U.S.	Production, others	507,617
Shire Human Genetic Therapies, Inc	Lexington, MA, U.S.	Production, others	399,192
Baxter AG	Vienna, Austria	Production, others	368,551
Baxalta Manufacturing S.a.r.l.	Neuchatel, Switzerland	Production, others	87,264
Baxalta Belgium Manufacturing S.A.	Lessines, Belgium	Production, others	135,538
BioLife Plasma Services LP	Bannockburn, IL, U.S.	Production, others	425,289
Baxalta Bioscience Manufacturing S.a.r.l, Singapore Branch	Singapore	Production, others	—

Notes:

(1) Head Office mainly consists of buildings, accompanying facilities and lands (includes dormitory and company housing).

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 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 Standards Board ("IASB"). IFRS includes IAS and related interpretations of the committees (SIC and IFRIC).

The following discussion and analysis contain 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 plc. ("Shire") in January 2019 (the "Shire Acquisition") strengthened our presence in Gastroenterology (GI) and Neuroscience, while providing us with a leading position in Rare Disease and Plasma-derived Therapies (PDT). Commercially, the Shire Acquisition significantly strengthened our presence in the United States, Europe and Growth and Emerging Markets. It also complemented our ongoing efforts to enhance our R&D engine. Through the Shire Acquisition, investments and our R&D partnership model, we have created a highly complementary, robust, modality-diverse pipeline.

We incurred significant indebtedness to finance the cash portion of the consideration of the Shire Acquisition. We plan to continue to reduce our debt primarily using operating cash flows which improved significantly through scale and integration synergies, allowing debt repayment, competitive R&D investment for long-term growth and commitment to our dividend and shareholder return.

Our business is organized 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. For the fiscal year ended March 31, 2021, our revenue and operating profit were 3,197.8 billion JPY and 509.3 billion JPY, respectively.

Factors Affecting Our Results of Operations

Our results are affected by global industry trends and our 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 R&D capabilities (including expanding into new methodologies) and to acquire new products (whether in the development pipeline or at the marketing stage) or enter other strategic regions. Similarly, we divest from 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 acquired and liabilities assumed 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 unwinding 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 JPY, of which 3,029.4 billion JPY was paid in cash and the remainder mainly in shares of our common stock. We incurred 3,295.9 billion JPY of indebtedness in order to finance the cash portion of the consideration, and as a result of the Shire Acquisition assumed 1,603.2 billion JPY of indebtedness from Shire which is included in our consolidated statements of financial position. During the fiscal year ended March 31, 2019, we recorded goodwill of 3,087.4 billion JPY and intangible assets of 3,899.3 billion JPY as of the acquisition date of Shire as a result of the preliminary purchase price allocation. During the fiscal year ended March 31, 2020, the purchase price allocation was completed and the fair value of assets acquired and liabilities assumed were retrospectively adjusted including retrospectively adjusted goodwill and intangible assets of 3,165.5 billion JPY and 3,769.1 billion JPY as of the acquisition date, respectively. See Note 31 to our audited consolidated financial statements for further details of completed purchase price allocation related to the Shire Acquisition.

The acquisition of Shire significantly changed our business through, among other things, the significant expansion of our product portfolio and geographic presence. Our results are 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.

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 divested from businesses and product lines to maintain our focus on our key growth drivers and provide additional cash flow to accelerate the repayment of debts. The following are major divestitures completed or announced in the fiscal years ended March 31, 2019, 2020, 2021 and through the issuance of this annual report.

- 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 Ltd.
- 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 for a sales price of 280 million USD or 30.7 billion JPY and a gain of 18.4 billion JPY was recognized in the fiscal year ended March 31, 2019.
- In July 2019, we completed the sale of XIIDRA (lifitegrast ophthalmic solution 5%) to Novartis AG for a sales price of 3,400 million USD or 375.5 billion JPY and up to additional 1,900 million USD or 210.0 billion JPY⁽¹⁾, in potential milestone receipts. The amount recognized in the consolidated statements of profit or loss as a result of the sale was immaterial.
- In March 2020, we completed the sale of select over-the-counter and non-core products in a number of Near East, Middle East and Africa countries to Acino International AG, and select over-the-counter and non-core products in Russia, Georgia, and a number of countries from within the Commonwealth of Independent States to STADA Arzneimittel AG for a sales price of both transactions totaling approximately 860 million USD or approximately 91.9 billion JPY and an impairment loss on classification as held for sale of totaling 12.9 billion JPY was recognized in the fiscal year ended March 31, 2020. The amount relating to a gain or loss on sales was immaterial.
- In November 2020, we completed the sale of a portfolio of select non-core over-the-counter and prescription pharmaceutical products sold exclusively in Asia Pacific to Celltrion Inc., for a total value of 278 million USD, or 26.8 billion JPY, inclusive of milestone payments and a gain of 15.8 billion JPY was recognized in the fiscal year ended March 31, 2021.
- In December 2020, we completed the sale of a portfolio of select non-core prescription pharmaceutical products sold predominantly in Europe and Canada to Cheplapharm for a total value of 562 million USD or 59.4 billion JPY and a gain of 21.4 billion JPY was recognized in the fiscal year ended March 31, 2021.
- In December 2020, we announced that we have entered into an agreement to divest from a portfolio of non-core prescription pharmaceutical products sold in China to Hasten Biopharmaceutic Co., Ltd. (China) for 322 million USD or 35.6 billion JPY⁽¹⁾, subject to customary legal and regulatory closing conditions.
- In January 2021, we completed the sale of a portfolio of select products sold in Latin America to Hypera S.A. for a total value of 825 million USD or 82.5 billion JPY and a gain of 35.3 billion JPY was recognized in the fiscal year ended March 31, 2021.
- In January 2021, we completed the sale of TachoSil® Fibrin Sealant Patch to Corza Health, Inc. for 350 million EUR or 42.9 billion JPY and a gain of 2.3 billion JPY was recognized in the fiscal year ended March 31, 2021.
- In March 2021, we completed the sale of a portfolio of select products to Orifarm Group for a sales price of 505 million USD or 55.8 billion JPY in cash at closing and approximately 70 million USD or 7.7 billion JPY⁽¹⁾ in non-contingent cash to be paid within four years post-closing. In addition, we may receive up to an additional 95 million USD or 10.5 billion JPY⁽¹⁾ in potential milestone receipts. Further, a gain of 14.7 billion JPY was recognized in the fiscal year ended March 31, 2021.
- In March 2021, we completed the sale of Takeda Consumer Healthcare Company Limited to Oscar A-Co KK, a company controlled by funds managed by The Blackstone Group Inc. and its affiliates for a total value of 242.0 billion JPY and a gain of 139.5 billion JPY was recognized in the fiscal year ended March 31, 2021.
- In April 2021, we completed the asset transfer associated with a portfolio of select non-core products in Japan to Teijin Pharma Limited for a total value of 133.0 billion JPY. The transaction is expected to have a favorable impact of approximately 130 billion JPY on profit (loss) before income tax for the fiscal year ending March 31, 2022.

Note:

- (1) Calculated using the Japanese yen—U.S. dollar exchange rate of 110.5 JPY and Euro exchange rate of 129.8 JPY as of March 31, 2021.

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, 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 U.S., 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 the generic drug “at risk” 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 PDT. Efforts to increase the collection of plasma may require strengthening acquisition and third-party contracting capacities and successful regulatory approval of additional plasma collection facilities and plasma fractionation facilities.

Foreign Exchange Fluctuations

In the fiscal year ended March 31, 2021, 82.5% of our revenue was from outside of Japan. 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. The following shows revenue at constant exchange rates for the year ended March 31, 2021 as compared to revenue for the year ended March 31, 2020.

	For the fiscal year ended March 31,						
	2020		2021		Change versus the previous year		
			(billions of yen, except percentages)				
Revenue	¥	3,291.2	¥	3,197.8	¥	(93.4)	(2.8)%
Effect of exchange rates				(77.2)			
Revenue at constant exchange rates		3,291.2		3,275.0		(16.2)	(0.5)%

Revenue at constant exchange rates is not a measure prepared in accordance with IFRS, or a “Non-IFRS Measure.” We strongly encourage investors to review our historical financial statements in their entirety and to use measures presented in accordance with IFRS as the primary means of evaluating our performance, value and prospects for the future, and to use this Non-IFRS Measure as a supplemental measure. The most directly comparable measure to revenue at constant exchange rate that is prepared in accordance with IFRS is revenue, and a reconciliation of revenue at constant exchange rates to revenue is shown above.

We present revenue at constant exchange rates because we believe that this measure is useful to investors to better understand the effect of exchange rates on our business, and to understand how our results of operations might have changed from year to year without the effect of fluctuations in exchange rates. These are the primary ways in which our management uses these measures to evaluate our results of operations. We also believe that this is a useful measure for investors as similar performance measures are frequently used by securities analysts, investors and other interested parties in the evaluation of the results of operations of other companies in our industry.

For a given fiscal year, revenue at constant exchange rates is defined as revenue as calculated by translating revenue of the current fiscal year using corresponding exchange rates of the previous fiscal year. The usefulness of this presentation has significant limitations including, but not limited to, that while revenue at constant exchange rates is calculated using the same exchange rates used to calculate revenue as presented under IFRS for the previous fiscal year, this does not necessarily mean that the transactions entered into during the relevant fiscal year could have been entered into or would have been recorded at the same exchange rates. Moreover, other companies in our industry using similarly titled measures may define and calculate those measures differently than we do, and therefore such measures may not be directly comparable. Accordingly, revenue at constant exchange rates should not be considered in isolation and is not, and should be viewed as, a substitute for revenue as prepared and presented in accordance with IFRS.

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 were lower in the fourth quarter of each of the fiscal years ended March 31, 2019, 2020, and 2021 partially due to wholesalers tendency to increase purchases ahead of the New Year holidays across the region, annual price increases and the reset of annual insurance deductibles in the US at the start of the calendar year.

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

Takeda's 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 Takeda expects 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 the 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 or 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 to the extent it is highly probable that a significant reversal will not occur.

Takeda's 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 judgment 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. Takeda monitors the obligation for these deductions on at least a quarterly basis and records adjustments when rebate trends, rebate programs and contract terms, legislative changes, or other significant events indicate that a change in the obligation is appropriate. Historically, adjustments to rebate accruals have not been material to net earnings. 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:** The U.S. Medicaid Drug Rebate Program is administered by state governments using state and federal funds to provide assistance to certain qualifying individuals and families, who cannot finance their own medical expenses. 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 estimated based upon identifying the products subject to a rebate, historical experience, patient demand, product pricing and the mix of contracts and specific terms in the individual state agreements. The provisions for Medicaid rebates are recorded in the same period that the corresponding revenues are recognized; however, the Medicaid rebates are not fully paid until subsequent periods. There is often a time lag of several months between Takeda recording the revenue deductions and Takeda's final accounting for Medicaid rebates. These expected product specific assumptions relate to estimating which of Takeda's revenue transactions will ultimately be subject to the U.S. Medicaid program.
- **U.S. Medicare:** 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, patient demand, product pricing and the mix of contracts. The provisions for Medicare Part D rebates are recorded in the same period that the corresponding revenues are recognized; however, the Medicare Part D rebates are not fully paid until subsequent periods. There is often a time lag of several months between Takeda recording the revenue deductions and Takeda's final accounting for Medicare Part D rebates. These expected product specific assumptions relate to estimating which of the Takeda's revenue transactions will ultimately be subject to the U.S. Medicare program.
- **Customer rebates:** Customer rebates including commercial managed care in the U.S. 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 Takeda's products. Since rebates are contractually agreed upon, the related provisions are estimated based on the terms of the individual agreements, historical experience, and patient demand. The provisions for commercial managed care rebates in the U.S. are recorded in the same period that the corresponding revenues are recognized; however, commercial managed care rebates in the U.S. are not fully paid until subsequent periods. There is often a time lag of several months between Takeda recording the revenue deductions and Takeda's final accounting for commercial managed care rebates in the U.S. These expected product specific assumptions relate to estimating which of Takeda's revenue transactions will ultimately be subject to the commercial managed care in the U.S.
- **Wholesaler chargebacks:** Takeda has 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 demand. Takeda has a legally enforceable right to set off the trade receivables and chargebacks and it intends either to settle them on a net basis or to realize the asset and settle the liability simultaneously. Thus the provision for chargebacks are recorded as a deduction from trade receivables on the consolidated statements of financial position.

- Return reserves: When Takeda sells a product providing a customer with the right to return, Takeda records a provision for estimated sales returns based on its sales return policy and historical return rates. Takeda estimates 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, expected product specific assumptions used in estimating which of Takeda's revenue transactions will ultimately be subject to the respective programs

Takeda generally receives payments from customers within 90 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 in which case 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 R&D 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 performs those transactions as a principal. Takeda also provides other services as a principal.

Impairment of 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. Intangible assets that are currently not amortized are reviewed for impairment at least annually. As of March 31, 2021, we have 3,909.1 billion JPY of intangible assets which represent 30.3% of our total assets.

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 patent life, and/or other factors depending on the expected economic benefits of the asset, ranging from 3 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.

Intangible 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. Our cash generating units or group of cash generating units are identified based on the smallest identifiable group of assets that generate independent cash inflows. 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 a change in the amount and timing of cash flows include IPR&D projects that are not successfully developed, fail during development, are abandoned or subject to significant delay or do not receive the relevant regulatory approvals and/or commercially marketed products whose value becomes impaired. 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 impairment and reversal of impairment related to intangible assets during the periods presented. See Notes 12 to our audited consolidated financial statements.

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 several assumptions including estimated future cash flows, discount rates, development and approval milestones, expected market performance and for contingent consideration; the likelihood of payment. New information about facts and circumstances existing at the acquisition date may be obtained within one year of the acquisition date that would give rise to measurement period adjustments. These adjustments may be made to the provisional fair values of assets and liabilities previously recognized or may result in the recognition of additional assets and liabilities, and they are applied on a retrospective basis with comparative prior periods revised in subsequent financial statements to include the effect of those adjustments.

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 statements of profit or loss.

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. In cases we 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, no provision is recognized for such cases. 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 statements of financial position. As of March 31, 2021, we have a provision of 73.4 billion JPY 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 record estimates based on these judgments and interpretations. In the normal course of business, our tax returns are subject to examination by various tax authorities, which may result in additional tax, interest or penalty assessment by these authorities. Inherent uncertainties exist in estimates of many uncertain 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 tax 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 tax 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. Future taxable profits according to profitability is estimated based on our business plan. The change in judgment upon determining the revenue forecast used for our business plan could have a significant impact on the amount of the deferred tax assets to be recognized. 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, 2021, we had unused tax losses, deductible temporary differences, and unused tax credits for which deferred tax assets were not recognized of 1,533.1 JPY, 241.2 billion JPY, and 9.7 billion JPY, respectively. A change in our estimates and 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 or 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 we have developed a detailed formal plan for the restructuring. The recognition of restructuring provision requires estimates including timing of payments and the number of individuals impacted by the restructuring. As a result of these estimates, the actual restructuring costs may differ from our estimates.

As of March 31, 2021, we have a provision of 32.3 billion JPY for restructuring costs. See Note 23 to our audited consolidated financial statements for a further description of our restructuring provisions and the change between periods.

Results of Operations

The following table provides selected consolidated statements of profit or loss information for the years ended March 31, 2019, 2020 and 2021.

	For the fiscal year ended March 31,					
	2019		2020		2021	
	(billions of yen)					
Revenue	¥	2,097.2	¥	3,291.2	¥	3,197.8
Cost of sales		(651.7)		(1,089.8)		(994.3)
Selling, general and administrative expenses		(717.6)		(964.7)		(875.7)
Research and development expenses		(368.3)		(492.4)		(455.8)
Amortization and impairment losses on intangible assets associated with products		(178.6)		(455.4)		(421.9)
Other operating income		159.9		60.2		318.0
Other operating expenses		(103.2)		(248.7)		(258.9)
Operating profit		237.7		100.4		509.3
Finance income		16.8		27.8		105.5
Finance expenses		(83.3)		(165.0)		(248.6)
Share of profit (loss) of investments accounted for using the equity method		(43.6)		(24.0)		0.1
Profit (loss) before tax		127.6		(60.8)		366.2
Income tax benefit		7.5		105.0		9.9
Net profit for the year	¥	135.1	¥	44.3	¥	376.2

Fiscal Year Ended March 31, 2021 compared with the Fiscal Year Ended March 31, 2020

Revenue. Revenue for the fiscal year ended March 31, 2021 was 3,197.8 billion JPY, a decrease of 93.4 billion JPY, or 2.8%, compared to the previous fiscal year.

Within our core therapeutic areas, Gastroenterology (“GI”) and Plasma-Derived Therapies (“PDT”) Immunology contributed to positive revenue growth; however, this was offset by intensified competition and generic erosion in Rare Diseases and the negative impact across the portfolio from changes in foreign exchange rates. Overall, while the global spread of COVID-19 did not have a material effect on our revenue for the fiscal year ended March 31, 2021, there were adverse effects due to COVID-19 observed in certain therapeutic areas, especially Neuroscience in which stay-at-home restrictions continued to reduce patient visits to medical care providers. This trend fluctuated throughout the fiscal year. These adverse impacts have been partially offset by benefits from prescribing trends during the pandemic, such as an expansion of certain products with a more convenient administration profile that was observed in the early phase of the outbreak.

Revenue outside of our core therapeutic areas decreased by 130.7 billion JPY, or 18.5%, mainly due to the effect of several divestitures, as well as a decline in sales of off-patented products such as ULORIC (for hyperuricemia) and COLCRYS (for gout).

The following shows revenue by geographic region:

	For the fiscal year ended March 31,					
	2020			2021		
	(billions of yen, except percentages)					
Revenue:						
Japan	¥	592.8	18.0%	¥	559.7	17.5%
United States		1,595.9	48.5		1,567.9	49.0
Europe and Canada		645.5	19.6		666.2	20.8
Russia/CIS		76.8	2.3		57.6	1.8
Latin America		143.5	4.4		121.6	3.8
Asia (excluding Japan)		165.4	5.0		156.2	4.9
Other ⁽¹⁾		71.3	2.2		68.5	2.1
Total	¥	3,291.2	100.0%	¥	3,197.8	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 table provides revenue by therapeutic area and product.

	For the Year Ended March 31,			
	2020	2021	Change versus the previous year	
	(billions of yen, except for percentages)			
Gastroenterology:				
ENTYVIO	¥ 347.2	¥ 429.3	¥ 82.1	23.6 %
TAKECAB-F ⁽¹⁾	72.7	84.8	12.1	16.7
GATTEX/REVESTIVE	61.8	64.6	2.8	4.5
DEXILANT	62.8	55.6	(7.2)	(11.5)
PANTOLOC/CONTROLOC ⁽²⁾	49.5	43.1	(6.3)	(12.8)
ALOFISEL	0.4	0.8	0.4	110.2
Others ⁽⁴⁾	103.5	99.7	(3.9)	(3.8)
Total Gastroenterology	697.9	777.8	79.9	11.4
Rare Diseases:				
Rare Metabolic:				
ELAPRASE	67.9	68.8	0.9	1.3
REPLAGAL	51.3	51.8	0.5	1.0
VPRIV	38.0	38.5	0.5	1.3
NATPARA/NATPAR	13.6	3.6	(10.1)	(74.0)
Total Rare Metabolic	170.8	162.6	(8.2)	(4.8)
Rare Hematology:				
ADVATE	157.9	128.5	(29.3)	(18.6)
ADYNOVATE/ADYNOVI	58.7	58.1	(0.6)	(1.0)
FEIBA	51.5	44.5	(7.0)	(13.6)
RECOMBINATE	17.1	13.4	(3.7)	(21.6)
Others ⁽⁴⁾	49.1	45.3	(3.8)	(7.7)
Total Rare Hematology	334.2	289.8	(44.4)	(13.3)
Hereditary Angioedema:				
TAKHZYRO	68.3	86.7	18.4	27.0
FIRAZYR	32.7	26.8	(5.8)	(17.9)
Others ⁽⁴⁾	28.9	25.8	(3.1)	(10.8)
Total HAE (Hereditary Angioedema)	129.8	139.3	9.5	7.3
Total Rare Diseases	634.9	591.7	(43.1)	(6.8)
PDT Immunology:				
immunoglobulin	298.7	334.9	36.2	12.1
albumin	67.2	57.6	(9.6)	(14.3)
Others ⁽⁴⁾	28.3	27.9	(0.3)	(1.1)
Total PDT Immunology	394.2	420.4	26.2	6.7
Oncology:				
VELCADE	118.3	101.1	(17.2)	(14.5)
LEUPLIN/ENANTONE	109.0	95.4	(13.7)	(12.5)
NINLARO	77.6	87.4	9.8	12.7
ADCETRIS	52.7	59.4	6.8	12.8
ICLUSIG	31.8	34.2	2.4	7.5
ALUNBRIG	7.2	8.8	1.6	21.7

Others ⁽⁴⁾	24.3	30.2	5.9	24.3
Total Oncology	421.0	416.5	(4.4)	(1.1)
Neuroscience:				
VYVANSE/ELVANSE	274.1	271.5	(2.5)	(0.9)
TRINTELLIX	70.7	68.9	(1.8)	(2.5)
Others ⁽⁴⁾	93.8	76.9	(16.9)	(18.0)
Total Neuroscience	438.5	417.3	(21.2)	(4.8)
Other:				
AZILVA-F ⁽¹⁾	76.7	82.2	5.5	7.1
NESINA/VIPIDIA-F ⁽¹⁾	58.0	57.7	(0.3)	(0.5)
LOTRIGA	31.8	31.8	0.0	0.0
Others ⁽³⁾⁽⁴⁾	538.3	402.4	(135.9)	(25.2)
Total Other	704.8	574.1	(130.7)	(18.5)
Total	¥ 3,291.2	¥ 3,197.8	¥ (93.4)	(2.8)%

Notes:

- (1) The figures include the amounts of fixed dose combinations and blister packs.
- (2) Generic name: pantoprazole
- (3) The figures include the revenue of Takeda Consumer Healthcare Company Limited, which was divested on March 31, 2021.
- (4) Products that are not individually listed in the table above are included in “Others” of each respective therapeutic area.

Year-on-year change in revenue for the fiscal year ended March 31, 2021 in each of our main therapeutic areas was primarily attributable to the following products:

- *GI*. In Gastroenterology, revenue was 777.8 billion JPY, a year-on-year increase of 79.9 billion JPY, or 11.4%. Growth was driven by Takeda's top-selling product ENTYVIO (for ulcerative colitis (“UC”) and Crohn’s disease (“CD”)), with sales of 429.3 billion JPY, a year-on-year increase of 82.1 billion JPY, or 23.6%. Sales in the U.S. increased by 55.0 billion JPY, or 23.0%, to 294.3 billion JPY and sales in Europe and Canada increased by 21.0 billion JPY, or 23.9%, versus the previous fiscal year to 108.9 billion JPY, respectively, due to an increase in demand. In Japan, the increase in sales was primarily driven by the UC indication. Sales of TAKECAB (for acid-related diseases) were 84.8 billion JPY, an increase of 12.1 billion JPY, or 16.7%, versus the previous fiscal year. This 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 and duodenal ulcers during low-dose aspirin administration. Sales of RESOLOR/MOTEGRITY (for chronic idiopathic constipation), increased by 4.7 billion JPY, or 71.2%, versus the previous fiscal year to 11.2 billion JPY, driven by further penetration into the U.S. market. Sales of GATTEX/REVESTIVE (for short bowel syndrome) increased by 2.8 billion JPY, or 4.5%, versus the previous fiscal year to 64.6 billion JPY, primarily due to increased average length of time on therapy for the adult population and increased volume of pediatric patients on therapy. Growth of ENTYVIO, TAKECAB, RESOLOR/MOTEGRITY and GATTEX/REVESTIVE fully absorbed the net decrease of other GI products such as off-patented PANTOLOC/CONTROLOC (generic name: pantoprazole) (for peptic ulcer), which declined by 6.3 billion JPY, as well as declines of DEXILANT (for acid reflux disease) by 7.2 billion JPY and AMITIZA (for chronic constipation) by 6.9 billion JPY primarily due to intensified competition coupled with the negative impact of the appreciation of the yen.
- *Rare Diseases*. In Rare Diseases, revenue decreased by 43.1 billion JPY, or 6.8%, to 591.7 billion JPY. Revenue in Rare Hematology decreased by 44.4 billion JPY, or 13.3%, to 289.8 billion JPY. Sales of ADVATE decreased by 29.3 billion JPY, or 18.6%, to 128.5 billion JPY and sales of ADYNOVATE decreased by 0.6 billion JPY, or 1.0%, to 58.1 billion JPY, respectively, primarily driven by the competitive landscape in the hemophilia A non-inhibitors market in the U.S. FEIBA sales decreased by 7.0 billion JPY, or 13.6%, to 44.5 billion JPY mainly due to competitive pressure in the prophylaxis segment of the inhibitors market in Europe. Revenue in Rare Metabolic decreased by 8.2 billion JPY, or 4.8%, to 162.6 billion JPY primarily due to the product recall of NATPARA (for hypoparathyroidism) in the U.S. in September 2019, which resulted in a decline of NATPARA/NATPAR sales of 10.1 billion JPY, or 74.0%, to 3.6 billion JPY. Revenue in Hereditary Angioedema (“HAE”) was 139.3 billion JPY, a year-on-year increase of 9.5 billion JPY, or 7.3%, driven by TAKHZYRO launches with strong patient uptake partially offset by the decreases in sales of FIRAZYR and CINRYZE. Sales of TAKHZYRO were 86.7 billion JPY, an increase of 18.4 billion JPY, or 27.0%, versus the previous fiscal year. Sales of FIRAZYR decreased by 5.8 billion JPY, or 17.9%, to 26.8 billion JPY, due to the continued impact of generic entrants and patient switches to TAKHZYRO. Sales of CINRYZE decreased by 2.5 billion JPY, or 10.2%, to 21.9 billion JPY, mainly due to patient switches to TAKHZYRO.
- *PDT Immunology*. In Plasma-Derived Therapies (“PDT”) Immunology, revenue increased by 26.2 billion JPY, or 6.7%, to 420.4 billion JPY. Aggregate sales of immunoglobulin products were 334.9 billion JPY, an increase of 36.2 billion JPY, or 12.1%, fueled by strong demand and

growing supply capabilities. In particular, GAMMAGARD LIQUID (for the treatment of primary immunodeficiency (“PID”) and multifocal motor neuropathy (“MMN”)) continued to build its position as a highly recognized IVIG (intravenous immunoglobulin) therapy that is the standard of care treatment for PID and MMN in the U.S. CUVITRU and HYQVIA, SCIG (subcutaneous immunoglobulin) therapies also marked double digit growth. Aggregate sales of albumin products including HUMAN ALBUMIN and FLEXBUMIN (primarily used for hypovolemia and hypoalbuminemia) were 57.6 billion JPY, a decrease of 9.6 billion JPY, or 14.3%, versus the previous fiscal year. The decline was partially due to the timing of shipments in China (higher sales in China during the first six-months of the previous fiscal year resulting from a supply phasing from the fiscal year prior to that) and partially due to a temporary interruption in submitting batches of HUMAN ALBUMIN for release in China which impacted sales during the second half of the fiscal year.

- **Oncology.** In Oncology, revenue was 416.5 billion JPY, a year-on-year decrease of 4.4 billion JPY, or 1.1%. Sales of NINLARO (for multiple myeloma) were 87.4 billion JPY, an increase of 9.8 billion JPY, or 12.7%, versus the previous fiscal year, reflecting strong growth in global sales particularly in the U.S. and China, driven in part by its oral administration profile that is more attractive or convenient in light of the spread of COVID-19 beginning in the first few months of the fiscal year. NINLARO is a once-weekly oral tablet that can be taken at home, which may reduce some of the logistical burden for patients as its administration does not require an infusion or injection at a hospital, clinic or physician’s office. Sales of ADCETRIS (for malignant lymphomas) increased by 6.8 billion JPY, or 12.8% to 59.4 billion JPY versus the previous fiscal year, reflecting strong growth in sales particularly in Japan where it has progressively expanded its approved indications in recent years. Sales of ICLUSIG (for leukemia) increased by 2.4 billion JPY, or 7.5%, versus the previous fiscal year to 34.2 billion JPY, benefiting from a new omnichannel promotion approach in the U.S. and from geographic expansion outside the U.S. Sales of ALUNBRIG (for non-small cell lung cancer) increased by 1.6 billion JPY, or 21.7%, versus the previous fiscal year to 8.8 billion JPY, as it continues to launch in European and emerging countries. Sales of VELCADE (for multiple myeloma) decreased by 17.2 billion JPY, or 14.5% to 101.1 billion JPY. This included royalty income of 4.8 billion JPY outside the U.S., a significant year-on-year decrease of 4.7 billion JPY, or 49.4%, due to generic entrants in Europe and China in 2019. Sales in the U.S. decreased by 12.5 billion JPY, or 11.5%, to 96.3 billion JPY versus the previous fiscal year, reflecting fewer new patient starts in first-line therapy. We believe this was a consequence of patients refraining from visiting medical care providers due to COVID-19 as well as the launch of a competitor’s subcutaneous formulation at the beginning of May 2020 in the U.S. Sales of LEUPLIN/ENANTONE (generic name: leuprorelin) (for endometriosis, uterine fibroids, premenopausal breast cancer, prostatic cancer, etc.), an off-patented product, decreased by 13.7 billion JPY, or 12.5%, versus the previous fiscal year to 95.4 billion JPY. This is in relation to production stoppages initiated at our manufacturing facility in Japan to enhance overall compliance in alignment with Takeda standards.
- **Neuroscience.** In Neuroscience, revenue was 417.3 billion JPY, a year-on-year decrease of 21.2 billion JPY, or 4.8%. This decrease was partially attributable to REMINYL (for Alzheimer’s disease), which faced the introduction of generic competitors in Japan in June 2020, and sales of which decreased by 10.1 billion JPY, or 58.3%, to 7.2 billion JPY. Sales of ROZEREM (for insomnia) decreased by 2.5 billion JPY, or 17.0%, to 12.0 billion JPY that was also negatively impacted by the loss of exclusivity in the U.S. in July 2019. Sales of ADDERALL XR (for attention deficit hyperactivity disorder (“ADHD”)) were 17.8 billion JPY, a decrease of 6.5 billion JPY, or 26.9%, primarily due to the continued impact of competition from generic entrants in the period. Sales of VYVANSE (for ADHD) were 271.5 billion JPY, a decrease of 2.5 billion JPY, or 0.9%, versus the previous fiscal year. Sales of TRINTELLIX (for major depressive disorder (“MDD”)) were 68.9 billion JPY, a decrease of 1.8 billion JPY, or 2.5%, versus the previous fiscal year. Sales of VYVANSE and TRINTELLIX have been negatively affected by COVID-19 most notably during periods when stay-at-home restrictions were in place reducing patient visits, subsequent diagnoses and creating temporary discontinuation of medication. The trend temporarily normalized to pre-COVID-19 levels, but has been affected again in the latest six-month period as transmission has increased in countries where Takeda markets these products. The decrease of these products was partially offset by the increase of INTUNIV (for ADHD) with its sales increased by 5.8 billion JPY, or 39.5%, to 20.4 billion JPY versus the previous fiscal year, primarily due to an increase in Japan driven by strong growth in demand coupled with stock-building by the licensee due to COVID-19.

Cost of Sales. Cost of Sales decreased by 95.5 billion JPY, or 8.8%, to 994.3 billion JPY and the Cost of Sales Ratio decreased by 2.0 percentage point to 31.1% for the fiscal year ended March 31, 2021. This was primarily caused by 118.3 billion JPY decrease in non-cash charges related to the unwind of the fair value step up on acquired inventory recognized in connection with the Shire Acquisition. These effects were partially offset by an increase in remaining Cost of Sales due to decline in high-margin products sales including off-patent products such as COLCRYS and VELCADE.

Selling, General and Administrative (SG&A) expenses. SG&A expenses decreased by 89.1 billion JPY, or 9.2%, to 875.7 billion JPY for the fiscal year ended March 31, 2021, primarily due to the favorable impact from cost efficiencies and synergies from the integration of Shire and lower spend resulting from COVID-19 such as less travel and fewer commercial events.

Research and Development (R&D) expenses. R&D expenses decreased by 36.5 billion JPY, or 7.4%, to 455.8 billion JPY, mainly due to lower costs related to pipeline prioritization and travel expenses resulting from COVID-19 partially offset by an increase in expenditures on certain R&D program including new candidates in preclinical studies.

Amortization and Impairment Losses on Intangible Assets Associated with Products. Amortization and Impairment Losses on Intangible Assets Associated with Products decreased by 33.6 billion JPY, or 7.4%, to 421.9 billion JPY for the fiscal year ended March 31, 2021. This decrease is primarily attributable to an impairment charge of intangible assets related to in-process research and development recognized in the previous fiscal year, including TAK-616 AMR triggered by our decision to terminate the program following the interim readout in May 2019, and TAK-607 due to a change in study design in March 2020.

Other Operating Income. Other Operating Income increased by 257.8 billion JPY, or 428.2%, to 318.0 billion JPY for the fiscal year ended March 31, 2021, predominantly driven by a 228.9 billion JPY divestiture gain from 139.5 billion JPY gain on sale of shares and relevant assets of Takeda Consumer Healthcare Company Limited and other non-core assets amounting to 89.4 billion JPY recorded in the current fiscal year. In addition, a 60.2 billion JPY revaluation gain triggered by an update to previously recognized liabilities for pipeline compound SHP647 and certain associated rights ("SHP647") to reflect management's decision to terminate the clinical trial program related to SHP647 upon the European Commission's decision in May 2020 to release Takeda's obligation to divest SHP647. The increase was partially offset by 12.7 billion JPY decrease in deferred gain due to an impairment of intangible assets related to long-listed products business transferred to Teva Takeda Pharma Ltd, a business venture of Takeda and Teva Pharmaceutical Industries Ltd, recorded in the previous fiscal year.

Other Operating Expenses. Other Operating Expenses were 258.9 billion JPY, an increase of 10.2 billion JPY, or 4.1%, for the fiscal year ended March 31, 2021. The increase mainly includes a 72.9 billion JPY loss recognized for the current fiscal year from changes in the fair value of contingent consideration assets from the previous sale of XIIDRA, and a 65.2 billion JPY decrease in restructuring expenses mainly comprised of Shire integration costs as an offset of the increase. The change in the fair value of the assets associated with contingent consideration arrangements is driven by changes in assumptions related to the future sales of XIIDRA, including the impact from Novartis' withdrawal of the Marketing Authorisation Application in Europe.

Operating Profit. As a result of the above factors, Operating Profit increased by 408.9 billion JPY, or 407.2% for the fiscal year ended March 31, 2021 to 509.3 billion JPY.

Net Finance Expenses. Net Finance Expenses were 143.1 billion JPY in the current year, an increase of 5.9 billion JPY compared to the previous fiscal year. This increase was due primarily to 11.0 billion JPY lower derivative gain in financial income recognized on the warrant to purchase stocks of a company that went public in October 2019 compared to the previous fiscal year partially offset by decrease in net interest expense.

Share of Profit of Investments Accounted for Using the Equity Method. Share of Profit of Investments Accounted for Using the Equity Method was 0.1 billion JPY compared to Share of Loss of Investments Accounted for Using the Equity Method of 24.0 billion JPY for the previous fiscal year, mainly due to a decrease of loss related to Takeda's shareholding ratio of impairment loss recognized by Teva Takeda Pharma Ltd. and a share of profit on the investment held by Takeda Ventures, Inc. recorded for the current fiscal year. The impairment loss recognized by Teva Takeda Pharma Ltd. for the current fiscal year was recorded resulting from the reassessment of the recoverable amount of relevant assets triggered by the decision made to divest a part of its generics business and a manufacturing plant, as well as by a revision of forecast in the long-listed drug business.

Income Tax Benefit. Income Tax Benefit was 9.9 billion JPY for the fiscal year ended March 31, 2021, compared to income tax benefit of 105.0 billion JPY for the previous fiscal year. This was mainly due to higher pretax earnings in the current fiscal year, the recognition of a non-cash deferred tax benefit of 94.6 billion JPY as a result of the enactment of a new taxing regime in Switzerland (Swiss Tax Reform) in the previous fiscal year, and the tax impacts of divestitures. These unfavorable changes were partially offset by favorable mix of statutory earnings, tax benefits from the recognition of previously unrecognized deferred tax assets, and favorable audit settlements in the current fiscal year.

Net Profit for the Year. Net Profit for the Year increased by 331.9 billion JPY, or 749.3% for the fiscal year ended March 31, 2021 to 376.2 billion JPY.

Fiscal Year Ended March 31, 2020 compared with the Fiscal Year Ended March 31, 2019

Revenue. Revenue for the fiscal year ended March 31, 2020 was 3,291.2 billion JPY, an increase of 1,194.0 billion JPY, or 56.9%, compared to the previous fiscal year. Revenue from the products obtained through the Shire Acquisition, which totaled 1,522.2 billion JPY, an increase of 1,213.0 billion JPY reflecting a full year of contribution to revenue, was the main driver of revenue growth.

The following shows revenue by geographic region:

	For the fiscal year ended March 31,			
	2019		2020	
	(billions of yen, except percentages)			
Revenue:				
Japan	¥	571.0	27.2%	¥ 592.8 18.0%
United States		829.0	39.5	1,595.9 48.5
Europe and Canada		405.6	19.3	645.5 19.6
Russia/CIS		59.7	2.8	76.8 2.3
Latin America		88.1	4.2	143.5 4.4
Asia (excluding Japan)		105.4	5.0	165.4 5.0
Other ⁽¹⁾		38.3	1.8	71.3 2.2
Total	¥	2,097.2	100.0%	¥ 3,291.2 100.0%

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 table provides revenue by therapeutic area and product.

	For the Year Ended March 31					
	2019		2020		Change versus the previous year	
	(billions of yen, except for percentages)					
Gastroenterology:						
ENTYVIO	¥	269.2	¥	347.2	¥	78.0 29.0 %
TAKECAB-F ⁽¹⁾		58.2		72.7		14.5 24.8
DEXILANT		69.2		62.8		(6.4) (9.2)
GATTEX/REVESTIVE		12.8		61.8		49.1 384.7
PANTOLOC/CONTROLOC ⁽²⁾		61.6		49.5		(12.2) (19.7)
ALOFISEL		0.0		0.4		0.3 728.9
Others		68.3		103.5		35.3 51.7
Total Gastroenterology		539.3		697.9		158.6 29.4
Rare Diseases:						
Rare Metabolic:						
ELAPRASE		15.1		67.9		52.8 350.3
REPLAGAL		11.4		51.3		39.8 348.1
VPRIV		8.7		38.0		29.3 337.5
NATPARA/NATPAR		7.1		13.6		6.5 92.2
Total Rare Metabolic		42.3		170.8		128.5 303.8
Rare Hematology:						
ADVATE		32.1		157.9		125.8 391.8
ADYNOVATE/ADYNOVI		10.7		58.7		47.9 446.3
FEIBA		9.6		51.5		41.9 434.7
Others		14.2		66.2		52.0 365.2
Total Rare Hematology		66.7		334.2		267.5 401.1

Hereditary Angioedema:				
TAKHZYRO	9.7	68.3	58.5	601.8
FIRAZYR	6.4	32.7	26.2	409.1
CINRYZE	3.1	24.3	21.2	684.4
KALBITOR	1.2	4.5	3.4	289.2
Total HAE (Hereditary Angioedema)	20.4	129.8	109.4	535.9
Total Rare Diseases	129.4	634.9	505.5	390.6
PDT Immunology:				
immunoglobulin	73.5	298.7	225.2	306.6
albumin	12.3	67.2	54.9	446.5
Others	7.7	28.3	20.5	266.0
Total PDT Immunology	93.5	394.2	300.7	321.7
Oncology:				
VELCADE	127.9	118.3	(9.5)	(7.5)
LEUPLIN/ENANTONE	110.1	109.0	(1.0)	(0.9)
NINLARO	62.2	77.6	15.4	24.7
ADCETRIS	42.9	52.7	9.8	22.8
ICLUSIG	28.7	31.8	3.1	10.8
ALUNBRIG	5.2	7.2	2.0	39.2
Others	22.5	24.3	1.8	7.9
Total Oncology	399.4	421.0	21.5	5.4
Neuroscience:				
VYVANSE/ELVANSE	49.4	274.1	224.7	455.3
TRINTELLIX	57.6	70.7	13.1	22.8
ADDERALL XR	5.4	24.3	18.9	349.7
Others	42.4	69.5	27.1	64.0
Total Neuroscience	154.7	438.5	283.9	183.5
Other:				
AZILVA-F ⁽¹⁾	70.8	76.7	6.0	8.5
NESINA/VIPIDIA-F ⁽¹⁾	54.8	58.0	3.2	5.8
LOTRIGA	30.9	31.8	0.9	2.9
Others	624.5	538.3	(86.2)	(13.8)
Total Other	780.9	704.8	(76.1)	(9.8)
Total	¥ 2,097.2	¥ 3,291.2	¥ 1,194.0	56.9 %

Note:

- (1) The figures include the amounts of fixed dose combinations and blister packs.
- (2) Generic name: pantoprazole

Year-on-year change in revenue for the fiscal year ended March 31, 2020 in each of our main therapeutic areas was primarily attributable to the following products:

- *GI*. In Gastroenterology, revenue was 697.9 billion JPY, a year-on-year increase of 158.6 billion JPY, or 29.4%. Growth was driven by ENTIVIO (for ulcerative colitis (“UC”) and Crohn’s disease (“CD”)), Takeda’s top-selling product, with sales of 347.2 billion JPY, a year-on-year increase of 78.0 billion JPY, or 29.0%. Market share growth in the U.S. and in Europe was driven by further penetration in the bio-naïve segment in UC and CD, combined with increased overall market share. In Japan, it obtained an additional indication for CD in the first quarter of the fiscal year ended March 31, 2020. Sales of TAKECAB (for acid-related diseases) were 72.7 billion JPY, an increase of 14.5 billion JPY, or 24.8% versus the previous fiscal 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 and duodenal ulcers during low-dose aspirin administration. The contribution of sales of GATTEX/REVESTIVE (for short bowel syndrome), obtained through the acquisition of Shire, increased by 49.1 billion JPY to 61.8 billion JPY for this fiscal year, reflecting its first full year contribution to revenue.
- *Rare Diseases*. Our Rare Disease products, obtained through the Shire Acquisition, increased by 505.5 billion JPY to 634.9 billion JPY for the fiscal year ended March 31, 2020, reflecting their first full year contribution to revenue. Sales of the biggest contributors in each therapeutic area

were 157.9 billion JPY of ADVATE in Rare Hematology (for hemophilia A), 68.3 billion JPY of TAKHZYRO, a prophylaxis against Hereditary Angioedema, and 67.9 billion JPY of ELAPRASE in Rare Metabolic (for Hunter syndrome), with growth of 125.8 billion JPY, 58.5 billion JPY, and 52.8 billion JPY, respectively.

- *PDT Immunology.* In PDT Immunology, revenue increased by 300.7 billion JPY compared to the previous fiscal year to 394.2 billion JPY, predominantly due to the addition of products obtained through the Shire Acquisition. The revenue includes product sales of a subsidiary, Nihon Pharmaceutical Co., Ltd., which has been engaging in PDT business in Japan since before the Shire Acquisition. Aggregate sales of immunoglobulin products were 298.7 billion JPY. The biggest contributor was GAMMAGARD LIQUID (mainly for the treatment of primary immunodeficiency (“PID”) and multifocal motor neuropathy (“MMN”)), a highly recognized intravenous immunoglobulin brand that is the standard of care treatment for PID and MMN in the U.S. Aggregate sales of albumin products including ALBUMIN GLASS and FLEXBUMIN (primarily used for hypovolemia and hypoalbuminemia) were 67.2 billion JPY and other PDT immunology products added 28.3 billion JPY of aggregate sales.
- *Oncology.* In Oncology, revenue was 421.0 billion JPY, a year-on-year increase of 21.5 billion JPY, or 5.4%. Sales of NINLARO (for multiple myeloma) were 77.6 billion JPY, an increase of 15.4 billion JPY, or 24.7%, versus the previous fiscal year, reflecting strong growth in global sales particularly in the U.S. and China. Additionally, sales of ADCETRIS (for malignant lymphomas) increased by 9.8 billion JPY, or 22.8%, to 52.7 billion JPY, reflecting strong growth in sales particularly in Japan where it has obtained an additional indication as a frontline treatment option for CD30-positive Hodgkin lymphoma. Revenue attributable to ALUNBRIG (for non-small cell lung cancer) increased by 2.0 billion JPY, or 39.2%, to 7.2 billion JPY, as it continues to launch in European countries. Sales of VELCADE (for multiple myeloma), a product which accounts for a large portion of revenue in Oncology, decreased by 9.5 billion JPY, or 7.5% compared to the previous fiscal year to 118.3 billion JPY, of which ex-U.S. royalty income was 9.6 billion JPY, a significant year-on-year decrease of 12.7 billion JPY, or 57.0%. Sales in the U.S. was increased by 3.1 billion JPY, or 2.9%, to 108.8 billion JPY, due to lesser impact than expected from additional competitor’s product in the market.
- *Neuroscience.* In Neuroscience, revenue was 438.5 billion JPY, a year-on-year increase of 283.9 billion JPY, or 183.5%. This increase was largely attributable to the neuroscience portfolio obtained through the Shire Acquisition, including VYVANSE (for attention deficit hyperactivity disorder (“ADHD”)) which increased by 224.7 billion JPY to 274.1 billion JPY for the fiscal year ended March 31, 2020, reflecting its first full year contribution to revenue. Sales of TRINTELLIX (for major depressive disorder (“MDD”)), which is a legacy Takeda product, were 70.7 billion JPY, an increase of 13.1 billion JPY, or 22.8%, versus the previous fiscal year driven by increase in new patients and improved persistence on therapy. Both brands were launched in Japan in the third quarter of the fiscal year ended March 31, 2020.

Cost of Sales. Cost of Sales increased by 438.0 billion JPY, or 67.2%, to 1,089.8 billion JPY for the fiscal year ended March 31, 2020. This increase was primarily caused by the inclusion of full year Cost of Sales related to the sale of products obtained through the Shire Acquisition and increase by 125.7 billion JPY in non-cash charges, mainly from the unwind of the fair value step up on acquired inventory recognized in connection with the Shire Acquisition. These effects were partially offset by a decrease in Cost of Sales for legacy Takeda products, primarily due to a more favorable product mix.

Selling, General and Administrative (“SG&A”) expenses. SG&A expenses increased by 247.1 billion JPY, or 34.4%, to 964.7 billion JPY for the fiscal year ended March 31, 2020, mainly due to expenses relating to the acquired operations of Shire. This increase was partially offset by the favorable impact of the Global Opex Initiative* and cost synergies from the integration of Shire. In addition, there was a 23.8 billion JPY of costs related to the Shire Acquisition incurred in the fiscal year ended March 31, 2019.

* Takeda’s global operating expense reduction initiative with the aim of delivering annual margin improvements driven by reduced consumption, procurement initiatives and organizational optimization.

Research and Development expenses. R&D expenses increased by 124.1 billion JPY, or 33.7%, to 492.4 billion JPY, primarily resulting from costs for the R&D programs acquired from Shire.

Amortization and Impairment Losses on Intangible Assets Associated with Products. Amortization and Impairment Losses on Intangible Assets Associated with Products increased by 276.8 billion JPY, or 155.0%, to 455.4 billion JPY for the fiscal year ended March 31, 2020, primarily attributable to 250.6 billion JPY increase in amortization of intangible assets related to the assets obtained through the Shire Acquisition. Impairment charges increased by 34.7 billion JPY from the previous fiscal year to 43.3 billion JPY. Those charges were related to certain marketed products and IPR&D assets, including a 15.6 billion JPY impairment charge related to our decision to terminate the TAK-616 AMR program following the interim readout in May 2019 and a 10.9 billion JPY impairment charge due to a change in study design related to TAK-607. Impairment charges recorded in the fiscal year ended March 31, 2019 were 8.6 billion JPY, with 7.2 billion JPY of such impairment relating to the termination of an R&D collaboration with Mersana Therapeutics.

Other Operating Income. Other Operating Income decreased by 99.7 billion JPY, or 62.3%, to 60.2 billion JPY for the fiscal year ended March 31, 2020. This decrease was primarily due to a 50.3 billion JPY gain on sale of property, plant and equipment and investment property including the building of Takeda’s previous headquarters in Tokyo and a 38.2 billion JPY gain on sale of shares of the subsidiary related to real estate businesses, recorded in the fiscal year ended March 31, 2019. In addition, the decrease was also due to an 18.4 billion JPY gain on the sale of 100% of the shares held in Guangdong Techpool Bio-Pharma Co., LTD. recorded in the previous fiscal year.

Other Operating Expenses. Other Operating Expenses were 248.7 billion JPY for the fiscal year ended March 31, 2020, an increase of 145.5 billion JPY, or 141.1%, compared to the previous fiscal year, primarily due to an increase of 98.1 billion JPY to 181.0 billion JPY in restructuring expenses for the current fiscal year compared to the previous fiscal year. The increase in restructuring expenses was mainly resulted from an increase of 75.7 billion JPY to 135.4 billion JPY in Shire integration costs compared to the previous fiscal year driven by the progress of the

Shire integration including site restructuring resulted in an impairment charge of a manufacturing facility in Ireland. The increase was also due to impairment of property, plant & equipment relating to the pending sale and leaseback of our Shonan iPark. The valuation reserve for pre-launch inventories was also negatively impacted by 34.5 billion JPY comprised of 30.4 billion JPY recorded for the current fiscal year whereas 4.1 billion JPY reversal of valuation reserve for pre-launch inventories recorded in the fiscal year ended March 31, 2019.

Operating Profit. As a result of the above factors, Operating Profit decreased by 137.3 billion JPY, or 57.8%, to 100.4 billion JPY for the fiscal year ended March 31, 2020.

Net Finance Expenses. Net Finance Expenses were 137.2 billion JPY for the fiscal year ended March 31, 2020, an increase of 70.7 billion JPY compared to the previous fiscal year, mainly due to an increase of 100.8 billion JPY interest expenses on bonds and loans issued to finance the Shire Acquisition. This increase of interest expenses was partially offset by 16.1 billion JPY in financing fees related to the bridge loan associated with the Shire Acquisition recorded in the fiscal year ended March 31, 2019 and a 21.3 billion JPY gain recognized on the warrant to purchase stocks of a privately held company upon that company's initial public offering for the fiscal year ended March 31, 2020.

Shares of Loss of Investments Accounted for Using the Equity Method. Shares of Loss of Investments Accounted for Using the Equity Method was 24.0 billion JPY for the fiscal year ended March 31, 2020, a decrease of 19.6 billion JPY, or 45.0% compared to the previous fiscal year, mainly due to a decrease of impairment charge recognized by Teva Takeda Pharma Ltd.

Income Tax Benefit. Income Tax Benefit was 105.0 billion JPY for the fiscal year ended March 31, 2020, compared to income tax benefit of 7.5 billion JPY for the previous fiscal year. This was mainly due to a non-cash deferred tax benefit of 94.6 billion JPY as a result of enactment of tax reform in Switzerland in the fiscal year ended March 31, 2020. The higher income tax benefit was also due to recognition of deferred tax assets for accumulated net operating loss, and lower pre-tax earnings primarily from expenses such as amortization expense, inventory unwind and integration costs related to the Shire Acquisition. These favorable changes were partially offset by higher tax provisions for uncertain tax positions and tax impacts of restructuring.

Net Profit for the Year. Net Profit for the Year decreased by 90.8 billion JPY, or 67.2%, compared to the previous fiscal year to 44.3 billion JPY.

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 R&D 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 statements of financial position, were 244.6 billion JPY and 246.3 billion JPY and 330.7 billion JPY for the fiscal years ended March 31, 2019, 2020 and 2021, respectively. As of March 31, 2021, we had contractual commitments for the acquisition of property, plant and equipment of 18.9 billion JPY. In addition, we had certain contractual agreements related to the acquisition of intangible assets as of March 31, 2021. See Note 32 to our consolidated financial statements for a description of our milestone payments of intangible assets. As part of our capital management, we periodically assess our level of capital expenditures in light of capital needs, market and other conditions and other relevant factors.

Our dividend payments for the fiscal years ended March 31, 2019, 2020 and 2021 were 143.0 billion JPY, 282.7 billion JPY and 283.7 billion JPY, respectively. It is our intention to continue to return capital to shareholders using dividends at an annual level of 180 JPY per share, consisting of interim and fiscal year-end dividends of 90 JPY 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, 2021, we had 99.4 billion JPY of interest due within one year and 243.2 billion JPY of principal payments on our borrowings due within one year. See "*Borrowings and Financial Obligations.*"

Our primary 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 that includes bonds from the global capital markets. Additionally, we have access to short-term uncommitted borrowing lines of 150 billion JPY and 750 million USD from financial institutions as of March 31, 2020 and 2021, respectively.

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.

We do not currently anticipate experiencing funding or liquidity shortfalls in the short term as a result of the spread of COVID-19 and the related effects on financial and other markets, although we continue to closely monitor our funding situation and market conditions. In addition to the ability to seek additional funding (if needed) from market and other sources, we may also manage our funding and liquidity needs by reconsidering, to the extent necessary and appropriate, our capital expenditure plans.

As of March 31, 2021, we held 966.2 billion JPY in cash and cash equivalents on hand of which 177.5 billion JPY related to deposits restricted to certain vaccine operations, in addition to 700 billion JPY in an undrawn bank 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, 2019, 2020 and 2021:

	For the fiscal year ended March 31,		
	2019	2020	2021
	(billions of yen)		
Net cash from operating activities	¥ 328.5	¥ 669.8	¥ 1,010.9
Net cash from (used in) investing activities	(2,835.7)	292.1	393.5
Net cash from (used in) financing activities	2,946.2	(1,005.2)	(1,088.4)
Net increase (decrease) in cash and cash equivalents	¥ 439.0	¥ (43.3)	¥ 316.1
Cash and cash equivalents at the beginning of the year	294.5	702.1	637.6
Effects of exchange rate changes on cash and cash equivalents	(31.3)	(21.8)	12.5
Net increase (decrease) in cash and cash equivalents resulting from a transfer to assets held for sale	(0.2)	0.6	—
Cash and cash equivalents at the end of the year	¥ 702.1	¥ 637.6	¥ 966.2

Fiscal Year Ended March 31, 2021 compared with the Fiscal Year Ended March 31, 2020

Net cash from operating activities was 1,010.9 billion JPY for the fiscal year ended March 31, 2021 compared to 669.8 billion JPY for the fiscal year ended March 31, 2020. The increase of 341.2 billion JPY was mainly due to a 331.9 billion JPY increase in net profit for the year. In addition, there was an increase in other financial liabilities of 166.2 billion JPY primarily attributable to an increase of deposits restricted to certain vaccines operations, and an increase of other favorable adjustments including a 95.1 billion JPY decrease in income tax benefit mainly due to an increase in deferred tax which is a non-cash expense. These increases were partially offset by an increase of unfavorable adjustments including a 213.2 billion JPY increase in gain on divestment of business and subsidiaries as well as an unfavorable impact of 111.5 billion JPY from a decrease in inventories in the current fiscal year due to a decrease of the unwind of the fair value step up on acquired inventory recorded in relation to the Shire Acquisition.

Net cash from investing activities was 393.5 billion JPY for the fiscal year ended March 31, 2021 compared to 292.1 billion JPY for the fiscal year ended March 31, 2020. This increase of 101.4 billion JPY was mainly due to an increase in proceeds from sales of business of 68.8 billion JPY reflecting the sale of shares of Takeda Consumer Healthcare Company Limited and other non-core assets in the current fiscal year compared to the sale of XIIDRA in the previous fiscal year. There was also an increase in proceeds from sales and redemption of investments of 25.2 billion JPY and an increase in proceeds from sales of property, plant and equipment of 33.9 billion JPY. These increases were partially offset by other decreases including 34.6 billion JPY decrease due to an increase of acquisition of intangible assets.

Net cash used in financing activities was 1,088.4 billion JPY for the fiscal year ended March 31, 2021 compared to 1,005.2 billion JPY for the fiscal year ended March 31, 2020. This increase in net cash used of 83.1 billion JPY was mainly due to an increase in repayments of bonds and long-term loans of 950.6 billion JPY primarily resulting from early redemptions and repayments in the current fiscal year. The increase in net cash used was partially offset by an increase in proceeds from issuance of bonds and long-term loans of 683.3 billion JPY as a result of the issuance of U.S. dollar-denominated senior notes 7,000 million USD and Euro-denominated senior notes 3,600 million EUR in the current fiscal year compared with the 500.0 billion JPY issuance of hybrid bonds in the previous fiscal year. In addition, there was a favorable impact from short-term loans and commercial paper of 202.2 billion JPY primarily due to the repayment of the short-term syndicated loans 500.0 billion JPY in June 2019, partially offset by a decrease in commercial paper drawings.

Fiscal Year Ended March 31, 2020 compared with the Fiscal Year Ended March 31, 2019

Net cash from operating activities was 669.8 billion JPY for the fiscal year ended March 31, 2020 compared to 328.5 billion JPY for the previous fiscal year. The increase of 341.3 billion JPY was driven by an increase of cash generated from operations excluding the impact of non-cash expenses mainly related to the Shire Acquisition whereas net profit for the year decreased by 90.8 billion JPY compared to the previous fiscal year. The impact of non-cash expenses reflected an increase in the reversal of depreciation and amortization of 336.0 billion JPY mainly attributable to intangible assets recorded upon the Shire Acquisition and impairment losses of 91.8 billion JPY relating to certain marketed products, IPR&D assets

and site restructuring such as manufacturing facilities in Ireland and Shonan iPark, as well as a decrease in inventories of 86.8 billion JPY primarily attributable to the unwind of the fair value step up on acquired inventory recorded in relation to the Shire Acquisition.

The increase in net cash from operating activities also includes other favorable adjustments such as an increase in net finance expenses of 70.7 billion JPY primarily due to the interest expenses in connection with the financing for the Shire Acquisition and the effect of changes in assets and liabilities such as accrued bonus for employees.

These increases were partially offset by an increase of income taxes paid of 183.1 billion JPY mainly due to tax payments by legacy Shire entities acquired in the previous fiscal year.

Net cash from investing activities was 292.1 billion JPY for the fiscal year ended March 31, 2020 compared to net cash used in investing activities of 2,835.7 billion JPY for the previous fiscal year. This increase of 3,127.8 billion JPY in investing activities was primarily attributable to 2,891.9 billion JPY of the total cash outflow for the Shire Acquisition in the previous fiscal year. In addition, proceeds from sales of business increased by 376.4 billion JPY reflecting the sale of XIIDRA of 375.5 billion JPY.

Net cash used in financing activities was 1,005.2 billion JPY for the fiscal year ended March 31, 2020 compared to net cash from financing activities of 2,946.2 billion JPY for the previous fiscal year. This decrease of 3,951.5 billion JPY was mainly the result of 2,795.9 billion JPY proceeds from the issuance of bonds and long-term loans related to the acquisition of Shire recorded in the previous year and 701.1 billion JPY repayment of bonds and long-term loans in the current year. There also was a decrease in short-term loans of 718.5 billion JPY and an increase of dividends paid by 139.6 billion JPY, as well as an increase of interest paid by 92.3 billion JPY mainly resulting from the financing for the Shire Acquisition.

For the fiscal year ended March 31, 2020, the proceeds from issuance of bonds and long-term loans were 496.2 billion JPY including the 500.0 billion JPY issuance of hybrid bonds, and net decrease in short-term loans was 351.2 billion JPY mainly due to repayment of 500.0 billion JPY for the short-term syndicated loans.

Borrowings and Financial Obligations

Our total bonds and loans were 5,093.3 billion JPY and 4,635.4 billion JPY as of March 31, 2020 and 2021, respectively. These borrowings include unsecured bonds and senior notes issued by Takeda and syndicated loans entered into by the company in prior years, borrowings incurred to fund a portion of the Shire Acquisition, debt assumed in connection with the Shire Acquisition and debt refinanced and are included in our consolidated statements of financial position. Our borrowings are mainly incurred in connection with acquisitions and therefore are not exposed to seasonality.

On July 9, 2020, Takeda issued unsecured U.S. dollar denominated senior notes (the “USD Notes”) with an aggregate principal amount of 7,000 million USD and unsecured Euro-denominated senior notes (the “EUR Notes”) with an aggregate principal amount of 3,600 million EUR. The maturity dates for the USD Notes are from March 31, 2030 to July 9, 2060 and for the EUR Notes are from July 9, 2027 to July 9, 2040, respectively. Under the terms and conditions of these notes, Takeda may redeem these notes, in whole or in part, at any time prior to maturity. Interest is payable semi-annually at a rate 2.050 – 3.375% for the USD Notes and annually at a rate 0.750 – 2.000% for the EUR Notes. The notes are unsecured, and Takeda is not subject to any financial covenants related to these notes. The proceeds from these notes were used to repay the Term Loan Credit Agreement loans of 3,250 million USD and 3,019 million EUR on July 10, 2020, together with the early redemption of unsecured senior notes with face values of 2,400 million USD and 1,250 million EUR on August 3, 2020 in advance of their original maturities of September 2021 and November 2020, respectively. Takeda further executed the early redemption of unsecured senior notes with face values of 2,450 million USD, comprising 1,250 million USD on February 26, 2021, 900 million USD on January 22, 2021, and 300 million USD on February 25, 2021 in advance of their original maturities of November 2021, September 2021 and January 2022 respectively.

In addition to the above, mandatory debt repayments were made in the fiscal year ended March 31, 2021. In April 2020, a mandatory repayment of 94 million USD was made on USD and EUR Term Loan Credit Agreement loans and in July 2020, 130 billion JPY in mandatory repayments of debt issued in July 2013 were made comprising 70 billion JPY in loans and 60 billion JPY in unsecured straight bonds. Additionally, in November 2020, a mandatory repayment of 1,000 million EUR in unsecured floating rate senior notes was made, the notes having been incurred in connection with the Shire Acquisition.

As of March 31, 2021, we had certain outstanding borrowings that contained financial covenants. A key financial covenant requires Takeda’s ratio of consolidated net debt to adjusted EBITDA, as defined in the loan agreements, for the previous twelve-month period to not surpass certain levels as of March 31 and September 30 of each year. Takeda was in compliance with all financial covenants as of March 31, 2021 in a similar manner to the prior year ended March 31, 2020. There are no restrictions on the ability to draw from the 700 billion JPY commitment line that was put in place in 2019 and has a current maturity of September 2025.

We currently have a Japanese unsecured commercial paper program in place to facilitate short-term liquidity management. The total amount drawn on the commercial paper program was 144 billion JPY and nil as of March 31, 2020 and 2021, respectively. We further have access to short-term uncommitted lines of 150 billion JPY and 750 million USD which were undrawn as of March 31, 2020 and 2021, respectively.

For further description of our borrowings, see Note 20 to our audited consolidated financial statements.

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 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, 2021, the contractual amount of potential milestone payments totaled 1,259.0 billion JPY, in each case excluding potential commercial milestone payments. See Note 13 and 32 to our audited consolidated financial statements for further details.

F. Tabular Disclosure of Contractual Obligations

The following table summarizes our contractual obligations as of March 31, 2021:

	Total contractual amount ⁽¹⁾	Within one year	Between one and three years	Between three and five years	More than five years
	(billions of yen)				
Bonds and loans: ⁽²⁾⁽³⁾					
Bonds ⁽⁴⁾	¥ 4,563.0	¥ 114.7	¥ 934.5	¥ 724.5	¥ 2,789.3
Loans ⁽⁴⁾	1,150.4	228.0	187.3	344.5	390.6
Purchase obligations for property, plant and equipment	18.9	18.9	—	—	—
Repayment of lease liabilities	610.3	50.2	89.0	79.7	391.3
Contributions to defined benefit plans ⁽⁵⁾	7.8	7.8	—	—	—
Total ⁽⁶⁾⁽⁷⁾	<u>¥ 6,350.4</u>	<u>¥ 419.6</u>	<u>¥ 1,210.8</u>	<u>¥ 1,148.7</u>	<u>¥ 3,571.2</u>

Notes:

- Obligations denominated in currencies other than Japanese yen have been translated into Japanese yen using period-end exchange rates for the fiscal year ended March 31, 2021 and may fluctuate due to changes in exchange rates.
- Repayment obligations may be accelerated if we breach the relevant covenants under the relevant instruments.
- Includes interest payment obligations.
- The contractual amount of bonds in "Within one year" includes a 0.2 billion USD principal amount of unsecured U.S. dollar-denominated senior notes in respect of an early redemption of the remaining principal amount of the bond on May 17, 2021. For the details of early redemption, see Note 33 to our audited consolidated financial statements. Furthermore, the contractual amount of loans in "Within one year" includes a 2.0 billion USD of the outstanding JBIC Loan floating rate amount of 3.7 billion USD as Takeda made a prepayment of the loan on June 11, 2021. The JBIC Loan was included in non-current liabilities of the consolidated statements of financial position as of

March 31, 2021 as the maturity date of the loan is December 11, 2025 and the notice to repay the loan was not issued until April 1, 2021. For the details of prepayment, see Note 33 to our audited consolidated financial statements. The contractual amount of bonds in “Between three and five years” includes 500.0 billion JPY principal amount of the hybrid subordinated bonds (the “Hybrid Bonds”) as Takeda may make an early repayment of all of the principal of the Hybrid Bonds on each interest payment date beginning October 6, 2024. For details on the principal and interest rates associated with these bonds and loans, see Note 20 to our audited consolidated financial statements.

- (5) Pension and post-retirement contributions cannot be determined beyond the fiscal year ended March 31, 2022 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.
- (6) Does not include contractual obligations whose timing we are unable to estimate, including defined benefit 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 financial liabilities associated with contingent consideration arrangements. The carrying amounts of derivative liabilities and financial liabilities associated with contingent consideration arrangements as of March 31, 2021 were 97.1 billion JPY and 27.8 billion JPY, respectively. Milestone payments that are dependent on the occurrence of certain future events are not included.
- (7) 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. Since September 2020, Mr. Weber has also served as Head of Global Business of Takeda Pharmaceuticals U.S.A., Inc. 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
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)	Representative Director, Japan General Affairs	Masato Iwasaki is Representative Director, Japan General Affairs of Takeda. 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. Dr. Iwasaki was named Director, Japan General Affairs in April 2021 and named Representative Director in June 2021.	Note 1

Name (Date of birth)	Responsibilities and status within Takeda	Business experience	End of term
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 Chairman at Majorelle International, External Director at Virbac SA, External Director at AlgoTherapeutix SAS and External Director at Reckitt Benckiser Group plc. Mr. Bohuon has previously served as External Director and Chairman at LEO Pharma A/S, 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
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 Olema Pharmaceuticals, 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 Senior Executive Advisor of CVC Asia Pacific (Japan) Kabushiki Kaisha, External Director of Oracle Corporation Japan, External Director of Riraku K.K. and External Director of Shiseido Company, Limited. He previously served as External Director of Tokyo Electric Power Company, Incorporated (currently Tokyo Electric Power Company Holdings, Incorporated), External Director of Toshiba Corporation 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 an 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 and Chairman of Codiak BioSciences, Inc., External Director of Homology Medicines, 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

Name (Date of birth)	Responsibilities and status within Takeda	Business experience	End of term
Masahiro Sakane (January 7, 1941)	External Director	Masahiro Sakane has served as External Director of Takeda since June 2014 and was appointed Chair of the Board of Directors meeting in June 2017. Mr. Sakane currently also serves as Advisor 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 External Director of Dynamic Map Platform 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
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., External Director of Accelerate Technologies Pte. Ltd., External Director of Varian Medical Systems, Inc., External Director of SGInnovate 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. and External Director of TOA CORPORATION. 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, Outside Corporate Auditor of Sunstar Inc, External Director of EBARA CORPORATION and External Director of Sony Financial Holdings Inc.	Note 1

Name (Date of birth)	Responsibilities and status within Takeda	Business experience	End of term
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. Mr. Hatsukawa started his career at Price Waterhouse accounting office in March 1974. Mr. Hatsukawa has previously served CEO of PricewaterhouseCoopers Arata and has held leadership positions at ChuoAoyama PricewaterhouseCoopers and Aoyama Audit Corporation. In addition, he has also served as Outside Audit and Supervisory Board Member of Accordia Golf co., Ltd. as well as Audit and Supervisory Board Member of The Norinchukin Bank.	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 KLA Corporation, External Director of Rambus Inc, and External Director of One Equity Partners Open Water I Corporation. Ms. Higashi previously served as External Director of MetLife Insurance K.K., External Director of InvenSense Inc., External Director of Sanken Electric Co., Ltd., CEO of Gilo Ventures, LLC, Managing Director of Investment Banking, Merrill Lynch & Co. and Director of Wasserstein Perella & Co., Inc.	Note 2
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 2
Masami Iijima (September 23, 1950)	External Director (Audit and Supervisory Committee Member)	Masami Iijima was appointed External Director who is a member of the Audit and Supervisory Committee of Takeda in June 2021. Mr. Iijima currently also serves as Counselor of Mitsui & Co., Ltd., External Director of Ricoh Company, Ltd., External Director of SoftBank Group Corp., Counsellor at Bank of Japan and External Director of Isetan Mitsukoshi Holdings Ltd. Mr. Iijima started his career at Mitsui & Co., Ltd. in April 1974. At Mitsui & Co., Ltd., he served in several senior leadership positions including Chairman of the Board of Directors and Representative Director, President and Chief Executive Officer.	Note 2

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, 2021 through the end of the ordinary general meeting of shareholders for the fiscal year ending March 31, 2022.
- (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, 2020 through the end of the ordinary general meeting of shareholders for the fiscal year ending March 31, 2022.
- (3) Notwithstanding the Note (2) above, the term of office for Masami Iijima, Director who is an Audit and Supervisory Committee member, is from the end of the ordinary general meeting of shareholders for the fiscal year ended March 31, 2021 through the end of the ordinary general meeting of shareholders for the fiscal year ending March 31, 2022. Since he was appointed as a substitute for Yasuhiko Yamanaka, who retired as Director who is an Audit and Supervisory Committee member at the end of the ordinary general meeting of shareholders for the fiscal year ended March 31, 2021, his term of office will remain until the expiration of Yasuhiko Yamanaka's term of office as Director who is an Audit and Supervisory Committee member, 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	<p>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.</p> <p>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.</p> <p>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.</p> <p>Prior to joining Takeda, Mr. Agosti worked in business development at Novartis in the U.K. and Switzerland and was also a consultant at McKinsey & Co.</p>
Teresa Bitetti (September 21, 1962)	President, Global Oncology Business Unit	<p>In April 2019, Teresa Bitetti joined Takeda as President of the Global Oncology Business Unit. She is responsible for oncology business activities.</p> <p>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.</p> <p>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.</p>
Lauren Duprey (May 13, 1984)	Chief Human Resources Officer	<p>Lauren Duprey is the Chief Human Resources Officer of Takeda Pharmaceutical Company Ltd. with responsibility for delivering an exceptional people experience across the globe. She joined Takeda in August 2019 as Head of Human Resources (HR) for the U.S. Business Unit, Global Product & Launch Strategy and the U.S. People Advisory Group. Since joining Takeda, Ms. Duprey has implemented a transformation of HR in the U.S., including a new operating model, structure, capabilities and technology. In addition, she built a new diversity, equity and inclusion (DE&I) organization which has shaped a leading-edge DE&I strategy for Takeda in the U.S.</p> <p>Prior to joining Takeda, Ms. Duprey served as Head of HR, U.S. Organization & Worldwide Medical at Biogen where she developed and drove the talent and organization strategy and served as a trusted advisor in regards to key business, talent and organizational decisions. She has held various HR roles at companies such as General Electric and began her career in management consulting at Clarion Healthcare focused on biopharma commercialization.</p> <p>Ms. Duprey holds a bachelor’s degree in biology from Harvard University and an MBA from Massachusetts Institute of Technology (MIT) Sloan School of Management.</p>

Name (Date of birth)	Responsibilities and status within Takeda	Business experience
Milano Furuta (February 26, 1978)	President, Japan Pharma Business Unit	<p>Milano Furuta is President, Japan Pharma Business Unit of Takeda Pharmaceutical Company Limited.</p> <p>Mr. Furuta joined Takeda in 2010 and has worked on various projects in corporate strategy, corporate development, and post-merger integration in Japan and Switzerland. He managed the Diabetes Business Unit in Mexico and served as General Manager in Sweden, leading the launch of new products in the areas of oncology, diabetes, cardiovascular and metabolism, while optimizing commercial organizations. He went on to serve as Corporate Strategy Officer and Chief of Staff in Japan for two years before his appointment to his current role.</p> <p>Prior to joining Takeda, Mr. Furuta worked as an equity research analyst at an investment management firm in the United States. He began his career in banking and private equity investment in Japan, where he was involved with several types of financial transactions, including leveraged buyouts and debt restructuring. Mr. Furuta holds an MBA from The Wharton School, University of Pennsylvania and a BA in international affairs from Hitotsubashi University, Japan.</p>
Gerard Greco, Ph.D. (February 8, 1962)	Global Quality Officer	<p>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.</p> <p>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.</p> <p>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.</p>
Takako Ohyabu (August 26, 1979)	Chief Global Corporate Affairs Officer	<p>Takako Ohyabu is Chief Global Corporate Affairs Officer overseeing global corporate communications, global corporate social responsibility, global public affairs, global security and crisis management, and sustainability for Takeda Pharmaceutical Company Limited. She joined the company in November 2019 as Chief Communications and Public Affairs Officer Designate.</p> <p>Prior to joining Takeda, Ms. Ohyabu led the Global Corporate Communications function at Nissan Motor Corporation. Before that she was with General Electric Company managing corporate communications for a variety of industries and building the corporate brand in both developed and emerging markets.</p> <p>Ms. Ohyabu holds a master’s degree in Public Administration from Columbia University’s School of International and Public Affairs and a bachelor’s degree in Political Science from the International Christian University in Japan.</p>
Julie Kim (June 6, 1970)	President, Plasma-Derived Therapies Business Unit	<p>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.</p> <p>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 U.S. healthcare space.</p> <p>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.</p>

Name (Date of birth)	Responsibilities and status within Takeda	Business experience
Mwana Lugogo (January 30, 1970)	Chief Ethics and Compliance Officer	<p>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.</p> <p>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.</p> <p>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.</p>
Ricardo Marek (May 30, 1970)	President, Growth and Emerging Markets Business Unit	<p>Ricardo Marek is President of Growth and Emerging Markets (“GEM”) Business Unit.</p> <p>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.</p> <p>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.</p> <p>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.</p>
Yoshihiro Nakagawa (July 26, 1960)	Global General Counsel	<p>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.</p> <p>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.</p> <p>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.</p>
Giles Platford (April 26, 1978)	President, Europe and Canada Business Unit	<p>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.</p> <p>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.</p> <p>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.</p>

Name (Date of birth)	Responsibilities and status within Takeda	Business experience
Koki Sato (December 10, 1980)	Corporate Strategy Officer and Chief of Staff	<p>Koki Sato is the Corporate Strategy Officer and Chief of Staff of Takeda Pharmaceutical Company Limited.</p> <p>Mr. Sato joined Takeda in 2003 and has been increasing responsibilities throughout his career with Takeda, spanning many countries and multiple functions. After he took a regional role in Emerging Markets in 2012, he has held several leadership roles, such as Country Manager of Belarus, General Manager of Ukraine cluster, and General Manager of India before taking his current role.</p> <p>Mr. Sato holds a bachelor’s degree in Economics from School of Political Science & Economics, Waseda University in Tokyo.</p>
Ramona Sequeira (November 21, 1965)	President, United States Business Unit and Global Portfolio Commercialization	<p>Ramona Sequeira is the President of United States Business Unit and leads Takeda’s Portfolio Commercialization globally. 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.</p> <p>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 recently appointed Treasurer of the Board. Prior to that, she served as Chair of PhRMA’s State Committee.</p> <p>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.</p>
Rajeev Venkayya, M.D. (March 6, 1967)	President, Global Vaccine Business Unit	<p>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).</p> <p>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 USD/year. While at the foundation, he served on the board of the Global Alliance for Vaccines and Immunization (“GAVI”).</p> <p>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 through the non-partisan White House Fellowship program in 2002.</p> <p>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.</p>
Thomas Wozniowski, Ph.D. (July 26, 1962)	Global Manufacturing and Supply Officer	<p>In July 2014, Thomas Wozniowski, Ph.D. joined Takeda as Global Manufacturing and Supply Officer. He has more than 20 years of experience in the pharmaceutical industry.</p> <p>Dr. Wozniowski 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.</p> <p>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. Wozniowski also worked at Boehringer Ingelheim, where he held several positions in quality and production.</p>

B. Compensation

The following table provides information about our Internal Directors' compensation on an individual basis in the fiscal year ended March 31, 2021.

Name (Position)	Total consolidated compensation (millions of yen)	Company	Amount of consolidated compensation by type (millions of yen)				
			Base compensation	Performance-based compensation		Non-monetary compensation	
				Annual bonus	Performance Shares ⁽¹⁾⁽²⁾	Restricted stock ⁽¹⁾	Other
Christophe Weber (Director)	¥ 1,874	Takeda	¥ 246 ⁽⁴⁾	¥ 247	¥ 900 ⁽⁵⁾	¥ 379 ⁽⁵⁾	¥ —
		Takeda Pharmaceuticals U.S.A., Inc. ⁽³⁾	21	81	—	—	—
Masato Iwasaki (Director)	289	Takeda (Director portion)	35	49	107 ⁽⁷⁾	37 ⁽⁷⁾	—
		Takeda (Employee portion) ⁽⁶⁾	27	32	—	—	—
Andrew S. Plump (Director)	911	Takeda	12	—	—	—	—
		Takeda Pharmaceuticals International, Inc. ⁽⁸⁾	122	172	421 ⁽⁹⁾	143 ⁽⁹⁾	42 ⁽¹⁰⁾
Costa Saroukos (Director)	626	Takeda (Director portion)	200 ⁽¹¹⁾	153	187 ⁽¹²⁾	85 ⁽¹²⁾	—
Yasuhiko Yamanaka (Director who is an Audit and Supervisory Committee Member) ⁽¹³⁾	50	Takeda	38	—	—	13 ⁽¹⁴⁾	—

Notes:

- (1) Compensation expense related to Performance Shares and Restricted Stock are 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, 2021.
- (2) Although Performance Share is categorized as both Performance-based Compensation and Non-monetary Remuneration, Performance Share is reported as Performance-based Compensation.
- (3) Shows the salary and annual bonus earned as Head of Global Business of Takeda Pharmaceuticals U.S.A., Inc.
- (4) Basic Compensation includes the grossed-up amount paid for residence and pension allowances etc. for the relevant officer (100 million JPY).
- (5) The amount recognized as an expense during the fiscal year for the stock incentive plan (Board Incentive Plan) grants awarded in fiscal years 2017-2020.
- (6) Shows the salary and other amounts earned as the President, Japan Pharma Business Unit etc. 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 & Supervisory Committee Members" as proposed at the 145th General Meeting of Shareholders held on June 29, 2021.
- (7) The amount recognized as an expense during the fiscal year for the stock incentive plan (Board Incentive Plan) grants awarded in fiscal years 2017-2020.
- (8) Shows the salary and other amounts earned as the President, Research and Development of Takeda Pharmaceuticals International, Inc.
- (9) The amount recognized as an expense during the fiscal year for the stock incentive plan (Employee Stock Ownership Plan and the Long Term Incentive Plan (LTIP)) grants awarded in fiscal years 2017-2020.
- (10) Amounts of local retirement plan contributions and other additional benefits paid by Takeda Pharmaceuticals International, Inc. during the fiscal year, as well as the amount equal to taxes on such amounts.
- (11) Basic Compensation includes the grossed up amount paid for residence, pension allowances, and educational allowances etc. for the relevant officer. (97 million JPY).
- (12) The amount recognized as an expense during the fiscal year for the stock incentive plan (Board Incentive Plan) grants awarded in fiscal years 2019 and 2020.
- (13) Yasuhiko Yamanaka retired at the close of 145th General Meeting of Shareholders held on June 29, 2021.
- (14) The amount recognized as an expense during the fiscal year for the stock incentive plan (Board Incentive Plan) grants awarded in fiscal years 2017-2020.

The following table provides information about our External Directors' compensation on an individual basis in the fiscal year ended March 31, 2021.

Name (Position)	Total consolidated compensation (millions of yen)	Company	Amount of consolidated compensation by type (millions of yen)				
			Base compensation	Performance-based compensation		Non-monetary compensation	
				Annual bonus	Performance Shares	Restricted stock ⁽¹⁾	Other
Masahiro Sakane (Director)	¥ 43	Takeda	¥ 24	¥ —	¥ —	¥ 19	¥ —
Olivier Bohuon (Director)	38	Takeda	19	—	—	19	—
Jean-Luc Butel (Director)	38	Takeda	19	—	—	19	—
Ian Clark (Director)	38	Takeda	19	—	—	19	—
Yoshiaki Fujimori (Director)	38	Takeda	19	—	—	19	—
Steven Gillis (Director)	38	Takeda	19	—	—	19	—
Shiro Kuniya (Director)	38	Takeda	19	—	—	19	—
Toshiyuki Shiga (Director)	38	Takeda	19	—	—	19	—
Koji Hatsukawa (Director who is an Audit and Supervisory Committee Member)	41	Takeda	22	—	—	19	—
Emiko Higashi (Director who is an Audit and Supervisory Committee Member)	43	Takeda	24	—	—	19	—
Michel Orsinger (Director who is an Audit and Supervisory Committee Member)	41	Takeda	22	—	—	19	—

Notes:

- (1) Compensation expense related to Restricted Stock 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, 2021.

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, 2019, 2020 and 2021, we recorded total compensation expense related to our share-based payment plans of 18.8 billion JPY, 30.0 billion JPY and 39.4 billion JPY, respectively, in our consolidated statements of profit or loss. 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.

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 independence 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. Except as described below, none of our directors have entered service contracts with us or any of our subsidiaries providing for benefits upon termination of employment.

Upon a termination by the relevant company, other than for cause, or the voluntary termination by the relevant director for good reason of his appointment as director or employment relationship, in each case as defined in the relevant agreement, and subject to the other conditions contained in such agreement, the following directors will be entitled to the severance payments or other benefits described below. The payments and benefits described below are in addition to any accrued and unpaid amounts that may be owed to the relevant director at the time of such termination.

Name	Company	Severance Payment	Other Benefits
Christophe Weber	Takeda	Sum of (i) 100% of annual base salary, (ii) 100% of annual target bonus and (iii) 100% of annual target value of Long-Term Incentive payments, subject to the approval of the shareholders’ meeting, to the extent required by applicable law and to the extent permitted in light of fiduciary duty and the duty of loyalty of the directors of Takeda	Certain repatriation-related benefits, subject to the approval of the shareholders’ meeting, to the extent required by applicable law and to the extent permitted in light of fiduciary duty and the duty of loyalty of the directors of Takeda
	Takeda Pharmaceuticals U.S.A, Inc.	Sum of (i) 100% of annual base salary and (ii) 100% of annual target value of Short-Term Incentive payments, subject to the approval of the shareholders’ meeting, to the extent required by applicable law and to the extent permitted in light of fiduciary duty and the duty of loyalty of the directors of Takeda	None

Costa Saroukos	Takeda	Sum of (i) 100% of annual base salary, (ii) 100% of annual target bonus and (iii) 100% of annual target value of Long-Term Incentive payments, subject to the approval of the shareholders' meeting, to the extent required by applicable law and to the extent permitted in light of fiduciary duty and the duty of loyalty of the directors of Takeda	Certain repatriation-related benefits, subject to the approval of the shareholders' meeting, to the extent required by applicable law and to the extent permitted in light of fiduciary duty and the duty of loyalty of the directors of Takeda
Andrew S. Plump	Takeda Pharmaceuticals International, Inc.	Sum of (i) 12 months of current monthly base salary (24 months in the case where Mr. Plump voluntarily terminates his employment for good reason) and (ii) 100% of annual target level bonus under the Short-Term Incentive Program	Certain health insurance benefits

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.

We entered into indemnity agreements with each of Takeda's directors for liability arising from their status as directors or out of an alleged wrongful act by them in such capacity to the extent permitted by applicable law.

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. Takeda executive team participates in Business Review Committee, which is responsible for consideration and determination of general management matters, a Portfolio Review Committee, which is responsible for R&D 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 JPY or more or those matters which will have substantial impact on us or our stakeholders) to the President and Chief Executive Officer, three directors belonging to the Business Review Committee, one director belonging to the Portfolio Review Committee, and one director belonging to the Risk, Ethics and Compliance 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, four

other external directors and one other director as an observer who is not an external director, and the Compensation Committee consists of one external director who serves as chairman, and three other external directors. Together, the committees serve to ensure transparency and objectivity in decision-making relating to personnel matters for 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

Under the Companies Act and our articles of incorporation, we may exempt, by resolution of the board of directors, our directors from liabilities to us arising in connection with their failure to execute their duties in good faith and without gross negligence, within the limits stipulated by applicable laws and regulations. In addition, 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.

D. Employees

As of March 31, 2019, 2020 and 2021, we had 49,578, 47,495 and 47,099 employees on a consolidated basis, respectively. These numbers of employee represent the number of permanent employees excluding temporary employees and were calculated on a full-time equivalent basis. The following table shows our employees by geographic locations as of March 31, 2021.

Japan	United States	Europe and Canada	Other	Total
5,586	19,139	13,867	8,507	47,099

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 as of March 31, 2021 owned by directors of the Company as of the date of this annual report.

Directors

Name	Number of shares held (number of shares scheduled to be issued pursuant to Board Incentive Plan (“BIP”) and Employee Stock Ownership Plan (“ESOP”))
Christophe Weber	355,500 (635,587)
Costa Saroukos	21,200 (164,449)
Masato Iwasaki	46,096 (70,728)
Andrew Plump	— (157,863)
Olivier Bohuon	— (12,458)
Ian Clark	— (12,458)

Name	Number of shares held (number of shares scheduled to be issued pursuant to Board Incentive Plan (“BIP”) and Employee Stock Ownership Plan (“ESOP”))
Yoshiaki Fujimori	4,400 (14,620)
Steven Gillis	— (12,458)
Masahiro Sakane	900 (14,620)
Toshiyuki Shiga	3,600 (14,620)
Jean-Luc Butel	— (16,634)
Shiro Kuniya	2,100 (14,620)
Koji Hatsukawa	2,400 (14,620)
Emiko Higashi	— (16,634)
Michel Orsinger	— (16,634)
Masami Iijima	— —
Total	436,196 (1,189,003)

Each of our directors held less than one percent of our total issued shares as of March 31, 2021. Shares held by directors have equal voting rights as common stock held by other holders.

Number of shares to be issued pursuant to the BIP and ESOP is comprised of restricted shares and performance shares. Restricted shares vest one third each year over a three-year period and performance shares vest three years from the date of grant. Included performance shares represent the total number of shares to be issued assuming that relevant targets are met at the 100% level; the actual number of shares issued may be fewer or greater depending on the level at which targets are met.

The above table does not include 52,965 ADSs held by Andrew Plump, 1,300 ADSs held by Olivier Bohuon, 2,096 ADSs held by Ian Clark and 8,257 ADSs held by Steven Gillis, in each case as of March 31, 2021. Furthermore, the above table does not include 238,784 ADSs scheduled to be issued to Andrew Plump pursuant to Long-Term Incentive Plan (“LTIP”). Each ADS represents one half of an ordinary share.

For detailed information about our share-based compensation plans, including BIP, ESOP, LTIP, stock option plan, stock incentive plan, phantom stock appreciation rights and restricted stock units, see Note 28 to our audited consolidated financial statements.

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, 2021.

Shareholder	Number of shares held of record	Percentage of issued shares ⁽¹⁾
	(thousands, except percentages)	
The Master Trust Bank of Japan, Ltd. (Trust account)	150,521	9.55 %
Custody Bank of Japan, Ltd. (Trust account)	84,159	5.34
The Bank of New York Mellon as depository bank for depository receipt holders (Standing proxy: Sumitomo Mitsui Banking Corporation)	78,566	4.98
Nippon Life Insurance Company (Standing proxy: The Master Trust Bank of Japan, Ltd.)	35,360	2.24
Custody Bank of Japan, Ltd. (Trust account 5)	25,510	1.62
State Street Bank West Client-Treaty 505234 (Standing proxy: Settlement & Clearing Services Department, Mizuho Bank, Ltd.)	25,343	1.61
Custody Bank of Japan, Ltd. (Trust account 6)	22,618	1.43
JP Morgan Chase Bank 385632 (Standing proxy: Settlement & Clearing Services Department, Mizuho Bank, Ltd.)	21,669	1.37
Custody Bank of Japan, Ltd. (Trust account 7)	20,368	1.29
Custody Bank of Japan, Ltd. (Trust account 1)	20,305	1.29
Total	484,418	30.73 %

Notes:

- (1) Percentage of issued shares excludes treasury stock held as of March 31, 2021. As of March 31, 2021, we held 13,029,749 shares of common stock as treasury stock, which include 172,947 shares held by us, 12,771,676 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.

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

As of March 31, 2021, there were 300 holders of record of our common stock with addresses in the U.S., whose shareholdings represented approximately 18% of our outstanding common stock on that date. One such shareholder was The Bank of New York Mellon as depository for holders of ADSs, which held 78.6 million shares, or 4.98% of the total number of shares in issue, as of March 31, 2021. Because some of these shares were held by brokers or other nominees, the number of holders of record with addresses in the U.S. might not fully reflect the number of beneficial owners in the U.S.

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, 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 fiscal year ended March 31, 2021 were 5.0 billion JPY. 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. See Note 30 to our audited consolidated financial statements for further details.

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 for a detailed discussion of legal proceedings.

Dividends

Our capital resource management is based on the following:

- investments in our internal R&D 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 of the focus areas 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	JPY (billions) Total dividends	Dividends per share JPY	Record date	Effective date
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
April 1, 2019, to March 31, 2020				
Q1 2019	140.8	90.00	March 31, 2019	June 28, 2019
Q3 2019	141.9	90.00	September 30, 2019	December 2, 2019
April 1, 2020, to March 31, 2021				
Q1 2020	141.9	90.00	March 31, 2020	June 25, 2020
Q3 2020	141.9	90.00	September 30, 2020	December 1, 2020

Dividend declared for which the effective date falls in the following fiscal year are as follows:

Dividends declared	JPY (billions) Total dividends	Dividends per share JPY	Record date	Effective date
April 1, 2021, to March 31, 2022				
Q1 2021	¥ 141.9	¥ 90.00	March 31, 2021	June 30, 2021

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.”

ADs, 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, 2021, our authorized share capital consisted of 3,500,000,000 shares of common stock of which 1,576,387,908 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 ADs will be required to withdraw their ADs 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;
- Computerized information processing services, development, purchase and sale of software, and information providing services;

- Support of businesses, and advice, training and assistance for management;
- 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 an all shareholders notice based on information provided by the account management institutions. Such an 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 a shareholder acquires our shares, unless such a 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 a 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.

Restrictions on the Distribution of Surplus

Under the Companies Act, we may distribute a 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 JPY:

- (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 profit and loss 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 profit and loss 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 a 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 a reduction less the portion thereof that has been transferred to share capital (if any);
- (V) in the event that we canceled treasury stock after the end of the previous fiscal year, the book value of such treasury stock;
- (VI) in the event that we distributed a 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 a 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, see “—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 a 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 issued 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 a 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 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 a 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 a 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 a meeting. Such notice may be given to shareholders by electronic means, subject to the consent of the relevant shareholders.

The Bill for Partially Amending the Industrial Competitiveness Act of Japan has been submitted to the Diet of Japan as of May 11, 2021, which allows companies to add a provision to their Articles of Incorporation stating that a general meeting of shareholders may be held without specifying a venue, subject to confirmation by the Minister of Economy, Trade and Industry and the Minister of Justice that such companies satisfy

the requirements specified by the Ordinance of the Ministry of Economy, Trade and Industry and the Ordinance of the Ministry of Justice, for falling under cases where holding a general meeting of shareholders without specifying a venue contributes to enhancing industrial competitiveness while securing the interests of shareholders.

Assuming cases where an infectious disease such as COVID-19 spreads or a natural disaster occurs and the impact thereof is ongoing or is reasonably expected to be ongoing at the time of the general meeting of shareholders, we believe that setting a venue for a general meeting of shareholders while asking shareholders to refrain from attending the venue out of consideration of shareholders' health and safety, may not always be the best option for us as the method of holding a general meeting of shareholders. Therefore, we submitted a proposal to our annual general meeting of shareholders held on June 29, 2021, which was approved by partially amending our Articles of Incorporation to the effect that we may hold a general meeting of shareholders without specifying a venue when our Board of Directors decides that, considering the interests of shareholders as well, it is not appropriate to hold the general meeting of shareholders with a specific venue in situations such as the spread of an infectious disease or the occurrence of a natural disaster. The partial amendment of our Articles of Incorporation based on this proposal will come into effect subject to the enactment in the Diet and the promulgation of the Act Partially Amending the Industrial Competitive Enhancement Act of Japan with the above mentioned content, and our obtaining the above mentioned confirmation by the Minister of Economy Trade and Industry and the Minister of Justice.

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 a 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 such a demand is dispatched, the requiring shareholder may, upon obtaining a court approval, convene such a 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 a matter together with a summary of the proposal to be submitted by such a 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 a 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 an 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-subsidary 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;
- any reverse stock splits; 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 a 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 a market on that day, the price at which the sale of the shares is effected on such a 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 a 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 a 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 canceled 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 a controlling shareholder will be required to issue a prior notice to us. If we approve such a 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 a 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 a 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

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. We incurred indebtedness in connection with the Shire Acquisition. Material agreements associated with such indebtedness are described below.

On June 8, 2018, we entered into the Term Loan Credit Agreement for an aggregate principal amount of 7.5 billion USD with, among others, JPMorgan Chase Bank N.A., Sumitomo Mitsui Banking Corporation, MUFG Bank, Ltd. and Mizuho Bank, Ltd. On March 12, 2020, we prepaid an aggregate principal amount of 0.7 billion USD outstanding under the Term Loan Credit Agreement and subsequently repaid a mandatory amount of 94 million USD on April 14, 2020, followed by the prepayment of the remaining outstanding balance on July 10, 2020.

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 EUR of senior notes on the same day. On August 3, 2020, we executed an early redemption of 1.25 billion EUR in aggregate principal amount of the 0.375% fixed rate senior notes as permitted by the Fiscal Agency Agreement. Additionally, on November 23, 2020, we made a mandatory repayment of 1.0 billion EUR in unsecured floating rate senior notes in line with the terms of the Fiscal Agency Agreement.

On November 26, 2018, we entered into an Indenture with MUFG Union Bank, N.A., as Trustee, under which we issued a total aggregate principal amount of 5.5 billion USD of senior notes on the same day. On August 29, 2019, 1.0 billion USD total aggregate principal amount of such senior notes was redeemed early. On February 26, 2021, we executed an early redemption of 1.25 billion USD in aggregate principal amount of the 4.00% fixed rate senior notes as permitted by the indenture.

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 USD. On December 25, 2018, we entered into Amendment No. 1 to the JBIC Loan to make certain technical changes thereto. On December 25, 2019, we entered into Amendment No.2 to the JBIC Loan to make certain changes thereto, including changes to various financial covenants. On June 11, 2021, we prepaid an aggregate principal amount of 2.0 billion USD under the terms permitted by the JBIC Loan.

On June 6, 2019, Takeda issued hybrid subordinated bonds (the “Hybrid Bonds”) with an aggregate principal amount of 500 billion JPY. The proceeds from the Hybrid Bonds were used to repay the existing syndicated loans comprised of a senior short-term loan facility that was utilized to finance the acquisition of Shire. The Hybrid Bonds will mature on June 6, 2079.

On July 9, 2020, we entered into an indenture with The Bank of New York Mellon, as trustee, pursuant to which we issued a total aggregate principal amount of 7.0 billion USD of USD-denominated senior notes and 3.6 billion EUR of Euro-denominated senior notes on the same day.

For a more detailed 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” “Item 5. Operating and Financial Review and Prospects—B. Liquidity and Capital Resources— Borrowings and Financial Obligations.”

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 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 shareholders (in each case as contemplated by the Letter Agreement).

The Letter Agreement is filed as an exhibit hereto.

Divestment of TCHC

In connection with our sale of Takeda Consumer Healthcare Company Limited (“TCHC”), on August 24, 2020, we entered into a Share Purchase Agreement with Oscar A-Co KK, a company controlled by funds managed by The Blackstone Group Inc. and its affiliates. The sale was completed on March 31, 2021. TCHC’s portfolio includes a variety of over-the-counter medicines and health products including Alinamin®, a vitamin B1 preparation and Benza®, a cold remedy. See “Item 5. Operating and Financial Review and Prospects—A. Operating Results-Divestitures” for further details of the transaction.

Asset Transfer to Teijin

On February 26, 2021, we entered into an asset purchase agreement with Teijin Limited and Teijin Pharma Limited (“Teijin Pharma”), to transfer our marketing rights of a portfolio of four brands of type 2 diabetes drugs (Nesina®, Liovel®, Inisync® and Zafatek®) sold in Japan, to Teijin Pharma. The transfer of the marketing rights was completed on April 1, 2021. We also entered into separate agreements with Teijin Pharma whereby we will continue to manufacture the products for, and provide the distribution channel of the products to, Teijin Pharma, and will, for the time being, continue holding the marketing authorizations of the products. See “Item 5. Operating and Financial Review and Prospects—A. Operating Results-Divestitures” for further details of the transaction.

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 Seagen Inc. (formerly 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 (*Gaikoku Kawase oyobi Gaikoku Boueki Hou*) (the “FEFTA”) 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 (excluding partnerships falling within (iv));
- (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;

- (iv) general partnerships or limited partnerships under Japanese law or any similar partnerships under the laws of foreign countries, where either: (A) 50% or more of the capital contributions to those entities are made by individuals who do not reside in Japan or certain other foreign investors or (B) a majority of the general partners of such entities are individuals who do not reside in Japan or certain other foreign investors; or
- (v) corporations or other entities of which 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 individuals who do not reside in Japan.

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 JPY 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

Inward Direct Investment

If a foreign investor acquires shares or voting rights of a Japanese corporation that is listed on a Japanese stock exchange, such as the shares of our common stock and ADSs, or that is 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 and holdings of its closely-related persons (as defined in the Foreign Exchange Regulations), directly or indirectly holds 1% or more of (i) the issued shares or (ii) the total voting rights of the relevant corporation (shares and voting rights of the relevant corporation to be acquired are referred to as the “Inward Direct Investment Shares”), such an acquisition constitutes an “inward direct investment” under the FEFTA.

Prior Notification

Where a foreign investor intends to acquire the Inward Direct Investment Shares, and any of the business conducted by the investee Japanese corporation falls within any business sectors designated under the Foreign Exchange Regulations (the “Designated Business Sectors”, *Shitei-Gyoshu*) (which is the case for Takeda), in principle, a notification of the acquisition must be made in advance to the Minister of Finance and any other competent Ministers having jurisdiction over that Japanese corporation (including the MHLW).

If such a notification is made, the proposed acquisition cannot be consummated until 30 days have passed from the date thereof (this period is referred to as the “Screening Period”); provided, however, that the Screening Period will be shortened unless any of the relevant Ministers finds it necessary to check whether the proposed acquisition should be restricted from the viewpoint of national security or certain other factors, and may be shortened to 5 business days, if the proposed acquisition is determined not to raise such concerns. If the relevant Ministers find it necessary to check whether the proposed acquisition should be restricted, the Ministers may extend the Screening Period for up to five months; and the Ministers may eventually recommend any modifications to, or abandonment of, the proposed acquisition if necessary from the viewpoint of national security or certain other factors. If the foreign investor does not accept any of the recommendations, the relevant Ministers may order that the proposed acquisition be modified or abandoned.

Foreign investors acquiring the Inward Direct Investment Shares by way of a stock split are not subject to these notification requirements.

In addition, in the event a foreign investor, in combination with any holdings of its closely-related persons, directly or indirectly holds 1% or more of the total voting rights of a Japanese listed corporation engaging in the Designated Business Sectors, certain other activities of such a foreign investor such as (i) voting for appointment of his/herself or a person related thereto as a director or corporate auditor of such corporation and (ii) proposal and voting for transfer or abolishment of business activities related to the Designated Business Sectors of such a corporation also constitute “inward direct investments” and, as a result, are subject to the prior notification requirements under the FEFTA.

Exemption from Prior Notification

Irrespective of the foregoing, where any of the business conducted by the investee Japanese corporation falls within certain Designated Business Sectors specified in the Foreign Exchange Regulations (the “Core Sectors”, Core Gyoshu) (we are currently conducting business falling within the Core Sectors), the foreign investor (including the foreign financial institutions specified in the Foreign Exchange Regulations and sovereign wealth funds or public pension funds which have been accredited by the Japanese government and excluding the foreign financial institutions specified in the Foreign Exchange Regulations), who (i) acquires less than 10% of the Inward Direct Investment Shares (comprised of the aggregate amount of any existing holdings and holdings of its closely-related persons) of such a Japanese company, and (ii) complies with the following conditions is not required to make a prior notification upon his/her acquisition of the Inward Direct Investment Shares since an exemption therefrom is applicable, as long as:

- (a) the foreign investor and its related persons (as defined in the Foreign Exchange Regulations) will not become board members of such corporation;
- (b) the foreign investor will not propose transfer or abolishment of the business activities related to the Designated Business Sectors to or at a general meeting of shareholders;

- (c) the foreign investor will not access non-public information about the technology of such a corporation in relation to business activities related to Designated Business Sectors;
- (d) the foreign investor will not attend the meetings of the board of directors or executive committees of corporation that make important decisions in connection with business activities related to the Core Sectors; and
- (e) the foreign investor will not make any proposals, in a written form, to the board of directors or executive committees that make important decisions or their members of such corporation requesting that they respond and/or take any action in connection with business activities related to the Core Sectors by a certain deadline.

Further, foreign financial institutions specified in the Foreign Exchange Regulations who comply with conditions (a), (b) and (c) above are exempted from prior notification requirements.

This exemption is not applicable to certain types of foreign investors (for example, a foreign investor with a certain record of sanctions due to violation of the Foreign Exchange Regulation, or state-owned enterprises except those who are accredited by the Minister of Finance), and such foreign investors must file the prior notification set forth above.

Post Transaction Report

A foreign investor who has made a prior notification, as mentioned above must file a post transaction report (the “Post Transaction Report”) with the Minister of Finance and any other competent Ministers having jurisdiction over that Japanese corporation within 45 days after his/hers acquisition of the Inward Direct Investment Shares.

A foreign investor who has acquired the Inward Direct Investment Shares in reliance on an exemption from prior notification, must, in principle, file a Post Transaction Report within 45 days after such acquisition, if the ratio of the total number of shares or voting rights held directly or indirectly by the foreign investor in combination with any existing holdings and holdings of its closely related persons after the acquisition to the number of (i) the total issued shares or (ii) the total voting rights of the relevant corporation reaches:

- (i) 1% or more but less than 3% for the first time;
- (ii) 3% or more but less than 10% for the first time; and
- (iii) 10% or more for each acquisition.

Provided, however, that foreign financial institutions specified in the Foreign Exchange Regulations are only required to file a Post Transaction Report for (iii) above.

Foreign investors acquiring the Inward Direct Investment Shares by way of a stock split are not subject to the Post Transaction Report 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.

Reporting of Substantial Shareholdings

The Financial Instruments and Exchange Act of Japan and its related regulations require any person, regardless of residence, who has become beneficially, solely or jointly, a holder of more than 5% of the total issued shares of common stock of a corporation that is listed on a Japanese stock exchange, or that is traded on an over-the-counter market in Japan, to file with the Director of the 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 issuable to such a person upon the 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 shares held by the holder and the total issued shares.

E. Taxation

Material U.S. Federal Income Tax Consequences

This section describes the material U.S. 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 U.S. 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 U.S. federal income tax purposes holds the ADSs, the U.S. 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 U.S. 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 U.S. federal income tax purposes:

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

You should consult your own tax advisor regarding the U.S. 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 U.S. 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 U.S. 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 U.S. federal income tax purposes. Except as discussed below under “PFIC Rules”, this discussion assumes that we are not classified as a PFIC for U.S. federal income tax purposes.

Distributions

Under U.S. 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 U.S. federal income tax purposes), other than certain pro-rata distributions of our shares, will be treated as a dividend that is subject to U.S. federal income taxation. If you are a non-corporate 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 U.S. in the year that we distribute the dividend. Our ADSs are listed on the NYSE, so our ADSs are currently treated as readily tradable on an established

securities market in the U.S. We therefore expect that dividends that we distribute on our ADSs will be qualified dividend income, provided the aforementioned holding period requirements are satisfied by the holder of our ADSs.

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 U.S. corporations in respect of dividends received from other U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S. federal income tax liability.

Dividends will generally be income from sources outside the U.S. 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 U.S. persons and (b) at least 10% of our earnings and profits are attributable to sources within the U.S., then for foreign tax credit purposes, a portion of our dividends would be treated as derived from sources within the U.S. With respect to any dividend paid for any taxable year, the U.S. 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 U.S. 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 U.S. federal income tax.

Capital Gains

If you are a U.S. holder and you sell or otherwise dispose of your ADSs, you will recognize a capital gain or loss for U.S. 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 U.S. for foreign tax credit limitation purposes.

PFIC Rules

We believe that ADSs should not currently be treated as stock of a PFIC for U.S. 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 U.S. 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 Form 8621. However, as mentioned above, we believe that ADSs should not currently be treated as stock of a PFIC for U.S. federal income tax purposes and we do not expect to become a PFIC in the foreseeable future.

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 U.S. 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 and Singapore, while the income tax treaties with, among others, Australia, Belgium, France, Hong Kong, the Netherlands, Portugal, Sweden, Switzerland, the United Arab Emirates, the U.K. and the U.S. generally reduce the withholding tax rate to 10% for portfolio investors and the income tax treaty, among others, with Spain generally reduce the withholding tax rate to 5% for portfolio investors. In addition, under the income tax treaty between Japan and the U.S., 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, among others, Belgium, Denmark, the Netherlands, Switzerland, and Spain and the U.K. 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 depository 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 depository 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 depository 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 a 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 depository. 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 donee, 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.

A copy of our filings may be reviewed 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. Such filings can be also viewed 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 depository'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 depository from time to time. The deposited shares of our common stock, together with any other securities, cash or other property held by the depository are referred to as the "deposited securities."

Fees and Expenses

Persons depositing or withdrawing shares of our common stock or ADS holders must pay:

5.00 USD (or less) per 100 ADSs (or portion of 100 ADSs)

0.05 USD (or less) per ADS

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

0.05 USD (or less) per ADS per calendar year

For:

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

Any cash distribution to ADS holders

Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depository to ADS holders

Depository 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 depository or its agent when persons deposit or withdraw shares of our common stock
Expenses of the depository	Cable and facsimile transmissions (when expressly provided in the deposit agreement) Converting foreign currency to U.S. dollars
Taxes and other governmental charges the depository or the custodian have 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 depository or its agents for servicing the deposited securities	As necessary

The depository 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 depository 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 depository may collect its annual fee for depository 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 depository 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 depository 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 depository may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depository and that may earn or share fees, spreads or commissions.

The depository 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 depository or its affiliate receives when buying or selling foreign currency for its own account. The depository 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 depository'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 depository 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 depository 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 Depository

The depository agreed to make revenue sharing payments to us based on a fixed portion of the net issuance, net cancellation cash dividend and net depository 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 depository. Starting with the cash dividend of the record date of September 30, 2020 and all subsequent cash dividends thereafter, the depository agreed to reduce the cash dividend fees and to not make revenue sharing payments to us based on such cash dividend fees collected. In the fiscal year ended March 31, 2021, we received 9.0 million USD of such revenue sharing payments.

The depository has also agreed to waive fees and expenses for services provided to us, to ADS holders or to their respective brokers by the depository in connection with the establishment, administration and ongoing servicing of the ADS program. Furthermore, the depository has agreed to waive fees for certain value-added services, including training for our staff, investor relations advisory services and access to the depository's analytics and reporting platform. Accordingly, in the fiscal year ended March 31, 2021, the depository waived approximately 0.1 million USD 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 Exchange Act, as of March 31, 2021. 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 our 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, our CEO and CFO have concluded that, as of March 31, 2021, our disclosure controls and procedures were effective at the reasonable assurance level.

Management’s Annual Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act. Takeda’s internal control over financial reporting is designed to provide reasonable assurance to management regarding the reliability of financial reporting and the preparation and fair presentation of its consolidated financial statements in accordance with IFRS. Management assessed the effectiveness of Takeda’s internal control over financial reporting as of March 31, 2021 based on the framework in Internal Control - Integrated Framework (2013 framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the assessment, management concluded that, Takeda’s internal control over financial reporting is effective as of March 31, 2021. The effectiveness of internal control over financial reporting as of March 31, 2021 has been audited by KPMG AZSA LLC, our independent registered public accounting firm. Its audit report, including its opinion on management’s assessment of internal control over financial reporting, is included in the audited consolidated financial statements.

Attestation Report of the Registered Public Accounting Firm

See “—Report of Independent Registered Public Accounting Firm” included in the audited consolidated financial statements.

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, 2021 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/global-ethics-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, 2021.

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, 2020 and 2021:

	For the fiscal year ended March 31,	
	2020	2021
	(billions of yen)	
Audit fees ⁽¹⁾	¥ 3.91	¥ 3.70
Audit-related fees ⁽²⁾	0.08	0.03
Tax fees ⁽³⁾	0.00	0.00
Other fees ⁽⁴⁾	0.00	0.00
Total fees	¥ 3.99	¥ 3.73

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 include fees related to assurance services with respect to our debt issuances and our sustainability report.
- (3) Tax fees were related to tax compliance and other tax-related services.
- (4) Other fees include fees related to advisory services for “International Financial Reporting Standards”.

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 JPY annually, subject to an aggregate annual limit of up to 250 million JPY 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.

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, 2021:

	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, 2020	238	¥ 3,394.82	—	—
May 1 to May 31, 2020	520,208	4,093.71	520,200	—
June 1 to June 30, 2020	286	4,027.47	—	—
July 1 to July 31, 2020	68	3,742.6	—	—
August 1 to August 31, 2020	479	3,911.37	—	—
September 1 to September 30, 2020	358	3,919.98	—	—
October 1 to October 31, 2020	165	3,589.58	—	—
November 1 to November 30, 2020	226	3,489.58	—	—
December 1 to December 31, 2020	430	3,826.31	—	—
January 1 to January 31, 2021	449	3,633.37	—	—
February 1 to February 28, 2021	358	3,715.33	—	—
March 1 to March 31, 2021	418	3,880.87	—	—
Total	523,683	¥ 4,091.56	520,200	—

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 June 2019, our general meeting of shareholders approved annual transfers of up to 5.0 billion JPY to the wholly-owned trust for the purpose of purchasing shares of our common stock in order to settle grants under the BIP during the three subsequent fiscal years. In May 2020, the wholly-owned trust used such funds to purchase 520,200 shares in respect of grants under the BIP, as reflected in the table above.

A total of 3,483 shares were purchased other than through publicly announced plans or programs during the fiscal year ended March 31, 2021, 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 12 are “external directors” under the Companies Act. Our Audit and Supervisory Committee is comprised of four of our directors, all 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 must 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 five directors (all of which are independent external directors for the purposes of Japanese law and the rules of the Tokyo Stock Exchange) plus one director as an observer who is not an external director. 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 four directors (all of which 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 (all of whom 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 of the registrant’s Annual Report on Form 20-F filed on June 24, 2020)
Exhibit 1.2*	Regulations of the Board of Directors of Takeda Pharmaceutical Company Limited (English Translation)
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*	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.
Exhibit 4.1**	Collaboration Agreement dated December 14, 2009 by and between Seattle Genetics, Inc. and Millennium Pharmaceuticals, Inc.
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 4.3	Takeda Pharmaceutical Company Limited Long Term Incentive Plan (incorporated by reference to Exhibit 99.1 to the Registration Statement on Form S-8 of the registrant filed on June 25, 2020).
Exhibit 8.1	List of subsidiaries of Takeda Pharmaceutical Company Limited, as of March 31, 2021: See “Item 4. Information on the Company—C. Organizational Structure.”
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.
Exhibit 15.1*	Consent of Independent Registered Public Accounting Firm.
Exhibit 15.2*	Consent of Independent Registered Public Accounting Firm.
101.INS*	Inline XBRL Instance Document—the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	The cover page for the registrant’s Annual Report on Form 20-F for the year ended March 31, 2021, has been formatted in Inline XBRL

* Filed herewith.

+ Certain confidential information contained in this exhibit, marked by brackets therein, has been omitted, because it is both not material and would likely cause competitive harm if publicly disclosed.

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% of 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: Director and Chief Financial Officer

Date: June 29, 2021

TAKEDA PHARMACEUTICAL COMPANY LIMITED AND ITS SUBSIDIARIES

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TAKEDA PHARMACEUTICAL COMPANY LIMITED AND ITS SUBSIDIARIES

Report of Independent Registered Public Accounting Firm

To the Shareholders and the 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 its subsidiaries (the “Company”) as of March 31, 2021 and 2020, the related consolidated statements of profit or loss, comprehensive income, changes in equity, and cash flows for each of the years in the three-year period ended March 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the three-year period ended March 31, 2021, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the Company’s internal control over financial reporting as of March 31, 2021, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated June 29, 2021 expressed an unqualified opinion on the effectiveness of the Company’s internal control over financial reporting.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Evaluation of the provisions for U.S. Medicaid, U.S. Medicare and U.S. commercial managed care rebates

As discussed in Notes 3 and 23 to the consolidated financial statements, the Company recorded provisions for contractual and statutory rebates payable under Commercial healthcare provider contracts and U.S. State and Federal government health programs (collectively, U.S. rebates) of 267,254 million JPY which included U.S. Medicaid and U.S. Medicare as well as U.S. commercial managed care programs as a reduction to gross sales to arrive at net sales as of March 31, 2021. The provisions for U.S. rebates are recorded in the same period that the corresponding revenues are recognized; however, the U.S. rebates are not fully paid until subsequent periods.

We identified the evaluation of the provisions for U.S. Medicaid, U.S. Medicare and U.S. commercial managed care rebates as a critical audit matter. A high degree of auditor judgement was required to evaluate the expected product specific assumptions used to estimate the provisions for the U.S. Medicaid, U.S. Medicare and U.S. commercial managed care rebates. The expected product specific assumptions relate to estimating which of the Company's revenue transactions will ultimately be subject to the U.S. Medicaid, U.S. Medicare and U.S. commercial managed care programs.

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design and tested operating effectiveness of certain internal controls over the Company's U.S. Medicaid, U.S. Medicare and U.S. commercial managed care programs provision process. This included controls related to the determination of the expected product specific assumptions used to estimate the provisions for U.S. Medicaid, U.S. Medicare and U.S. commercial managed care programs. We developed independent expectations of U.S. Medicaid, U.S. Medicare and U.S. commercial managed care programs provisions based on the ratios of historical U.S. Medicaid, U.S. Medicare and U.S. commercial managed care programs claims paid to historical gross sales and compared the results to the Company's estimated U.S. Medicaid, U.S. Medicare and U.S. commercial managed care programs provisions. We compared a selection of U.S. Medicaid, U.S. Medicare and U.S. commercial managed care programs claims paid by the Company for consistency with the contractual terms of the Company's rebate agreements. We evaluated the Company's ability to accurately estimate the provisions for U.S. Medicaid, U.S. Medicare and U.S. commercial managed care programs by comparing historically recorded provisions to the actual amounts that were ultimately paid by the Company.

/s/ KPMG AZSA LLC

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

Tokyo, Japan
June 29, 2021

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors

Takeda Pharmaceutical Company Limited:

Opinion on Internal Control Over Financial Reporting

We have audited Takeda Pharmaceutical Company Limited and its subsidiaries' (the "Company") internal control over financial reporting as of March 31, 2021, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of March 31, 2021, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated statements of financial position of the Company as of March 31, 2021 and 2020, the related consolidated statements of profit or loss, comprehensive income, changes in equity, and cash flows for each of the years in the three-year period ended March 31, 2021, and the related notes (collectively, the consolidated financial statements), and our report dated June 29, 2021 expressed an unqualified opinion on those consolidated financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ KPMG AZSA LLC

Tokyo, Japan
June 29, 2021

TAKEDA PHARMACEUTICAL COMPANY LIMITED AND ITS SUBSIDIARIES

Consolidated Statements of Profit or Loss for the Year Ended March 31,

	Note	JPY (millions, except per share data)		
		2019	2020	2021
Revenue	4	¥ 2,097,224	¥ 3,291,188	¥ 3,197,812
Cost of sales		(651,729)	(1,089,764)	(994,308)
Selling, general and administrative expenses		(717,599)	(964,737)	(875,663)
Research and development expenses		(368,298)	(492,381)	(455,833)
Amortization and impairment losses on intangible assets associated with products	12	(178,617)	(455,420)	(421,864)
Other operating income	5	159,863	60,213	318,020
Other operating expenses	5	(103,159)	(248,691)	(258,895)
Operating profit		237,685	100,408	509,269
Finance income	6	16,843	27,831	105,521
Finance expenses	6	(83,289)	(165,006)	(248,631)
Share of profit (loss) of investments accounted for using the equity method	14	(43,627)	(23,987)	76
Profit (loss) before tax		127,612	(60,754)	366,235
Income tax benefit	7	7,468	105,044	9,936
Net profit for the year		¥ 135,080	¥ 44,290	¥ 376,171
Attributable to:				
Owners of the Company	8	¥ 135,192	¥ 44,241	¥ 376,005
Non-controlling interests		(112)	49	166
Net profit for the year		¥ 135,080	¥ 44,290	¥ 376,171
Earnings per share (JPY)				
Basic earnings per share	8	¥ 140.61	¥ 28.41	¥ 240.72
Diluted earnings per share	8	139.82	28.25	238.96

See accompanying notes to consolidated financial statements.

TAKEDA PHARMACEUTICAL COMPANY LIMITED AND ITS SUBSIDIARIES

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

	Note	JPY (millions)		
		2019	2020	2021
Net profit for the year		¥ 135,080	¥ 44,290	¥ 376,171
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	(3,512)	61,866
Remeasurement of defined benefit pension plans	9	(11,665)	(6,398)	4,866
		(5,665)	(9,910)	66,732
Items that may be reclassified subsequently to profit or loss:				
Exchange differences on translation of foreign operations	9	30,976	(207,072)	309,304
Cash flow hedges	9	(33,793)	(25,689)	(45,345)
Hedging cost	9	(4,909)	(857)	(9,147)
Share of other comprehensive loss of investments accounted for using the equity method	9, 14	(94)	(181)	(299)
		(7,820)	(233,799)	254,513
Other comprehensive income (loss) for the year, net of tax	9	(13,485)	(243,709)	321,245
Total comprehensive income (loss) for the year		¥ 121,595	¥ (199,419)	¥ 697,416
Attributable to:				
Owners of the Company		¥ 121,859	¥ (199,569)	¥ 697,202
Non-controlling interests		(264)	150	214
Total comprehensive income (loss) for the year		¥ 121,595	¥ (199,419)	¥ 697,416

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)	
		2020	2021
Assets			
Non-current assets:			
Property, plant and equipment	10	¥ 1,386,370	¥ 1,453,917
Goodwill	11	4,012,528	4,033,917
Intangible assets	12	4,171,361	3,909,106
Investments accounted for using the equity method	14	107,334	112,468
Other financial assets	15	262,121	235,882
Other non-current assets		103,846	100,341
Deferred tax assets	7	308,102	353,769
Total non-current assets		<u>10,351,662</u>	<u>10,199,400</u>
Current assets:			
Inventories	16	759,599	753,881
Trade and other receivables	17	757,005	783,091
Other financial assets	15	15,822	36,598
Income taxes receivable		27,916	29,623
Other current assets		114,196	122,789
Cash and cash equivalents	18	637,614	966,222
Assets held for sale	19	157,280	20,689
Total current assets		<u>2,469,432</u>	<u>2,712,893</u>
Total assets		<u>¥ 12,821,094</u>	<u>¥ 12,912,293</u>

See accompanying notes to consolidated financial statements.

	Note	JPY (millions)	
		2020	2021
Liabilities and Equity			
Liabilities:			
Non-current liabilities:			
Bonds and loans	20	¥ 4,506,487	¥ 4,613,218
Other financial liabilities	21	399,129	517,677
Net defined benefit liabilities	22	156,617	158,857
Income taxes payable		54,932	33,690
Provisions	23	37,605	38,748
Other non-current liabilities	24	52,793	56,898
Deferred tax liabilities	7	710,147	542,852
Total non-current liabilities		<u>5,917,710</u>	<u>5,961,940</u>
Current liabilities:			
Bonds and loans	20	586,817	22,153
Trade and other payables	25	318,816	343,838
Other financial liabilities	21	95,706	248,053
Income taxes payable		182,738	145,203
Provisions	23	405,245	471,278
Other current liabilities	24	499,386	542,651
Liabilities held for sale	19	87,190	—
Total current liabilities		<u>2,175,898</u>	<u>1,773,176</u>
Total liabilities		<u>8,093,608</u>	<u>7,735,116</u>
Equity:			
Share capital		1,668,123	1,668,145
Share premium		1,680,287	1,688,424
Treasury shares		(87,463)	(59,552)
Retained earnings		1,369,972	1,509,906
Other components of equity		92,564	366,114
Equity attributable to owners of the Company		<u>4,723,483</u>	<u>5,173,037</u>
Non-controlling interests		4,003	4,140
Total equity		<u>4,727,486</u>	<u>5,177,177</u>
Total liabilities and equity		<u>¥ 12,821,094</u>	<u>¥ 12,912,293</u>

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															
	Share capital				Other components of equity							Total		Non-controlling interests		Total 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	Remeasurement of defined benefit pension plans	Other comprehensive income related to assets held for sale	Total	Non-controlling interests			
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				15,401		84,672	(73,037)	(1,378)			10,257		25,658	(10)	25,648	
Restated 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				135,192									135,192	(112)	135,080	
Other comprehensive income (loss)					26,301	5,938		(33,793)	(4,909)	(11,665)	(18,128)	4,795	(13,333)	(152)	(13,485)	
Comprehensive income (loss) for the year				135,192	26,301	5,938	—	(33,793)	(4,909)	(11,665)	(18,128)	4,795	121,859	(264)	121,595	
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)	¥1,595,431	¥ 299,128	¥ 46,380	¥ —	¥ 2,959	¥ 1,412	¥ —	¥ 349,879	¥ —	¥5,181,985	¥ 4,006	¥ 5,185,991	

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												
	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	Cash flow hedges	Hedging cost	Remeasurement of defined benefit pension plans	Total	Total	Non-controlling interests	Total equity
As of April 1, 2019	¥1,643,585	¥1,650,232	¥ (57,142)	¥1,595,431	¥ 299,128	¥ 46,380	¥ 2,959	¥ 1,412	¥ —	¥ 349,879	¥ 5,181,985	¥ 4,006	¥ 5,185,991
Cumulative effects of changes in accounting policies				(512)						—	(512)		(512)
Restated opening balance	1,643,585	1,650,232	(57,142)	1,594,919	299,128	46,380	2,959	1,412	—	349,879	5,181,473	4,006	5,185,479
Net profit for the year				44,241						—	44,241	49	44,290
Other comprehensive income (loss)					(207,280)	(3,586)	(25,689)	(857)	(6,398)	(243,810)	(243,810)	101	(243,709)
Comprehensive income (loss) for the year	—	—	—	44,241	(207,280)	(3,586)	(25,689)	(857)	(6,398)	(243,810)	(199,569)	150	(199,419)
Transactions with owners:													
Issuance of new shares	24,538	24,538								—	49,076		49,076
Acquisition of treasury shares			(52,750)							—	(52,750)		(52,750)
Disposal of treasury shares		(0)	1							—	1		1
Dividends (Note 26)				(282,693)						—	(282,693)	(153)	(282,846)
Transfers from other components of equity				13,505		(19,903)			6,398	(13,505)	—		—
Share-based compensation (Note 28)		29,122								—	29,122		29,122
Exercise of share-based awards (Note 28)		(23,605)	22,428							—	(1,177)		(1,177)
Total transactions with owners	24,538	30,055	(30,321)	(269,188)	—	(19,903)	—	—	6,398	(13,505)	(258,421)	(153)	(258,574)
As of March 31, 2020	¥1,668,123	¥1,680,287	¥ (87,463)	¥1,369,972	¥ 91,848	¥ 22,891	¥ (22,730)	¥ 555	¥ —	¥ 92,564	¥ 4,723,483	¥ 4,003	¥ 4,727,486

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												
	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	Cash flow hedges	Hedging cost	Remeasurement of defined benefit pension plans	Total	Total	Non-controlling interests	Total equity
As of April 1, 2020	¥ 1,668,123	¥ 1,680,287	¥ (87,463)	¥ 1,369,972	¥ 91,848	¥ 22,891	¥ (22,730)	¥ 555	¥ —	¥ 92,564	¥ 4,723,483	¥ 4,003	¥ 4,727,486
Net profit for the year				376,005						—	376,005	166	376,171
Other comprehensive income (loss)					308,950	61,873	(45,345)	(9,147)	4,866	321,197	321,197	48	321,245
Comprehensive income (loss) for the year				376,005	308,950	61,873	(45,345)	(9,147)	4,866	321,197	697,202	214	697,416
Transactions with owners:													
Issuance of new shares	22	22								—	44		44
Acquisition of treasury shares			(2,141)							—	(2,141)		(2,141)
Disposal of treasury shares		(0)	2							—	2		2
Dividends (Note 26)				(283,718)						—	(283,718)	(77)	(283,795)
Transfers from other components of equity				47,647		(42,781)			(4,866)	(47,647)	—		—
Share-based compensation (Note 28)		37,663								—	37,663		37,663
Exercise of share-based awards (Note 28)		(29,548)	30,050							—	502		502
Total transactions with owners	22	8,137	27,911	(236,071)	—	(42,781)	—	—	(4,866)	(47,647)	(247,648)	(77)	(247,725)
As of March 31, 2021	¥ 1,668,145	¥ 1,688,424	¥ (59,552)	¥ 1,509,906	¥ 400,798	¥ 41,983	¥ (68,075)	¥ (8,592)	¥ —	¥ 366,114	¥ 5,173,037	¥ 4,140	¥ 5,177,177

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)		
		2019	2020	2021
Cash flows from operating activities:				
Net profit for the year		¥ 135,080	¥ 44,290	¥ 376,171
Depreciation and amortization		247,691	583,649	559,671
Impairment losses		10,120	101,882	25,452
Equity-settled share-based compensation		20,084	29,122	37,663
Change in estimate of liabilities related to SHP647	5	—	—	(60,179)
Gain on sales and disposal of property, plant and equipment		(45,220)	(990)	(2,109)
Gain on divestment of business and subsidiaries		(82,975)	(16,755)	(229,993)
Loss (gain) on liquidation of foreign operations		(2,669)	399	—
Change in fair value of financial assets and liabilities associated with contingent consideration arrangements, net		(5,966)	(18,387)	59,277
Finance (income) and expenses, net		66,446	137,175	143,110
Share of loss (profit) of investments accounted for using the equity method		43,627	23,987	(76)
Income tax benefit		(7,468)	(105,044)	(9,936)
Changes in assets and liabilities:				
Increase in trade and other receivables		(13,382)	(34,826)	(9,316)
Decrease in inventories		50,717	137,492	25,978
Increase (decrease) in trade and other payables		(16,413)	(29,932)	36,620
Increase in provisions		47,063	21,938	49,099
Increase (decrease) in other financial liabilities		(4,008)	7,158	173,400
Other, net		(69,339)	15,362	37,786
Cash generated from operations		373,388	896,520	1,212,618
Income taxes paid		(51,536)	(234,612)	(235,801)
Tax refunds and interest on tax refunds received		6,627	7,844	34,114
Net cash from operating activities		328,479	669,752	1,010,931
Cash flows from investing activities:				
Interest received		6,305	11,487	1,105
Dividends received		2,739	1,382	387
Acquisition of property, plant and equipment		(77,677)	(127,082)	(111,206)
Proceeds from sales of property, plant and equipment		50,717	12,578	46,453
Acquisition of intangible assets		(56,437)	(90,628)	(125,262)
Acquisition of investments		(17,099)	(7,551)	(12,596)
Proceeds from sales and redemption of investments		65,035	49,402	74,604
Acquisition of businesses, net of cash and cash equivalents acquired		(2,958,686)	(4,890)	—
Proceeds from sales of business, net of cash and cash equivalents divested		85,131	461,546	530,388
Proceeds from withdrawal of restricted deposits		71,844	—	—
Other, net		(7,570)	(14,125)	(10,343)
Net cash from (used in) investing activities		(2,835,698)	292,119	393,530
Cash flows from financing activities:				
Net increase (decrease) in short-term loans and commercial papers	27	367,319	(351,223)	(149,043)
Proceeds from issuance of bonds and long-term loans	27	2,795,926	496,190	1,179,515
Repayments of bonds and long-term loans	27	—	(701,057)	(1,651,706)
Payments for settlement of forward rate agreement related to bonds		—	—	(34,830)
Acquisition of treasury shares		(1,172)	(3,737)	(2,141)
Interest paid		(34,914)	(127,211)	(107,350)
Dividends paid		(142,952)	(282,582)	(283,357)
Acquisition of non-controlling interests		(2,392)	(1,700)	—
Repayments of lease liabilities (2019: Repayments of obligations under finance lease)	27	(1,741)	(30,000)	(39,270)
Facility fees paid for loan agreements		(19,507)	—	—
Other, net		(14,330)	(3,893)	(172)
Net cash from (used in) financing activities		2,946,237	(1,005,213)	(1,088,354)
Net increase (decrease) in cash and cash equivalents		439,018	(43,342)	316,107
Cash and cash equivalents at the beginning of the year				
(Consolidated statements of financial position)	18	294,522	702,093	637,614
Cash and cash equivalents reclassified back from assets held for sale		451	629	—
Cash and cash equivalents at the beginning of the year		294,973	702,722	637,614
Effects of exchange rate changes on cash and cash equivalents		(31,269)	(21,766)	12,501
Cash and cash equivalents at the end of the year		702,722	637,614	966,222
Cash and cash equivalents reclassified to assets held for sale		(629)	—	—
Cash and cash equivalents at the end of the year				
(Consolidated statements of financial position)	18	702,093	637,614	966,222

See accompanying notes to consolidated financial statements.

TAKEDA PHARMACEUTICAL COMPANY LIMITED AND ITS SUBSIDIARIES

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, R&D-driven biopharmaceutical company with an innovative portfolio, engaged primarily in the research, development, production and global commercialization of pharmaceutical products. Our intent is to translate science into highly innovative life transforming medicines. Takeda has 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. Takeda’s principal pharmaceutical products include medicines in the following key business areas: gastroenterology (“GI”), rare diseases, Plasma-Derived Therapies (“PDT”), oncology, and neuroscience.

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 interpretation’s committees (Standard Interpretations Committee (“SIC”) and International Financial Reporting Interpretations Committee (“IFRIC”).

Approval of Financial Statements

The Company’s consolidated financial statements presented were approved on June 29, 2021 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 equity investments, derivative financial instruments, and financial assets and liabilities associated with contingent consideration arrangements.

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, 2021, there were no new accounting standards applied by Takeda that had a significant impact on Takeda’s consolidated financial statements.

New Accounting Standards and Interpretations Issued and Not Yet Adopted

There were no new or amended accounting standards and interpretations issued and not yet adopted that would be expected to have a significant impact on Takeda’s consolidated financial statements.

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 intangible assets (Note 12)
- Measurement of fair value of assets acquired and liabilities assumed and contingent consideration in business combinations (Note 27 and Note 31)
- Measurement of provisions (Note 23)
- Estimation of rebates and return reserves associated with Takeda's product sales (Note 3 and Note 23)
- Probability of an outflow of resources embodying economic benefits on contingent liabilities (Note 32)

Although the COVID-19 pandemic could potentially impact business activities within Takeda, the overall impact on Takeda's consolidated financial results has been limited to date. Therefore, the pandemic did not have a significant impact on accounting estimates and assumptions used for the preparation of the consolidated financial statements. Takeda will continue to reassess estimates and assumptions as the situation evolves.

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 associates. 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 in 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 at the acquisition date. 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 profit or loss.

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 remeasured 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 remeasured 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 remeasured 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 remeasured at the exchange rate at the date of the initial transaction. Exchange differences arising from the remeasurement 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 remeasurement 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

Takeda's 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 Takeda expects 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 the 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 or 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 to the extent it is highly probable that a significant reversal will not occur.

Takeda's 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 judgment 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. Takeda monitors the obligation for these deductions on at least a quarterly basis and records adjustments when rebate trends, rebate programs and contract terms, legislative changes, or other significant events indicate that a change in the obligation is appropriate. Historically, adjustments to rebate accruals have not been material to net earnings. The United States (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: The U.S. Medicaid Drug Rebate Program is administered by state governments using state and federal funds to provide assistance to certain qualifying individuals and families, who cannot finance their own medical expenses. 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 estimated based upon identifying the products subject to a rebate, historical experience, patient demand, product pricing and the mix of contracts and specific terms in the individual state agreements. The provisions

for Medicaid rebates are recorded in the same period that the corresponding revenues are recognized; however, the Medicaid rebates are not fully paid until subsequent periods. There is often a time lag of several months between Takeda recording the revenue deductions and Takeda's final accounting for Medicaid rebates. These expected product specific assumptions relate to estimating which of Takeda's revenue transactions will ultimately be subject to the U.S. Medicaid program.

- U.S. Medicare: 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, patient demand, product pricing and the mix of contracts. The provisions for Medicare Part D rebates are recorded in the same period that the corresponding revenues are recognized; however, the Medicare Part D rebates are not fully paid until subsequent periods. There is often a time lag of several months between Takeda recording the revenue deductions and Takeda's final accounting for Medicare Part D rebates. These expected product specific assumptions relate to estimating which of the Takeda's revenue transactions will ultimately be subject to the U.S. Medicare program.
- Customer rebates: Customer rebates including commercial managed care in the U.S. 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 Takeda's products. Since rebates are contractually agreed upon, the related provisions are estimated based on the terms of the individual agreements, historical experience, and patient demand. The provisions for commercial managed care rebates in the U.S. are recorded in the same period that the corresponding revenues are recognized; however, commercial managed care rebates in the U.S. are not fully paid until subsequent periods. There is often a time lag of several months between Takeda recording the revenue deductions and Takeda's final accounting for commercial managed care rebates in the U.S. These expected product specific assumptions relate to estimating which of Takeda's revenue transactions will ultimately be subject to the commercial managed care in the U.S.
- Wholesaler chargebacks: Takeda has 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 demand. Takeda has a legally enforceable right to set off the trade receivables and chargebacks and it intends either to settle them on a net basis or to realize the asset and settle the liability simultaneously. Thus the provision for chargebacks are recorded as a deduction from trade receivables on the consolidated statements of financial position.
- Return reserves: When Takeda sells a product providing a customer with the right to return, Takeda records a provision for estimated sales returns based on its sales return policy and historical return rates. Takeda estimates 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, expected product specific assumptions used in estimating which of Takeda's revenue transactions will ultimately be subject to the respective programs.

Takeda generally receives payments from customers within 90 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 in which case 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 R&D 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 performs 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 in 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 in profit or loss and offset the related expenses over the periods in which Takeda recognizes costs for which the grants are intended to compensate.

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 profit or loss in the

consolidated statements of profit or loss. Property, plant and equipment used for R&D 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 taxes 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. Income taxes payable and income taxes 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 using tax rates and tax law that have been enacted or substantively enacted by the reporting date, reflecting uncertainty related to income taxes, if any. Takeda's current taxes also include liabilities related to uncertain tax positions. Inherent uncertainties exist in estimates of many uncertain tax positions due to changes in tax law resulting from legislation, regulation, and/or as concluded through the various jurisdictions' tax court systems. When Takeda concludes that it is not probable that a tax authority will accept an uncertain tax position, Takeda recognizes the best estimate of the expenditure required to settle a tax uncertainty. This is measured either based on the most likely amount or the expected value amount, depending on which method provides a better prediction of the resolution of the uncertainty. The amount of unrecognized tax benefits is adjusted for changes in facts and circumstances. 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 Takeda to evaluate and assess the probability of future taxable profit and Takeda's business plan, which are inherently uncertain. The change in judgment upon determining the revenue forecast used for Takeda's business plan could have a significant impact on the amount of the deferred tax assets to be recognized. Uncertainty of estimates of future taxable profit could increase due to changes in economies in which Takeda operates, 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. ROU 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 (CGUs) or groups of cash-generating units that represent the lowest level within the entity for which information about goodwill is available and monitored for internal management purposes and are not larger than an operating segment. Goodwill is only allocated to CGUs or groups of CGUs that are expected to benefit from synergies related to the business combination from which goodwill arose and the method of allocation depends on the facts and circumstances of the business combination. Goodwill is tested for impairment annually or whenever there is any indication of impairment. Impairment losses on goodwill are recognized in the consolidated statements of profit or loss 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 patent life, and/or other factors depending on the expected economic benefits of the asset, 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 profit or loss. Amortization and impairment losses on intangible assets associated with products is separately stated in the consolidated statements of profit or loss 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 R&D 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 achieved.

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 R&D 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 profit or loss.

Leases

Subsequent to April 1, 2019

As Lessee

Takeda assesses whether a contract is or contains a lease at inception of a contract. As a lessee, Takeda recognizes a ROU asset and a corresponding lease liability for all contracts in which it is a lessee in the consolidated statements of financial position at the lease commencement date.

The ROU asset is initially measured at cost, being the initial amount of the lease liability adjusted for any lease payments made at or before the lease commencement date and subsequently at cost less any accumulated depreciation and impairment losses. The ROU asset is subsequently depreciated using the straight-line method over the shorter of the lease term or the estimated useful life of the underlying asset. The ROU asset is subject to impairment assessment.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted using the interest rate implicit in the lease or, if not readily determinable, the Takeda's incremental borrowing rate.

Generally, Takeda uses its incremental borrowing rate as the discount rate. The lease term comprises a non-cancellable period of lease contracts and periods covered by an option to extend or terminate the lease if Takeda is reasonably certain to exercise that option. After initial recognition, the lease liability is measured at amortized cost using the effective interest method. If there is a change in future lease payments, such as from reassessment of whether an extension or termination option will be exercised, the lease liability is remeasured. A corresponding adjustment is made to the ROU asset or is recorded in the consolidated statements of profit or loss when the right-of-use asset has been fully depreciated.

Takeda has elected to apply recognition exemption for leases that have a lease term of 12 months or less and leases of low-value assets. The lease payments for such leases are recognized as an expense on a straight-line basis over the lease term.

As a practical expedient, Takeda has elected not to separate non-lease components from lease components, and instead accounts for each lease component and any associated non-lease components as a single lease component.

Prior to April 1, 2019

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 recognized 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 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 net defined benefit assets. 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 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 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, net of depreciation and amortization, 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 or 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 as defined benefit plans or defined contribution plans, depending on the characteristics of the 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. If the defined benefit plan has a surplus, the net defined benefit asset is limited to the present value of any future economic benefits available in the form of refunds from the plan or reductions in future contributions to the plan. 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.

Remeasurement 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 employees render related services.

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

Initial Recognition and Measurement

Financial assets are recognized in the consolidated statements of financial position when Takeda becomes a party to the contract of the instruments. Financial assets, except for investments in debt instruments measured 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 measured 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 deductions such as impairment loss allowance and cash discounts.
- Investments in debt instruments measured 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 measured at FVTPL: Assets that do not meet the criteria for amortized cost or FVTOCI are measured at FVTPL.
- Equity instruments measured at FVTOCI: On initial recognition, Takeda makes 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 measured 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 measured 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 measured 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 arising from changes in fair value are recognized in other comprehensive income. Upon derecognition of the investments, the gains and losses accumulated in other comprehensive income related to the investment is reclassified to profit or loss.
- Investments in debt instruments measured 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 measured 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 other comprehensive income and are never reclassified to profit or loss. Upon derecognition of the investments, the amounts in other comprehensive income related to the investment is reclassified within equity to retained earnings.

Impairment

Loss allowances are established using an Expected Credit Loss (“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, the contract assets and the lease receivables in the consolidated statements of financial position and the estimated collectible net amount.

Financial Liabilities

Initial Recognition and Measurement

Financial liabilities are recognized in the consolidated statements of financial position when Takeda becomes a party to the contract of financial instruments. Financial liabilities are classified, at initial recognition, as financial liabilities measured at FVTPL, bonds and loans, or payables.

Financial liabilities, except for those measured at FVTPL, are initially measured at fair value less transaction costs that are directly attributable to the issuance.

Subsequent Measurement

- Financial liabilities measured at FVTPL: Financial liabilities measured at FVTPL are measured at fair value, and any gains or losses arising on re-measurement are recognized in profit or loss. Financial liabilities measured at FVTPL include derivatives and financial liabilities associated with contingent consideration arrangements.
- 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, canceled, 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 its exposure to fluctuations in foreign currency exchange rates and interest rates using derivatives such as foreign exchange forward contracts, currency options, interest rate swaps, cross currency interest rate swaps and interest rate future. 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 designated 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

For foreign currency exposure as a result of translation risk, Takeda designates certain non-derivatives, such as foreign currency denominated debt and certain derivatives such as foreign currency forwards, 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, currency options and cross

currency interest rate swaps, as cash flow hedges of forecasted transactions. For interest risk exposure, Takeda designates derivatives such as interest and cross currency interest rate swaps and forward rate agreements, 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 profit or loss. 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 in foreign operations: the gain or loss on hedging instruments in foreign operation 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.

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 profit or loss 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 profit or loss.

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 Takeda are included in share capital and share premium.

Treasury Shares

When Takeda acquires treasury shares, the consideration paid is recognized as a deduction from equity. When Takeda 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, marketing and out-licensing of pharmaceutical 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.

Disaggregation of Revenue Information

Takeda's revenue from contracts with customers is comprised of the following:

Revenue by Type of Good or Service

	JPY (millions)		
	For the Year Ended March 31		
	2019	2020	2021
Sales of pharmaceutical products	¥ 2,026,273	¥ 3,204,152	¥ 3,105,376
Out-licensing and service income	70,951	87,036	92,436
Total	¥ 2,097,224	¥ 3,291,188	¥ 3,197,812

Revenue by Therapeutic Area and Product

	JPY (millions)		
	For the Year Ended March 31		
	2019	2020	2021
Gastroenterology:			
ENTYVIO	¥ 269,199	¥ 347,196	¥ 429,281
TAKECAB-F ⁽¹⁾	58,241	72,713	84,822
GATTEX/REVESTIVE	12,753	61,812	64,564
DEXILANT	69,197	62,797	55,572
PANTOLOC/CONTROLOC ⁽²⁾	61,629	49,463	43,120
ALOFISEL	45	373	784
Others	68,254	103,542	99,657
Total Gastroenterology	539,318	697,896	777,800
Rare Diseases:			
Rare Metabolic:			
ELAPRASE	15,083	67,924	68,786
REPLAGAL	11,437	51,253	51,764
VPRIV	8,688	38,013	38,518
NATPARA/NATPAR	7,094	13,635	3,552
Total Rare Metabolic	42,302	170,825	162,620
Rare Hematology:			
ADVATE	32,099	157,856	128,535
ADYNOVATE/ADYNOVI	10,740	58,672	58,070
FEIBA	9,634	51,508	44,495
RECOMBINATE	2,769	17,089	13,389
Others	11,462	49,115	45,310
Total Rare Hematology	66,704	334,240	289,799
Hereditary Angioedema:			
TAKHZYRO	9,729	68,271	86,718
FIRAZYR	6,416	32,662	26,824
Others	4,270	28,890	25,785
Total HAE (Hereditary Angioedema)	20,415	129,823	139,327
Total Rare Diseases	129,421	634,888	591,746

	JPY (millions) For the Year Ended March 31		
PDT Immunology:			
immunoglobulin	73,462	298,697	334,874
albumin	12,299	67,215	57,580
Others	7,718	28,253	27,935
Total PDT Immunology	93,479	394,165	420,389
Oncology:			
VELCADE	127,869	118,321	101,112
LEUPLIN/ENANTONE	110,074	109,048	95,365
NINLARO	62,171	77,555	87,396
ADCETRIS	42,903	52,672	59,432
ICLUSIG	28,705	31,815	34,193
ALUNBRIG	5,199	7,237	8,806
Others	22,519	24,308	30,208
Total Oncology	399,440	420,956	416,512
Neuroscience:			
VYVANSE/ELVANSE	49,354	274,077	271,531
TRINTELLIX	57,550	70,666	68,869
Others	47,766	93,777	76,897
Total Neuroscience	154,670	438,520	417,297
Other:			
AZILVA-F ⁽¹⁾	70,762	76,749	82,205
NESINA/VIPIDIA-F ⁽¹⁾	54,789	57,958	57,670
LOTRIGA	30,856	31,752	31,765
Others ⁽³⁾	624,489	538,304	402,428
Total Other	780,896	704,763	574,068
Total	¥ 2,097,224	¥ 3,291,188	¥ 3,197,812

⁽¹⁾ The figures include the amounts of fixed dose combinations and blister packs.

⁽²⁾ Generic name: pantoprazole

⁽³⁾ The figures include the revenue of Takeda Consumer Healthcare Company Limited, which was divested on March 31, 2021.

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	
2019	¥	571,016	¥	828,985	¥	405,641	¥	59,741	¥	88,115	¥	105,411	¥	38,315	¥	2,097,224
2020		592,786		1,595,922		645,528		76,835		143,456		165,401		71,260		3,291,188
2021		559,748		1,567,931		666,177		57,560		121,638		156,240		68,518		3,197,812

“Other” includes the Middle East, Oceania and Africa. This disaggregation provides revenue attributable to countries or regions based on the customer location.

Takeda's non-current assets are held in the following geographic locations:

	JPY (millions)				
	As of March 31				
	Japan	United States	Switzerland	Other	Total
2020	¥ 385,709	¥ 6,533,733	¥ 1,484,238	¥ 1,240,046	¥ 9,643,726
2021	413,402	6,345,039	1,494,239	1,210,197	9,462,877

Non-current assets exclude financial instruments, deferred tax assets and net defined benefit assets.

Information Related to Major Customers

During the year ended March 31, 2019, Medipal Holdings Corporation and its subsidiaries (collectively, "Medipal Group") represented more than 10% of Takeda's sales. The sales to Medipal Group were 225,962 million JPY for the year ended March 31, 2019.

During the years ended March 31, 2020 and 2021, AmerisourceBergen Corporation and its subsidiaries (collectively, "AmerisourceBergen Group") and McKesson Corporation and its subsidiaries (collectively, "McKesson Group") represented more than 10% of Takeda's sales. The sales to AmerisourceBergen Group were 367,625 million JPY and 370,759 million JPY for the years ended March 31, 2020 and 2021, respectively. The sales to McKesson Group were 342,210 million JPY and 345,292 million JPY for the years ended March 31, 2020 and 2021, respectively.

Other Revenue Information

Contract Balances

	JPY (millions)	
	As of March 31	
	2020	2021
Receivables from contracts with customers		
Trade receivables (Note 17)	¥ 670,708	¥ 707,487
Contract assets		
Unbilled receivables	5,315	5,680
Contract liabilities		
Deferred income (Note 24)	3,890	31,995
Advance payments	1,898	2,768

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.

Takeda's contract liabilities primarily relate to out-licensing arrangements or product purchase and supply agreements where Takeda receives cash consideration prior to the completion of its performance obligations under the agreements. The revenue recognized during the years ended March 31, 2020, and 2021 that was included in the contract liability balance as of the beginning of the year was 2,704 million JPY and 1,165 million JPY, respectively. The revenue recognized during the years ended March 31, 2020 and 2021 from performance obligations satisfied (or partially satisfied) in previous periods was 48,825 million JPY and 57,903 million JPY, respectively, and primarily relates to royalty income.

Transaction price allocated to the remaining performance obligations

	JPY (millions)			
	Total	Duration of the remaining performance obligations		
		Within one year	Between one and five years	More than five years
Contract liabilities as of March 31, 2020	¥ 5,788	¥ 2,598	¥ 1,003	¥ 2,187
Contract liabilities as of March 31, 2021	34,763	31,788	2,263	712

5. Other Operating Income and Expenses

	JPY (millions)					
	For the Year Ended March 31					
	2019		2020		2021	
Other operating income:						
Change in fair value of financial assets and liabilities associated with contingent consideration arrangements (Note 27)	¥	5,966	¥	18,383	¥	13,663
Gain on sales of property, plant and equipment and investment property		50,330		3,152		4,734
Gain on divestment of business to Teva Takeda Yakuhin (Note 14)		30,366		14,166		1,460
Gain on divestment of business and subsidiaries (Note 19)		56,625		2,553		228,923
Insurance proceeds		799		8,279		479
Change in estimate of liabilities related to SHP647 (Note 19)		—		—		60,179
Other		15,777		13,680		8,582
Total	¥	159,863	¥	60,213	¥	318,020
Other operating expenses:						
Donations and contributions	¥	3,627	¥	8,513	¥	8,412
Restructuring expenses (Note 23)		82,962		181,040		115,875
Loss on liquidation of foreign operations		2,112		—		—
Change in fair value of financial assets associated with contingent consideration arrangements (Note 27)		—		—		72,940
Loss on sale of shares of subsidiaries		4,016		—		—
Valuation reserve for pre-launch inventories (reversal)		(4,113)		30,411		19,486
Impairment of assets held for sale (Note 19)		—		12,897		530
Other		14,555		15,830		41,652
Total	¥	103,159	¥	248,691	¥	258,895

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 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.

For the year ended March 31, 2020, impairment of asset held for sale relates to divestment of a portfolio of selected over-the-counter and prescription pharmaceutical assets sold in Near East, Middle East and Africa countries as well as Russia, Georgia and countries within the Commonwealth of Independent States.

For the year ended March 31, 2021, gain on divestment of business and subsidiaries includes sale of shares and relevant assets of Takeda Consumer Healthcare Company Limited and other non-core assets, as further described in Note 19. Change in estimate of liabilities related to SHP647 for the year ended March 31, 2021 is revaluation gain of liabilities for the future costs, such as program termination costs of pipeline compound SHP647 and certain associated rights ("SHP647")^(Note). This revaluation gain was recorded upon the European Commission's decision in May 2020 to release Takeda's obligation to divest SHP647.

(Note) Upon the Shire Acquisition in 2018, the European Commission required Takeda to divest SHP647 and certain associated rights and we recorded a liability associated with that obligation.

Change in fair value of financial assets associated with contingent consideration arrangements included in other operating expenses for the year ended March 31, 2021 is driven by changes in assumptions related to the future sales of XIIDRA previously sold to Novartis, including the impact from Novartis' withdrawal of the Marketing Authorisation Application in Europe. Other in other operating expenses for the year ended March 31, 2021 includes mainly legal provision for certain legal proceeding of 17,401 million JPY.

6. Finance Income and Expenses

	JPY (millions)					
	For the Year Ended March 31					
	2019		2020		2021	
Finance Income:						
Interest income						
Interest income from financial assets measured at amortized cost	¥	6,171	¥	10,763	¥	1,117
Interest income from financial assets measured at fair value through P&L		448		248		660
Interest income on sublease		—		191		4
Total interest income		6,619		11,202		1,781
Dividend income						
Dividend income from financial assets measured at fair value through OCI and disposed of during the period		1,353		603		252
Dividend income from financial assets measured at fair value through OCI and held at end of the period		1,116		745		120
Dividend income from financial assets measured at fair value through P&L		145		96		—
Total dividend income		2,614		1,444		372
Gain on derivative financial assets		—		—		91,990
Gain on foreign currency exchange, net		7,007		10,979		—
Change in fair value of financial assets associated with contingent consideration arrangements (Note 27)		—		3,478		3,294
Other		603		728		8,084
Total	¥	16,843	¥	27,831	¥	105,521
Finance Expenses:						
Interest expense						
Interest expense on financial debt			¥	137,176	¥	118,682
Interest expense on lease liabilities				11,834		12,124
Total interest expense	¥	48,158		149,010		130,806
Change in fair value of financial liabilities associated with contingent consideration arrangements (Note 27)		3,743		4,637		3,601
Loss on derivative financial assets		11,365		1,790		—
Loss on foreign currency exchange, net		—		—		97,319
Financing fees for bridge loan for acquisition of Shire		16,102		—		—
Other		3,921		9,569		16,905
Total	¥	83,289	¥	165,006	¥	248,631

7. Income Taxes

Income Tax Expense (Benefit)

The composition of income tax expense (benefit) is as follows:

	JPY (millions)					
	For the Year Ended March 31					
	2019		2020		2021	
Current tax expenses	¥	61,606	¥	238,856	¥	131,952
Deferred tax benefits		(69,074)		(343,900)		(141,888)
Total	¥	(7,468)	¥	(105,044)	¥	(9,936)

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 10,875 million JPY, 4,667 million JPY and 12,236 million JPY for the years ended March 31, 2019, 2020 and 2021, respectively.

Deferred tax benefits include the benefits arising from previously unrecognized tax losses, tax credits and temporary differences of prior periods. These effects decreased deferred tax expenses by 6,975 million JPY, 62,015 million JPY and 57,200 million JPY for the years ended March 31, 2019, 2020 and 2021, respectively.

Takeda is mainly subject to income taxes, inhabitant tax, and deductible enterprise tax in Japan. The statutory tax rate calculated based on these taxes is 30.6% for the years ended March 31, 2019, 2020 and 2021.

The following is a reconciliation from income tax expenses (benefits) at Takeda's domestic (Japanese) statutory tax rate to Takeda's income tax expenses (benefits) reported for the year ended March 31:

	JPY (millions)		
	2019	2020	2021
Profit (loss) before tax	¥ 127,612	¥ (60,754)	¥ 366,235
Income tax expenses (benefits) at Takeda's domestic (Japanese) statutory tax rate of 30.6%	39,024	(18,579)	111,995
Non-deductible expenses for tax purposes ⁽¹⁾	22,024	26,074	25,114
Changes in unrecognized deferred tax assets and deferred tax liabilities ⁽²⁾	(58,388)	(126,071)	(137,032)
Tax credits ⁽³⁾	(12,750)	(35,100)	(25,673)
Differences in applicable tax rates of overseas subsidiaries ⁽⁴⁾	4,762	71,526	(258)
Changes in tax effects of undistributed profit of overseas subsidiaries	7,469	2,388	5,951
Effect of changes in applicable tax rates and tax law ⁽⁵⁾	1,800	(94,969)	(5,073)
Tax contingencies ⁽⁶⁾	(9,530)	17,124	(13,164)
Non-deductible impairment of goodwill	—	5,529	—
Changes in fair value of contingent consideration	(1,955)	(1,201)	746
Effect of prior year items	(648)	(3,520)	(10,689)
Entity reorganizations/Divestments ⁽⁷⁾	—	58,815	36,117
Other	724	(7,060)	2,030
Income tax benefits reported for the year	¥ (7,468)	¥ (105,044)	¥ (9,936)

⁽¹⁾ Amounts for the years ended March 31, 2019, 2020 and 2021 include the impact from intra territory eliminations, the pre-tax effect of which has been eliminated in arriving at Takeda's consolidated income from continuing operations before income taxes.

Amount for the year ended March 31, 2019 also includes non-deductible transaction costs related to the Shire acquisition and amount for the year ended March 31, 2021 also includes non-deductible interest due to Japanese earnings stripping rules.

⁽²⁾ Amounts for the years ended March 31, 2019, 2020 and 2021 primarily driven by capital tax losses related to restructuring of subsidiaries. Both amounts for the years ended March 31, 2020 and 2021 also include deferred tax benefits from the reversal of write down of carried forward net operating losses and Swiss tax basis step-up.

⁽³⁾ Amount for the year ended March 31, 2020 includes (10,389) million JPY impact from enhanced credit claims related to prior fiscal years.

⁽⁴⁾ Amounts for the years ended March 31, 2019, 2020 and 2021 include unitary and minimum taxes on overseas subsidiaries.

⁽⁵⁾ Amount for the year ended March 31, 2020 primarily relates to the deferred tax benefit from Swiss Tax Reform enactment.

⁽⁶⁾ Tax benefit amounts for the years ended March 31, 2019 and 2021 primarily relate to the tax benefits driven by favorable audit settlements.

⁽⁷⁾ 58,815 million JPY impact for the year ended March 31, 2020 primarily relates to deferred tax expenses arising from the change in tax jurisdictions as a result of realignment of intangible assets with business operations and tax costs incurred in legal entity reorganizations. 36,117 million JPY impact for the year ended March 31, 2021 primarily relates to tax accounting impact of basis difference between accounting which reflects goodwill and tax basis of divested assets.

As a result of the Federal Act on Tax Reform and AHV Financing ("TRAF"), also known as the "Swiss Tax Reform") approved by public referendum nationally on May 19, 2019 and in the canton of Zurich on September 1, 2019, Takeda recognized a net asset tax basis step-up related to the estimated value of one of the Takeda's Swiss subsidiary's assets that is amortizable as a tax deduction to partially offset future taxable earnings generated by the subsidiary over tax years 2020 through 2029. The net asset tax basis step-up resulted in a deferred tax benefit of 102,499 million JPY for the year ended March 31, 2020. In addition to the recognition of the deferred tax asset related to the net asset tax basis step-up, Takeda also recorded a net deferred tax expense of 7,888 million JPY relating to the remeasurement of other Swiss deferred tax assets and liabilities for the change in the Federal and cantonal tax rates. As a result of Swiss Tax Reform enactment, Takeda recognized a net tax benefit of 94,611 million JPY during the year ended March 31, 2020 (in Effect of changes in applicable tax rates and tax law).

For the year ended March 31, 2021, Takeda recorded a deferred tax benefit of 4,369 million JPY for the additional net asset tax basis step-up recognized in the Swiss subsidiary as a result of the finalization of the Swiss subsidiary's statutory financial statements (in Effect of changes in applicable tax rates and tax law).

The increase in Takeda's income tax benefit between the years ended March 31, 2019 and 2020 was primarily due to a non-cash deferred tax benefit as a result of enactment of tax reform in Switzerland in effect of changes in applicable tax rates and tax law and the recognition of deferred tax assets for accumulated net operating loss in changes in unrecognized deferred tax assets and deferred tax liabilities in the fiscal year ended March 31, 2020. These favorable changes were partially offset by higher tax provisions for uncertain tax positions in tax contingencies and tax impacts of restructuring in entity reorganizations/divestments.

The decrease in Takeda's income tax benefit between the years ended March 31, 2020 and 2021 was primarily due to tax provision on higher pretax earnings in the fiscal year ended March 31, 2021, the recognition of a non-cash deferred tax benefit of 94,611 million JPY as a result of the enactment of Swiss Tax Reform in the fiscal year ended March 31, 2020, and the tax impacts of divestitures in entity reorganizations/divestments. These unfavorable changes were partially offset by favorable mix of statutory earnings in differences in applicable tax rates of overseas subsidiaries, tax benefits from the recognition of previously unrecognized deferred tax assets, and favorable audit settlements in the fiscal year ended March 31, 2021 in tax contingencies.

Deferred Taxes

Deferred tax assets and liabilities reported in the consolidated statements of financial position are as follows:

	JPY (millions) As of March 31	
	2020	2021
Deferred tax assets	¥ 308,102	¥ 353,769
Deferred tax liabilities	(710,147)	(542,852)
Net deferred tax liabilities	¥ (402,045)	¥ (189,083)

The major items and changes in deferred tax assets and liabilities are as follows:

	JPY (millions)				
	As of April 1, 2019	Recognized in profit or (loss)	Recognized in other comprehensive income	Other ⁽¹⁾	As of March 31, 2020
Research and development expenses	¥ 29,856	¥ 1,403	¥ —	¥ 1,916	¥ 33,175
Inventories	18,187	31,156	—	(6,786)	42,557
Property, plant and equipment	(90,326)	12,857	—	(5,058)	(82,527)
Intangible assets	(812,445)	234,184	—	(121,589)	(699,850)
Financial assets measured at FVTOCI	(29,282)	(1,754)	3,210	8,409	(19,417)
Accrued expenses and provisions	99,456	29,056	—	7,408	135,920
Defined benefit plans	16,448	1,679	749	4,208	23,084
Deferred income	17,483	(2,862)	—	92	14,713
Unused tax losses	123,698	(8,892)	—	10,085	124,891
Tax credits	73,678	10,413	—	(1,967)	82,124
Investments in subsidiaries and associates	(73,535)	8,979	—	1,697	(62,859)
Other	(5,683)	27,681	11,694	(27,548)	6,144
Total	¥ (632,465)	¥ 343,900	¥ 15,653	¥ (129,133)	¥ (402,045)

JPY (millions)

	As of April 1, 2020	Recognized in profit or (loss)	Recognized in other comprehensive income	Other⁽¹⁾	As of March 31, 2021
Research and development expenses	¥ 33,175	¥ 1,837	¥ —	¥ 449	¥ 35,461
Inventories	42,557	35,228	—	12,944	90,729
Property, plant and equipment	(82,527)	5,612	—	(3,429)	(80,344)
Intangible assets	(699,850)	113,219	—	24,681	(561,950)
Financial assets measured at FVTOCI	(19,417)	506	(17,498)	12,643	(23,766)
Accrued expenses and provisions	135,920	8,822	—	(5,503)	139,239
Defined benefit plans	23,084	(6,322)	2,719	(211)	19,270
Deferred income	14,713	6,191	—	66	20,970
Unused tax losses	124,891	2,690	25,066	(1,696)	150,951
Tax credits	82,124	(18,504)	—	(1,231)	62,389
Investments in subsidiaries and associates	(62,859)	(6,027)	—	(265)	(69,151)
Other	6,144	(1,364)	24,004	(1,665)	27,119
Total	¥ (402,045)	¥ 141,888	¥ 34,291	¥ 36,783	¥ (189,083)

⁽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 charged directly to equity. The aggregate amount of deferred tax related to items charged directly to equity for the years ended March 31, 2020 and March 31, 2021 was nil and (730) million JPY, respectively.

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	
	2020	2021
Unused tax losses	¥ 1,580,235	¥ 1,533,050
Deductible temporary differences	333,336	241,203
Unused tax credits	9,278	9,660

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	
	2020	2021
Unused tax losses		
1st year	¥ —	¥ 23
2nd year	—	18
3rd year	40	19,136
4th year	23,454	482
5th year	753	387,574
After 5th year	1,522,251	1,066,134
Indefinite	33,737	59,683
Total	¥ 1,580,235	¥ 1,533,050

	JPY (millions) As of March 31	
	2020	2021
Unused tax credits		
Less than 5 years	¥ 2,606	¥ 1,370
5 years or more	6,394	8,290
Indefinite	278	—
Total	¥ 9,278	¥ 9,660

The aggregate amounts of temporary differences associated with investments in subsidiaries for which deferred tax assets were not recognized were 1,638,847 million JPY and 948,723 million JPY as of March 31, 2020 and 2021, respectively. The decrease was primarily due to legal entity restructurings during the fiscal year ended March 31, 2021. There was no impact from this decrease on the consolidated statements of profit or loss.

The aggregate amounts of temporary differences associated with investments in subsidiaries for which deferred tax liabilities were not recognized were 3,496,081 million JPY and 212,322 million JPY as of March 31, 2020 and 2021, respectively. The decrease was primarily due to legal entity restructurings during the fiscal year ended March 31, 2021. There was no impact from this decrease on the consolidated statements of profit or loss.

8. Earnings per Share

The basis for calculating basic and diluted earnings per share (“EPS”) (attributable to owners of the Company) is as follows:

	For the Year Ended March 31		
	2019	2020	2021
Net profit for the year attributable to owners of the Company:			
Net profit for the year attributable to owners of the Company JPY (millions)	¥ 135,192	¥ 44,241	¥ 376,005
Net profit used for calculation of earnings per share JPY (millions)	135,192	44,241	376,005
Weighted-average number of ordinary shares outstanding during the year (thousands of shares) [basic]	961,477	1,557,204	1,562,006
Dilutive effect (thousands of shares)	5,420	9,000	11,531
Weighted-average number of ordinary shares outstanding during the year (thousands of shares) [diluted]	966,897	1,566,204	1,573,537
Earnings per share			
Basic (JPY)	140.61	28.41	240.72
Diluted (JPY)	139.82	28.25	238.96

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 814 thousand shares that are anti-dilutive, such as stock options, and therefore not included in the calculation of diluted EPS for the years ended March 31, 2019, 2020 and 2021, respectively.

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		
	2019	2020	2021
Remeasurement of defined benefit pension plans:			
Amounts arising during the year	¥ (14,906)	¥ (7,147)	¥ 2,147
Tax effects	3,241	749	2,719
Remeasurement of defined benefit pension plans	<u>¥ (11,665)</u>	<u>¥ (6,398)</u>	<u>¥ 4,866</u>
Exchange differences on translation of foreign operations:			
Amounts arising during the year	¥ 39,276	¥ (190,190)	¥ 284,350
Reclassification adjustments to profit or (loss)	(3,134)	399	(112)
Before tax effects	36,142	(189,791)	284,238
Tax effects	(5,166)	(17,281)	25,066
Exchange differences on translation of foreign operations	<u>¥ 30,976</u>	<u>¥ (207,072)</u>	<u>¥ 309,304</u>
Changes in fair value of financial assets measured at fair value through OCI:			
Amounts arising during the year	¥ 7,202	¥ (6,722)	¥ 79,364
Tax effects	(1,202)	3,210	(17,498)
Changes in fair value of financial assets measured at fair value through OCI	<u>¥ 6,000</u>	<u>¥ (3,512)</u>	<u>¥ 61,866</u>
Cash flow hedges:			
Amounts arising during the year	¥ (28,063)	¥ (37,626)	¥ (40,833)
Reclassification adjustments to profit or (loss)	(6,363)	620	(24,485)
Before tax effects	(34,426)	(37,006)	(65,318)
Tax effects	633	11,317	19,973
Cash flow hedges	<u>¥ (33,793)</u>	<u>¥ (25,689)</u>	<u>¥ (45,345)</u>
Hedging cost:			
Amounts arising during the year	¥ (4,088)	¥ (344)	¥ (9,978)
Reclassification adjustments to profit or (loss)	(908)	(890)	(3,200)
Before tax effects	(4,996)	(1,234)	(13,178)
Tax effects	87	377	4,031
Hedging cost	<u>¥ (4,909)</u>	<u>¥ (857)</u>	<u>¥ (9,147)</u>
Share of other comprehensive income of investments accounted for using the equity method:			
Amounts arising during the year	¥ (101)	¥ (181)	¥ (299)
Reclassification adjustments to profit or (loss)	7	—	—
Before tax effects	(94)	(181)	(299)
Tax effects	—	—	—
Share of other comprehensive income of investments accounted for using the equity method	<u>¥ (94)</u>	<u>¥ (181)</u>	<u>¥ (299)</u>
Total other comprehensive income (loss) for the year	<u>¥ (13,485)</u>	<u>¥ (243,709)</u>	<u>¥ 321,245</u>

10. Property, Plant and Equipment

JPY (millions)

	Buildings and structures	Machinery and vehicles	Tools, furniture, and fixtures	Land	Construction in progress	Total
Acquisition cost						
As of March 31, 2019	¥ 957,045	¥ 648,974	¥ 122,136	¥ 100,808	¥ 142,559	¥ 1,971,522
Adoption of IFRS 16	187,986	11,222	48	—	—	199,256
As of April 1, 2019	¥ 1,145,031	¥ 660,196	¥ 122,184	¥ 100,808	¥ 142,559	¥ 2,170,778
Additions	23,745	11,548	10,269	2,290	93,097	140,949
Transfers	(35,993)	23,232	8,153	11	(57,826)	(62,423)
Disposals and other decreases	(14,354)	(10,391)	(9,374)	—	(195)	(34,314)
Reclassification to assets held for sale (Note 19)	(26,786)	(7,042)	(296)	(3,465)	(45,286)	(82,875)
Foreign currency translation differences	(18,979)	(16,990)	(4,012)	(3,015)	(4,726)	(47,722)
Other	(661)	(861)	1,930	—	(677)	(269)
As of March 31, 2020	¥ 1,072,003	¥ 659,692	¥ 128,854	¥ 96,629	¥ 126,946	¥ 2,084,124
Additions	109,034	22,318	8,376	—	74,010	213,738
Transfers	27,164	32,125	5,523	(145)	(64,667)	—
Disposals and other decreases	(91,232)	(24,306)	(14,172)	(2,917)	(926)	(133,553)
Reclassification to assets held for sale (Note 19)	(13,413)	(21,030)	(3,071)	(808)	(327)	(38,649)
Foreign currency translation differences	29,853	17,398	8,444	2,475	8,099	66,269
Other	(3)	(62)	(125)	1	(5)	(194)
As of March 31, 2021	¥ 1,133,406	¥ 686,135	¥ 133,829	¥ 95,235	¥ 143,130	¥ 2,191,735
Accumulated depreciation and accumulated impairment losses						
As of April 1, 2019	¥ (250,148)	¥ (311,317)	¥ (74,962)	¥ (374)	¥ (2,790)	¥ (639,591)
Depreciation expenses	(60,570)	(58,860)	(19,324)	—	—	(138,754)
Impairment losses	(18,057)	(710)	(647)	(601)	—	(20,015)
Transfers	37,101	3,931	882	—	—	41,914
Disposals and other decreases	3,842	7,816	8,835	—	—	20,493
Reclassification to assets held for sale (Note 19)	17,600	5,158	252	—	—	23,010
Foreign currency translation differences	7,427	6,856	2,449	15	8	16,755
Other	(439)	1,491	(2,618)	—	—	(1,566)
As of March 31, 2020	¥ (263,244)	¥ (345,635)	¥ (85,133)	¥ (960)	¥ (2,782)	¥ (697,754)
Depreciation expenses	(53,061)	(55,794)	(15,549)	—	—	(124,404)
Impairment losses	(161)	(105)	(67)	—	(103)	(436)
Transfers	—	—	—	—	—	—
Disposals and other decreases	53,017	18,978	13,508	601	15	86,119
Reclassification to assets held for sale (Note 19)	6,319	14,748	2,171	—	—	23,238
Foreign currency translation differences	(9,037)	(6,716)	(7,807)	(72)	(100)	(23,732)
Other	(538)	(321)	11	—	(1)	(849)
As of March 31, 2021	¥ (266,705)	¥ (374,845)	¥ (92,866)	¥ (431)	¥ (2,971)	¥ (737,818)

JPY (millions)

Carrying amount	Buildings and structures	Machinery and vehicles	Tools, furniture, and fixtures	Land	Construction in progress	Total
As of April 1, 2019	¥ 894,883	¥ 348,879	¥ 47,222	¥ 100,434	¥ 139,769	¥ 1,531,187
As of March 31, 2020	808,759	314,057	43,721	95,669	124,164	1,386,370
As of March 31, 2021	866,701	311,290	40,963	94,804	140,159	1,453,917

Leases

The changes in acquisition cost of property, plant and equipment for the years ended March 31, 2020 and 2021 include the following changes in ROU assets:

JPY (millions)

Acquisition cost of ROU Assets	Buildings and structures	Machinery and vehicles	Tools, furniture, and fixtures	Total
As of April 1, 2019	¥ 396,824	¥ 15,981	¥ 864	¥ 413,669
Additions	16,077	2,211	93	18,381
Disposals and other decreases	(11,666)	(3,329)	(239)	(15,234)
Reclassification to assets held for sale (Note 19)	(1,545)	(47)	—	(1,592)
Foreign currency translation differences	(1,604)	(503)	(2)	(2,109)
Other	355	(345)	2	12
As of March 31, 2020	¥ 398,441	¥ 13,968	¥ 718	¥ 413,127
Additions	87,721	7,880	54	95,655
Disposals and other decreases	(29,473)	(7,048)	(313)	(36,834)
Reclassification to assets held for sale (Note 19)	(3,190)	(175)	—	(3,365)
Foreign currency translation differences	9,750	501	14	10,265
Other	(452)	(86)	(1)	(539)
As of March 31, 2021	¥ 462,797	¥ 15,040	¥ 472	¥ 478,309

The changes in accumulated depreciation and accumulated impairment losses for the years ended March 31, 2020 and 2021 include the following changes in accumulated depreciation and accumulated impairment loss related to ROU assets:

JPY (millions)

Accumulated depreciation and accumulated impairment losses of ROU Assets	Buildings and structures	Machinery and vehicles	Tools, furniture, and fixtures	Total
As of April 1, 2019	¥ (29,169)	¥ (3,428)	¥ (596)	¥ (33,193)
Depreciation expenses	(32,422)	(4,214)	(147)	(36,783)
Impairment losses	(1,831)	—	(6)	(1,837)
Disposals and other decreases	1,665	1,118	233	3,016
Reclassification to assets held for sale (Note 19)	1,375	—	—	1,375
Foreign currency translation differences	1,011	162	1	1,174
Other	137	3	(1)	139
As of March 31, 2020	¥ (59,234)	¥ (6,359)	¥ (516)	¥ (66,109)
Depreciation expenses	(33,755)	(4,322)	(94)	(38,171)
Impairment losses	(45)	—	—	(45)
Disposals and other decreases	10,495	2,794	313	13,602
Reclassification to assets held for sale (Note 19)	1,646	109	—	1,755
Foreign currency translation differences	(2,508)	(257)	(6)	(2,771)
Other	408	(198)	—	210
As of March 31, 2021	¥ (82,993)	¥ (8,233)	¥ (303)	¥ (91,529)

The carrying amount of property, plant and equipment includes the carrying amount of following ROU Assets:

Carrying amount of ROU Assets	JPY (millions)			
	Buildings and structures	Machinery and vehicles	Tools, furniture, and fixtures	Total
As of April 1, 2019	¥ 367,655	¥ 12,553	¥ 268	¥ 380,476
As of March 31, 2020	339,207	7,609	202	347,018
As of March 31, 2021	379,804	6,807	169	386,780

Takeda recognized expenses related to leases not included in the measurement of the lease liabilities as follows:

	JPY (millions)	
	For the Year Ended March 31	
	2020	2021
Expense relating to short-term leases	¥ 5,772	¥ 4,802
Expense relating to leases of low-value assets that are not short-term leases expenses	1,560	1,250
Expense relating to variable lease payments	8,172	6,315
Total expenses not included in lease liabilities	¥ 15,504	¥ 12,367

The total cash outflow for leases for the years ended March 31, 2020 and 2021 was 41,834 million JPY and 51,394 million JPY, respectively.

Rent expense for operating lease contracts and sublease income recognized in profit or loss under IAS 17 (prior to April 1, 2019) were 27,444 million JPY and 3,579 million JPY, respectively, for the year ended March 31, 2019.

Impairment

Takeda recognized the following impairment losses, which are reflected as follows, in the consolidated statements of profit or loss:

	JPY (millions)		
	For the Year Ended March 31		
	2019	2020	2021
Cost of sales	¥ (35)	¥ (29)	¥ (139)
Selling, general and administrative expenses	(354)	(469)	(149)
Research and development expenses	(41)	(293)	(68)
Other operating expenses	(191)	(19,224)	(80)
Total	¥ (621)	¥ (20,015)	¥ (436)

Impairment losses 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.

Impairment losses for the year ended March 31, 2020 were related primarily to Shonan Health Innovation Park and recorded as part of restructuring expenses (Note 5).

Impairment losses for the year ended March 31, 2021 resulted primarily from facilities for administrative and sales activities in Japan that were disposed in the year ended March 31, 2021.

The carrying amounts of the impaired assets were reduced to the recoverable amounts, which were measured at fair value less costs of disposal. Fair value less costs of disposal was measured by the sale price indicated on the anticipated sale of the facility or similar transaction less costs of disposal such as property sale commission fee. This fair value is classified as Level 3 in the fair value hierarchy.

11. Goodwill

	JPY (millions)			
	For the Year Ended March 31			
	2020		2021	
Acquisition cost				
As of beginning of the year	¥	4,240,251	¥	4,012,528
Acquisitions		3,387		—
Reclassification to assets held for sale (Note 19)		(116,524)		(144,836)
Foreign currency translation differences		(114,586)		166,225
As of end of the year	¥	<u>4,012,528</u>	¥	<u>4,033,917</u>
Carrying amount				
As of beginning of the year	¥	4,240,251	¥	4,012,528
As of end of the year		4,012,528		4,033,917

Impairment Testing of Goodwill

As of March 31, 2020 and 2021, respectively, goodwill was tested for impairment at the single operating segment level (one CGU), which is the level at which goodwill is monitored for internal management purposes. 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 of disposal, or value in use.

Recoverable amount of goodwill was determined on a fair value less costs to dispose basis using the market value of Takeda's outstanding shares. Takeda's market capitalization was compared to the book value of the company's net assets and this indicated a significant surplus as of March 31, 2020 and 2021, respectively.

12. Intangible Assets

	JPY (millions)			
	Software	Intangible assets associated with products	Other	Total
Acquisition cost				
As of April 1, 2019	¥ 160,237	¥ 5,862,950	¥ 22,333	¥ 6,045,520
Additions	28,274	77,016	44	105,334
Disposals and other decreases	(20,078)	(5,179)	(10,573)	(35,830)
Reclassification to assets held for sale (Note 19)	(83)	(179,788)	—	(179,871)
Foreign currency translation differences	(3,430)	(151,746)	(38)	(155,214)
As of March 31, 2020	¥ 164,920	¥ 5,603,253	¥ 11,766	¥ 5,779,939
Additions	32,930	84,034	—	116,964
Disposals and other decreases	(10,659)	(106)	(1)	(10,766)
Reclassification to assets held for sale (Note 19)	(806)	(85,913)	—	(86,719)
Deconsolidation	(4)	—	—	(4)
Foreign currency translation differences	12,484	104,767	(179)	117,072
As of March 31, 2021	¥ 198,865	¥ 5,706,035	¥ 11,586	¥ 5,916,486
Accumulated amortization and accumulated impairment losses				
As of April 1, 2019	¥ (62,943)	¥ (1,220,429)	¥ (10,979)	¥ (1,294,351)
Amortization	(32,771)	(412,074)	(29)	(444,874)
Impairment losses	(4,731)	(43,346)	—	(48,077)
Disposals and other decreases	19,784	3,029	10,573	33,386
Reclassification to assets held for sale (Note 19)	—	96,608	—	96,608
Foreign currency translation differences	2,101	46,629	—	48,730
As of March 31, 2020	¥ (78,560)	¥ (1,529,583)	¥ (435)	¥ (1,608,578)
Amortization	(28,346)	(405,268)	—	(433,614)
Impairment losses	(39)	(16,596)	—	(16,635)
Disposals and other decreases	8,354	—	—	8,354
Reclassification to assets held for sale (Note 19)	531	39,260	—	39,791
Deconsolidation	(20)	—	—	(20)
Foreign currency translation differences	(5,314)	8,636	—	3,322
As of March 31, 2021	¥ (103,394)	¥ (1,903,551)	¥ (435)	¥ (2,007,380)
Carrying amount				
As of April 1, 2019	¥ 97,294	¥ 4,642,521	¥ 11,354	¥ 4,751,169
As of March 31, 2020	86,360	4,073,670	11,331	4,171,361
As of March 31, 2021	95,471	3,802,484	11,151	3,909,106

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, 2019	¥ 4,135,520	¥ 507,001	¥ 4,642,521
As of March 31, 2020	3,602,384	471,286	4,073,670
As of March 31, 2021	3,427,527	374,957	3,802,484

Marketed products mainly represent license rights associated with commercialized products. 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).

The table below provides information about significant intangible assets.

		JPY (millions)		Remaining
		Carrying amount		amortization period
		As of March 31		As of March 31
		2020	2021	2021
immunoglobulin	Marketed products	¥ 788,628	¥ 753,203	14 years
TAKHZYRO	Marketed products	567,589	536,445	13 years
VYVANSE	Marketed products	517,695	441,577	5 years
ADVATE & ADYNOVATE	Marketed products	313,509	293,697	9 years
ALUNBRIG	In-process R&D	160,580	—	—
	Marketed products	76,688	220,969	10 years

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 8,698 million JPY, 48,077 million JPY, and 16,635 million JPY during the years ended March 31, 2019, 2020, and 2021, respectively. These losses are primarily recognized in amortization and impairment losses on intangible assets associated with products in the consolidated statements of profit or loss.

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.

During the year ended March 31, 2020, Takeda recorded impairment losses of 48,077 million JPY. The recoverable amount of the combined impaired assets amounted to 11,815 million JPY. The impairment losses primarily resulted from a decision to terminate development of a rare diseases product and an increase in estimated future development costs due to a change in study design related to a rare diseases product.

During the year ended March 31, 2021, Takeda recorded impairment losses of 16,635 million JPY. The recoverable amount of the combined impaired assets amounted to 18,255 million JPY. The impairment losses include the loss which resulted from the decision to terminate Takeda's interest in development of an oncology product.

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)
March 31, 2019	11.0%
March 31, 2020	7.0% - 8.0%
March 31, 2021	7.0%

As of March 31, 2019, and 2020, a part of the recoverable amount was measured at 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 a 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 products 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.

The following is a description of Takeda's significant out-licensing agreement which Takeda entered into for the past 3 fiscal years.

Neurocrine Biosciences, Inc. ("Neurocrine Biosciences")

In June 2020, Takeda entered into a strategic collaboration with Neurocrine Biosciences to develop and commercialize compounds in Takeda's early-to-mid-stage neuroscience pipeline, including TAK-041, TAK-653 and TAK-831. Takeda received an upfront cash payment in July 2020 and is entitled to certain development milestones, commercial milestones and royalties on net sales. At certain development events, Takeda may elect to opt in or out of a 50:50 profit share on all clinical programs on an asset-by-asset basis. For any asset in which Takeda is participating in a 50:50 profit share arrangement, Takeda will not be eligible to receive development or commercial milestones.

Collaborations and in-licensing arrangements

These agreements generally provide for commercialization rights to a product or products being developed by the partner, and in exchange, often resulted in an up-front payment being paid upon execution of the agreement and resulted in 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 products 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)		
	2019	2020	2021
Initial up-front and milestone payments	¥ 29,857	¥ 77,016	¥ 84,034
Acquisition of shares of collaboration and in-licensing partners	5,994	1,317	1,504

The following is a description of Takeda's significant collaborations and in-licensing agreements which Takeda entered into for the past 3 fiscal years.

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 provided 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. In March 2021, the partnership officially terminated. The impact on the consolidated financial statements from the termination of the partnership was not material.

AB Biosciences Inc. (“AB Biosciences”)

In January 2019, Takeda acquired a licensing agreement with AB Biosciences through its acquisition of Shire. The agreement granted 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 was eligible to receive contingent research, development, and commercialization milestone payments and tiered royalty payments. In October 2020, Takeda and AB Biosciences terminated the partnership. The impact on the consolidated financial statements from the termination of the partnership was not material.

The University of Texas MD Anderson Cancer Center (“MD Anderson”)

In October 2019, Takeda entered into an exclusive license agreement and research agreement with MD Anderson to develop cord blood-derived chimeric antigen receptor-directed natural killer (CAR NK)-cell therapies, ‘armored’ with IL-15, for the treatment of B-cell malignancies and other cancers. Under the agreement, Takeda will receive access to MD Anderson’s CAR NK platform and the exclusive rights to develop and commercialize up to four programs, including a CD19-targeted CAR NK-cell therapy and a B-cell maturation antigen (“BCMA”)-targeted CAR NK-cell therapy. Takeda and MD Anderson will also conduct a research collaboration to further develop these CAR NK programs. Takeda is responsible for the development, manufacturing and commercialization of CAR NK products resulting under the agreement. MD Anderson received an upfront payment and is eligible to receive development and commercial milestones for each target as well as tiered royalties on net sales of any such CAR NK product.

Arrowhead Pharmaceuticals Inc. (“Arrowhead”)

In October 2020, Takeda entered into a collaboration and licensing agreement with Arrowhead to develop ARO-AAT, a Phase 2 investigational RNA interference (RNAi) therapy in development to treat alpha-1 antitrypsin-associated liver disease (AATLD). ARO-AAT is a potential first-in-class therapy designed to reduce the production of mutant alpha-1 antitrypsin protein, the cause of AATLD progression. Under the terms of the agreement, Takeda and Arrowhead will co-develop ARO-AAT which, if approved, will be co-commercialized in the United States under a 50/50 profit-sharing structure. Outside the U.S., Takeda will lead the global commercialization strategy and receive an exclusive license to commercialize ARO-AAT with Arrowhead eligible to receive tiered royalties on net sales if approved and commercialized. Arrowhead received an upfront payment and is eligible to receive potential development, regulatory and commercial milestones.

Ovid Therapeutics Inc. (“Ovid”)

In March 2021, Takeda secured global rights from Ovid to develop and commercialize the investigational medicine Soticlestat (TAK-935/OV935) for the treatment of developmental and epileptic encephalopathies, including Dravet syndrome (DS) and Lennox-Gastaut syndrome (LGS). Original 2017 collaboration between Ovid and Takeda concluded, and Takeda takes the sole responsibility for global development and commercialization. Ovid received an upfront at closing and is also eligible to receive additional development, regulatory and sales milestones and tiered royalties on sales of Soticlestat, if approved and commercialized.

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 representing 49% of such difference. The deferred gain 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 condensed financial statements of Teva Takeda Pharma and Teva Takeda Yakuhin is as follows:

	JPY (millions)		
	For the Year Ended March 31		
	2019	2020	2021
Revenue	¥ 89,686	¥ 79,987	¥ 68,788
Net loss for the year	(87,106)	(49,443)	(20,214)
Other comprehensive income (loss)	—	—	—
Total comprehensive loss for the year	(87,106)	(49,443)	(20,214)
Total comprehensive loss for the year (49.0%)	(42,682)	(24,227)	(9,905)
Other	211	32	14
Takeda's share of comprehensive loss for the year	¥ (42,471)	¥ (24,195)	¥ (9,891)

	JPY (millions)	
	As of March 31	
	2020	2021
Non-current assets	¥ 93,221	¥ 72,175
Current assets	114,827	118,771
Non-current liabilities	(11,365)	(7,028)
Current liabilities	(17,631)	(14,186)
Equity	¥ 179,052	¥ 169,732
Takeda's share of equity (49.0%)	¥ 87,735	¥ 83,169
Goodwill	10,921	5,583
Deferred gain	(24,689)	(22,096)
Carrying amount of investments accounted for using the equity method	¥ 73,967	¥ 66,656

Net loss for the year of Teva Takeda Pharma and Teva Takeda Yakuhin for the years ended March 31, 2020 and 2021 included impairment losses of 68,546 million JPY and 36,049 million JPY, of which 30,070 million JPY and 14,793 million JPY represent Takeda's share, respectively.

The impairment loss for the year ended March 31, 2020 was due to the changes in the business environment such as the Drug Pricing Reform, while the impairment loss for the year ended March 31, 2021 was recorded resulting from the reassessment of the recoverable amount of relevant assets triggered by the decision Teva Takeda Pharma made to divest a part of generic business and a manufacturing plant, as well as by a revision of forecast in the long-listed drug business.

There were no dividends received from Teva Takeda Pharma for the years ended March 31, 2020 and 2021. 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 ownership interests of Takeda.

	JPY (millions)		
	For the Year Ended March 31		
	2019	2020	2021
Net profit (loss) for the year	¥ (1,156)	¥ 208	¥ 9,967
Other comprehensive income (loss)	(94)	(181)	(299)
Total comprehensive income (loss) for the year	¥ (1,250)	¥ 27	¥ 9,668

The carrying amount of the investments in associates, which are individually immaterial to Takeda, is as follows:

	JPY (millions)	
	As of March 31	
	2020	2021
Carrying amount of investments accounted for using the equity method	¥ 33,367	¥ 45,812

15. Other Financial Assets

	JPY (millions)	
	As of March 31	
	2020	2021
Derivative assets	¥ 25,629	¥ 64,100
Investment in convertible notes at fair value through P&L	9,418	12,176
Investment in debt instruments at fair value through P&L	1,029	800
Investment in equity instruments at fair value through OCI	127,455	145,070
Financial assets associated with contingent consideration arrangements	92,516	25,446
Restricted deposits	8,490	3,371
Other	13,406	21,517
Total	¥ 277,943	¥ 272,480
Non-current	¥ 262,121	¥ 235,882
Current	¥ 15,822	¥ 36,598

As of March 31, 2020 and 2021, equity instruments included 79,218 million JPY and 92,602 million JPY, respectively, 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, 2020 and 2021, financial assets associated with contingent consideration arrangements are assets mainly recognized in relation to the divestiture of XIIDRA (Note 27) and are considered Level 3 investments in the fair value hierarchy.

As of March 31, 2020, the restricted deposits mainly represent amounts related to Takeda's business combinations and insurance contracts and as of March 31, 2021, the restricted deposits represent amounts related to insurance contracts.

16. Inventories

	JPY (millions)	
	As of March 31	
	2020	2021
Finished products and merchandise	¥ 205,979	¥ 216,403
Work-in-process	395,842	387,917
Raw materials and supplies	157,778	149,561
Total	¥ 759,599	¥ 753,881

The amount of inventory write-offs recognized was 9,321 million JPY, 37,210 million JPY, and 24,269 million JPY for the years ended March 31, 2019, 2020 and 2021 respectively, and was included in cost of sales.

17. Trade and Other Receivables

	JPY (millions)	
	As of March 31	
	2020	2021
Trade receivables	¥ 715,159	¥ 788,284
Other receivables	86,297	75,604
Impairment loss allowance	(5,197)	(8,637)
Chargebacks and other allowances	(39,254)	(72,160)
Total	¥ 757,005	¥ 783,091

18. Cash and Cash Equivalents

	JPY (millions)	
	As of March 31	
	2020	2021
Cash and deposits	¥ 188,640	¥ 335,027
Short-term investments	448,974	631,195
Total	¥ 637,614	¥ 966,222

19. Assets and Disposal Groups Held for Sale

Takeda has classified certain assets as held for sale in the consolidated statements 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 are recorded as other operating income or expenses.

Disposal Groups Held for Sale

	JPY (millions)	
	As of March 31	
	2020	2021
Property, plant and equipment	¥ 41,316	¥ —
Goodwill	63,538	12,078
Intangible assets	27,513	8,018
Inventories	3,266	392
Deferred tax assets	21,073	—
Other	574	201
Total assets	¥ 157,280	¥ 20,689
Provisions	¥ 80,841	¥ —
Deferred tax liabilities	6,349	—
Total liabilities	¥ 87,190	¥ —

For the year ended March 31, 2020, Takeda sold the disposal group held for sale associated with XIIDRA product for 375,536 million JPY with no material impact on the consolidated statements of profit or loss. In addition, for the year ended March 31, 2020, Takeda entered into an agreement to divest a portfolio of selected over-the-counter and prescription pharmaceutical assets sold in Near East, Middle East and Africa countries as well as Russia, Georgia and countries within the Commonwealth of Independent States. Takeda classified the corresponding assets and liabilities to the disposal groups held for sale and completed the sales for 85,578 million JPY within the same fiscal year. The proceeds from sale of disposal group held for sale associated with XIIDRA product and portfolio sale of selected over-the-counter and prescription pharmaceutical assets comprised the majority of Takeda's proceeds from sales of business in the consolidated statements of cash flows of 461,546 million JPY.

The disposal groups held for sale consisted mainly of the following and its fair value are classified as Level 3 in the fair value hierarchy as of March 31, 2020:

- The R&D program referred to as SHP647 that was classified as the disposal group held for sale in the year ended March 31, 2019 remained as the disposal group held for sale as of March 31, 2020 as Takeda did not reach a sales agreement during the year ended March 31, 2020. For the year ended March 31, 2021, Takeda ceased to classify assets and liabilities related to SHP647 following the European Commission's decision to release Takeda from the obligation to divest SHP647 in May 2020. As a result, Takeda recognized a 60,179 million JPY revaluation gain in other operating income, as further described in Note 5.
- Property, plant and equipment related to a manufacturing site in Ireland was classified as held for sale in the year ended March 31, 2020 following management decision to sell the site and signing a sales agreement. The divestiture was completed in September 2020, and the impact from this divestiture on the consolidated statements of profit or loss for the year ended March 31, 2021 was not material.
- Property, plant and equipment related to Shonan Health Innovation Park in Japan was classified as held for sale following management decision to sell the site and signing a sales agreement in the year ended March 31, 2020. Following the completion of divestiture in

September 2020, a sale and leaseback was executed and Takeda recognized 75,131 million JPY and 63,859 million JPY of right-of use assets and lease liabilities, respectively.

- Takeda classified the assets and liabilities such as intangible assets and goodwill related to the portfolio of non-core selected over-the-counter and prescription pharmaceutical assets in Latin America which Takeda entered into a sales agreement with Hypera S.A. in March 2020 and completed the divestiture in January 2021.
- Takeda classified the assets and liabilities such as intangible assets and goodwill related to TachoSil (Fibrin Sealant Patch) product in May 2019. The divestiture of the assets and liabilities related to this product was completed in January 2021. The impact from this divestiture on the consolidated statements of profit or loss for the year ended March 31, 2021 was not material.

Furthermore, Takeda completed the following divestiture agreements for the year ended March 31, 2021.

- Takeda completed divestitures of a portfolio of selected non-core over-the-counter and prescription pharmaceutical assets sold exclusively in Asia Pacific as well as a portfolio of selected non-core prescription pharmaceutical products sold predominantly in Europe and Canada. In addition, a portfolio of select over-the-counter and prescription pharmaceutical products sold in Europe and two manufacturing sites located in Denmark and Poland were divested.
- Takeda entered into an agreement to divest Takeda Consumer Healthcare Company Limited and classified the corresponding assets and liabilities to the disposal groups held for sale and completed the sale for 234,105 million JPY within the same fiscal year.

Upon the completion of the above divestiture agreements, in addition to revaluation gain related to SHP647, Takeda also recognized 228,923 million JPY divestiture gain in other operating income (Note 5) for the year ended March 31, 2021. Takeda's proceeds from sales of business in the consolidated statements of cash flows of 530,388 million JPY is mainly comprised of the proceeds from sale of disposal group held for sale with the divestitures completed for the year ended March 31, 2021.

During the years ended March 31, 2020 and 2021, Takeda also recorded an impairment loss of 33,790 million JPY and 5,824 million JPY in other operating expenses, respectively. A part of the impairment loss recorded in other operating expenses for the year ended March 31, 2020 and 2021 is included in restructuring expenses.

The disposal groups held for sale as of March 31, 2021 is mainly a group of assets and liabilities related to a portfolio of non-core prescription pharmaceutical assets sold in China, which was classified to the disposal groups held for sale in December 2020. The fair value of the disposal groups is classified as Level 3 in the fair value hierarchy as of March 31, 2021.

20. Bonds and Loans

	JPY (millions)	
	As of March 31	
	2020	2021
Bonds	¥ 3,204,965	¥ 3,532,202
Short-term loans	5,014	69
Long-term loans	1,883,325	1,103,100
Total	¥ 5,093,304	¥ 4,635,371
Non-current	¥ 4,506,487	¥ 4,613,218
Current	¥ 586,817	¥ 22,153

The composition of bonds is as follows:

Instrument	Principal amount in contractual currency (millions)	JPY (millions) Carrying amount		Interest rate (%)	Maturity
		As of March 31, 2020	As of March 31, 2021		
15th Unsecured Straight Bonds	¥ 60,000	¥ 59,993	¥ —	0.704%	— ⁽⁹⁾
Hybrid subordinated bonds	¥ 500,000	496,773	497,485	1.720% per annum through October 6, 2024 and 6 month LIBOR + margin (1.750-2.750%) thereafter	June 2079
USD Unsecured Senior Notes	\$ 500 as of March 31, 2020 \$ 200 as of March 31, 2021	54,129	22,084	2.450%	January 2022 ⁽⁶⁾
2018 EUR Unsecured Senior Notes – variable rate	€ 1,750 as of March 31, 2020 € 750 as of March 31, 2021	208,229	97,221	3 month EURIBOR + margin 2020:(0.550-1.100%) 2021:(1.100%)	November 2022 ⁽¹⁰⁾
2018 EUR Unsecured Senior Notes – fixed rate	€ 5,750 as of March 31, 2020 € 4,500 as of March 31, 2021	681,244	580,805	2020:0.375-3.000% 2021:1.125-3.000%	November 2022 - November 2030 ⁽³⁾
2018 USD Unsecured Senior Notes – fixed rate	\$ 4,500 as of March 31, 2020 \$ 3,250 as of March 31, 2021	485,780	357,296	2020:4.000-5.000% 2021:4.400-5.000%	November 2023 - November 2028 ⁽⁴⁾
Unsecured Senior Notes Assumed in Shire Acquisition	\$ 8,800 as of March 31, 2020 \$ 5,500 as of March 31, 2021	910,252	577,426	2020:2.400-3.200% 2021:2.875-3.200%	September 2023 - September 2026 ⁽²⁾⁽⁵⁾
Unsecured Senior Notes Assumed in Shire Acquisition	\$ 1,520	164,565	167,972	3.600-5.250%	June 2022 - June 2045
2020 USD Unsecured Senior Notes – fixed rate	\$ 7,000	—	768,133	2.050-3.375%	March 2030 - July 2060
2020 EUR Unsecured Senior Notes – fixed rate	€ 3,600	—	463,780	0.750-2.000%	July 2027 - July 2040
Commercial Paper	¥ 144,000	144,000	—		—
Total		¥ 3,204,965	¥ 3,532,202		

The composition of loans is as follows:

Instrument	Principal amount in contractual currency (millions)	JPY (millions) Carrying amount		Interest rate (%)	Maturity
		As of March 31, 2020	As of March 31, 2021		
Syndicated Loans 2013	¥ 60,000	¥ 60,000	¥ —	3 month LIBOR + 0.010%	— ⁽⁸⁾
Syndicated Loans 2016	¥ 200,000	200,000	200,000	0.200–0.300 %	April 2023 - April 2026
Syndicated Loans 2017	¥ 113,500	113,500	113,500	0.350%	April 2027
USD Syndicated Loans 2017	\$ 1,500	162,442	165,538	6 month LIBOR + 0.500%	April 2027
USD Syndicated Loans 2019	\$ 6,800	720,581	—	LIBOR + variable margin (0.750-1.500%)	— ⁽¹⁾⁽⁷⁾
USD Japan Bank for International Cooperation 2019	\$ 3,700	401,450	408,980	6 month LIBOR + 0.600%	December 2025
Other		230,366	215,151		— ⁽⁸⁾
Total		¥ 1,888,339	¥ 1,103,169		

On July 9, 2020, Takeda issued unsecured U.S. dollar-denominated senior notes (the “USD Notes”) with an aggregate principal amount of 7,000 million USD and unsecured Euro-denominated senior notes (the “EUR Notes”) with an aggregate principal amount of 3,600 million EUR. The maturity dates for the USD Notes are from March 31, 2030 to July 9, 2060 and for the EUR Notes are from July 9, 2027 to July 9, 2040, respectively. Under the terms and conditions of these notes, Takeda may redeem these notes, in whole or in part, at any time prior to maturity. Interest is payable semi-annually at a rate 2.050 – 3.375% for the USD Notes and annually at a rate 0.750 – 2.000% for the EUR Notes. The notes are unsecured, and Takeda is not subject to any financial covenants related to these notes. The proceeds from these notes were used to repay the Term Loan Credit Agreement loans of 3,250 million USD and 3,019 million EUR on July 10, 2020 in advance of their original maturities of January 2024⁽¹⁾, together with the early redemption of unsecured senior notes with face values of 2,400 million USD and 1,250 million EUR on August 3, 2020 in advance of their original maturities of September 2021⁽²⁾ and November 2020⁽³⁾, respectively. Takeda further executed the early redemption of unsecured senior notes with face values of 2,450 million USD, comprising 1,250 million USD on February 26, 2021, 900 million USD on January 22, 2021, and 300 million USD on February 25, 2021 in advance of their original maturities of November 2021⁽⁴⁾, September 2021⁽⁵⁾ and January 2022⁽⁶⁾ respectively.

In addition to the above, mandatory debt repayments were made in the fiscal year ended March 31, 2021. In April 2020, a mandatory repayment of 94 million USD⁽⁷⁾ was made on USD and EUR Term Loan Credit Agreement loans and in July 2020, 130 billion JPY in mandatory repayments of debt issued in July 2013 were made comprising 70 billion JPY⁽⁸⁾ in loans and 60 billion JPY⁽⁹⁾ in unsecured straight bonds. Additionally, in November 2020, a mandatory repayment of 1,000 million EUR⁽¹⁰⁾ in unsecured floating rate senior notes was made, the notes having been incurred in connection with the Shire Acquisition.

On June 6, 2019, Takeda issued hybrid subordinated bonds (the “Hybrid Bonds”) with an aggregate principal amount of 500 billion JPY. The proceeds from the Hybrid Bonds were used to repay the existing syndicated loans comprised of a 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 1.720% through October 6, 2024 and 6 month LIBOR + margin (1.750 - 2.750%) thereafter subject to annual revision. The Hybrid Bonds are unsecured, and Takeda is not subject to any financial covenants related to these bonds.

In September 2019, Takeda reached an agreement on a commitment facility of 700 billion JPY with various Japanese and non-Japanese banks. The commitment facility has a current maturity of September 2025 with optionality in the agreement to permit the extension to September 2026 should Takeda’s banking partners be supportive. The purpose of the commitment facility is for general business use. There were no drawdowns on the 700 billion JPY commitment facility as of March 31, 2020 and 2021 respectively.

There are long-term financing agreements that contain financial covenants, a key one of which requires Takeda’s ratio of consolidated net debt to adjusted EBITDA, as defined in the loan agreements, for the previous twelve-month period to not surpass certain levels as of March 31 and September 30 of each year. Takeda was in compliance with all financial covenants as of March 31, 2020 and 2021 respectively.

In 2017, Takeda entered into USD to JPY cross currency interest rate swap agreements to fix the interest rate for 925 million USD of the floating rate USD Syndicated Loans 2017. In respect of the remaining 575 million USD of the floating rate USD Syndicated Loans 2017, Takeda entered into an interest rate swap agreement to fix the applicable interest rate and also entered into a USD to JPY cross currency swap for 200 million USD of the fixed rate USD Unsecured Senior Notes issued in 2017. Furthermore, in 2020, Takeda entered into USD to JPY cross currency swaps on 1,750 million USD of the fixed rate 2018 USD Unsecured Senior Notes and 4,000 million USD of the fixed rate 2020 USD Unsecured Senior Notes.

21. Other Financial Liabilities

	JPY (millions)	
	As of March 31	
	2020	2021
Derivative liabilities (Note 27)	¥ 52,589	¥ 97,091
Lease liabilities (Note 27)	369,459	436,412
Financial liabilities associated with contingent consideration arrangements (Note 27)	41,664	27,770
Other	31,123	204,457
Total	¥ 494,835	¥ 765,730
Non-current	¥ 399,129	¥ 517,677
Current	¥ 95,706	¥ 248,053

The increase in “Other” is mainly due to deposits related to certain vaccines operations received during the fiscal year ended March 31, 2021.

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 are the most significant plans among 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. 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 profit or loss and the consolidated statements of financial position are as follows:

Consolidated statements of profit or loss

	JPY (millions)		
	For the Year Ended March 31		
	2019	2020	2021
Japan	¥ 4,621	¥ 4,769	¥ (2,696)
Foreign	6,786	11,493	10,655
Defined benefit costs	¥ 11,407	¥ 16,262	¥ 7,959

Consolidated statements of financial position

	JPY (millions)		
	As of March 31, 2020		
	Japan	Foreign	Total
Present value of defined benefit obligations	¥ 190,552	¥ 226,400	¥ 416,952
Fair value of plan assets	211,114	79,600	290,714
Net defined benefit liabilities (assets)	¥ (20,562)	¥ 146,800	¥ 126,238
Consolidated statements of financial position			
Net defined benefit liabilities	¥ 9,817	¥ 146,800	¥ 156,617
Net defined benefit assets	30,379	—	30,379
Net amount of liabilities (assets) recognized in the consolidated statements of financial position	¥ (20,562)	¥ 146,800	¥ 126,238
	JPY (millions)		
	As of March 31, 2021		
	Japan	Foreign	Total
Present value of defined benefit obligations	¥ 180,321	¥ 251,767	¥ 432,088
Fair value of plan assets	231,038	102,354	333,392
Effect of asset ceiling	25,757	—	25,757
Net defined benefit liabilities (assets)	¥ (24,960)	¥ 149,413	¥ 124,453
Consolidated statements of financial position			
Net defined benefit liabilities	¥ 9,444	¥ 149,413	¥ 158,857
Net defined benefit assets	34,404	—	34,404
Net amount of liabilities (assets) recognized in the consolidated statements of financial position	¥ (24,960)	¥ 149,413	¥ 124,453

Net defined benefit assets were included in other non-current assets on the consolidated statements of financial position.

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, 2020		
	Japan	Foreign	Total
At beginning of the year	¥ 198,293	¥ 227,975	¥ 426,268
Current service cost	4,832	9,580	14,412
Interest cost	1,166	4,021	5,187
Remeasurement of defined benefit pension plans			
From changes in demographic assumptions	(1,787)	(1,155)	(2,942)
From changes in financial assumptions	(5)	4,417	4,412
Experience adjustments	(1,351)	(2,495)	(3,846)
Past service cost	46	(580)	(534)
Settlement	(70)	48	(22)
Benefits paid	(10,390)	(10,419)	(20,809)
Effect of business combinations and disposals	(182)	62	(120)
Foreign currency translation differences	—	(5,054)	(5,054)
At end of the year	<u>¥ 190,552</u>	<u>¥ 226,400</u>	<u>¥ 416,952</u>

	JPY (millions)		
	For the Year Ended March 31, 2021		
	Japan	Foreign	Total
At beginning of year	¥ 190,552	¥ 226,400	¥ 416,952
Current service cost	4,621	8,937	13,558
Interest cost	1,145	3,772	4,917
Remeasurement of defined benefit pension plans			
From changes in demographic assumptions	1,359	(2,336)	(977)
From changes in financial assumptions	(1,497)	7,161	5,664
Experience adjustments	6,163	2,148	8,311
Past service cost	(7,195)	(781)	(7,976)
Benefits paid	(13,344)	(8,961)	(22,305)
Contributions by the employees	—	2,307	2,307
Effect of business combinations and disposals	(1,483)	(131)	(1,614)
Foreign currency translation differences	—	13,251	13,251
At end of the year	<u>¥ 180,321</u>	<u>¥ 251,767</u>	<u>¥ 432,088</u>

The remaining weighted average duration of the defined benefit obligations was 15.9 years and 15.4 years as of March 31, 2020 and 2021, respectively.

Significant actuarial assumptions used to determine the present value are as follows:

	Discount rate	Future salary increases
2020		
Japan	0.6%	2.6%
Foreign	1.7%	2.9%
2021		
Japan	0.7%	2.5%
Foreign	1.4%	2.7%

As of March 31, 2020 and 2021, future salary increases were not used to determine the present value of the defined benefit obligations related to certain defined benefit plans.

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
2020				
Japan	+0.50 %	¥ (11,855)	+0.50 %	¥ 484
	-0.50 %	13,322	-0.50 %	(457)
Foreign	+0.50 %	(19,559)	+0.50 %	3,041
	-0.50 %	18,972	-0.50 %	(2,668)
2021				
Japan	+0.50 %	(11,546)	+0.50 %	6
	-0.50 %	13,012	-0.50 %	(6)
Foreign	+0.50 %	(19,818)	+0.50 %	3,689
	-0.50 %	22,881	-0.50 %	(3,347)

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			
	2020		2021	
Balance at beginning of the year	¥	303,816	¥	290,714
Interest income on plan assets		2,803		2,540
Remeasurement of defined benefit plans				
Return on plan assets		(9,680)		40,902
Contributions by the employer		9,036		7,940
Contributions by the employees		—		2,307
Settlement		851		—
Benefits paid		(17,226)		(14,291)
Effect of business combinations and disposals		70		(1,218)
Foreign currency translation differences		1,044		4,498
Balance at end of the year	¥	290,714	¥	333,392

Takeda expects to contribute 7,750 million JPY to the defined benefit plans for the year ending March 31, 2022.

The breakdown of fair value by asset class is as follows:

	JPY (millions)							
	As of March 31							
	2020				2021			
	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	¥	10,519	¥	2,622	¥	11,789	¥	3,520
Foreign		16,786		80,298		23,849		96,744
Bonds:								
Japan		2,196		13,080		1,441		16,846
Foreign		10,203		39,965		13,395		44,159
Life insurance company general accounts		—		89,599		—		95,859
Cash and cash equivalent		14,481		—		9,625		—
Others		(1,215)		12,180		199		15,966
Total plan assets	¥	52,970	¥	237,744	¥	60,298	¥	273,094

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 pooled basis.

Changes in effect of asset ceiling for the periods presented are as follows:

	JPY (millions)			
	For the Year Ended March 31			
	2020		2021	
Balance at beginning of the year	¥	—	¥	—
Remeasurement				
Changes in effect of asset ceiling		—		25,757
Balance at end of the year	¥	—	¥	25,757

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 21,068 million JPY, 25,138 million JPY, and 34,052 million JPY for the years ended March 31, 2019, 2020 and 2021, 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					
	2019		2020		2021	
Salary	¥	272,930	¥	417,860	¥	418,087
Bonuses		89,439		135,938		105,772
Other		93,711		157,722		163,443

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 March 31, 2019	¥ 46,775	¥ 49,681	¥ 295,243	¥ 30,785	¥ 422,484
Adoption of IFRS 16	—	(129)	—	(10,070)	(10,199)
As of April 1, 2019	¥ 46,775	¥ 49,552	¥ 295,243	¥ 20,715	¥ 412,285
Increases	24,238	59,484	771,233	27,114	882,069
Decreases (utilized)	(18,911)	(59,414)	(738,242)	(11,705)	(828,272)
Decreases (reversed)	(1,965)	(1,360)	(4,940)	(486)	(8,751)
Deconsolidation	—	—	—	(40)	(40)
Foreign currency translation differences	(426)	(3,215)	(7,004)	(3,796)	(14,441)
As of March 31, 2020	¥ 49,711	¥ 45,047	¥ 316,290	¥ 31,802	¥ 442,850
Increases	26,189	47,446	822,479	17,898	914,012
Decreases (utilized)	(3,182)	(46,732)	(752,165)	(16,019)	(818,098)
Decreases (reversed)	(996)	(13,658)	(18,812)	(7,827)	(41,293)
Reclassification to liabilities held for sale (Note 19)	—	—	(3,807)	(99)	(3,906)
Foreign currency translation differences	1,673	194	13,787	807	16,461
As of March 31, 2021	¥ 73,395	¥ 32,297	¥ 377,772	¥ 26,562	¥ 510,026

The current portion of the provision is 387,127 million JPY, 405,245 million JPY, and 471,278 million JPY as of April 1, 2019, March 31, 2020 and 2021, respectively. The non-current portion of the provision is 25,158 million JPY, 37,605 million JPY and 38,748 million JPY, as of April 1, 2019, March 31, 2020 and 2021, respectively.

Restructuring

Takeda has various restructuring efforts in place during the years ended March 31, 2019, 2020 and 2021, in connection with the following:

- Transform its R&D function – Takeda has led various restructuring efforts during the years ended March 31, 2019, 2020 and 2021, 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 years ended March 31, 2019, 2020 and 2021, Takeda directed various restructuring efforts following the Shire acquisition. 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. These programs were completed in the year ended March 31, 2020.
- Various other efforts to improve the efficiency of its operations and related facilities.

A restructuring provision is recorded when Takeda has developed 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 for the fiscal years ended March 31, 2019, 2020 and 2021 are as follows:

	JPY (millions)		
	For the Year Ended March 31		
	2019	2020	2021
Cash:			
Severance	¥ 17,574	¥ 33,538	¥ 28,031
Consulting fees	19,040	18,086	5,704
Other	44,906	78,746	70,742
Total	<u>¥ 81,520</u>	<u>¥ 130,370</u>	<u>¥ 104,477</u>
Non-Cash:			
Depreciation and impairment	¥ 1,442	¥ 50,670	¥ 11,398
Total	<u>¥ 82,962</u>	<u>¥ 181,040</u>	<u>¥ 115,875</u>

Other restructuring expenses for the fiscal years ended March 31, 2019, 2020 and 2021 includes personnel expenses of 20,754 million JPY, 28,140 million JPY, and 8,091 million JPY, respectively, and mainly related to retention bonus and salary of employees fully dedicated to restructuring programs. Other restructuring expenses for the fiscal year ended March 31, 2021 also includes expenses related to system optimization by the integration of Shire in digital transformation initiatives.

Rebates and Returns

Takeda has recognized a provision related mainly to sales rebates and returns for products and merchandises. The balances stated in the summary table above include provisions of 213,189 million JPY and 267,254 million JPY as of March 31, 2020 and 2021, respectively, for contractual and statutory rebates payable under Commercial healthcare provider contracts and U.S. State and Federal government health programs, such as U.S. Medicaid and U.S. Medicare as well as U.S. commercial managed care programs. These are expected to be paid out generally within one year. Return reserves are recorded primarily for credits expected to be issued to customers for certain expired product that will be returned. Sales rebates and sales returns reserves 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	
	2020	2021
Accrued expenses	¥ 456,621	¥ 459,384
Deferred income	31,591	50,228
Other	63,967	89,937
Total	<u>¥ 552,179</u>	<u>¥ 599,549</u>
Non-current	¥ 52,793	¥ 56,898
Current	¥ 499,386	¥ 542,651

Accrued expenses include accrued employee benefit expenses of 193,981 million JPY and 184,805 million JPY as of March 31, 2020 and 2021, respectively.

Deferred income includes contract liabilities related to out-licensing agreements, product procurement and supply agreements, and government grants for the purchase of property, plant and equipment. The grants received were 15,810 million JPY and 10,194 million JPY during the years ended March 31, 2020 and 2021, 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.

25. Trade and Other Payables

	JPY (millions) As of March 31	
	2020	2021
Trade payables	¥ 211,627	¥ 232,105
Other payables	107,189	111,733
Total	¥ 318,816	¥ 343,838

26. Equity and Other Equity Items

	Thousands of Shares For the Year Ended March 31	
	2020	2021
Authorized shares as of the beginning of the year	3,500,000	3,500,000
Shares issued:		
At the beginning of the year	1,565,006	1,576,374
Exercise of stock options	18	14
Issuance of shares	11,350	—
As of the end of the year	1,576,374	1,576,388

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 shares issued was 10,226 thousand shares, 18,608 thousand shares, and 13,030 thousand shares as of April 1, 2019, March 31, 2020, and 2021, respectively. The number of treasury shares as of April 1, 2019, March 31, 2020 and 2021 includes 9,976 thousand shares, 18,353 thousand shares and 12,772 thousand shares, respectively, held by the Employee Stock Ownership Plan (“ESOP”) Trust and the Board Incentive Plan (“BIP”) Trust. During the year ended March 31, 2020, The ESOP and BIP Trust acquired 12,343 thousand shares and sold 3,966 thousand shares. During the year ended March 31, 2021, The ESOP and BIP Trust acquired 520 thousand shares and sold 6,101 thousand shares.

During the year ended March 31, 2020, the Company issued 11,350 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 24,505 million JPY and share premium of 24,505 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 49,009 million JPY in the consolidated statements of financial position.

Dividends declared and paid	JPY (millions)		Dividends per share JPY		Record date	Effective date
	Total dividends					
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
April 1, 2019, to March 31, 2020						
Q1 2019		140,836		90.00	March 31, 2019	June 28, 2019
Q3 2019		141,857		90.00	September 30, 2019	December 2, 2019
April 1, 2020, to March 31, 2021						
Q1 2020		141,858		90.00	March 31, 2020	June 25, 2020
Q3 2020		141,860		90.00	September 30, 2020	December 1, 2020

Dividends declared for which the effective date falls in the following fiscal year are as follows:

Dividends declared	JPY (millions)		Dividends per share JPY		Record date	Effective date
	Total dividends					
April 1, 2021, to March 31, 2022						
Q1 2021	¥	141,859	¥	90.00	March 31, 2021	June 30, 2021

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 foreign exchange rates, interest rates and market prices of commodities and other financial holdings. Each of these risks is managed in accordance with Takeda's policies.

Financial Assets and Liabilities

		JPY (millions)							
		As of March 31, 2020							
	Financial assets 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	¥ —	¥ 127,455	¥ —	¥ —	¥ —	¥ —	¥ 127,455		
Derivative financial instruments	—	—	25,509	120	—	—	25,629		
Investments in convertible notes	—	—	9,418	—	—	—	9,418		
Investments in debt instruments	—	—	1,029	—	—	—	1,029		
Financial assets associated with contingent consideration arrangements	—	—	92,516	—	—	—	92,516		
Total	¥ —	¥ 127,455	¥ 128,472	¥ 120	¥ —	¥ —	¥ 256,047		
Financial assets not measured at fair value									
Other financial assets -									
Other	¥ 21,896	¥ —	¥ —	¥ —	¥ —	¥ —	¥ 21,896		
Trade and other receivables	757,005	—	—	—	—	—	757,005		
Cash and cash equivalents	637,614	—	—	—	—	—	637,614		
Total	¥ 1,416,515	¥ —	¥ —	¥ —	¥ —	¥ —	¥ 1,416,515		
Financial liabilities measured at fair value									
Other financial liabilities -									
Derivative financial instruments	¥ —	¥ —	¥ 13,673	¥ 38,916	¥ —	¥ —	¥ 52,589		
Financial liabilities associated with contingent consideration arrangements	—	—	41,664	—	—	—	41,664		
Other	—	—	9,057	—	—	—	9,057		
Total	¥ —	¥ —	¥ 64,394	¥ 38,916	¥ —	¥ —	¥ 103,310		
Financial liabilities not measured at fair value									
Other financial liabilities -									
Lease liabilities	¥ —	¥ —	¥ —	¥ —	¥ 369,459	¥ —	¥ 369,459		
Other	—	—	—	—	22,066	—	22,066		
Trade and other payables	—	—	—	—	318,816	—	318,816		
Bonds and loans	—	—	—	—	5,093,304	—	5,093,304		
Total	¥ —	¥ —	¥ —	¥ —	¥ 5,803,645	¥ —	¥ 5,803,645		

JPY (millions)
As of March 31, 2021

	Financial assets 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	¥ —	¥ 145,070	¥ —	¥ —	¥ —	¥ 145,070
Derivative financial instruments	—	—	62,594	1,506	—	64,100
Investments in convertible notes	—	—	12,176	—	—	12,176
Investments in debt instruments	—	—	800	—	—	800
Financial assets associated with contingent consideration arrangements	—	—	25,446	—	—	25,446
Total	¥ —	¥ 145,070	¥ 101,016	¥ 1,506	¥ —	¥ 247,592

Financial assets not measured at fair value

Other financial assets -						
Other	¥ 24,888	¥ —	¥ —	¥ —	¥ —	¥ 24,888
Trade and other receivables	783,091	—	—	—	—	783,091
Cash and cash equivalents	966,222	—	—	—	—	966,222
Total	¥ 1,774,201	¥ —	¥ —	¥ —	¥ —	¥ 1,774,201

Financial liabilities measured at fair value

Other financial liabilities -						
Derivative financial instruments	¥ —	¥ —	¥ 12,116	¥ 84,975	¥ —	¥ 97,091
Financial liabilities associated with contingent consideration arrangements	—	—	27,770	—	—	27,770
Other	—	—	2,693	—	—	2,693
Total	¥ —	¥ —	¥ 42,579	¥ 84,975	¥ —	¥ 127,554

Financial liabilities not measured at fair value

Other financial liabilities -						
Lease liabilities	¥ —	¥ —	¥ —	¥ —	¥ 436,412	¥ 436,412
Other	—	—	—	—	201,764	201,764
Trade and other payables	—	—	—	—	343,838	343,838
Bonds and loans	—	—	—	—	4,635,371	4,635,371
Total	¥ —	¥ —	¥ —	¥ —	¥ 5,617,385	¥ 5,617,385

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)						
		As of March 31, 2020						
		Level 1	Level 2	Level 3	Total			
Assets:								
Financial assets measured at fair value through profit or loss								
Derivatives	¥	—	¥	25,509	¥	—	¥	25,509
Investment in convertible notes		—		—		9,418		9,418
Investment in debt instruments		—		—		1,029		1,029
Financial assets associated with contingent consideration arrangements		—		—		92,516		92,516
Derivatives for which hedge accounting is applied		—		120		—		120
Financial assets measured at fair value through OCI								
Equity instruments		79,218		—		48,237		127,455
Total	¥	79,218	¥	25,629	¥	151,200	¥	256,047
Liabilities:								
Financial liabilities measured at fair value through profit or loss								
Derivatives	¥	—	¥	13,673	¥	—	¥	13,673
Financial liabilities associated with contingent consideration arrangements		—		—		41,664		41,664
Other		—		—		9,057		9,057
Derivative for which hedge accounting is applied		—		38,916		—		38,916
Total	¥	—	¥	52,589	¥	50,721	¥	103,310

		JPY (millions)						
		As of March 31, 2021						
		Level 1	Level 2	Level 3	Total			
Assets:								
Financial assets measured at fair value through profit or loss								
Derivatives	¥	—	¥	62,594	¥	—	¥	62,594
Investment in convertible notes		—		—		12,176		12,176
Investment in debt instruments		—		—		800		800
Financial assets associated with contingent consideration arrangements		—		—		25,446		25,446
Derivatives for which hedge accounting is applied		—		1,506		—		1,506
Financial assets measured at fair value through OCI								
Equity instruments		92,602		—		52,468		145,070
Total	¥	92,602	¥	64,100	¥	90,890	¥	247,592
Liabilities:								
Financial liabilities measured at fair value through profit or loss								
Derivatives	¥	—	¥	12,116	¥	—	¥	12,116
Financial liabilities associated with contingent consideration arrangements		—		—		27,770		27,770
Other		—		—		2,693		2,693
Derivative for which hedge accounting is applied		—		84,975		—		84,975
Total	¥	—	¥	97,091	¥	30,463	¥	127,554

Valuation Techniques

The fair value of derivatives is measured based on Treasury management system valuation models or the Black-Scholes model, whose significant inputs are based on observable market data. During the year ended March 31, 2020, a 25,660 million JPY valuation gain was recognized at the timing of public offering in finance income on the warrant to purchase stocks of a privately held company upon that company's initial public offering.

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 instruments are not held for trading. If equity instruments or investments in debt instruments 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 instruments are not quoted in an active market, the fair value is calculated utilizing an adjusted net assets book value method or multiples of EBITDA approach based on available information as of each period-end-date and company comparable. The principal input that is not observable and utilized for the calculation of the fair value of equity instruments and investments in debt instruments classified as Level 3 is the EBITDA rate used for the EBITDA multiples approach, which ranges from 3.4 times to 9.8 times. During the years ended March 31, 2020 and 2021, cumulative gains on equity investments of 19,903 million JPY and 42,781 million JPY were reclassified from other comprehensive income to retained earnings, respectively, upon the disposal of certain equity investments in publicly traded companies. The fair value of these investments on the dates of disposal during the years ended March 31, 2020 and 2021 were 35,435 million JPY and 73,875 million JPY, respectively. The investments were disposed of after management's assessment of these investments relative to the investment strategy.

Financial assets and liabilities associated with contingent consideration arrangements are valued at fair value at the time of the divestiture or the acquisition date of business combination. When the contingent consideration arrangement meets the definition of a financial asset or liability, it is subsequently re-measured to fair value at each closing 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 financial assets associated with contingent consideration arrangements are recognized mainly in relation to the divestiture of XIIDRA. The financial liabilities associated with contingent consideration arrangements are discussed in *Financial liabilities associated with contingent consideration arrangements*.

The joint venture net written option, included in other Level 3 liabilities above is valued at fair value, and subsequently re-measured to fair value at each closing 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 are 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 transfers from Level 3 to Level 1 recorded in the years ended March 31, 2020 and 2021. 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, 2020 and 2021, 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, 2020 and 2021, respectively. There were no other transfers between levels of the fair value hierarchy during the years ended March 31, 2020 and 2021.

Level 3 financial assets fair values

Takeda invests in equity instruments mainly for research collaboration. The following table shows a reconciliation from the opening balances to the closing balances for Level 3 financial asset fair values for the years ended March 31, 2020 and 2021. The disclosure related to Level 3 financial liabilities which are financial liabilities associated with contingent consideration arrangements are included in *Financial liabilities associated with contingent consideration arrangements*. There are no significant changes in fair value during the changes in certain assumptions which influence the fair value measurement for Level 3 financial assets.

JPY (millions)
For the Year Ended March 31

	2020		2021	
	Financial assets associated with contingent consideration arrangements	Equity instruments	Financial assets associated with contingent consideration arrangements	Equity instruments
As of the beginning of the period	¥ —	¥ 48,825	¥ 92,516	¥ 48,237
Recognition of financial assets associated with contingent consideration arrangements	83,245	—	3,318	—
Changes recognized as finance income	3,478	—	3,294	—
Changes in fair value of financial assets associated with contingent consideration due to other elements than time value ⁽¹⁾	5,652	—	(72,940)	—
Changes in fair value of financial assets measured at fair value through OCI and exchange differences on translation of foreign operations	141	15,157	(742)	8,126
Purchases	—	7,187	—	12,559
Sales	—	(191)	—	(7,013)
Transfers to Level 1	—	(17,334)	—	(9,241)
Acquisition from conversion of convertible notes	—	273	—	—
Transfers from investments accounted for using the equity method	—	199	—	—
Transfers to investments accounted for using the equity method	—	(5,879)	—	—
Reclassification to assets held for sale	—	—	—	(200)
As of the end of the period	¥ 92,516	¥ 48,237	¥ 25,446	¥ 52,468

⁽¹⁾ During the year ended March 31, 2021, Takeda recognized other operating expenses of 72,940 million JPY as the loss from changes in the fair value of the assets associated with contingent consideration arrangements from the previous sale of XIIDRA. It was driven by changes in assumptions related to the future sales of XIIDRA, including the impact from Novartis' withdrawal of the Marketing Authorisation Application in Europe, as also described in Note 5.

Financial liabilities associated with contingent consideration arrangements

Financial liabilities associated with contingent consideration arrangements represent consideration related to business combinations or license agreements that are 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 an appropriate discount rate.

As of March 31, 2020 and 2021, 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 50,882 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			
	2020		2021	
As of the beginning of the year	¥	67,294	¥	41,664
Changes in the fair value during the period		(8,094)		(10,062)
Settled and paid during the period		(15,253)		(4,206)
Settled during the period and reclassified to other payables		(95)		—
Foreign currency translation differences		(1,426)		374
Other		(762)		—
As of the end of the year	¥	41,664	¥	27,770

	JPY (millions)			
	As of March 31			
	2020		2021	
Payment term (undiscounted)				
Within one year	¥	4,610	¥	7,400
Between one and three years		9,918		2,273
Between three and five years		5,014		1,174
More than five years		45,229		40,035

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			
		2020		2021	
Probability of technical milestones being achieved for Shire's historical contingent consideration arrangements	Increase by 5%	¥	4,051	¥	3,690
	Decrease by 5%		(4,051)		(3,690)
Discount rate	Increase by 0.5%		(1,367)		(1,089)
	Decrease by 0.5%		1,367		1,089

Financial instruments not measured at fair value

The carrying amount and fair value of financial instruments that are not measured at fair value in the consolidated statements of financial position are as follows:

	JPY (millions)			
	As of March 31			
	2020		2021	
	Carrying amount	Fair value	Carrying amount	Fair value
Bonds	¥ 3,204,965	¥ 3,351,400	¥ 3,532,202	¥ 3,762,266
Long-term loans	1,883,325	1,876,613	1,103,100	1,098,526

Long-term financial liabilities are recognized at their carrying amount. The fair value of bonds is measured at quotes whose significant inputs to the valuation model used are based on observable market data. The fair value of loans is measured at the present value of future cash flows discounted using the applicable market rate on the loans in consideration of the credit risk by each group classified in a specified period. The fair value of bonds and long-term loans 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 Takeda's net investments in foreign subsidiaries. Takeda manages foreign currency risks in a centralized manner using derivative financial instruments. Takeda's policy does not permit the use of speculative foreign currency financial instruments or derivatives.

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 and forward exchange contracts as hedging instruments of net investments in foreign operations. As of March 31, 2020 and 2021, the total fair value of the foreign currency denominated loans was 1,292,239 million JPY and 579,864 million JPY, respectively, and the total fair value of the foreign currency denominated bonds was 2,636,053 million JPY and 3,245,901 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 9,635 million JPY and 11,057 million JPY as of March 31, 2020 and 2021, 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 as well as impact of certain hedging instruments which would mitigate foreign currency risk of JPY depreciation. 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)				
	As of March 31, 2020				
	Contract amount		Contract amount to be settled in more than one year		Fair value
Forward exchange contracts:					
Selling:					
Euro	¥	15,478	¥	—	¥ (93)
United States Dollar		212,638		—	2,764
Buying:					
Euro		111,249		—	(3,845)
United States Dollar		423,060		—	(8,095)
Currency swaps:					
Buying:					
United States Dollar		123,959		123,924	(473)
Currency collar options:					
Russian Ruble		10,124		—	(89)
Brazilian Real		6,753		—	(63)
Indian Rupee		1,258		—	(1)

		JPY (millions)			
		As of March 31, 2021			
		Contract amount		Contract amount to be settled in more than one year	
				Fair value	
Forward exchange contracts:					
Selling:					
Euro	¥	131,729	¥	—	¥ (3,362)
United States Dollar		865,407		—	(11,270)
Buying:					
Euro		134,762		—	3,407
United States Dollar		1,364,837		—	7,873
Other		13,515		—	422
Currency swaps:					
Buying:					
United States Dollar		739,948		717,114	(56,787)

The above currency swaps were related to bonds and loans denominated in foreign currency that the Company designated as hedging instruments in a cash flow hedge. 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 debts with floating interest rates. Takeda uses interest and cross currency interest rate swaps that fix the amount of future payments to manage interest and foreign exchange rate risks through cash flow hedge strategies. Takeda may also use derivatives that effectively convert its fixed rate debt to floating through fair-value hedge strategies. The following summarizes interest and cross currency interest rate swaps designated as cash flow hedges as of March 31:

		JPY (millions)			
		As of March 31			
		Contract amount		Contract amount to be settled in more than one year	
				Fair value	
2020	¥	640,205	¥	184,450	¥ (38,796)
2021		164,443		164,443	(3,271)

The above swaps are related to the outstanding debts with floating interest rates that 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 and does not include impacts of certain hedging instruments.

		JPY (millions)			
		As of March 31, 2020		As of March 31, 2021	
		Interest rate		Interest rate	
		+1%	-1%	+1%	-1%
Impact on net profit or loss before tax	¥	(15,432)	¥ 15,432	¥ (5,064)	¥ 5,064
Impact on other comprehensive income (before tax effect)		34,296	(34,296)	10,234	(10,234)

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, Takeda 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 7,922 million JPY and 9,260 million JPY for the years ended March 31, 2020 and 2021, 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's overseas 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 on 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 ("balance sheet hedges") that do not qualify for hedge accounting but are utilized to manage the underlying foreign currency exposure risk. Balance sheet hedges are used to offset the foreign currency impact from assets and liabilities on Takeda balance sheet denominated in non-functional currencies. Given these foreign currency derivatives work on an offset basis they do not require hedge accounting. Takeda does not use financial instruments for speculative purposes. Takeda 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 tables represent the items designated as hedging instruments, amounts within other components of equity related to items designated as hedged items and amounts of changes in fair value of hedging instruments recorded in other comprehensive income and the amounts reclassified from the hedge cost reserve to profit or loss as of and for the year ended March 31, 2020:

	Notional	JPY (millions) As of March 31, 2020		Line item in the statement of financial position where hedging instrument is included	Average rate used for the fair value of the hedging instrument
		Carrying amount – assets	Carrying amount – liabilities		
Cash flow hedges					
Interest risk					
Interest rate swaps	60,000 million JPY	¥ —	¥ 223	Other financial liabilities	0.68 %
	575 million USD	—	7,081	Other financial liabilities	2.83 %
Forward interest rate	2,000 million USD	—	28,642	Other financial liabilities	1.81 %
	1,500 million EUR	33	2,410	Other financial asset / liabilities	0.13 %
Currency and interest risk					
Currency and interest rate swaps	1,125 million USD	87	560	Other financial asset / liabilities	109.97 JPY 0.03%
Net investment hedges					
Foreign currency denominated bonds and loans	12,415 million USD	—	1,347,047	Bonds and loans	
	10,552 million EUR	—	1,257,492	Bonds and loans	

	JPY (millions) As of March 31, 2020	
	Balance in cash flow hedges and net investment hedges	Balance in hedge cost reserve
Cash flow hedges		
Interest risk		
Interest rate swaps	¥ (5,070)	¥ —
Forward interest rate	(21,488)	—
Currency and interest risk		
Currency and interest rate swaps	266	555
Currency risk		
Hedge related to acquisition	3,560	—
Net investment hedges		
Foreign currency denominated bonds and loans	71,795	—

JPY (millions)						
For the year ended March 31, 2020						
	Amounts recognized in OCI			Amount reclassified to profit or loss		
	Change in fair value of hedging instruments	Hedging costs	Cash flow hedge	Hedging costs	Line item in which reclassification adjustment is included	
Cash flow hedges						
Interest risk						
Interest rate swaps	¥ (7,409)	¥ —	¥ 627	¥ —	Financial expenses	
Forward interest rate	(31,022)	—	21	—	Financial expenses	
Currency and interest risk						
Currency and interest rate swaps	568	(344)	(28)	(890)	Financial income and Financial expenses	
Currency risk						
Hedge related to acquisition	237	—	—	—		
Net investment hedges						
Foreign currency denominated bonds and loans	(72,854)	—	—	—		

The following tables represent the items designated as hedging instruments, amounts within other components of equity related to items designated as hedged items and 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 and for the year ended March 31, 2021:

JPY (millions)					
As of March 31, 2021					
	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 instrument
Cash flow hedges					
Interest risk					
Interest rate swaps	575 million USD	¥ —	¥ 4,777	Other financial liabilities	2.83 %
Currency and interest risk					
Currency and interest rate swaps	6,875 million USD	1,506	58,293	Other financial assets / liabilities	107.63 JPY 1.80%
Net investment hedges					
Foreign currency denominated bonds and loans	8,819 million USD	—	974,779	Bonds and loans	
	8,857 million EUR	—	1,149,950	Bonds and loans	
Forward exchange contracts					
	3,291 million USD	—	18,539	Other financial liabilities	
	998 million EUR	—	3,366	Other financial liabilities	

		JPY (millions) As of March 31, 2021	
		Balance in cash flow hedges and net investment hedges	Balance in hedge cost reserve
Cash flow hedges			
Interest risk			
Interest rate swaps	¥	(3,316)	¥ —
Forward interest rate		(22,499)	—
Currency and interest risk			
Currency and interest rate swaps		(45,820)	(8,592)
Currency risk			
Hedge related to acquisition		3,560	—
Net investment hedges			
Foreign currency denominated bonds and loans		15,436	—
Forward exchange contracts		20,476	—

		JPY (millions) For the year ended March 31, 2021				
		Amounts recognized in OCI		Amount reclassified to profit or loss		
		Change in fair value of hedging instruments	Hedging costs	Cash flow hedge	Hedging costs	Line item in which reclassification adjustment is included
Cash flow hedges						
Interest risk						
Interest rate swaps	¥	1,400	¥ —	¥ 1,127	¥ —	Financial expenses
Forward interest rate		(3,087)	—	1,630	—	Financial expenses
Currency and interest risk						
Currency and interest rate swaps		(39,146)	(9,978)	(27,242)	(3,200)	Financial income and Financial expenses
Net investment hedges						
Foreign currency denominated bonds and loans		112,620	—	—	—	
Forward exchange contracts		19,804	—	—	—	

The amount relating to the ineffectiveness recorded in profit or loss was immaterial for the years ended March 31, 2020 and 2021. 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, 2020 and 2021.

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 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 statements of financial position. Takeda regularly monitors the status of credit risk exposure with banks and financial institutions.

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 carrying amount of the trade receivables categorized by due date and the analysis of impairment loss allowance as of March 31, 2020 and 2021:

**JPY (millions) except for percentage
As of March 31, 2020**

	Amount past due						Total
	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	
Gross carrying amount	¥ 626,334	¥ 15,341	¥ 8,635	¥ 5,692	¥ 12,010	¥ 7,893	¥ 675,905
Impairment loss allowance	(748)	(316)	(168)	(198)	(438)	(3,329)	(5,197)
Net carrying amount	625,586	15,025	8,467	5,494	11,572	4,564	670,708
Weighted average loss rate	0.1 %	2.1 %	1.9 %	3.5 %	3.6 %	42.2 %	0.8 %

**JPY (millions) except for percentage
As of March 31, 2021**

	Amount past due						Total
	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	
Gross carrying amount	¥ 643,819	¥ 17,632	¥ 12,017	¥ 6,214	¥ 16,762	¥ 19,680	¥ 716,124
Impairment loss allowance	(1,336)	(20)	(11)	(120)	(646)	(6,504)	(8,637)
Net carrying amount	642,483	17,612	12,006	6,094	16,116	13,176	707,487
Weighted average loss rate	0.2 %	0.1 %	0.1 %	1.9 %	3.9 %	33.0 %	1.2 %

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, 2020 and 2021, 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 impairment loss allowance for trade receivables for the years ended March 31, 2020 and 2021. 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 assets	Total
As of April 1, 2019	¥ 1,391	¥ 1,927	¥ 3,318
Increases	2,061	2,275	4,336
Decreases (written off)	(908)	(302)	(1,210)
Decreases (reversed)	(617)	(329)	(946)
Foreign currency translation differences	(257)	(44)	(301)
As of March 31, 2020	¥ 1,670	¥ 3,527	¥ 5,197
Increases	1,733	3,710	5,443
Decreases (written off)	(292)	(348)	(640)
Decreases (reversed)	(866)	(872)	(1,738)
Foreign currency translation differences	114	261	375
As of March 31, 2021	¥ 2,359	¥ 6,278	¥ 8,637

Other Counterparty Credit Risk

Cash reserves of Takeda are concentrated mostly with the Company and entities acting as the cash pool leader in the U.S. 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 contracts only with financial counterparties rated investment grade or higher in order to minimize counterparty risk.

Liquidity Risk

Takeda 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 on an ongoing basis. 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, 2020 and 2021 are undiscounted cash flows using the respective spot foreign exchange rates as of March 31, 2020 and 2021.

	JPY (millions)									
	Carrying amount	Total	Within one year	Between one and two years	Between two and three years	Between three and four years	Between four and five years	More than five years		
As of March 31, 2020										
Bonds and loans										
Bonds	¥ 3,204,965	¥ 3,728,427	¥ 551,728	¥ 621,138	¥ 354,268	¥ 489,171	¥ 544,236	¥ 1,167,886		
Loans	1,888,339	1,984,005	137,812	55,478	170,844	677,391	59,424	883,056		
Trade and other payables	318,816	318,816	318,816	—	—	—	—	—		
Lease liabilities	369,459	545,688	41,084	40,623	33,085	30,407	28,747	371,742		
Derivative liabilities	52,589	48,806	44,255	1,396	804	695	510	1,146		
Derivative assets	(25,629)	(10,059)	(5,433)	(551)	(562)	(652)	(722)	(2,139)		
As of March 31, 2021										
Bonds and loans										
Bonds	¥ 3,532,202	¥ 4,563,035	¥ 114,712	¥ 407,866	¥ 526,605	¥ 573,221	¥ 151,308	¥ 2,789,323		
Loans	1,103,169	1,150,358	227,950	80,349	106,972	59,593	284,877	390,617		
Trade and other payables	343,838	343,838	343,838	—	—	—	—	—		
Lease liabilities	436,412	610,270	50,187	45,076	43,949	41,180	38,551	391,327		
Derivative liabilities	97,091	(61,375)	29,274	(5,770)	(5,380)	(6,996)	(6,793)	(65,710)		
Derivative assets	(64,100)	(43,560)	(31,816)	(776)	(1,133)	(1,797)	(2,422)	(5,616)		

The contractual amount of bonds in “Within one year” as of March 31, 2021 includes a 200 million USD principal amount of unsecured U.S. dollar-denominated senior notes in respect of an early redemption of the remaining principal amount of the bond on May 17, 2021. For the details of early redemption, see Note 33. Furthermore, the contractual amount of loans in “Within one year” as of March 31, 2021 includes a 2,000 million USD of the outstanding JBIC Loan floating rate amount of 3,700 million USD as Takeda made a prepayment of the loan on June 11, 2021. The JBIC Loan was included in non-current liabilities of the consolidated statements of financial position as of March 31, 2021 as the maturity date of the loan is December 11, 2025 and the notice to repay the loan was not issued until April 1, 2021. For the details of prepayment, see Note 33. The contractual amount of bonds in “Between four and five years” as of March 31, 2020 and “Between three and four years” as of March 31, 2021, includes 500,000 million JPY principal amount of the hybrid subordinated bonds (the “Hybrid Bonds”) as Takeda may make an early repayment of all of the principal of the Hybrid Bonds on each interest payment date beginning October 6, 2024. For details on the principal and interest rates associated with these bonds and loans, see Note 20.

Reconciliation of liabilities arising from financing activities

JPY (millions)							
	Bonds	Long-term loans	Short-term loans	Lease liabilities	Derivative assets used for hedge of debts	Derivative liabilities used for hedge of debts	Total
As of April 1, 2019	¥ 3,196,365	¥ 2,054,584	¥ 500,002	¥ 396,736	¥ (3,329)	¥ 708	¥ 6,145,066
Cash flows from financing activities							
Net increase (decrease) in short-term loans and commercial papers	144,000	—	(495,223)	—	—	—	(351,223)
Proceeds from issuance of bonds	496,190	—	—	—	—	—	496,190
Repayments of long-term loans	—	(137,444)	—	—	—	—	(137,444)
Repayments of bonds	(563,613)	—	—	—	—	—	(563,613)
Repayments of lease liabilities	—	—	—	(30,000)	—	—	(30,000)
Interest paid	—	—	—	(11,834)	—	—	(11,834)
Non-cash items							
Foreign exchange movement	(85,541)	(34,980)	235	(15,658)	—	—	(135,944)
Change in fair value	—	—	—	—	3,242	(148)	3,094
New, amended and terminated leases	—	—	—	18,381	—	—	18,381
Others	17,564	1,165	—	11,834	—	—	30,563
As of March 31, 2020	¥ 3,204,965	¥ 1,883,325	¥ 5,014	¥ 369,459	¥ (87)	¥ 560	¥ 5,463,236

JPY (millions)							
	Bonds	Long-term loans	Short-term loans	Lease liabilities	Derivative assets used for hedge of debts	Derivative liabilities used for hedge of debts	Total
As of April 1, 2020	¥ 3,204,965	¥ 1,883,325	¥ 5,014	¥ 369,459	¥ (87)	¥ 560	¥ 5,463,236
Cash flows from financing activities							
Net increase (decrease) in short-term loans and commercial papers	(144,000)	—	(5,043)	—	—	—	(149,043)
Proceeds from issuance of bonds	1,179,452	—	—	—	63	—	1,179,515
Repayments of long-term loans	—	(792,497)	—	—	—	—	(792,497)
Repayments of bonds	(859,209)	—	—	—	—	—	(859,209)
Repayments of lease liabilities	—	—	—	(39,270)	—	—	(39,270)
Interest paid	—	—	—	(12,124)	—	—	(12,124)
Non-cash items							
Foreign exchange movement	134,651	10,462	98	6,541	—	—	151,752
Change in fair value	—	—	—	—	(1,482)	57,733	56,251
New, amended and terminated leases	—	—	—	99,682	—	—	99,682
Others	16,343	1,810	—	12,124	—	—	30,277
As of March 31, 2021	¥ 3,532,202	¥ 1,103,100	¥ 69	¥ 436,412	¥ (1,506)	¥ 58,293	¥ 5,128,570

Others includes increase in debts due to application of amortized cost method.

28. Share-based Payments

Takeda maintains share-based compensation payment plans for the benefit of its directors and certain of employees of the Company and its subsidiaries and affiliates worldwide. Takeda recorded total compensation expense related to its share-based payment plans of 18,787 million JPY, 30,016 million JPY, and 39,428 million JPY for the years ended March 31, 2019, 2020 and 2021, respectively, in its consolidated statements of profit or loss.

Equity-settled Plans

Stock Options

Takeda previously provided a stock option plan under which it granted awards to members Takeda's board of directors (the "Board"), corporate officers, 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 members of the Board and 20 years for options held by corporate officers and senior management. The individual must be either a Board member or an employee of the Company or one of its subsidiaries or affiliates to exercise the options, unless the individual retired due to the expiration of their term of office, mandatory retirement or other acceptable reasons.

There was no compensation expense recorded during the years ended March 31, 2019, 2020 and 2021 as all awards were fully vested.

The following table summarizes the stock option activities:

	For the Year Ended March 31					
	2019		2020		2021	
	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	3,403,800	¥ 4,054	3,389,200	¥ 4,055	3,371,200	¥ 4,065
Exercised	(14,600)	3,721	(18,000)	2,266	(14,000)	1
As of end of the year	<u>3,389,200</u>	<u>4,055</u>	<u>3,371,200</u>	<u>4,065</u>	<u>3,357,200</u>	<u>4,082</u>

All of the stock options were exercisable as of March 31, 2019, 2020 and 2021.

The weighted-average share price at the date of exercise was 4,679 JPY, 4,390 JPY and 4,115 JPY during the years ended March 31, 2019, 2020 and 2021, respectively. The weighted-average exercise price and weighted-average remaining contractual life of the share options outstanding were 4,055 JPY and 13 years, 4,065 JPY and 12 years, and 4,082 JPY and 11 years, as of March 31, 2019, 2020 and 2021, respectively.

Stock Incentive Plans

Takeda has 3 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 Board members whereby restricted share and performance share awards are granted to Board members. Each award is settled in a single share of the Company common stock. 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 value of the awards is based on stock price and subject to, among other things, applicable tax withholding, foreign exchange rates (in countries other than Japan) and the value of company dividends during the vesting period. Performance shares are subject to certain service-based conditions and also subject to the achievement of certain performance metrics that are intended to align with Takeda's strategic focus and long-term growth. For purposes of the performance shares, the performance metrics primarily consisted of: (i) 3-year accumulated underlying revenue; (ii) core operating profit margin; (iii) 3-year accumulated free cash flow; (iv) certain R&D goals; and (v) 3-year relative total shareholder return. Performance stock unit awards vest three years from the date of grant. Takeda, through a wholly owned trust, buys shares of the Company common stock in the market on the grant date, and uses these shares to settle the awards upon vesting. 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 resident in Japan. For individuals resident outside of Japan the trust sells the share the individual is eligible to receive and pays the cash to the individual in settlement of the award.

Employee Stock Ownership Plan ("ESOP") - The ESOP is a stock-based incentive plan for senior management of the Company and its subsidiaries and affiliates whereby awards are granted to the employees. Each award is settled in a single share of the Company common stock. 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 value of the awards is based on stock price and subject to, among other things, applicable tax withholding and the value of company dividends during the vesting period. Performance shares are subject to certain service-based conditions and also subject to the achievement of certain performance metrics that are intended to align with Takeda's strategic focus and long-term growth. For purposes of the performance shares, the performance metrics primarily consisted of (i) 3-year accumulated underlying revenue; (ii) core operating profit margin; (iii) 3-year accumulated free cash flow; (iv) certain R&D goals; and (v) 3-year relative total shareholder return. Performance stock unit awards vest three years from the date of grant. Takeda issues shares the Company common stock to a wholly owned trust on the grant date and uses

these shares to settle the awards upon vesting. The number of shares the individual receives is based on the achievement of the performance criteria and vesting of the award.

Long-Term Incentive Plan (“LTIP”) - The LTIP was approved by the Board on June 24, 2020 and is an incentive plan that provides for the grant of awards to eligible employees, including members of senior management of the Company and its subsidiaries and affiliates. The LTIP provides for the grant of restricted stock unit awards and performance stock units, as well other equity based awards. Grants under the LTIP may be settled in shares of the Company common stock, American Depositary Shares (“ADSs”) or cash, or a combination thereof.

Takeda first granted awards under the LTIP on July 1, 2020 in the form of restricted stock unit awards and performance stock unit awards, and no other forms of award have been granted under the LTIP to date. Restricted stock unit awards are subject to certain service-based conditions and vest ratably over three years. The value of such awards when such awards are to be settled in ADSs is based on the fair market value of the shares of the Company common stock converted into ADSs, subject to, among other things, applicable tax withholding, foreign exchange rates and the value of company dividends during the vesting period. Performance stock units are subject to certain service-based conditions and also subject to the achievement of certain performance metrics that are intended to align with Takeda’s strategic focus and long-term growth. For purposes of the performance stock unit awards granted during the reporting period, the performance metrics consisted of: (i) 3-year accumulated underlying revenue; (ii) core operating profit margin; (iii) 3-year accumulated free cash flow; (iv) certain R&D goals; and (v) 3-year relative total shareholder return. Performance stock units vest three years from the date of grant. Performance stock units granted on July 1, 2020 are scheduled to vest, subject to the conditions described above, as well as any other applicable conditions pursuant to the individual award agreements, on July 1, 2023.

Restricted stock unit awards and performance stock unit awards granted under the LTIP are to be settled in the Company common stock to award recipients resident and employed in Japan and in ADS to award recipients resident and employed in countries outside of Japan where settlement in ADSs is permitted by local law and regulation. In countries outside of Japan where such form of settlement is not permissible due to legal, regulatory and/or administrative reasons, restricted stock unit awards and performance stock units awards are structured such that settlement is to be made in cash and accounted as a “Cash-Settled LTIP Award” (please refer to Cash-Settled LTIP Awards). To date, all grants made under the LTIP have been granted to award recipients that are resident and employed in countries outside of Japan and are subject to settlement either in ADSs or cash, and no grants to be settled in shares of the Company common stock have been made.

The total compensation expense recognized related to these plans was 20,084 million JPY, 29,122 million JPY and 37,663 million JPY during the years ended March 31, 2019, 2020 and 2021, respectively.

The weighted average fair value of the awards at the grant date is as follows (in JPY):

	For the Year Ended March 31		
	2019	2020	2021
BIP:			
Weighted average fair value at grant date	¥ 4,631	¥ 3,857	¥ 3,765
ESOP:			
Weighted average fair value at grant date	4,678	3,857	3,765
Equity-Settled LTIP:			
Weighted average fair value at grant date			1,907 (US\$17.64 in contractual currency)

The grant date fair value for BIP and ESOP was calculated using the share price of the Company common stock on the grant date while the grant date fair value for LTIP was calculated using the share price of ADS as it was determined to be approximately the same as the fair value of the awards. One ADS equals 0.5 of the Company common stock.

The following table summarizes the award activity related to the stock incentive plans (number of awards):

	For the Year Ended March 31						
	2019		2020		2021		Equity-Settled LTIP
	BIP	ESOP	BIP	ESOP	BIP	ESOP	
At beginning of the year	433,260	6,891,762	485,232	7,939,675	819,229	13,398,751	—
Granted	252,647	5,021,627	591,508	11,152,440	518,965	791,687	25,223,010
Forfeited/expired before vesting	(17,832)	(781,033)	(22,689)	(2,003,789)	—	(794,005)	(1,744,170)
Settled	(182,843)	(3,192,681)	(234,822)	(3,689,575)	(302,351)	(5,644,481)	—
Transfer to Cash-Settled LTIP	—	—	—	—	—	—	(65,846)
At end of the year	485,232	7,939,675	819,229	13,398,751	1,035,843	7,751,952	23,412,994

There were no exercisable shares as of March 31, 2019, 2020, and 2021. The weighted average remaining contractual life of the outstanding awards was one year as of each year end for both the BIP, the ESOP and the LTIP plans.

Cash-Settled Awards

Takeda has a phantom stock appreciation rights (“PSARs”) plan and a restricted stock units (“RSUs”) plan for certain of employees of subsidiaries of the Company. The value of these awards is linked to share price of the Company and are settled in cash. Moreover, where settlement of awards granted under the LTIP described under “—Equity Settled Plans” above in ADSs or shares of common stock is not permissible due to legal, regulatory and/or administrative reasons, such awards are settled in cash. The total compensation expense recorded associated with these plans was 894 million JPY and 1,765 million JPY during the years ended March 31, 2020 and 2021. 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, 2020 and 2021, is 1,620 million JPY and 2,115 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 (the number of awards) (1 award represents 1 share of the Company common stock) :

	For the Year Ended March 31					
	2019		2020		2021	
	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	4,584,937	¥ 4,650	4,175,347	¥ 4,849	2,686,749	¥ 4,873
Exercised	(214,296)	4,428	(17,737)	4,284	—	—
Forfeited/expired after vesting	(195,294)	4,940	(1,470,861)	4,562	(416,310)	4,641
As of end of the year	<u>4,175,347</u>	4,849	<u>2,686,749</u>	4,873	<u>2,270,439</u>	4,997

All PSARs were vested and exercisable as of March 31, 2019, 2020 and 2021. There was no intrinsic value of vested cash-settled share-based payments as of March 31, 2020 and 2021.

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 (the number of awards) (1 award represents 1 share of the Company common stock):

	For the Year Ended March 31		
	2019	2020	2021
As of the beginning of the year	398,479	401,153	1,439,536
Granted	279,436	1,403,045	23,541
Forfeited/expired before vesting	(92,829)	(188,383)	(155,551)
Settled	(183,933)	(176,279)	(529,075)
As of the end of the year	<u>401,153</u>	<u>1,439,536</u>	<u>778,451</u>

There are no exercisable balances as of March 31, 2019, 2020 and 2021.

Cash-Settled LTIP Awards

As noted above, for purposes of restricted stock unit awards and performance stock units granted under the LTIP in countries where settlement in ADSs is not permissible due to legal, regulatory and/or administrative reasons, such grants are structured such that settlement is to be made in cash and accounted for as Cash-Settled LTIP Awards.

The following table summarizes the award activity related to the Cash-Settled LTIP Awards (the number of awards)(1 award represents 1 ADS):

	For the Year Ended March 31
	2021
As of the beginning of the year	—
Granted	286,316
Forfeited/expired before vesting	(29,478)
Settled	(59,690)
Transfer from Equity-Settled LTIP	65,846
As of the end of the year	262,994

There are no exercisable balances as of March 31, 2021.

29. Subsidiaries and Associates

The number of consolidated subsidiaries decreased by 89 in the year ended March 31, 2021, primarily due to mergers and liquidations to organize capital in subsidiaries acquired as part of integration with Shire. The number of associates accounted for using the equity method decreased by 1 due to a divestiture.

The following is a listing of the Company's consolidated subsidiaries (including partnerships) as of March 31, 2021:

Company name	Country	Voting share capital Hd
Takeda Austria GmbH	Austria	100.0%
Baxter AG	Austria	100.0%
Baxatla Innovations GmbH	Austria	100.0%
Takeda Distribuidora Ltda.	Brazil	100.0%
Takeda Canada Inc.	Canada	100.0%
Takeda (China) Holdings Co., Ltd.	China	100.0%
Takeda Pharmaceutical (China) Company Limited	China	100.0%
Takeda (China) International Trading	China	100.0%
Takeda Pharma A/S	Denmark	100.0%
Takeda France S.A.S.	France	100.0%
Takeda GmbH	Germany	100.0%
Takeda 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%
Nihon Pharmaceutical Co., Ltd.	Japan	87.3%
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 Farmaceutica Espana S.A.	Spain	100.0%
Takeda Pharmaceuticals International AG	Switzerland	100.0%
Baxalta GmbH	Switzerland	100.0%
Baxalta Manufacturing, S.a.r.l.	Switzerland	100.0%
Takeda UK Limited	United Kingdom ("U.K.")	100.0%
Takeda Development Centre Europe Ltd.	U.K.	100.0%
Shire Pharmaceuticals Limited	U.K.	100.0%
Takeda Pharmaceuticals U.S.A., Inc.	U.S.	100.0%
Millennium Pharmaceuticals, Inc.	U.S.	100.0%
ARIAD Pharmaceuticals, Inc.	U.S.	100.0%
Takeda California, Inc.	U.S.	100.0%
Takeda Vaccines, Inc.	U.S.	100.0%
Takeda Development Center Americas, Inc.	U.S.	100.0%
Baxalta Incorporated	U.S.	100.0%
Dyax Corp.	U.S.	100.0%
Takeda Ventures, Inc.	U.S.	100.0%
Baxalta US Inc.	U.S.	100.0%

200 immaterial subsidiaries

The following is a listing of the Company's associates accounted for using the equity method as of March 31, 2021:

Company name	Country	Voting share capital Hd
Amato Pharmaceutical Products, Ltd.	Japan	30.0%
Teva Takeda Pharma Ltd.	Japan	49.0%
19 immaterial associates		

30. Related Party Transactions

Transactions with Associates

Takeda has one major associate, 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, 2020 and 2021 were 5,869 million JPY and 4,970 million JPY, respectively. Balances of receivables and payables are as follows:

	JPY (millions) As of March 31			
	2020		2021	
Trade receivables	¥	1,456	¥	1,336
Other receivables		2,612		1,841
Other payables		23,733		21,339

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. The compensation for key management personnel is as follows:

	JPY (millions) For the Year Ended March 31					
	2019		2020		2021	
Basic compensation and bonuses	¥	2,226	¥	2,441		1,664
Share-based compensation (expensed amount)		1,305		2,143		2,483
Other		73		45		42
Total	¥	3,604	¥	4,629		4,189

31. Business Combinations

Acquisitions during the Year ended March 31, 2021

There was no material business combination during the year ended March 31, 2021.

Acquisitions during the Year ended March 31, 2020

There was no material business combination during the year ended March 31, 2020.

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 USD 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 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.

The total consideration transferred was comprised of the following:

	JPY (millions)
	Amount
Cash	¥ 3,029,431
Equity of the Company (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.

As of March 31, 2019, the fair value of assets acquired and liabilities assumed was provisional. During the year ended March 31, 2020, Takeda completed the purchase price allocation and retrospectively adjusted the provisional amounts recognized at the acquisition date to reflect new information obtained about facts and circumstances that existed as of the acquisition date. The adjustments principally relate to certain intangible assets which consist of marketed products for which the future sales forecasts are used as primary assumptions in estimating their respective fair values.

The following represents the purchase price allocation of Shire as of the acquisition date.

	JPY (millions)
	Amount
Cash and cash equivalents	¥ 227,223
Trade and other receivables	326,154
Inventories	751,832
Property, plant and equipment	699,631
Intangible assets	3,769,076
Assets held for sale	474,596
Other assets	96,331
Trade and other payables	(61,382)
Provisions	(336,573)
Bonds and loans	(1,603,199)
Deferred tax liabilities	(657,487)
Liabilities held for sale	(211,663)
Other liabilities	(389,610)
Basis adjustments	(37,107)
Goodwill	3,165,513
Net assets acquired	¥ <u>6,213,335</u>

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.

Provisions include 29,570 million JPY associated with amounts payable related to legal proceedings. 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 48,599 million JPY.

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 100,002 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	
Revenue	¥	3,412,468
Net profit		53,900

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 would 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 the purchase price allocation of TiGenix as of the acquisition date.

	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.

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.

32. Commitments and Contingent Liabilities

Purchase commitments

The amount of contractual commitments for the acquisition of property, plant and equipment was 18,922 million JPY as of March 31, 2021.

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 1,259,011 million JPY as of March 31, 2021. These commitments include development, regulatory approval and launch milestone payments in relation to R&D programs under development. The related commercial milestone payments were not included in the commitments given the payments were not deemed reasonably likely to occur. As Takeda will strategically focus on R&D in future years, the scope of milestone payments as of March 31, 2021 was reassessed to include regulatory approval and launch milestones and to remove commercial milestones.

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. In late-November / early-December 2020, a hearing took place before the Irish Tax Appeals Commission and Takeda anticipates receiving a ruling within twelve months after the hearing.

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. The factors Takeda considers in developing a provision include the merits and jurisdiction of the litigation, the nature and the number of other similar current and past litigation, 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. As of March 31, 2020 and 2021, Takeda's aggregate provisions for legal and other disputes were 49,711 million JPY and 73,395 million JPY, respectively. 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 statements. Matters that were previously disclosed may no longer be reported because, as a result of rulings in the case, settlements, changes in our business or other developments, in our judgment, they are no longer material to our financial condition or operating results.

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

Product Liability Claims

First initiated in 2011, 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 U.S. for a period of time, also is named as a defendant in many of these lawsuits. Under the parties' co-promotion agreement, Takeda 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 entered into a settlement agreement with the lead plaintiffs' lawyers that resolved more than 95% 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. As part of the settlement, Takeda 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. Although Takeda subsequently received additional claims from plaintiffs not resolved by the settlement, nearly all of those claims have now been resolved. These lawsuits are no longer material to Takeda.

Economic Loss Cases

Takeda has been named in several ACTOS-related lawsuits brought by plaintiffs that do not assert any claims for personal injuries. Instead plaintiffs claim they suffered an economic loss by paying for ACTOS prescriptions that allegedly would not have been written had Takeda provided additional information about the alleged risks of bladder cancer associated with ACTOS. A putative class of third party payors and consumers brought suit against Takeda in the U.S. District Court for the Central District of California. Discovery is ongoing in that case. A case brought by a separate group of third party payors asserting similar claims was filed in the U.S. District Court for the Southern District of New York in June 2019. Takeda's motion to dismiss is pending in that case.

The States of Mississippi and Louisiana also filed lawsuits against Takeda and Lilly alleging that defendants did not warn about bladder cancer and other risks of ACTOS. The lawsuits sought 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. Takeda and Lilly entered into settlement agreements that resolved the lawsuits brought by the State of Mississippi and the State of Louisiana, in November 2018 and September 2019, respectively.

Proton Pump Inhibitor ("PPI") Product Liability Claims

As of March 31, 2021, more than 6,600 product liability lawsuits related to the use of PREVACID and DEXILANT have been filed against Takeda in U.S. federal and state courts. Most of these cases are pending in U.S. federal court and 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 or, in some cases, gastric cancer as a result of taking PREVACID and/or DEXILANT, and that Takeda failed to adequately warn them of these potential risks. 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.

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.

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. Takeda filed patent infringement lawsuits against the ANDA filers in federal court in Delaware. A first Markman hearing took place on May 29, 2019 and a claim construction ruling was issued on July 16, 2019. A second Markman hearing took place on December 18, 2019. A trial took place from January 15 to January 28, 2021.

ADYNOVATE

On December 5, 2016, Bayer Healthcare LLC ("Bayer") filed a lawsuit in the U.S. District Court for the District of Delaware against Baxalta Incorporated and Baxalta US Inc. (collectively "Baxalta"), which are now subsidiaries of Takeda, 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 has filed an appeal with the Court of Appeals of the Federal Circuit (CAFC) in September 2019. The CAFC upheld the District Court's decision on March 1, 2021. The Appeal Mandate was issued on April 7, 2021. On May 14, 2021, Takeda settled this litigation and related pending litigations. The settlement allows both Baxalta and Bayer to continue selling their respective products. Takeda also made a payment in settlement of these cases but the settlement had no material impact on Takeda's consolidated statements of profit or loss as Takeda had established a provision against this case as of March 31, 2021.

NINLARO

Takeda received a paragraph IV notice letter from Sun Pharmaceutical Industries Limited ("Sun") on January 17, 2020. Sun alleged that U.S. Patent numbers 7,442,830, 8,859,504, and 9,175,017 are invalid, unenforceable, and/or will not be infringed. Takeda filed a complaint against Sun in the U.S. District Court for the District of Delaware on February 27, 2020. On June 18, 2021, Takeda entered into a settlement agreement with Sun. The impact of the settlement was not material to Takeda's consolidated statements of profit or loss.

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

Antitrust Case

In December 2013, the first of two antitrust class action lawsuits was filed against Takeda in the U.S. District Court for the Southern District of New York by a putative class of patients who were prescribed ACTOS. The second class action was filed against Takeda in the same court in April 2015 by a putative class of wholesalers that purchased ACTOS from Takeda. In both actions, plaintiffs allege, inter alia, that Takeda improperly characterized certain patents for ACTOS in the FDA Orange Book, which they claim imposed requirements on generic companies that filed Abbreviated New Drug Applications and, in turn, resulted in delayed market entry for generic forms of ACTOS. In October 2019, the District Court denied Takeda's motion to dismiss. Takeda subsequently sought an interlocutory appeal of the District Court's decision which is still pending.

Investigation of Patient Assistance Programs

In November 2016, the U.S. Department of Justice ("DOJ") (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. Takeda is cooperating in the investigation.

In June 2019, the DOJ (through the U.S. Attorney's Office in Boston) 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. Takeda is cooperating with the investigation.

Department of Justice Civil Investigative Demands

On February 19, 2020, Takeda received a Civil Investigative Demand ("CID") from the DOJ (through its office in Washington, DC). The CID seeks information as part of an investigation of possible off-label promotion and violations of the Anti-kickback Statute in connection with the promotion and sale of TRINTELLIX. Takeda is cooperating with the DOJ's investigation.

On February 28, 2020, Takeda received a CID from the DOJ (through its office in Washington, DC). The CID seeks information as part of an investigation of possible kickbacks to a Florida allergy center in connection with the promotion and sale of Takeda's subcutaneous IG products, CUVITRU, HYQVIA and GAMMAGARD. Takeda is cooperating with the DOJ's investigation.

33. Subsequent Events

On April 1, 2021, Takeda provided a notice of prepayment to the lenders of the JBIC Loan in respect of 2,000 million USD of the outstanding loan amount of 3,700 million USD that has an original maturity date of December 11, 2025, and prepaid it on June 11, 2021.

On April 16, 2021, Takeda provided a notice of redemption to the holders of the remaining 200 million USD of unsecured U.S. dollar-denominated senior notes issued in July 2017 in advance of their original maturity date of January 18, 2022, and redeemed it on May 17, 2021.

The impact from the accelerated debt prepayments on the consolidated statements of profit or loss was not material.