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# Quarterly Securities Report

(The third quarter of 145th Business Term)
for The Nine-month Period and Three-month
Quarter Ended December 31, 2021

TAKEDA PHARMACEUTICAL COMPANY LIMITED
AND ITS SUBSIDIARIES

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| [Company Name] | Takeda Pharmaceutical Company Limited |
| [Title and Name of Representative] | Christophe Weber, Representative Director, President & Chief Executive Officer |
| [Address of Head Office] | 1-1, Doshomachi 4-chome, Chuo-ku, Osaka<br>(The above address is the registered head office location and the ordinary business operations are conducted at the "Nearest Place of Contact") |
| [Telephone Number] | Not applicable |
| [Name of Contact Person] | Not applicable |
| [Nearest Place of Contact] | 1-1, Nihonbashi-Honcho 2-chome, Chuo-ku, Tokyo<br>(Global Headquarters) |
| [Telephone Number] | +81-3-3278-2111 (Main telephone number) |
| [Name of Contact Person] | Norimasa Takeda, Chief Accounting Officer & Corporate Controller, Global Finance |
| [Place for public inspection] | Takeda Pharmaceutical Company Limited (Global Headquarters)<br>(1-1, Nihonbashi Honcho 2-chome, Chuo-ku, Tokyo)<br>Tokyo Stock Exchange, Inc.<br>(2-1, Nihonbashi Kabutocho, Chuo-ku, Tokyo)<br>Nagoya Stock Exchange, Inc.<br>(8-20, Sakae 3-chome, Naka-ku, Nagoya)<br>Fukuoka Stock Exchange<br>(14-2, Tenjin 2-chome, Chuo-ku, Fukuoka)<br>Sapporo Stock Exchange<br>(14-1, Minamiichijonishi 5-chome, Chuo-ku, Sapporo) |

# A. Company Information

## I. Overview of Takeda

### 1. Key Consolidated Financial Data

| | JPY (millions), unless otherwise indicated | | |
|---|---|---|---|
| Term | Nine-month period ended December 31, 2020 | Nine-month period ended December 31, 2021 | For the year ended March 31, 2021 |
| Revenue | 2,427,538 | 2,695,717 | 3,197,812 |
| <Three-month period ended December 31> | 836,753 | 901,294 | |
| Profit before tax | 235,357 | 356,618 | 366,235 |
| Net profit for the period | 179,027 | 241,541 | 376,171 |
| Net profit attributable to owners of the Company | 178,907 | 241,417 | 376,005 |
| <Three-month period ended December 31> | 92,359 | 57,770 | |
| Total comprehensive income for the period | 169,450 | 459,044 | 697,416 |
| Total equity | 4,639,428 | 5,331,822 | 5,177,177 |
| Total assets | 12,286,137 | 12,698,519 | 12,912,293 |
| Basic earnings per share (JPY) | 114.57 | 154.09 | 240.72 |
| <Three-month period ended December 31> | 59.08 | 36.91 | |
| Diluted earnings per share (JPY) | 113.72 | 153.03 | 238.96 |
| Ratio of equity attributable to owners of the Company to total assets (%) | 37.7 | 42.0 | 40.1 |
| Net cash from (used in) operating activities | 609,971 | 747,521 | 1,010,931 |
| Net cash from (used in) investing activities | 100,199 | (172,487) | 393,530 |
| Net cash from (used in) financing activities | (718,282) | (826,465) | (1,088,354) |
| Cash and cash equivalents at the end of the period | 617,635 | 724,341 | 966,222 |

(Note 1) All amounts shown are rounded to the nearest million JPY.
(Note 2) The key consolidated financial data for the nine-month period ended December 31, 2020 and 2021 are based on the condensed interim consolidated financial statements prepared in accordance with IAS 34.

## 2. Business Overview

There has been no significant change in our business for the nine-month period ended December 31, 2021.

Changes in number of our group companies were as follows:

During the three-month period ended June 30, 2021, Takeda added 1 subsidiary while deconsolidated 9 entities mainly due to the mergers and liquidations of subsidiaries acquired in the acquisition of Shire plc. In addition, Takeda added 1 associate accounted for using the equity method and excluded 1 entity from associates accounted for using the equity method.

During the three-month period ended September 30, 2021, Takeda deconsolidated 14 entities mainly due to the mergers and liquidations of subsidiaries acquired in the acquisition of Shire plc. In addition, Takeda added 1 associate accounted for using the equity method.

During the three-month period ended December 31, 2021, Takeda added 4 subsidiaries in association with the acquisition of the associate accounted for using the equity method and deconsolidated 3 entities due to the mergers and liquidation of subsidiaries. In addition, Takeda excluded 2 entities from associate accounted for using the equity method.

As a result, as of December 31, 2021, Takeda consisted of 239 entities comprised of 218 consolidated subsidiaries (including partnerships), 20 associates accounted for using the equity method, and Takeda Pharmaceutical Company Limited.

## II. Operating and Financial Review

### 1. Risk Factors

For the nine-month period ended December 31, 2021, there were no unusual changes in our business performance, financial position, and cash flows, as well as no significant changes in the risk factors compared to what we reported in our Annual Securities Report for the year ended March 31, 2021 which was filed in Japan.

For the impact of the spread of COVID-19 and Takeda's initiatives in response, please refer to "2. Analysis on Business Performance, Financial Position and Cash Flows (3) Management Policy, Management Environment and Management Issues."

### 2. Analysis on Business Performance, Financial Position and Cash Flows

**(1) Consolidated Financial Results (April 1 to December 31, 2021):**

| | | | Billion JPY or percentage | |
|---|---|---|---|---|
| | FY2020 Q3YTD | FY2021 Q3YTD | Change versus the same period of the previous fiscal year | |
| Revenue | 2,427.5 | 2,695.7 | 268.2 | 11.0 % |
| Cost of sales | (740.9) | (798.5) | (57.6) | 7.8 % |
| Selling, general and administrative expenses | (641.3) | (662.9) | (21.7) | 3.4 % |
| Research and development expenses | (342.5) | (382.5) | (39.9) | 11.7 % |
| Amortization and impairment losses on intangible assets associated with products | (307.6) | (323.6) | (16.1) | 5.2 % |
| Other operating income | 118.5 | 34.3 | (84.3) | (71.1)% |
| Other operating expenses | (155.1) | (100.0) | 55.1 | (35.5)% |
| Operating profit | 358.7 | 462.5 | 103.7 | 28.9 % |
| Finance income and (expenses), net | (115.4) | (100.6) | 14.8 | (12.8)% |
| Share of loss of investments accounted for using the equity method | (8.0) | (5.3) | 2.8 | (34.4)% |
| Profit before tax | 235.4 | 356.6 | 121.3 | 51.5 % |
| Income tax expenses | (56.3) | (115.1) | (58.7) | 104.3 % |
| Net profit for the period | 179.0 | 241.5 | 62.5 | 34.9 % |

***Revenue.*** Revenue for the nine-month period ended December 31, 2021 was 2,695.7 billion JPY, an increase of 268.2 billion JPY, or 11.0%, compared to the same period of the previous fiscal year. Excluding the impact from fluctuations in foreign exchange rates, which was calculated by translating revenue of the nine-month period ended December 31, 2021 using corresponding exchange rates in the same period of the previous fiscal year, the increase in revenue was 6.1%. In April 2021, Takeda completed the sale of a portfolio of diabetes products in Japan to Teijin Pharma Limited for 133.0 billion JPY, which was recorded as revenue and accounted for 5.5 percentage points ("pp") of the increase in revenue. Excluding this selling price from revenue for the nine-month period ended December 31, 2021, the increase was 5.6%.

Each of our core therapeutic areas (i.e. Gastroenterology ("GI"), Rare Diseases, Plasma-Derived Therapies ("PDT") Immunology, Oncology, and Neuroscience) contributed to positive revenue growth; however, Rare Diseases would have declined if not for the positive impact of the depreciation of the yen. Intensified competition impacted some products in this area, especially treatments for Rare Hematology. Overall, throughout the nine-month period ended December 31, 2021, the global spread of COVID-19 did not have a material effect on our revenue.

During the third quarter of the fiscal year ending March 31, 2022, LIVTENCITY (for post-transplant cytomegalovirus ("CMV") infection/disease) was launched in the U.S. in December 2021, following the launch of EXKIVITY (for non-small cell lung cancer) in the U.S. in September 2021.

Revenue outside of our core therapeutic areas increased by 36.7 billion JPY, or 8.2%, compared to the same period of the previous fiscal year to 482.2 billion JPY, largely due to the 133.0 billion JPY selling price of the diabetes portfolio in Japan, offsetting the impact from divestitures. Revenue from distributing Moderna's COVID-19 vaccine, SPIKEVAX Intramuscular Injection, in Japan also contributed to the growth.

Year-on-year change in revenue for this nine-month period in each of our main therapeutic areas was primarily attributable to the following products:

- *GI.* In Gastroenterology, revenue was 665.7 billion JPY, a year-on-year increase of 76.9 billion JPY, or 13.1%. Growth was driven by Takeda's top-selling product ENTYVIO (for ulcerative colitis ("UC") and Crohn's disease ("CD")), with sales of 395.4 billion JPY, a year-on-year increase of 76.1 billion JPY, or 23.8%. Sales in the U.S. increased by 46.7 billion JPY, or 21.3%, to 266.0 billion JPY driven by increase in the first line biologic inflammatory bowel disease ("IBD") population both in UC and CD. Sales in Europe and Canada increased by 21.7 billion JPY, or 26.9%, to 102.2 billion JPY. In the Growth and Emerging Markets, the increase in sales was primarily driven by Brazil and China. Sales of TAKECAB (for acid-related diseases) were 78.4 billion JPY, an increase of 14.2 billion JPY, or 22.2%, versus the same period of the previous fiscal year. This increase was mainly 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 GATTEX/REVESTIVE (for short bowel syndrome) were 56.6 billion JPY, an increase of 6.5 billion JPY, or 12.9%, primarily due to increased market penetration and new country launches including Japan. Sales of AMITIZA (for chronic constipation) decreased by 13.0 billion JPY, or 68.8%, to 5.9 billion JPY, due to generic entrants in the U.S. in January 2021.

- *Rare Diseases*. In Rare Diseases, revenue was 462.9 billion JPY, a year-on-year increase of 16.2 billion JPY, or 3.6%.

  Revenue in Rare Metabolic increased by 11.6 billion JPY, or 9.5%, compared to the same period of the previous fiscal year to 133.4 billion JPY. Sales of enzyme replacement therapies ELAPRASE (for Hunter syndrome), VPRIV (for Gaucher disease) and REPLAGAL (for Fabry disease) increased primarily in Europe and Growth and Emerging Markets.

  Revenue in Rare Hematology decreased by 7.0 billion JPY, or 3.2%, to 211.6 billion JPY. Sales of ADVATE decreased by 7.8 billion JPY, or 8.0%, to 89.3 billion JPY. Sales of ADYNOVATE/ADYNOVI increased by 2.1 billion JPY, or 4.8%, to 45.9 billion JPY, partially helped by the positive impact of the depreciation of the yen. Both products were impacted by the competitive landscape in the hemophilia A non-inhibitors market in the U.S. FEIBA sales decreased by 5.3 billion JPY, or 15.4%, to 29.0 billion JPY, negatively impacted by the difference in timing of government tenders in Growth and Emerging Markets.

  Revenue in Hereditary Angioedema ("HAE") was 117.7 billion JPY, a year-on-year increase of 11.4 billion JPY, or 10.7%. Sales of TAKHZYRO were 78.4 billion JPY, an increase of 12.5 billion JPY, or 19.0%, versus the same period of the previous fiscal year primarily due to expansion of the prophylactic market, continued geographic expansion and strong patient uptake. Sales of CINRYZE decreased by 2.6 billion JPY, or 14.8%, to 14.7 billion JPY, primarily due to conversion to TAKHZYRO and a shift to newer agents marketed by competitors.

- *PDT Immunology.* In Plasma-Derived Therapies ("PDT") Immunology, revenue increased by 50.2 billion JPY, or 16.0%, compared to the same period of the previous fiscal year to 363.2 billion JPY. Aggregate sales of immunoglobulin products were 278.3 billion JPY, an increase of 30.3 billion JPY, or 12.2%, compared to the same period of the previous fiscal year. In particular, sales of GAMMAGARD LIQUID (for the treatment of primary immunodeficiency ("PID") and multifocal motor neuropathy ("MMN")) increased due to higher demand versus the same period of the previous fiscal year. In addition, CUVITRU and HYQVIA, which are SCIG (subcutaneous immunoglobulin) therapies, marked double digit growth. Aggregate sales of albumin products including HUMAN ALBUMIN and FLEXBUMIN (primarily used for hypovolemia and hypoalbuminemia) were 61.5 billion JPY, an increase of 17.9 billion JPY, or 41.0%, versus the same period of the previous fiscal year driven by higher China sales following the resolution of the supply interruption which impacted HUMAN ALBUMIN for release in China in the second half of the previous fiscal year.

- *Oncology.* In Oncology, revenue was 359.1 billion JPY, a year-on-year increase of 40.6 billion JPY, or 12.8%. Sales of VELCADE (for multiple myeloma) increased by 8.6 billion JPY, or 11.3% versus the same period of the previous fiscal year to 84.5 billion JPY. U.S. sales increased by 9.6 billion JPY, or 13.3%, versus the same period of the previous fiscal year. This reflects a rebound in demand after lower sales in the first quarter of the previous fiscal year, when prescribers favored orally administered products over infusions or injections early in the COVID-19 pandemic. In addition, increased use of VELCADE as part of initial treatment for new patients contributed to the growth this year in the U.S. Royalty income outside the U.S. decreased due to continued generic erosion. Sales of NINLARO (for multiple myeloma) were 70.7 billion JPY, an increase of 2.9 billion JPY, or 4.2%, versus the same period of the previous fiscal year. In the U.S., NINLARO's profile as an effective oral treatment led to a temporary increase in demand early in the COVID-19 pandemic in 2020 because its oral administration facilitated treatment in the at-home setting. This benefit has been less impactful in the U.S. this year; however, there have been strong demand increases in other countries, particularly in China. Sales of LEUPLIN/ENANTONE (generic name: leuprorelin) (for endometriosis, uterine fibroids, premenopausal breast cancer, prostatic cancer, etc.), an off-patented product, increased by 7.0 billion JPY, or 9.2%, versus the same period of the previous fiscal year to 82.2 billion JPY mainly driven by an increased supply in the U.S. which was partially offset by a decrease in Japan due to generic erosion and competition. Sales of ADCETRIS (for malignant lymphomas)

increased by 7.4 billion JPY, or 16.7% versus the same period of the previous fiscal year to 51.8 billion JPY, led by strong growth in sales in Growth and Emerging Markets, particularly in China where it was approved in May 2020. Sales of ALUNBRIG (for non-small cell lung cancer) were 10.1 billion JPY, an increase of 3.6 billion JPY, or 56.2% due to new launches and market penetration around the world.

- *Neuroscience.* In Neuroscience, revenue was 362.6 billion JPY, a year-on-year increase of 47.5 billion JPY, or 15.1%. Sales of VYVANSE/ELVANSE (for attention deficit hyperactivity disorder ("ADHD")) were 245.0 billion JPY, an increase of 42.6 billion JPY, or 21.0%, versus the same period of the previous fiscal year. VYVANSE/ELVANSE has been negatively affected by COVID-19 during the course of the pandemic, most notably during periods when stay-at-home restrictions have been in place reducing patient visits, subsequent diagnoses and creating temporary discontinuation of medication. The trend has been fluctuating throughout 2020 and into 2021; however, there has been a positive impact from increasing prescriptions versus the same period of the previous fiscal year. Sales of TRINTELLIX (for major depressive disorder ("MDD")) were 63.0 billion JPY, an increase of 10.4 billion JPY, or 19.6%, versus the same period of the previous fiscal year, primarily due to increasing prescriptions in the U.S. and in Japan. The increase of these products was partially offset by the decrease of other neuroscience products such as REMINYL (for Alzheimer's disease), attributable to the continued impact of competition from generic products.

Revenue by Geographic Region:

Billion JPY; percentages are portion of total revenue

| Revenue: | FY2020 Q3YTD | | FY2021 Q3YTD | |
|---|---|---|---|---|
| Japan[*1] | 435.1 | 17.9 % | 530.2 | 19.7 % |
| United States | 1,189.0 | 49.0 % | 1,297.0 | 48.1 % |
| Europe and Canada | 500.0 | 20.6 % | 541.0 | 20.1 % |
| Asia (excluding Japan) | 119.2 | 4.9 % | 139.8 | 5.2 % |
| Latin America | 95.4 | 3.9 % | 93.5 | 3.5 % |
| Russia/CIS | 38.7 | 1.6 % | 43.6 | 1.6 % |
| Other[*2] | 50.2 | 2.1 % | 50.6 | 1.9 % |
| Total | 2,427.5 | 100.0 % | 2,695.7 | 100.0 % |

*1 The 133.0 billion JPY selling price of the sale of diabetes portfolio in Japan is included in the nine-month period ended December 31, 2021.
*2 Other includes the Middle East, Oceania and Africa.

***Cost of Sales.*** Cost of Sales increased by 57.6 billion JPY, or 7.8%, to 798.5 billion JPY. The increase was primarily due to the depreciation of the yen and a sales increase of products with higher cost of sales ratio as compared to the same period of the previous fiscal year. The increase was partially offset by a 42.5 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 acquisition of Shire plc. The Cost of Sales Ratio decreased by 0.9 pp compared to the same period of the previous fiscal year to 29.6%. The main reason for the decrease in the Cost of Sales Ratio was the effect of the sale of a portfolio of diabetes products in Japan with the selling price of 133.0 billion JPY being recorded in revenue.

***Selling, General and Administrative (SG&A) expenses.*** SG&A expenses increased by 21.7 billion JPY, or 3.4%, to 662.9 billion JPY compared to the same period of the previous fiscal year, mainly due to the impact from the depreciation of the yen in the current period.

***Research and Development (R&D) expenses.*** R&D expenses increased by 39.9 billion JPY, or 11.7%, to 382.5 billion JPY compared to the same period of the previous fiscal year, mainly due to further investment in prioritized new molecular entities as well as the impact from the depreciation of the yen in the current period.

***Amortization and Impairment Losses on Intangible Assets Associated with Products.*** Amortization and Impairment Losses on Intangible Assets Associated with Products increased by 16.1 billion JPY, or 5.2%, to 323.6 billion JPY compared to the same period of the previous fiscal year mainly due to impairment charges related to certain in-process R&D assets recorded in the current period.

***Other Operating Income.*** Other Operating Income was 34.3 billion JPY, a decrease of 84.3 billion JPY, or 71.1%, compared to the same period of the previous fiscal year, mainly driven by a 60.2 billion JPY revaluation gain recorded in the same period of the previous fiscal year 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 following the

European Commission's decision in May 2020 to release Takeda's obligation to divest SHP647. The decrease was also driven by the effect of a 37.2 billion JPY divestiture gain on the sale of non-core assets in Asia Pacific, Europe, and Canada recorded in the same period of the previous fiscal year.

***Other Operating Expenses.*** Other Operating Expenses were 100.0 billion JPY, a decrease of 55.1 billion JPY, or 35.5%, compared to the same period of the previous fiscal year. This is mainly attributable to a 27.3 billion JPY decrease in restructuring expenses mainly attributable to lower Shire integration costs. There was also a 18.7 billion JPY loss recognized in the same period of the previous year from changes in the fair value of financial assets associated with contingent consideration arrangements from the divestment of XIIDRA.

***Operating Profit***. As a result of the above factors, Operating Profit increased by 103.7 billion JPY, or 28.9% compared to the same period of the previous fiscal year to 462.5 billion JPY.

***Net Finance Expenses.*** Net Finance Expenses were 100.6 billion JPY in the current period, a decrease of 14.8 billion JPY, or 12.8%, compared to the same period of the previous fiscal year. The decrease is mainly due to a decrease in interest expense primarily driven by the reduction in outstanding balances of bonds and loans and a gain on prior equity method investments related to the acquisition of Maverick Therapeutics, Inc. in April 2021.

***Share of Loss of Investments Accounted for Using the Equity Method.*** Share of Loss of Investments Accounted for Using the Equity Method was 5.3 billion JPY, a decrease of 2.8 billion JPY, or 34.4%, compared to the same period of the previous fiscal year, mainly due to Takeda's share of impairment loss recognized by Teva Takeda Pharma Ltd. in the same period of the previous fiscal year resulting from the reassessment of the recoverable amount of relevant assets triggered by the decision to divest a part of its generics business and a manufacturing plant.

***Income Tax Expenses.*** Income Tax Expenses were 115.1 billion JPY, an increase of 58.7 billion JPY, or 104.3%, compared to the same period of the previous year. This increase was primarily due to a tax charge of 64.6 billion JPY for tax and interest, net of 0.5 billion JPY of associated tax benefit, arising from tax assessment involving Irish taxation of the break fee Shire received from AbbVie in connection with the terminated offer to acquire Shire made by AbbVie in 2014 as well as higher pretax earnings in the current period. These increases were partially offset by an increase in tax credits and a decrease in unitary tax in overseas subsidiaries in the current period versus the same period of the previous year.

***Net Profit for the Period.*** Net Profit for the Period increased by 62.5 billion JPY, or 34.9%, compared to the same period of the previous fiscal year to 241.5 billion JPY.

## Underlying Results (April 1 to December 31, 2021)

### *Definition of Core and Underlying Growth*

Takeda uses the concept of Underlying Growth for internal planning and performance evaluation purposes.

Underlying Growth compares two periods (fiscal quarters or years) of financial results under a common basis and is used by management to assess the business. These financial results are calculated on a constant currency basis using a full year plan rate and exclude the impacts of divestitures and other amounts that are unusual, non-recurring items or unrelated to our ongoing operations. Although these are not measures defined by IFRS, Takeda believes Underlying Growth is useful to investors as it provides a consistent measure of our performance.

Takeda uses "Underlying Revenue Growth", "Underlying Core Operating Profit Growth", and "Underlying Core EPS Growth" as key financial metrics.

Underlying Revenue represents revenue on a constant currency basis and excluding non-recurring items and the impact of divestitures that occurred during the reported periods presented.

Underlying Core Operating Profit represents Core Operating Profit (as defined below) on a constant currency basis and further adjusted to exclude the impacts of divestitures that occurred during the reporting periods presented.

Underlying Core EPS represents net profit based on a constant currency basis, adjusted to exclude the impact of divestitures, items excluded in the calculation of Core EPS (as defined below), divided by the outstanding shares (excluding treasury shares) as of the end of the comparative period.

Core Revenue represents revenue adjusted to exclude significant items unrelated to Takeda's core operations.

Core Operating Profit represents net profit adjusted to exclude income tax expenses, the share of profit or loss of investments accounted for using the equity method, finance expenses and income, other operating expenses and income, amortization and impairment losses on acquired intangible assets and other items unrelated to Takeda’s core operations, such as non-recurring items, purchase accounting effects and transaction related costs.

Core EPS represents net profit adjusted to exclude the impact of items excluded in the calculation of Core Operating Profit, and other non-operating items (e.g. amongst other items, fair value adjustments and the imputed financial charge related to contingent consideration) that are unusual, non-recurring in nature or unrelated to Takeda’s ongoing operations and the tax effect of each of the adjustments, divided by the average outstanding shares (excluding treasury shares) of the reporting periods presented.

### *Underlying Results*

| **FY2021 Q3YTD** | |
|---|---|
| Underlying Revenue Growth | +7.1% |
| Underlying Core Operating Profit Growth | +5.4% |
| Underlying Core Operating Profit Margin | 29.4% |
| Underlying Core EPS Growth | +9.9% |

***Underlying Revenue Growth*** was 7.1% compared to the same nine-month period of the previous fiscal year. Underlying revenue attributable to Takeda’s 14 global brands* grew by 12.0%, which constitute approximately 42% of the total Underlying revenue, led by ENTYVIO, TAKHZYRO, HUMAN ALBUMIN/FLEXBUMIN, GAMMAGARD LIQUID/ KIOVIG and CUVITRU.

* Takeda's 14 global brands
GI: ENTYVIO, GATTEX/REVESTIVE, ALOFISEL
Rare Diseases: NATPARA/NATPAR, ADYNOVATE/ADYNOVI, TAKHZYRO, ELAPRASE, VPRIV
PDT Immunology: GAMMAGARD LIQUID/KIOVIG, HYQVIA, CUVITRU, HUMAN ALUBUMIN/FLEXBUMIN
Oncology: NINLARO, ALUNBRIG

| Underlying Revenue Growth by Therapeutic Area | |
|---|---|
| GI | +7.6% |
| Rare Diseases | -1.0% |
| Rare Metabolic | +5.2% |
| Rare Hematology | -7.6% |
| Hereditary Angioedema | +5.4% |
| PDT Immunology | +10.3% |
| Oncology | +8.2% |
| Neuroscience | +10.0% |
| Other | +10.6% |
| Total | +7.1% |

(Note) Underlying Revenue represents revenue on a constant currency basis and excluding non-recurring items and the impact of divestitures. Please refer to II. Operating and Financial Review, 2. Analysis on Business Performance, Financial Position and Cash Flows, (1) Consolidated Financial Results (April 1 to December 31, 2021), *Revenue.*, for the revenue of each core therapeutic areas and sales of major products before underlying adjustments.

The impact of major non-recurring items and divestitures excluded to calculate Underlying Revenue:

- Revenue of select over-the-counter and non-core products in Asia Pacific is excluded from the same period of the previous fiscal year as the divestiture was completed in November 2020.
- Revenue of select non-core prescription pharmaceutical products predominantly in Europe is excluded from the same period of the previous fiscal year as the divestiture was completed in December 2020.
- Revenue of select over-the-counter and non-core products in Latin America is excluded from the same period of the previous fiscal year as the divestiture was completed in January 2021.
- Net sales from TACHOSIL, a surgical patch, are excluded from the same period of the previous fiscal year as the divestiture was completed in January 2021.
- Revenue of select over-the-counter and non-core products predominantly in Europe is excluded from the same period of the previous fiscal year as the divestiture was completed in March 2021.
- Revenue of the former subsidiary, Takeda Consumer Healthcare Company Limited is excluded from the same period of the previous fiscal year as the divestiture was completed in March 2021.
- Net sales from a portfolio of diabetes products in Japan (NESINA, LIOVEL, INISYNC and ZAFATEK) are excluded from the same period of the previous fiscal year as the divestiture was completed at the beginning of April 2021. In addition, the non-recurring item of the 133.0 billion JPY selling price as the result of the completion of the divestiture is excluded from the current period.
- Revenue of select non-core prescription pharmaceutical products in China is excluded from both the current period and the same period of the previous fiscal year as the divestiture was publicly announced and had been expected to complete within the first half of the current fiscal year. It is now expected to complete in the second half of the current fiscal year.

***Underlying Core Operating Profit Growth*** was 5.4% over the same nine-month period of the previous fiscal year, attributable to Underlying Revenue Growth.

Core Operating Profit for the current period, which excludes items unrelated to Takeda's core operations such as the sale of a portfolio of diabetes products in Japan, was 757.9 billion JPY.

***Underlying Core Operating Profit Margin*** for the current period was 29.4%.

***Underlying Core EPS Growth*** for the current period was 9.9%.

**(2) Consolidated Financial Position**

***Assets.*** Total Assets as of December 31, 2021 were 12,698.5 billion JPY, reflecting a decrease of 213.8 billion JPY compared to the previous fiscal year-end. Cash and cash equivalents decreased by 241.9 billion JPY and Intangible Assets decreased by 117.2 billion JPY mainly due to amortization. These decreases were partially offset by an increase in Goodwill of 134.1 billion JPY mainly due to the effect of foreign currency translation.

Although there was a decline in share price during the three-month period ended December 31, 2021 that eliminated our surplus in market capitalization compared to the carrying value of our one cash-generating unit (CGU), we concluded there was no indication of goodwill impairment as of December 31, 2021.

***Liabilities.*** Total Liabilities as of December 31, 2021 were 7,366.7 billion JPY, reflecting a decrease of 368.4 billion JPY compared to the previous fiscal year-end. Bonds and Loans decreased by 280.5 billion JPY to 4,354.9 billion JPY* primarily as a result of the repayment of loans and the redemption of bonds. In addition, Other Financial Liabilities decreased by 114.7 billion JPY.

* The carrying amount of Bonds was 3,653.7 billion JPY and Loans was 701.2 billion JPY as of December 31, 2021. Breakdown of Bonds and Loans carrying amount is as follows.

Bonds:

| Name of Bond (Face Value if Denominated in Foreign Currency) | Issuance | Maturity | Carrying Amount (Billion JPY) |
|---|---|---|---|
| Unsecured US dollar denominated senior notes (1,520 million USD) | June 2015 | June 2022 ~ June 2045 | 175.1 |
| Unsecured US dollar denominated senior notes (5,500 million USD) | September 2016 | September 2023 ~ September 2026 | 606.6 |
| Unsecured Euro denominated senior notes (3,750 million EUR) | November 2018 | November 2022 ~ November 2030 | 486.3 |
| Unsecured US dollar denominated senior notes (3,250 million USD) | November 2018 | November 2023 ~ November 2028 | 372.3 |
| Hybrid bonds (subordinated bonds) | June 2019 | June 2079 | 498.0 |
| Unsecured US dollar denominated senior notes (7,000 million USD) | July 2020 | March 2030 ~ July 2060 | 800.1 |
| Unsecured Euro denominated senior notes (3,600 million EUR) | July 2020 | July 2027 ~ July 2040 | 466.0 |
| Unsecured JPY denominated senior bonds | October 2021 | October 2031 | 249.3 |
| Total | | | 3,653.7 |

Loans:

| Name of Loan (Face Value if Denominated in Foreign Currency) | Execution | Maturity | Carrying Amount (Billion JPY) |
|---|---|---|---|
| Syndicated loans | April 2016 | April 2023 ~ April 2026 | 200.0 |
| Syndicated loans | April 2017 | April 2027 | 113.5 |
| Syndicated loans (1,500 million USD) | April 2017 | April 2027 | 172.4 |
| Bilateral loans | March 2016 ~ April 2017 | March 2023 ~ March 2026 | 210.0 |
| Other | | | 5.3 |
| Total | | | 701.2 |

On May 17, 2021, Takeda redeemed 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. Following this, on June 11, 2021, Takeda prepaid 2,000 million USD of the Japan Bank for International Cooperation loan ("JBIC Loan") amount of 3,700 million USD (that was entered into on December 3, 2018) in advance of its original maturity date of December 11, 2025. On August 10, 2021, Takeda redeemed 1,500 million EUR of unsecured senior notes issued in November 2018 in advance of their original maturity date of November 21, 2022. On October 14, 2021, Takeda issued 10-year unsecured senior bonds with an aggregate principal amount of 250 billion JPY and a maturity date of October 14, 2031. Following this, on December 13, 2021 Takeda prepaid the remaining 1,700 million USD amount outstanding on the JBIC Loan in advance of its original maturity date of December 11, 2025.

***Equity.*** Total Equity as of December 31, 2021 was 5,331.8 billion JPY, an increase of 154.6 billion JPY compared to the previous fiscal year-end. This was mainly due to an increase of 215.5 billion JPY in Other Components of Equity mainly due to fluctuation in currency translation adjustments reflecting the depreciation of yen. This increase was partially offset by a decrease in Retained Earnings of 43.0 billion JPY and an increase in Treasury Shares of 31.5 billion JPY. The decrease in Retained Earnings resulted primarily from dividend payments of 284.2 billion JPY whereas Net Profit for the Period was recorded.

**Consolidated Cash Flow**

| | Billion JPY | |
|---|---|---|
| | **FY2020 Q3YTD** | **FY2021 Q3YTD** |
| Net cash from (used in) operating activities | 610.0 | 747.5 |
| Net cash from (used in) investing activities | 100.2 | (172.5) |
| Net cash from (used in) financing activities | (718.3) | (826.5) |
| Net increase (decrease) in cash and cash equivalents | (8.1) | (251.4) |
| Cash and cash equivalents at the beginning of the year | 637.6 | 966.2 |
| Effects of exchange rate changes on cash and cash equivalents | (11.8) | 9.5 |
| Net increase (decrease) in cash and cash equivalents resulting from a transfer from (to) assets held for sale | (0.1) | — |
| Cash and cash equivalents at the end of the period | 617.6 | 724.3 |

***Net cash from operating activities*** was 747.5 billion JPY for the current period compared to 610.0 billion JPY for the same period of the previous year. The increase of 137.6 billion JPY was primarily driven by higher net profit for the period adjusted for non-cash items and other adjustments, including the income relating to the release from the obligation to divest the pipeline compound SHP 647 and certain associated rights in the same period of the previous year. In addition, there was a decrease in trade and other receivables mainly due to the trade receivables sales program put in place in the current period. These favorable impacts were partially offset by a decrease in provisions due to payments.

***Net cash used in investing activities*** was 172.5 billion JPY for the current period compared to net cash from investing activities of 100.2 billion JPY for the same period of the previous year. This increase in net cash used of 272.7 billion JPY was mainly due to a decrease of 122.8 billion JPY in proceeds from sales of business, net of cash and cash equivalents divested reflecting the sales of the non-core assets in the same period of the previous year, a decrease of 57.7 billion JPY in proceeds from sales and redemptions of investments, and an increase of 49.7 billion JPY in acquisition of businesses, net of cash and cash equivalents acquired.

***Net cash used in financing activities*** was 826.5 billion JPY for the current period compared to 718.3 billion JPY for the same period of the previous year. The increase of 108.2 billion JPY was mainly due to a decrease in proceeds from issuance of bonds and long-term loans of 930.2 billion JPY as a result of the issuance of U.S. dollar-denominated senior notes of 7,000 million USD and Euro-denominated senior notes of 3,600 million EUR in the same period of the previous year compared to the 250 billion JPY issuance of senior bond in the current period. In addition, purchase of treasury shares increased by 50.4 billion JPY mainly due to the share buybacks in the current period. These were partially offset by a decrease in repayments of bonds and long-term loans of 754.1 billion JPY and the favorable impact from short-term loans and commercial papers of 85.0 billion JPY.

**(3) Management Policy, Management Environment and Management Issues**

There was no significant change in management policy, management environment and management issues for the nine-month period ended December 31, 2021.

Impact of the spread of the novel coronavirus infectious disease (COVID-19) and Takeda's initiatives in response are as follows:

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

Takeda continues to respond to the COVID-19 pandemic 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 for almost two years, and monitor any potential impacts of effects and evolution of COVID-19, including new variants like Omicron, on our business activities.

In monitoring demand for our products, we have seen limited impact 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 seen, nor do we anticipate, any material potential supply distribution issues due to the COVID-19 outbreak. Where appropriate and in accordance with local public health guidance and regulations, our field employees have resumed some face-to-face engagements with customers, with the majority of all interactions still virtual. Clinical trial activities that were temporarily paused during the previous fiscal year have generally been resumed while we continue to monitor the evolution of the pandemic.

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.

Major updates to Takeda's initiatives in response to the spread of COVID-19 in the current period are as below.

- The highly contagious Omicron variant has temporarily slowed the roll out of a new hybrid working model in parts of the business. Moving forward, implementation of this model will vary by job function, and on the local level, given differences in public health guidance and regulations, changes in population and epidemiology over time and standards of practice in the community.
- Takeda has undertaken a number of efforts to help the world respond to COVID-19. This includes bringing COVID-19 vaccines to Japan through two partnerships. 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. In September 2021, Takeda concluded the agreement with the Government of Japan's Ministry of Health, Labour and Welfare (MHLW) to provide 150 million doses of Novavax' COVID-19 vaccine candidate manufactured in Japan by Takeda subject to licensing and approval, starting in early calendar year 2022. In December 2021, Takeda submitted a New Drug Application (NDA) to the MHLW in Japan for TAK-019.

  The second partnership is with Moderna and the MHLW to import and distribute Moderna's mRNA COVID-19 vaccine (SPIKEVAX Intramuscular Injection (former product name: COVID-19 Vaccine Moderna Intramuscular Injection)) in Japan. Since May 2021, Takeda has been distributing the Moderna COVID-19 vaccine in Japan. In October 2021, Takeda and Moderna published an investigation report prompted by the recall of three lots of the Moderna COVID-19 vaccine in Japan based on the observation of foreign particles in unpunctured vials from a single lot. The report concluded that the event does not pose an undue risk to patient safety or adversely affect the benefit/risk profile of the product.

  Takeda will continue distribution of the vaccine in Japan in 2022 via an additional three-way agreement with Moderna and the MHLW. Specifically, the parties reached to an agreement in December 2021, to import and distribute 18 million additional doses of Moderna's COVID-19 vaccine, bringing the total to 93 million doses in 2022.

**(iii) FY2021 Q3YTD financial impact from COVID-19**

Overall, the global spread of COVID-19 did not have a material effect on our financials for the nine-month period ended December 31, 2021. Over the course of the pandemic, there have been adverse effects due to COVID-19 observed in certain therapeutic areas, especially in Neuroscience during periods when stay-at-home restrictions have been in place, reducing patient visits to medical care providers. This was notable especially in the early months of the previous fiscal year. The trend has fluctuated since then, and we have not yet seen a full recovery to pre-COVID-19 levels, however, a certain number of our life-saving medicines have shown resilience and have grown even under such an environment. We have not experienced a material disruption from the rapid spread of COVID-19 due to the Omicron variant.

**(4) Research & Development Activities and Results**

Research and development expenses for the nine-month period ended December 31, 2021 were 382.5 billion JPY.

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.

Takeda's pipeline is positioned to support both near-term and sustained growth of the company. Once first approval is achieved, there is ongoing R&D support for geographical expansion and additional indications, as well as post-marketing commitment and potential additional formulation work. Takeda's R&D team works closely with the commercial functions to maximize the value of marketed products and reflect commercial insights in its R&D strategies and portfolio.

Major progress on R&D events since April 2021 are listed as follows:

**R&D pipeline**

**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 products ALUNBRIG, EXKIVITY, and development programs in targeted lung cancer populations; and (3) pursuing novel immuno-oncology targets and next-generation platforms, as well as exploring innovative cell therapies harnessing the power of the innate immune system.

*NINLARO / Generic name: ixazomib*

- In May 2021, Takeda announced that it received approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) for a partial amendment to the manufacturing and marketing approval of NINLARO to expand the eligible patient population for this medicine to those requiring a maintenance therapy after first-line treatment for multiple myeloma without prior stem cell transplant. The approval is based primarily on the results of the TOURMALINE-MM4 study, a randomized and placebo-controlled double-blind multicenter international Phase III clinical trial. The study achieved its primary endpoint, demonstrating a statistically significant improvement in progression-free survival (PFS) in adult patients with multiple myeloma receiving NINLARO maintenance who had not undergone stem cell transplantation. The safety profile of NINLARO as a maintenance therapy is similar to its established safety profile in the monotherapy setting, and, notably, no new concerns were identified in the TOURMALINE-MM4 study.

*ICLUSIG / Generic name: ponatinib*

- In June 2021, Takeda presented primary analysis data from the Phase II OPTIC (Optimizing Ponatinib Treatment in CML) trial during an oral session at the virtual 57$^{th}$ American Society of Clinical Oncology (ASCO) Annual Meeting, and as an oral session at the virtual 26$^{th}$ European Hematology Association (EHA) Annual Meeting. The OPTIC trial, which evaluated treatment in patients with resistant disease, with and without mutations, met its primary endpoint. The study demonstrated that the optimal benefit-risk profile for ICLUSIG in patients with CP-CML is achieved with a daily starting dose of 45-mg and, upon achieving ≤1% BCR-ABL1$^{IS}$, dose reduction to 15-mg. The results also suggest a clinically manageable safety and arterial occlusive event (AOE) profile for ICLUSIG.

*ALUNBRIG / Generic name: brigatinib*

- In June 2021, Takeda announced that ALUNBRIG can be used for first-line treatment of patients with non-small cell lung cancer (NSCLC) who are ALK fusion gene positive (ALK-positive) as determined by the companion diagnostic ALK fusion protein kit, Ventana OptiView ALK (D5F3) (Ventana) in Japan. Ventana, developed by Roche Diagnostics, which uses as its assay principle the immunohistochemical staining method (IHC method), received an additional indication through a partial change of the drug's manufacturing and marketing approval to include its use to ALUNBRIG. The additional approval of ALUNBRIG for the indication of Ventana, in addition to the Fluorescence *In Situ* Hybridization (FISH) diagnostic, will provide a wider range of ALK-positive NSCLC patients with the opportunity to be treated with ALUNBRIG.

*ADCETRIS / Generic name: brentuximab vedotin*

- In September 2021, Takeda announced that it submitted a Supplemental New Drug Application (sNDA) of ADCETRIS in the first-line treatment of CD30-positive Hodgkin lymphoma in pediatric patients in Japan. This application is based on the results of a global Phase 1/2 trial (C25004 Trial) evaluating the efficacy and safety of ADCETRIS in combination with AVD (doxorubicin, vinblastine and dacarbazine) as a first-line therapy in pediatric patients with previously untreated advanced-stage Hodgkin lymphoma.

*CABOMETYX / Generic name: cabozantinib*

- In August 2021, Takeda and Ono Pharmaceutical (Ono) announced that the companies received an approval from the Japanese Ministry of Health. Labour and Welfare (MHLW) for CABOMETYX and Ono's OPDIVO (nivolumab), a human anti-human PD-1 monoclonal antibody, in combination therapy for the treatment of unresectable or metastatic renal cell carcinoma (RCC), for a partial change in approved items of the manufacturing and marketing approval. This approval is based on results from the global, multi-center, randomized, open-label Phase 3 CheckMate-9ER study, evaluating OPDIVO and CABOMETYX combination therapy versus sunitinib alone in patients with previously untreated advanced or metastatic RCC. In this study, OPDIVO and CABOMETYX combination therapy demonstrated a significant and clinically meaningful improvement in the primary endpoint of progression-free survival (PFS) as assessed by the blind independent central review (BICR), compared to sunitinib alone at the final analysis, as well as the secondary endpoints of overall survival (OS) and objective response rate (ORR) as assessed by the BICR. The safety profiles of OPDIVO and CABOMETYX combination therapy observed in the study were consistent with the previously reported safety profile of each product.

*ZEJULA / Generic name: niraparib*

- In September 2021, Takeda announced that it has received approval from the Japanese Ministry of Health. Labour and Welfare (MHLW) to manufacture and market ZEJULA tablets 100mg (ZEJULA tablets) as an additional formulation for ZEJULA capsules 100mg (ZEJULA capsules), an oral poly (ADP-ribose) polymerase (PARP) inhibitor. The approval was granted based on the results of a human bioequivalence trial (3000-01-004 trial) and an dissolution study that confirmed the equivalence of ZEJULA capsules and ZEJULA tablets. ZEJULA capsules require refrigerated storage, however the newly approved ZEULA tablets can be stored at room temperature.

*EXKIVITY / Generic name: mobocertinib*

- In May 2021, Takeda announced updated data from the Phase 1/2 trial of mobocertinib in patients with epidermal growth factor receptor (EGFR) Exon20 insertion mutation-positive (insertion+) metastatic non-small cell lung cancer (mNSCLC) who received prior platinum-based chemotherapy. The results showed mobocertinib continued to demonstrate clinically meaningful benefit after over a year of follow up and were presented at the virtual 57th American Society of Clinical Oncology (ASCO) Annual Meeting. Results showed a median overall survival (OS) of 24 months with a median follow up of 14 months, and responses were observed across diverse EGFR Exon20 insertion variants. Other key data points such as confirmed objective response rate (ORR), a median duration of response (DoR) and a disease control rate (DCR), remained consistent with previously reported data. The safety profile observed was manageable and consistent with previous findings.

- In July 2021, Takeda announced that Center for Drug Evaluation (CDE) of the National Medical Products Administration of China (NMPA) has accepted the New Drug Application (NDA) for mobocertinib and granted priority review for this Class-1 innovative drug, for the treatment of adult patients with non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) Exon20 insertion mutations.
- In September 2021, Takeda announced that the U.S. Food and Drug Administration (FDA) has approved EXKIVITY for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy. The FDA approval is based on results from the platinum-pretreated population in the Phase 1/2 trial of EXKIVITY, which consisted of 114 patients with EGFR Exon20 insertion+ NSCLC who received prior platinum-based therapy and were treated at the 160 mg dose once- daily. EXKIVITY, which was granted priority review and received Breakthrough Therapy Designation, Fast Track Designation and Orphan Drug Designation from the FDA, is the first and only approved oral therapy specifically designed to target EGFR Exon20 insertion mutations. This indication is approved under Accelerated Approval based on overall response rate (ORR) and duration of response (DoR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. The FDA simultaneously approved Thermo Fisher Scientific's Oncomine Dx Target Test as an next-generation sequencing (NGS) companion diagnostic for EXKIVITY to identify NSCLC patients with EGFR Exon20 insertions.

*Development code: TAK-924 / Generic name: pevonedistat*

- In September 2021, Takeda announced the Phase 3 PANTHER (Pevonedistat-3001) study did not achieve pre-defined statistical significance for the primary endpoint of event-free survival (EFS). The trial evaluated whether the combination of pevonedistat plus azacitidine as first-line treatment for patients with higher-risk myelodysplastic syndromes (MDS), chronic myelomonocytic leukemia (CMML) and low-blast acute myeloid leukemia (AML) improved EFS versus azacitidine alone. An event in the trial was defined as death or transformation to AML in participants with higher-risk MDS or CMML, whichever occurred first, and death in participants with AML. Takeda discontinued all research and development.

**Rare Genetics & Hematology**

In Rare Genetics & Hematology, Takeda focuses on several areas of high unmet medical need. In hereditary angioedema, Takeda aspires to transform the treatment paradigm, including through TAKHZYRO, with continued investment in lifecycle management programs including evaluating Takhzyro in Bradykinin-mediated angioedema with normal C1-inhibitor. In rare hematology, Takeda focuses on addressing today's needs in the treatment of bleeding disorders, including through ADVATE and ADYNOVATE/ADYNOVI, as well as on the development of pipeline assets including TAK-755 for the treatment of immune thrombotic thrombocytopenic purpura (iTTP) and congenital thrombotic thrombocytopenic purpura (cTTP). In rare metabolic diseases, Takeda is developing treatments for lysosomal storage disorders (LSDs), with a portfolio that includes commercial products such as ELAPRASE and REPLAGAL, and late-stage investigational therapies and pipeline candidates. We are also building differentiated gene therapy capabilities for the development and delivery of functional cures to patients with rare diseases.

*TAKHZYRO / Generic name: lanadelumab*

- In July 2021, Takeda announced the results from two final analyses from the Phase 3 HELP (Hereditary Angioedema Long-term Prophylaxis) Study™ Open-label Extension (OLE), which evaluated the long-term safety (primary endpoint) and efficacy of TAKHZYRO (lanadelumab) 300 mg every two weeks for up to 2.5 years. In the first analysis, the mean (min, max) reduction in the attack rate compared to baseline observed in the study population (N=212) was of 87.4 percent (-100; 852.8), and the median reduction was 97.7 percent and patients received treatment for a mean (standard deviation) duration of 29.6 (8.2) months. At steady state – day 70 to the end of the treatment period – attack rates were further reduced to a mean of 92.4 percent and a median reduction of 98.2 percent. An additional analysis further suggests TAKHZYRO was a well-tolerated treatment that prevented HAE attacks over an extended planned 132 week treatment period across specific HAE patient demographic and disease characteristic subgroups. These data were presented at the 2021 European Academy of Allergy and Clinical Immunology (EAACI) Hybrid Congress.

*REPLAGAL / Generic name: agalsidase alfa*

- In November 2021, Takeda and Sumitomo Dainippon Pharma Co., Ltd. (Sumitomo Dainippon Pharma) announced that Takeda will assume the manufacturing and marketing authorization (and the marketing rights) of REPLAGAL 3.5mg for Fabry disease, an α-galactosidase enzyme intravenous (IV) infusion, from Sumitomo Dainippon Pharma as of February 15, 2022 in Japan.

*FIRAZYR / Generic name: icatibant*

- In December 2021, Takeda announced that it has submitted an application for a revision to the marketing approval for the selective bradykinin B2 receptor blocker FIRAZYR for the treatment of pediatric patients with hereditary angioedema (HAE) in Japan. This application is based primarily on a Japanese Phase III open-label study and an overseas Phase III open-label study evaluating the safety, efficacy and pharmacokinetics of subcutaneous administration of FIRAZYR in children mainly aged between two and 18 years. The Japanese pediatric treatment response in the Japanese Phase III open-label study was similar to the pediatric treatment response in Japanese and overseas adults and in the overseas Phase III open-label study.

*VONVENDI / Generic name: von Willebrand factor (Recombinant)*

- In January 2022, Takeda announced that the U.S. Food & Drug Administration (FDA) approved VONVENDI for routine prophylaxis to reduce the frequency of bleeding episodes in patients with severe Type 3 von Willebrand disease (VWD) receiving on-demand therapy. The approval is based on data from a prospective, open-label, international multicenter study to evaluate efficacy and safety of prophylactic treatment of VONVENDI in reducing the frequency of bleeding episodes in 10 adult patients diagnosed with severe Type 3 VWD who were previously treated on-demand. VONVENDI is now indicated for routine prophylaxis in adults with severe Type 3 VWD receiving on-demand therapy, as well as on-demand and perioperative bleed management in adults with VWD.

*LIVTENCITY / Generic name: maribavir*

- In May 2021, Takeda announced that the U.S. Food and Drug Administration (FDA) accepted a New Drug Application (NDA), granting priority review, for maribavir for the treatment of CMV infections that are refractory with or without resistance (R/R), in solid organ transplant (SOT) or hematopoietic cell transplant (HCT) recipients. The application is based on the pivotal Phase 3 TAK-620-303 (SOLSTICE) trial. Maribavir has been granted Orphan Drug Designation by the FDA for treatment of clinically significant CMV viremia and disease in at-risk patients. The FDA has also granted maribavir Breakthrough Therapy Designation as a treatment for CMV infection and disease in transplant patients resistant or refractory to prior therapy.
- In June 2021, Takeda announced the results from a new subgroup analysis of SOT recipients in the Phase 3 TAK-620-303 (SOLSTICE) trial, for the investigational drug maribavir, at the American Transplant Congress (ATC) 2021 Virtual Connect. More than twice (55.6%, 79/142) as many SOT recipients with R/R CMV infection at baseline treated with maribavir achieved confirmed CMV viremia clearance at Study Week 8 (end of treatment phase) compared to those treated with conventional antiviral therapies (26.1%, 18/69) (investigator assigned treatment; IAT consists of one or a combination of ganciclovir, valganciclovir, foscarnet or cidofovir) (adjusted difference [95% CI]: 30.5% [17.3, 43.6]). The results presented showed consistent efficacy in SOT recipients receiving maribavir in heart, lung and kidney transplants.
- In October 2021, Takeda announced that the U.S. Food and Drug Administration (FDA) Antimicrobial Drugs Advisory Committee (AMDAC) voted unanimously to recommend use of maribavir for the treatment of refractory cytomegalovirus (CMV) infection and disease with genotypic resistance to ganciclovir, valganciclovir, foscarnet or cidofovir in transplant recipients. The committee also voted unanimously to recommend use of maribavir for the treatment of refractory CMV infection and disease without genotypic resistance to ganciclovir, valganciclovir, foscarnet or cidofovir in transplant recipients. Both recommendations were based on the results of the Phase 2 and Phase 3 TAK-620-303 (SOLSTICE) trials. The New Drug Application (NDA) for maribavir is currently under Priority Review by the FDA. The FDA will consider the vote as part of its review of the NDA and is not bound by the AMDAC's recommendation.

- In November 2021, Takeda announced that the U.S. Food and Drug Administration (FDA) approved LIVTENCITY for the treatment of adults and pediatric patients (12 years of age or older and weighing at least 35 kg) with post-transplant cytomegalovirus (CMV) infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir, or foscarnet. Prior to FDA approval, LIVTENCITY was granted Orphan Drug Designation by the FDA for treatment of clinically significant CMV viremia and disease in at-risk patients, as well as Breakthrough Therapy Designation as a treatment for CMV infection and disease in transplant patients resistant or refractory to prior therapy. Takeda is also investigating LIVTENCITY as a first-line treatment of CMV in hematopoietic stem cell transplant recipients in an ongoing Phase 3 clinical trial.
- In December 2021, Takeda announced that the data from the pivotal Phase 3 SOLSTICE clinical trial of LIVTENCITY in post-transplant refractory CMV infections with or without resistance (R/R) were published in the journal of Clinical Infectious Diseases. The SOLSTICE study primary endpoint was met, with 55.7% (131/235) of adult patients on LIVTENCITY achieving confirmed CMV DNA level below the lower limit of quantification (<LLOQ, i.e. <137 IU/mL) at the end of Study Week 8 (end of treatment phase) in comparison with 23.9% (28/117) of patients on conventional antiviral therapies (one or a combination of ganciclovir, valganciclovir, foscarnet or cidofovir); adjusted difference [95% CI]: 32.8% [22.80 to 42.74]; P<0.001. The key secondary endpoint of the composite achievement of CMV DNA level <LLOQ and symptom control at Week 8 maintained through Week 16 was met, with a higher proportion of patients in the LIVTENCITY arm (18.7%, 44/235) meeting the endpoint compared to those on conventional antiviral therapies (10.3%, 12/117); adjusted difference [95% CI]: 9.5% [2.02 to 16.88]; P=0.013.

**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, in particular, on potential investigative therapies for sleep-wake disorders such as narcolepsy and idiopathic hypersomnia with a franchise of orexin-2 receptor agonists (TAK-994, TAK-861, TAK-925, etc.), and rare epilepsies with soticlestat (TAK-935). Other rare neurology diseases of focus include Amyotrophic Lateral Sclerosis, Huntington's disease and other ataxias. Takeda also makes targeted investments to potentially address well-defined segments of neurodegenerative diseases (e.g., Parkinson's Disease).

*Development code: TAK-994*

- In July 2021, Takeda announced that the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation (BTD) to TAK-994, its Phase 2 investigational oral orexin agonist, which is designed to selectively target orexin 2 receptors. TAK-994 is currently being studied in an ongoing Phase 2 (TAK-994-1501) study for the treatment of excessive daytime sleepiness (EDS) in patients with narcolepsy type 1 (NT1), a chronic neurological disorder that alters the sleep-wake cycle. The TAK-994 BTD was based, in part, on early phase and preliminary clinical data that indicates Takeda's investigational oral orexin agonist may demonstrate substantially improved objective and subjective measurements of daytime wakefulness in NT1 patients.
- In October 2021, Takeda announced that a safety signal has emerged in Phase 2 studies of TAK-994 (TAK-994-1501 study and TAK-994-1504 study). As an immediate precautionary measure, Takeda has suspended dosing of patients and has decided to stop both Phase 2 studies early. This allows for the timely interpretation of the benefit/risk profile of TAK-994 and to determine next steps for the program.

**Gastroenterology (GI)**

In Gastroenterology, Takeda focuses on delivering innovative, life-changing therapeutics for patients with gastrointestinal and liver diseases. Takeda is maximizing the potential of our inflammatory bowel disease (IBD) franchise around ENTYVIO, including development of a subcutaneous formulation as well as a needle free device. Takeda is also expanding its position with GATTEX / REVESTIVE, and ALOFISEL, which is in ongoing P-3 trials to support further potential geographic expansion, including in the U.S. Furthermore, Takeda is progressing a pipeline built through partnerships exploring opportunities in IBD, celiac disease, select liver diseases, and motility disorders.

*ENTYVIO / Generic name: vedolizumab*

- In October 2021, Takeda announced the update on the U.S. development program for the investigational subcutaneous (SC) formulation of ENTYVIO as a maintenance therapy in adults with moderate to severe ulcerative colitis (UC). Through our ongoing interactions with the U.S. Food and Drug Administration (FDA), Takeda has received feedback which has provided clarity on the regulatory package and critical elements for the resubmission of the Biologics License Application (BLA) for Entyvio SC, and we are moving forward accordingly. We are reviewing our development program timelines and currently anticipate potential approval in FY 2023.
- In December 2021, Takeda announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended the approval of intravenous (IV) ENTYVIO for the treatment of adult patients with moderately to severely active chronic pouchitis, who have undergone proctocolectomy and ileal pouch-anal anastomosis for ulcerative colitis, and have had an inadequate response with or lost response to antibiotic therapy. The positive opinion from the CHMP was based on the EARNEST trial, recently presented at the United European Gastroenterology's annual meeting, UEG Week Virtual 2021, which assessed the safety and efficacy of ENTYVIO IV in the treatment of active chronic pouchitis. Moreover, information from a number of retrospective studies of historical data indicating that ENTYVIO can have a positive impact on patients with inflammation of the pouch was also included in the application. In January 2022, European Commission (EC) approved ENTYVIO as the first treatment indicated for active chronic pouchitis across the European Union.

*GATTEX / REVESTIVE / Generic name: teduglutide*

- In June 2021, Takeda announced that it obtained approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) to manufacture and market REVESTIVE 3.8 mg for subcutaneous injection as a treatment for short bowel syndrome. The approval is mainly based on the results of several trials conducted overseas, as well as Phase 3 clinical trials (SHP633-302, SHP633-305, SHP633-306, and SHP633-307) conducted in pediatric and adult patients in Japan.
- In November 2021, Takeda announced that it submitted the New Drug Application to the Japanese Ministry of Health, Labour and Welfare (MHLW) for the low dose formulation (0.95 mg) as an additional dosage for REVESTIVE as a treatment for short bowel syndrome (SBS). This new formulation would allow REVESTIVE to be administered to SBS patients weighing less than 10 kg, or less than 20 kg with moderate or severe renal impairment (creatinine clearance of less than 50 mL/min), who cannot be dosed with the 3.8 mg formulation.

*ALOFISEL / Generic name: darvadstrocel*

- In September 2021, Takeda announced that it has received approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) to manufacture and market ALOFISEL for the treatment of complex perianal fistulas in patients with non-active or mildly active luminal Crohn's disease (CD). This product is indicated for the treatment of patients who have shown an inadequate response to at least one existing medicinal treatment. The approval is based on data from two trials , the Japanese Study Darvadstrocel-3002 and the ADMIRE-CD trial, conducted in Europe and Israel. ALOFISEL is the first expanded human allogeneic adipose-derived mesenchymal stem cell therapy to be approved in Japan, which exhibits immunomodulatory and local anti-inflammatory effects at the site of inflammation.

*Development code: TAK-721 (Planned trade name: Eohilia) / Generic name: budesonide oral suspension*

- In December 2021, Takeda announced that it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) in response to its New Drug Application (NDA) for TAK-721 for the treatment of eosinophilic esophagitis, a chronic inflammatory disease of the esophagus. The CRL indicates the FDA has completed its review of the TAK-721 NDA and determined that it cannot be approved in its present form. In addition, the FDA recommended an additional clinical study in order to help resolve FDA feedback. Takeda announced the discontinuation of this program in February 2022.

**Plasma-Derived Therapies (PDT)**

Takeda created a dedicated PDT business unit with a focus to manage the business end-to-end, from plasma collection to manufacturing, R&D, and commercialization. In PDT, we aspire to develop life-saving plasma derived treatments which are essential for patients with a variety of rare and complex chronic diseases. The dedicated R&D organization in PDT is charged with maximizing the value of existing therapies, identifying new targeted therapies, and optimizing efficiencies of current product manufacturing. Near-term, our priority is focused on delivering value from our broad immunoglobulin portfolio (HYQVIA, CUVITRU, GAMMAGARD and GAMMAGARD S/D) through pursuit of new indications, geographic expansions, and enhanced patient experience through integrated healthcare technologies. In our hematology and specialty care portfolio, our priority is pursuing new indication and formulation development opportunities for PROTHROMPLEX (4F-PCC), FEIBA, CEPROTIN and ARALAST. Additionally, we are developing next generation immunoglobulin products with 20% fSCIg (TAK-881), IgG Low IgA (TAK-880) and pursuing other early stage opportunities that would add to our diversified commercial portfolio of more than 20 therapeutic products distributed worldwide.

*Development code: CoVIg-19 (previously TAK-888) / Generic name: anti-SARS-CoV-2 polyclonal hyperimmune immunoglobulin*

- In April 2021, The CoVIg-19 Plasma Alliance announced that the Phase 3 Inpatient Treatment with Anti-Coronavirus Immunoglobulin (ITAC) clinical trial sponsored and funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), did not meet its endpoints. No serious safety signals were raised in the trial. The study aimed to determine whether an investigational anti-coronavirus hyperimmune intravenous immunoglobulin (H-Ig) medicine could reduce the risk of disease progression when added to standard of care treatment including remdesivir in hospitalized adult patients at risk for serious complications. Analyses remain ongoing and NIAID and the INSIGHT Network intend to publish the full results of the trial soon. Following the outcome of the ITAC trial, the CoVIg-19 Plasma Alliance's work has now concluded.

**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.

*SPIKEVAX (formerly COVID-19 Vaccine Moderna) Intramuscular Injection / Development code: mRNA-1273 (Japanese development code: TAK-919)*

- In May 2021, Takeda announced positive interim results from the ongoing Phase 1/2 immunogenicity and safety clinical trial of TAK-919 in Japan have been submitted to the Japan Pharmaceuticals and Medical Devices Agency (PMDA). Takeda currently has a three-way agreement with Moderna, Inc. (Moderna) and the Government of Japan's Ministry of Health Labour and Welfare (MHLW) to import and distribute 50 million doses of TAK-919 in Japan. This interim analysis showed binding antibody and neutralizing antibody titres were elevated at 28 days after the second dose in 100% of people vaccinated with two 0.5ml doses of TAK-919 given 28 days apart. The vaccine candidate was generally well-tolerated with no significant safety concerns reported. The study results were submitted to the Japan Pharmaceuticals and Medical Devices Agency (PMDA) to be evaluated as part of the New Drug Application submitted in March 2021, which also includes safety and efficacy results from Moderna's pivotal Phase 3 COVE trial conducted in the U.S.
- In May 2021, Takeda announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) granted special approval under article 14-3 of the Pharmaceuticals and Medical Devices Act for emergency use of COVID-19 Vaccine Moderna Intramuscular Injection in Japan. The approval is based on positive clinical data from Takeda's Phase 1/2 immunogenicity and safety clinical trial of COVID-19 Vaccine Moderna Intramuscular Injection in Japan, which showed an immune response consistent with results from Moderna's pivotal Phase 3 COVE trial conducted in the United States. Takeda has started distribution in Japan.
- In July 2021, Takeda announced an additional agreement with Moderna and the Government of Japan's Ministry of Health, Labour and Welfare (MHLW) to import and distribute an additional 50 million doses of COVID-19 Vaccine Moderna Intramuscular Injection in Japan from as early as the beginning of 2022. This agreement includes the potential to secure and supply vaccines corresponding to COVID-19 variants or booster products, should they

be successfully developed by Moderna and licensed by the MHLW. Takeda will import and distribute the totaling 100 million doses including the additional 50 million doses in 2022 and 50 million doses announced in October, 2020.

- In July 2021, Takeda announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) accepted the change in age indication in the package insert for COVID-19 Vaccine Moderna Intramuscular Injection to expand to 12 years of age and older. This change is based on the results of Moderna's Phase 2/3 study conducted in 3,732 subjects aged 12 to 17 years in the United States. The serum neutralizing antibody titer and neutralizing antibody titer response rate 28 days after the second vaccination of adolescents (12 to 17 years old), which are the primary endpoints, showed non-inferiority to young adults (18 to 25 years old) in the overseas phase 3 study (mRNA-1273-P301 study). Additionally, the results indicating a high preventive effect at the vaccine efficacy rate 2 weeks after the second vaccination, which was set as a secondary endpoint. No significant safety concerns were reported, as was the case with the results of clinical studies in patients aged 18 years or older.
- In December 2021, Takeda announced that Japan's Ministry of Health, Labour and Welfare (MHLW) has granted regulatory approval for a 50 µg booster dose of SPIKEVAX Intramuscular Injection, previously known as COVID-19 Vaccine Moderna Intramuscular Injection, in Japan for administration at least six months after completion of the primary series in those who are 18 years and older. The approval is based on previously-reported positive Moderna Phase 2 study results. Moderna's Phase 2 study was amended to offer a 50 µg booster dose to interested participants aged 18 years and older six to eight months following their second dose of the primary series of Moderna's COVID-19 vaccine. The results showed that a booster dose of the vaccine greatly increased neutralizing titers measured against the original virus strain compared to pre-boost levels. The reactogenicity profile observed following the booster dose was similar to the second dose of the primary series and the safety profile was also similar to that following any dose of Moderna's COVID-19 vaccine of the primary series.
- In December 2021, Takeda announced a third agreement with Japan's Ministry of Health, Labour and Welfare (MHLW) and Moderna to import and distribute 18 million additional doses of SPIKEVAX Intramuscular Injection in Japan in 2022. Takeda previously announced a three-way agreement with Moderna and MHLW to distribute 50 million doses of SPIKEVAX in Japan in 2021, and announced a second agreement for Takeda to import and distribute an additional 50 million doses in 2022, totaling 100 million doses between the two agreements. Due to the approval of the 50 microgram booster dose described in the foregoing paragraph, which is half of the dosage level used in the initial two-dose series of the vaccine (100 microgram per dose), the doses per vial for the second 50 million doses will increase, meaning Takeda will be able to deliver 75 million booster doses (at 15 doses per vial). With this third agreement for 18 million doses (at 15 doses per vial), Takeda will now deliver a total of 93 million doses to Japan in 2022.

*Development code: NVX-CoV2373 (Japanese development code: TAK-019) / Generic name: COVID-19 vaccine*

- In September 2021, Takeda announced the agreement that the Japanese Ministry of Health, Labour and Welfare (MHLW) will purchase 150 million doses of Novavax, Inc. (Novavax)'s vaccine candidate (TAK-019 in Japan) manufactured in Japan by Takeda subject to licensing and approval. Takeda is establishing the capability to manufacture TAK-019 at its facilities in Japan and aims to begin distribution in early calendar year 2022. Novavax is licensing and transferring manufacturing technologies to enable Takeda to manufacture the vaccine antigen and is supplying the Matrix-M™ adjuvant to Takeda for fill/finish together with the antigen. Takeda is responsible for the Japanese clinical trial and regulatory submission and will distribute TAK-019 in Japan should it be approved by the MHLW.
- In December 2021, Takeda announced the submission of a New Drug Application (NDA) to the Ministry of Health, Labour and Welfare (MHLW) in Japan for TAK-019. The NDA submission includes an analysis from the ongoing Phase 1/2 immunogenicity and safety clinical trial of TAK-019 in Japan as well as safety and efficacy data from Novavax' global clinical trial program with more than 50,000 participants, including two pivotal Phase 3 trials, one conducted in the U.K. and another trial conducted in the U.S. and Mexico. Takeda's interim trial results showed that two 0.5 ml doses given 21 days apart induced robust anti-SARS-CoV-2 immune responses in healthy Japanese adults. No serious adverse events were reported in the TAK-019 group and the vaccine candidate was also well-tolerated. These results are consistent with previously reported global clinical trial results of Novavax' recombinant protein COVID-19 vaccine candidate (NVX-CoV2373). Takeda submitted all available Chemistry, Manufacturing and Controls (CMC), non-clinical and clinical data as of December 2021. Some additional CMC data will be subsequently submitted to the Japan Pharmaceuticals and Medical Devices Agency (PMDA) during the NDA review period. Through its partnership with Novavax including technology transfer, Takeda is establishing the capability to manufacture TAK-019 at its facilities in Japan and aims to begin distribution in early calendar year 2022, pending regulatory approval.

*Development code: TAK-003 / Generic name: Dengue vaccine*

- In May 2021, Takeda announced that TAK-003 demonstrated continued protection against dengue illness and hospitalization, regardless of an individual's previous dengue exposure, with no important safety risks identified through three years after vaccination in the ongoing pivotal Phase 3 Tetravalent Immunization against Dengue Efficacy Study (TIDES) trial. TIDES enrolled more than 20,000 healthy children and adolescents ages four to 16 years in dengue-endemic countries in Latin America and Asia. Safety and efficacy results from the 36-month follow-up exploratory analysis of TIDES were presented at the 17th Conference of the International Society of Travel Medicine (CISTM). Through three years (36 months after the second dose), observations of varied vaccine efficacy by serotype remained consistent with previously reported results. No evidence of disease enhancement was observed. TAK-003 was generally well tolerated, and there were no important safety risks observed. TIDES safety and efficacy data through 36-months follow-up was included in regulatory submissions to the European Union and dengue-endemic countries and will be part of additional filings planned for 2021, including in the United States.

***Building a sustainable research platform / Enhancing R&D collaboration***

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.

- In July 2021, Takeda and PeptiDream Inc. announced an expansion of its research collaboration and exclusive license agreement, announced in December 2020, to create peptide-drug conjugates (PDCs) for several central nervous system (CNS) targets, which play important roles in chronic neurodegenerative diseases. This new collaboration expands the use of the TfR1 binding peptide ligands for CNS targets associated with neurodegeneration allowing Takeda to conjugate the peptides with therapeutic cargoes optimized to cross the blood-brain barrier (BBB). A significant challenge to the development of effective medicines for neurodegenerative diseases is the ability to deliver therapeutic molecules across the BBB into the brain. Peptide carriers that bind to TfR1 when conjugated to various therapeutic payloads facilitate the transport of the payload across the BBB into the brain, and thereby significantly improve functional benefit. This TfR1 BBB shuttle approach has the potential to accelerate the development of therapies for which BBB penetration remains challenging. This approach may also enable broad brain region biodistribution that is frequently needed to effectively treat many neurodegenerative diseases for which few, if any, effective drugs currently exist.
- In July 2021, Takeda and Frazier Healthcare Partners announced a collaboration to launch HilleVax, Inc. (HilleVax), a biopharmaceutical company to develop and commercialize Takeda's norovirus vaccine candidate. Takeda has granted a license to HilleVax for the exclusive development and commercialization rights to its norovirus vaccine candidate, HIL-214 (formerly TAK-214), worldwide outside of Japan, in exchange for upfront consideration, as well as future cash milestones and royalties on net sales. Takeda will retain commercialization rights in Japan and HilleVax will integrate certain Japan development activities into its global development. HIL-214, which is a virus-like particle (VLP) based vaccine candidate, completed a randomized, placebo-controlled Phase 2b field efficacy study in 4,712 adult subjects in which HIL-214 was well-tolerated and demonstrated clinical proof of concept in preventing moderate-to-severe cases of acute gastroenteritis from norovirus infection.1 To date, the candidate has been studied in nine human clinical trials with safety data from over 4,500 subjects and immunogenicity data from over 2,000 subjects.
- In September 2021, Takeda and Mirum Pharmaceuticals, Inc. (Mirum) announced that the companies have entered into an exclusive licensing agreement for the development and commercialization of maralixibat chloride (maralixibat) (US trade name: LIVMARLI ), an apical sodium dependent bile acid transporter (ASBT) inhibitor, in Japan for Alagille syndrome (ALGS), progressive familial intrahepatic cholestasis (PFIC), and biliary atresia (BA). Maralixibat, an investigational, orally administered medication, is being evaluated globally in ALGS, PFIC, and BA. Under the terms of the agreement, Takeda will be responsible for regulatory approval and commercialization of maralixibat in Japan. Takeda will also be responsible for development, including conducting clinical studies in cholestatic indications.
- In September 2021, Takeda and JCR Pharmaceuticals Co., Ltd. (JCR) announced a geographically-focused exclusive collaboration and license agreement to commercialize JR-141 (pabinafusp alfa), an investigational, next-generation recombinant fusion protein of an antibody against the human transferrin receptor and iduronate-2-sulfatase (IDS) enzyme for the treatment of Hunter syndrome (also known as Mucopolysaccharidosis type II or MPS II). JR-141, applied with J-Brain Cargo, JCR's proprietary blood-brain barrier (BBB) technology, is engineered to transport the therapeutic enzyme across the BBB to directly reach the brain and address both the somatic and neuronopathic manifestations of the disease, which can lead to progressive cognitive decline. Under the terms of the exclusive

collaboration and license agreement, Takeda will exclusively commercialize JR-141 outside of the United States, including Canada, Europe, and other regions (excluding Japan and certain other Asia-Pacific countries). The two companies will collaborate to bring this therapy to patients as quickly as possible upon completion of the global Phase 3 program, which will be conducted by JCR. Takeda receives an option under a separate option agreement, which allows Takeda to acquire an exclusive license to commercialize JR-141 in the U.S. upon completion of the Phase 3 program.

- In October 2021, Takeda announced the exercise of its option to acquire GammaDelta Therapeutics Limited ("GammaDelta"), a company focused on exploiting the unique properties of gamma delta (γδ) T cells for immunotherapy. Through the acquisition, Takeda will obtain GammaDelta's allogeneic variable delta 1 (Vδ1) gamma-delta (γδ) T cell therapy platforms, which includes both blood-derived and tissue-derived platforms, in addition to early-stage cell therapy programs. The deal is expected to be finalized in Q1 of Takeda's fiscal year 2022. Closing of the transaction is contingent on completion of review under antitrust laws, including the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR) in the U.S. Takeda received HSR clearance for the transaction from the United States Federal Trade Commission (FTC) in January, 2022.
- In January 2022, Takeda announced the exercise of its option to acquire Adaptate Biotherapeutics Ltd. ("Adaptate"), a UK company focused on developing antibody-based therapeutics for the modulation of variable delta 1 (Vδ1) gamma delta (γδ) T cells. Through the acquisition, Takeda will acquire Adaptate's antibody-based γδ T cell engager platform, including pre-clinical candidate and discovery pipeline programs. Adaptate's γδ T cell engagers are designed to specifically modulate γδ T cell-mediated immune responses at tumor sites while sparing damage to healthy cells. The planned acquisition of Adaptate follows Takeda's recently exercised option to acquire GammaDelta Therapeutics and is intended to further accelerate the development of innovative γδ T cell-based therapies. The deal is expected to be finalized in Q1 of Takeda's fiscal year 2022.

**3. Material Contracts**

The material contracts entered into, amended or terminated during the three-month period ended December 31, 2021 are as follows:

On October 14, 2021, Takeda issued 10-year unsecured senior bonds with an aggregate principal amount of 250 billion JPY and a maturity date of October 14, 2031.

On December 13, 2021 Takeda prepaid the remaining 1,700 million USD outstanding JBIC Loan (Note) amount, and canceled the JBIC Loan.

(Note) This agreement was entered into, with the Japan Bank for International Cooperation, on December 3, 2018.

## III. Information on the Company

### 1. Information on the Company's Shares

(1) Total number of shares and other related information

1) Total number of shares

| Class | Total number of shares authorized to be issued (Shares) |
|---|---|
| Common stock | 3,500,000,000 |
| Total | 3,500,000,000 |

2) Number of shares issued

| Class | Number of shares outstanding (As of December 31, 2021) | Number of shares outstanding as of the filing date (February 10, 2022) | Stock exchange on which the Company is listed | Description |
|---|---|---|---|---|
| Common stock | 1,582,252,525 | 1,582,252,525 | Tokyo, Nagoya (both listed on the first section), Fukuoka, Sapporo, New York | The number of shares per one unit of shares is 100 shares. |
| Total | 1,582,252,525 | 1,582,252,525 | — | — |

(Note1) The Company's American Depositary Shares (ADS) are listed on the New York Stock Exchange.
(Note2) The number of shares outstanding as of the filing date does not include newly issued shares exercised by stock acquisition rights from February 1, 2022 to the filing date of Quarterly Securities Report (February 10, 2022).

(2) Status of stock acquisition rights

1) Contents of stock option plans

Not applicable.

2) Status of other stock acquisition rights

Not applicable.

(3) Exercise status of bonds with stock acquisition rights containing a clause for exercise price adjustments

Not applicable.

(4) Changes in the total number of issued shares and the amount of share capital and capital reserve

| Date | Change in the total number of issued shares (Thousand of shares) | Balance of the total number of issued shares (Thousand of shares) | Change in share capital JPY (millions) | Balance of share capital JPY (millions) | Change in capital reserve JPY (millions) | Balance of capital reserve JPY (millions) |
|---|---|---|---|---|---|---|
| From July 1, 2021 to December 31, 2021 (Note) 1 | — | 1,582,253 | — | 1,676,263 | — | 1,668,276 |

(Note) There was no increase in the total number of issued shares, share capital or capital reserve due to the exercise of stock acquisition rights from January 1, 2022 to January 31, 2022.

(5) Major shareholders

No information required in the 3rd quarter.

(6) Information on voting rights

1) Total number of shares

| | As of December 31, 2021 | | | |
|---|---|---|---|---|
| **Classification** | **Number of shares (Shares)** | | **Number of voting rights (Units)** | **Description** |
| Shares without voting rights | | — | — | — |
| Shares with restricted voting rights (Treasury stock and other) | | — | — | — |
| Shares with restricted voting rights (Others) | | — | — | — |
| Shares with full voting rights (Treasury stock and other) | (Treasury stock) Common stock | 15,511,200 | — | — |
| | (Crossholding stock) Common stock | 287,000 | — | — |
| Shares with full voting rights (Others) | Common stock | 1,565,190,800 | 15,651,908 | — |
| Shares less than one unit | Common stock | 1,263,525 | — | Shares less than one unit (100 shares) |
| Number of issued shares | | 1,582,252,525 | — | — |
| Total number of voting rights | | — | 15,651,908 | — |

(Note1) Based on the resolution at the Board of Directors Meeting on October 28, 2021, the Company acquired 15,335,700 of treasury stocks by open-market repurchase through a trust bank from November 2, 2021 to November 30, 2021.

(Note2) "Shares with full voting rights (Others)" includes 7,018,000 (voting rights: 70,180) and 2,143,100 (voting rights: 21,431) of the shares held by the ESOP and BIP trust, respectively.

(Note3) "Shares less than one unit" includes 63 of the shares as the treasury stock, and 140 and 102 of the shares held by the ESOP and BIP trust, respectively.

2) Treasury stock and other

| | | As of December 31, 2021 | | | |
|---|---|---|---|---|---|
| **Name of shareholders** | **Address** | **Number of shares held under own name (Shares)** | **Number of shares held under the name of others (Shares)** | **Total shares held (Shares)** | **Percentage of total issued shares issued (%)** |
| (Treasury stock) | | | | | |
| Takeda Pharmaceutical Company Limited | 1-1, Doshomachi 4-chome, Chuo-ku, Osaka | 15,511,200 | — | 15,511,200 | 0.98 |
| (Crossholding stock) | | | | | |
| Amato Pharmaceutical Products, Ltd. | 5-3, Shinsenri Higashi-machi 1-chome, Toyonaka-city, Osaka | 275,000 | — | 275,000 | 0.02 |
| Watanabe Chemical, Co.,Ltd. | 6-1, Hiranomachi 3-chome, Chuo-ku, Osaka-city, Osaka | 12,000 | — | 12,000 | 0.00 |
| Total | | 15,798,200 | — | 15,798,200 | 1.00 |

(Note1) Based on the resolution at the Board of Directors Meeting on October 28, 2021, the Company acquired 15,335,700 of treasury stocks by open-market repurchase through a trust bank from November 2, 2021 to November 30, 2021.

(Note2) In addition to the above treasury stock and shares less than one unit of 63 shares, 7,018,140 of the shares held by the ESOP trust and 2,143,202 of the shares held by the BIP trust are included in treasury stock on the condensed interim consolidated financial statements.

**2. Members of the Board of Directors**

No changes from the latest Annual Securities Report.

## IV. Financial Information

Basis of Preparation of the Condensed Interim Consolidated Financial Statements

Takeda has prepared the condensed interim consolidated financial statements in accordance with IAS 34 “Interim Financial Reporting” based on the provision of Article 93 of Ordinance on Terminology, Forms and Preparation Methods of Quarterly Consolidated Financial Statements (Ordinance of the Ministry of Finance No. 64, 2007 in Japan).

## 1. Condensed Interim Consolidated Financial Statements

### (1) Condensed Interim Consolidated Statements of Profit or Loss

| | | JPY (millions, except per share data) | | | |
|---|---|---|---|---|---|
| | | Nine-month Period Ended December 31, | | Three-month Period Ended December 31, | |
| | Note | 2020 | 2021 | 2020 | 2021 |
| Revenue | 4 | 2,427,538 | 2,695,717 | 836,753 | 901,294 |
| Cost of sales | | (740,862) | (798,466) | (253,142) | (281,404) |
| Selling, general and administrative expenses | | (641,275) | (662,932) | (222,644) | (231,078) |
| Research and development expenses | | (342,544) | (382,459) | (117,566) | (128,378) |
| Amortization and impairment losses on intangible assets associated with products | | (307,570) | (323,632) | (99,473) | (118,087) |
| Other operating income | 5 | 118,532 | 34,269 | 49,069 | 14,734 |
| Other operating expenses | 6 | (155,090) | (100,034) | (49,856) | (40,596) |
| Operating profit | | 358,729 | 462,463 | 143,141 | 116,484 |
| Finance income | | 58,030 | 42,949 | 28,402 | 4,145 |
| Finance expenses | | (173,389) | (143,539) | (62,669) | (46,706) |
| Share of profit (loss) of investments accounted for using the equity method | 7 | (8,013) | (5,255) | 922 | (1,730) |
| Profit before tax | | 235,357 | 356,618 | 109,796 | 72,193 |
| Income tax expenses | 8, 15 | (56,330) | (115,077) | (17,358) | (14,373) |
| Net profit for the period | | 179,027 | 241,541 | 92,438 | 57,820 |
| Attributable to: | | | | | |
| Owners of the Company | | 178,907 | 241,417 | 92,359 | 57,770 |
| Non-controlling interests | | 120 | 124 | 79 | 51 |
| Net profit for the period | | 179,027 | 241,541 | 92,438 | 57,820 |
| Earnings per share (JPY) | | | | | |
| Basic earnings per share | 9 | 114.57 | 154.09 | 59.08 | 36.91 |
| Diluted earnings per share | 9 | 113.72 | 153.03 | 58.61 | 36.68 |

See accompanying notes to condensed interim consolidated financial statements.

**(2) Condensed Interim Consolidated Statements of Comprehensive Income**

| | JPY (millions) | | | |
|---|---|---|---|---|
| | Nine-month Period Ended December 31, | | Three-month Period Ended December 31, | |
| | 2020 | 2021 | 2020 | 2021 |
| Net profit for the period | 179,027 | 241,541 | 92,438 | 57,820 |
| 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 | 69,336 | (5,951) | 37,984 | (10,220) |
| Remeasurement of defined benefit pension plans | (4,879) | (2,912) | (2,120) | (1,210) |
| | 64,457 | (8,862) | 35,864 | (11,430) |
| Items that may be reclassified subsequently to profit or loss: | | | | |
| Exchange differences on translation of foreign operations | (42,370) | 206,582 | (10,967) | 139,883 |
| Cash flow hedges | (21,596) | 13,958 | (15,707) | 2,406 |
| Hedging cost | (10,288) | 5,969 | 3,256 | 185 |
| Share of other comprehensive income (loss) of investments accounted for using the equity method | 220 | (145) | 123 | (108) |
| | (74,034) | 226,365 | (23,295) | 142,365 |
| Other comprehensive income for the period, net of tax | (9,577) | 217,503 | 12,569 | 130,935 |
| Total comprehensive income for the period | 169,450 | 459,044 | 105,007 | 188,756 |
| Attributable to: | | | | |
| Owners of the Company | 169,301 | 458,887 | 105,029 | 188,689 |
| Non-controlling interests | 149 | 157 | (22) | 66 |
| Total comprehensive income for the period | 169,450 | 459,044 | 105,007 | 188,756 |

See accompanying notes to condensed interim consolidated financial statements.

**(3) Condensed Interim Consolidated Statements of Financial Position**

| | Note | JPY (millions) As of March 31, 2021 | As of December 31, 2021 |
|---|---|---|---|
| **ASSETS** | | | |
| Non-current assets: | | | |
| Property, plant and equipment | | 1,453,917 | 1,493,587 |
| Goodwill | | 4,033,917 | 4,167,993 |
| Intangible assets | | 3,909,106 | 3,791,875 |
| Investments accounted for using the equity method | | 112,468 | 104,507 |
| Other financial assets | | 235,882 | 230,305 |
| Other non-current assets | | 100,341 | 79,645 |
| Deferred tax assets | | 353,769 | 352,715 |
| Total non-current assets | | 10,199,400 | 10,220,626 |
| Current assets: | | | |
| Inventories | | 753,881 | 811,324 |
| Trade and other receivables | 10 | 783,091 | 715,515 |
| Other financial assets | | 36,598 | 27,555 |
| Income taxes receivable | | 29,623 | 40,602 |
| Other current assets | | 122,789 | 138,352 |
| Cash and cash equivalents | | 966,222 | 724,341 |
| Assets held for sale | 11 | 20,689 | 20,203 |
| Total current assets | | 2,712,893 | 2,477,893 |
| Total assets | | 12,912,293 | 12,698,519 |
| **LIABILITIES AND EQUITY** | | | |
| **LIABILITIES** | | | |
| Non-current liabilities: | | | |
| Bonds and loans | 12 | 4,613,218 | 4,231,939 |
| Other financial liabilities | | 517,677 | 461,692 |
| Net defined benefit liabilities | | 158,857 | 169,803 |
| Income taxes payable | | 33,690 | 30,874 |
| Provisions | | 38,748 | 34,042 |
| Other non-current liabilities | | 56,898 | 70,486 |
| Deferred tax liabilities | | 542,852 | 558,607 |
| Total non-current liabilities | | 5,961,940 | 5,557,443 |
| Current liabilities: | | | |
| Bonds and loans | 12 | 22,153 | 122,936 |
| Trade and other payables | | 343,838 | 351,185 |
| Other financial liabilities | | 248,053 | 189,298 |
| Income taxes payable | 15 | 145,203 | 185,441 |
| Provisions | | 471,278 | 421,481 |
| Other current liabilities | | 542,651 | 538,913 |
| Total current liabilities | | 1,773,176 | 1,809,254 |
| Total liabilities | | 7,735,116 | 7,366,697 |

| | Note | JPY (millions) As of March 31, 2021 | As of December 31, 2021 |
|---|---|---|---|
| **EQUITY** | | | |
| Share capital | 13 | 1,668,145 | 1,676,263 |
| Share premium | 13 | 1,688,424 | 1,697,562 |
| Treasury shares | 13 | (59,552) | (91,013) |
| Retained earnings | | 1,509,906 | 1,466,926 |
| Other components of equity | | 366,114 | 581,592 |
| Equity attributable to owners of the company | | 5,173,037 | 5,331,330 |
| Non-controlling interests | | 4,140 | 493 |
| Total equity | | 5,177,177 | 5,331,822 |
| Total liabilities and equity | | 12,912,293 | 12,698,519 |

See accompanying notes to condensed interim consolidated financial statements.

## (4) Condensed Interim Consolidated Statements of Changes in Equity

Nine-month period ended December 31, 2020 (From April 1 to December 31, 2020)

| | | JPY (millions) | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Equity attributable to owners of the Company | | | | | | | | | | | | |
| | | | | | | Other components of equity | | | | | | | | |
| | Note | 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 | Remeasurements 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 period | | | | | 178,907 | | | | | | — | 178,907 | 120 | 179,027 |
| Other comprehensive income (loss) | | | | | | (42,191) | 69,348 | (21,596) | (10,288) | (4,879) | (9,606) | (9,606) | 29 | (9,577) |
| Comprehensive income (loss) for the period | | — | — | — | 178,907 | (42,191) | 69,348 | (21,596) | (10,288) | (4,879) | (9,606) | 169,301 | 149 | 169,450 |
| Transaction with owners: | | | | | | | | | | | | | | |
| Issuance of new shares | | 22 | 22 | | | | | | | | — | 44 | | 44 |
| Acquisition of treasury shares | | | | (2,138) | | | | | | | — | (2,138) | | (2,138) |
| Disposal of treasury shares | | | (0) | 2 | | | | | | | — | 2 | | 2 |
| Dividends | 13 | | | | (283,718) | | | | | | — | (283,718) | (77) | (283,795) |
| Transfers from other components of equity | | | | | 41,407 | | (46,286) | | | 4,879 | (41,407) | — | | — |
| Share-based compensation | | | 28,119 | | | | | | | | — | 28,119 | | 28,119 |
| Exercise of share-based awards | | | (29,772) | 30,032 | | | | | | | — | 260 | | 260 |
| Total transactions with owners | | 22 | (1,631) | 27,896 | (242,311) | — | (46,286) | — | — | 4,879 | (41,407) | (257,431) | (77) | (257,508) |
| As of December 31, 2020 | | 1,668,145 | 1,678,656 | (59,567) | 1,306,568 | 49,657 | 45,953 | (44,326) | (9,733) | — | 41,551 | 4,635,353 | 4,075 | 4,639,428 |

See accompanying notes to condensed interim consolidated financial statements.

Nine-month period ended December 31, 2021 (From April 1 to December 31, 2021)

| | | JPY (millions) | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Equity attributable to owners of the Company | | | | | | | | | | | | |
| | | | | | | Other components of equity | | | | | | | | |
| | Note | 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 | Remeasurements of defined benefit pension plans | Total | Total | Non-controlling interests | Total equity |
| As of April 1, 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 |
| Net profit for the period | | | | | 241,417 | | | | | | — | 241,417 | 124 | 241,541 |
| Other comprehensive income (loss) | | | | | | 206,337 | (5,883) | 13,958 | 5,969 | (2,912) | 217,470 | 217,470 | 33 | 217,503 |
| Comprehensive income (loss) for the period | | — | — | — | 241,417 | 206,337 | (5,883) | 13,958 | 5,969 | (2,912) | 217,470 | 458,887 | 157 | 459,044 |
| Transaction with owners: | | | | | | | | | | | | | | |
| Issuance of new shares | 13 | 8,118 | 14,036 | | | | | | | | — | 22,154 | | 22,154 |
| Acquisition of treasury shares | 13 | | | (54,451) | | | | | | | — | (54,451) | | (54,451) |
| Disposal of treasury shares | | | (0) | 1 | | | | | | | — | 1 | | 1 |
| Dividends | 13 | | | | (284,246) | | | | | | — | (284,246) | | (284,246) |
| Changes in ownership | | | | | (2,143) | | | | | | — | (2,143) | (3,804) | (5,948) |
| Transfers from other components of equity | | | | | 1,992 | | (4,904) | | | 2,912 | (1,992) | — | | — |
| Share-based compensation | | | 32,057 | | | | | | | | — | 32,057 | | 32,057 |
| Exercise of share-based awards | | | (36,955) | 22,989 | | | | | | | — | (13,966) | | (13,966) |
| Total transactions with owners | | 8,118 | 9,138 | (31,461) | (284,397) | — | (4,904) | — | — | 2,912 | (1,992) | (300,594) | (3,804) | (304,399) |
| As of December 31, 2021 | | 1,676,263 | 1,697,562 | (91,013) | 1,466,926 | 607,135 | 31,196 | (54,116) | (2,623) | — | 581,592 | 5,331,330 | 493 | 5,331,822 |

See accompanying notes to condensed interim consolidated financial statements.

## (5) Condensed Interim Consolidated Statements of Cash Flows

| | Notes | JPY (millions) Nine-month Period Ended December 31, 2020 | 2021 |
|---|---|---|---|
| Cash flows from operating activities: | | | |
| Net profit for the period | | 179,027 | 241,541 |
| Depreciation and amortization | | 420,281 | 430,877 |
| Impairment losses | | 10,118 | 14,666 |
| Equity-settled share-based compensation | | 28,119 | 32,057 |
| Change in estimate of liabilities related to SHP647 | 5 | (60,179) | — |
| Loss (gain) on sales and disposal of property, plant and equipment | | (3,435) | 258 |
| Gain on divestment of business and subsidiaries | | (38,273) | (1,095) |
| Change in fair value of financial assets and liabilities associated with contingent consideration arrangements, net | 6 | 8,888 | (9,683) |
| Finance (income) and expenses, net | | 115,359 | 100,589 |
| Share of loss of investments accounted for using the equity method | | 8,013 | 5,255 |
| Income tax expenses | | 56,330 | 115,077 |
| Changes in assets and liabilities: | | | |
| Decrease (increase) in trade and other receivables | | (49,908) | 82,243 |
| Decrease (increase) in inventories | | 6,059 | (39,268) |
| Decrease in trade and other payables | | (5,082) | (1,797) |
| Increase (decrease) in provisions | | 66,844 | (70,098) |
| Increase (decrease) in other financial liabilities | | 25,939 | (51,158) |
| Other, net | | (11,810) | (858) |
| Cash generated from operations | | 756,290 | 848,607 |
| Income taxes paid | | (174,694) | (107,224) |
| Tax refunds and interest on tax refunds received | | 28,375 | 6,138 |
| Net cash from operating activities | | 609,971 | 747,521 |
| Cash flows from investing activities: | | | |
| Interest received | | 752 | 2,468 |
| Dividends received | | 215 | 2,598 |
| Acquisition of property, plant and equipment | | (75,041) | (87,673) |
| Proceeds from sales of property, plant and equipment | | 42,818 | 412 |
| Acquisition of intangible assets | | (49,469) | (46,541) |
| Acquisition of investments | | (9,479) | (7,600) |
| Proceeds from sales and redemption of investments | | 73,717 | 16,065 |
| Acquisition of businesses, net of cash and cash equivalents acquired | | — | (49,672) |
| Proceeds from sales of business, net of cash and cash equivalents divested | | 124,969 | 2,138 |
| Other, net | | (8,283) | (4,683) |
| Net cash from (used in) investing activities | | 100,199 | (172,487) |

| | Notes | JPY (millions) Nine-month Period Ended December 31, 2020 | 2021 |
|---|---|---|---|
| Cash flows from financing activities: | | | |
| Net decrease in short-term loans and commercial papers | | (84,997) | (2) |
| Proceeds from issuance of bonds and long-term loans | | 1,179,515 | 249,334 |
| Repayments of bonds and long-term loans | | (1,389,102) | (635,047) |
| Payments for settlement of forward rate agreement related to bonds | | (34,830) | — |
| Acquisition of treasury shares | | (2,138) | (52,538) |
| Interest paid | | (84,185) | (84,917) |
| Dividends paid | | (274,679) | (273,024) |
| Repayments of lease liabilities | | (27,710) | (29,904) |
| Other, net | | (156) | (366) |
| Net cash used in financing activities | | (718,282) | (826,465) |
| Net decrease in cash and cash equivalents | | (8,112) | (251,430) |
| Cash and cash equivalents at the beginning of the year | | | |
| (Consolidated statements of financial position) | | 637,614 | 966,222 |
| Effects of exchange rate changes on cash and cash equivalents | | (11,797) | 9,549 |
| Cash and cash equivalents at the end of the period | | 617,705 | 724,341 |
| Cash and cash equivalents reclassified to assets held for sale | | (70) | — |
| Cash and cash equivalents at the end of the period | | | |
| (Consolidated statements of financial position) | | 617,635 | 724,341 |

See accompanying notes to condensed interim consolidated financial statements.

**Notes to Condensed Interim 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

(1) Compliance

Takeda has prepared the condensed interim consolidated financial statements in accordance with IAS 34 "Interim Financial Reporting" as issued by the International Accounting Standards Board ("IASB").

The condensed interim consolidated financial statements do not contain all the information required in consolidated financial statements as of the end of a fiscal year. Therefore, the condensed interim consolidated financial statements should be used with the consolidated financial statements as of and for the fiscal year ended March 31, 2021.

(2) Approval of Financial Statements

Takeda's condensed interim consolidated financial statements as of and for the period ended December 31, 2021 were approved on February 10, 2022 by Representative Director, President & Chief Executive Officer ("CEO") Christophe Weber and Director & Chief Financial Officer Costa Saroukos.

(3) Functional Currency and Presentation Currency

The condensed interim 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, except when otherwise indicated. In tables with rounded figures, sums may not add up due to rounding.

(4) Use of Judgments, Estimates and Assumptions

The preparation of the condensed interim consolidated financial statements requires management to make certain judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, revenues and expenses, as well as 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.

The condensed interim consolidated financial statements are prepared based on the same judgments and estimations as well as the accounting estimates and assumptions applied and described in Takeda's consolidated financial statements for the fiscal year ended March 31, 2021.

Although the COVID-19 pandemic could potentially impact business activities within Takeda due to its further spread, the overall impact on Takeda's condensed interim 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 condensed interim consolidated financial statements. Takeda will continue to reassess estimates and assumptions as the situation evolves.

## 3. Significant Accounting Policies

Significant accounting policies adopted for the condensed interim consolidated financial statements are the same as those adopted for the consolidated financial statements of the fiscal year ended March 31, 2021.

Takeda calculated income tax expenses for the nine-month period ended December 31, 2021, based on the estimated average annual effective tax rate.

## 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.

(1) 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) Nine-month Period Ended December 31, | |
|---|---|---|
| | 2020 | 2021 |
| Sales of pharmaceutical products | 2,358,501 | 2,485,164 |
| Out-licensing and service income | 69,037 | 210,552 |
| Total | 2,427,538 | 2,695,717 |

| | JPY (millions) Three-month period ended December 31, | |
|---|---|---|
| | 2020 | 2021 |
| Sales of pharmaceutical products | 813,997 | 873,882 |
| Out-licensing and service income | 22,756 | 27,412 |
| Total | 836,753 | 901,294 |

*Revenue by Therapeutic Area and Product*

| | JPY (millions) Nine-month Period Ended December 31, | |
|---|---|---|
| | 2020 | 2021 |
| Gastroenterology: | | |
| ENTYVIO | 319,307 | 395,373 |
| TAKECAB-F [(1)] | 64,134 | 78,373 |
| GATTEX/REVESTIVE | 50,149 | 56,635 |
| DEXILANT | 43,458 | 40,136 |
| PANTOLOC/CONTROLOC [(2)] | 32,383 | 30,068 |
| ALOFISEL | 565 | 1,353 |
| Others | 78,815 | 63,745 |
| Total Gastroenterology | 588,811 | 665,683 |
| Rare Diseases: | | |
| Rare Metabolic: | | |
| ELAPRASE | 51,531 | 57,714 |
| REPLAGAL | 38,874 | 39,568 |
| VPRIV | 28,868 | 32,171 |
| NATPARA/NATPAR | 2,503 | 3,926 |
| Total Rare Metabolic | 121,776 | 133,378 |
| Rare Hematology: | | |
| ADVATE | 97,112 | 89,315 |
| ADYNOVATE/ADYNOVI | 43,765 | 45,873 |
| FEIBA | 34,235 | 28,978 |
| RECOMBINATE | 10,457 | 9,586 |

| | JPY (millions) Nine-month Period Ended December 31, | |
|---|---|---|
| | 2020 | 2021 |
| Others | 33,005 | 37,840 |
| Total Rare Hematology | 218,574 | 211,592 |
| Hereditary Angioedema: | | |
| TAKHZYRO | 65,891 | 78,425 |
| FIRAZYR | 20,100 | 21,471 |
| Others | 20,366 | 17,842 |
| Total Hereditary Angioedema | 106,357 | 117,738 |
| Others | — | 190 |
| Total Rare Diseases | 446,707 | 462,897 |
| PDT Immunology: | | |
| Immunoglobulin | 248,031 | 278,309 |
| Albumin | 43,599 | 61,490 |
| Others | 21,410 | 23,448 |
| Total PDT Immunology | 313,040 | 363,247 |
| Oncology: | | |
| VELCADE | 75,892 | 84,459 |
| LEUPLIN/ENANTONE | 75,255 | 82,215 |
| NINLARO | 67,863 | 70,747 |
| ADCETRIS | 44,385 | 51,786 |
| ICLUSIG | 26,259 | 26,687 |
| ALUNBRIG | 6,483 | 10,127 |
| Others | 22,325 | 33,075 |
| Total Oncology | 318,462 | 359,096 |
| Neuroscience: | | |
| VYVANSE/ELVANSE | 202,430 | 244,994 |
| TRINTELLIX | 52,680 | 63,030 |
| Others | 59,988 | 54,607 |
| Total Neuroscience | 315,098 | 362,630 |
| Other: | | |
| AZILVA-F [(1)] | 62,793 | 60,057 |
| LOTRIGA | 24,466 | 24,753 |
| Others [(3)] | 358,161 | 397,354 |
| Total Other | 445,420 | 482,163 |
| Total | 2,427,538 | 2,695,717 |

[(1)] The figures include the amounts of fixed dose combinations and blister packs.
[(2)] Generic name: pantoprazole
[(3)] The figure for the nine-month period ended December 31, 2020 includes the revenue of Takeda Consumer Healthcare Company Limited, which was divested on March 31, 2021.
The figure for the nine-month period ended December 31, 2021 includes the 133,043 million JPY selling price on sales of four diabetes products (NESINA, LIOVEL, INISYNC and ZAFATEK) in Japan to Teijin Pharma Limited recorded as revenue. As Takeda transferred only the assets, marketing rights and, eventually, marketing authorization associated with the pharmaceutical products which do not entail transfer of employees or associated contracts, Takeda applied IFRS 15 to the transaction and recorded the selling price in revenue.

| | JPY (millions) Three-month period ended December 31, | |
|---|---|---|
| | 2020 | 2021 |
| Gastroenterology: | | |
| ENTYVIO | 112,333 | 139,465 |
| TAKECAB-F [1] | 24,182 | 29,261 |
| GATTEX/REVESTIVE | 16,930 | 19,800 |
| DEXILANT | 15,055 | 14,432 |
| PANTOLOC/CONTROLOC [2] | 10,918 | 10,207 |
| ALOFISEL | 284 | 554 |
| Others | 29,283 | 22,874 |
| Total Gastroenterology | 208,985 | 236,594 |
| Rare Diseases: | | |
| Rare Metabolic: | | |
| ELAPRASE | 17,215 | 22,901 |
| REPLAGAL | 13,907 | 13,635 |
| VPRIV | 10,034 | 11,182 |
| NATPARA/NATPAR | 997 | 1,446 |
| Total Rare Metabolic | 42,153 | 49,164 |
| Rare Hematology: | | |
| ADVATE | 33,704 | 28,027 |
| ADYNOVATE/ADYNOVI | 14,264 | 15,906 |
| FEIBA | 13,663 | 8,804 |
| RECOMBINATE | 3,535 | 3,288 |
| Others | 10,599 | 13,981 |
| Total Rare Hematology | 75,765 | 70,005 |
| Hereditary Angioedema: | | |
| TAKHZYRO | 22,149 | 30,895 |
| FIRAZYR | 4,952 | 7,126 |
| Other | 6,326 | 5,461 |
| Total Hereditary Angioedema | 33,427 | 43,481 |
| Other | — | 190 |
| Total Rare Diseases | 151,345 | 162,839 |
| PDT Immunology: | | |
| Immunoglobulin | 85,364 | 96,992 |
| Albumin | 15,028 | 19,746 |
| Others | 6,748 | 8,481 |
| Total PDT Immunology | 107,140 | 125,219 |
| Oncology: | | |
| VELCADE | 25,880 | 29,350 |
| LEUPLIN/ENANTONE | 25,389 | 28,362 |
| NINLARO | 23,506 | 24,942 |
| ADCETRIS | 13,815 | 17,644 |
| ICLUSIG | 9,414 | 8,826 |
| ALUNBRIG | 2,215 | 3,888 |
| Others | 8,193 | 12,367 |
| Total Oncology | 108,412 | 125,380 |
| Neuroscience: | | |
| VYVANSE/ELVANSE | 69,810 | 85,714 |

| | JPY (millions) | |
|---|---|---|
| | Three-month period ended December 31, | |
| | 2020 | 2021 |
| TRINTELLIX | 17,725 | 22,980 |
| Others | 19,772 | 20,218 |
| Total Neuroscience | 107,307 | 128,912 |
| Other: | | |
| AZILVA-F [1] | 22,866 | 19,704 |
| LOTRIGA | 8,808 | 8,690 |
| Others [3] | 121,890 | 93,955 |
| Total Other | 153,564 | 122,350 |
| Total | 836,753 | 901,294 |

[1] The figures include the amounts of fixed dose combinations and blister packs.
[2] Generic name: pantoprazole
[3] The figure for the three-month period ended December 31, 2020 includes the revenue of Takeda Consumer Healthcare Company Limited, which was divested on March 31, 2021.

(2) Geographic Information

Takeda's revenue from contracts with customers is based in the following geographic locations:

| | JPY (millions) | |
|---|---|---|
| | Nine-month Period Ended December 31, | |
| | 2020 | 2021 |
| Japan | 435,112 | 530,245 |
| U.S. | 1,188,965 | 1,297,020 |
| Europe and Canada | 499,962 | 540,978 |
| Asia (excluding Japan) | 119,178 | 139,770 |
| Latin America | 95,414 | 93,545 |
| Russia/CIS | 38,724 | 43,582 |
| Other | 50,183 | 50,577 |
| Total | 2,427,538 | 2,695,717 |

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

| | JPY (millions) | |
|---|---|---|
| | Three-month period ended December 31, | |
| | 2020 | 2021 |
| Japan | 152,729 | 139,377 |
| U.S. | 402,847 | 458,644 |
| Europe and Canada | 172,801 | 187,007 |
| Asia (excluding Japan) | 40,887 | 50,063 |
| Latin America | 36,445 | 32,174 |
| Russia/CIS | 17,063 | 18,494 |
| Other | 13,981 | 15,536 |
| Total | 836,753 | 901,294 |

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

## 5. Other Operating Income

Other Operating Income for the nine-month period ended December 31, 2020 was 118,532 million JPY, including 60,179 million JPY revaluation gain triggered by an update to previously recognized liabilities for pipeline compound SHP647 and certain associated rights ("SHP647") to reflect a change in expected future costs, such as program termination costs, to reflect management's decision to terminate the clinical trial program following the European Commission's decision in May 2020 to release Takeda's obligation to divest SHP647. Takeda also recorded a 37,203 million JPY divestiture gain from divestiture of non-core assets in Asia Pacific, Europe, and Canada due to completion of the deals.

Other Operating Income for the nine-month period ended December 31, 2021 was 34,269 million JPY, including a gain from change in fair value of financial assets and liabilities associated with contingent consideration arrangements as well as a compensation for damages from a litigation and a legal settlement.

## 6. Other Operating Expenses

Other operating expenses was 155,090 million JPY and 100,034 million JPY for the nine-month period ended December 31, 2020 and 2021, respectively.

Restructuring expenses such as reductions in the workforce and consolidation of sites included in other operating expenses were 86,435 million JPY and 59,102 million JPY for the nine-month period ended December 31, 2020 and 2021, respectively. Restructuring expenses for the nine-month period ended December 31, 2020 and nine-month period ended December 31, 2021 included Shire integration costs related to the acquisition of Shire plc.

Other operating expenses also included 11,480 million JPY and 12,395 million JPY of pre-launch inventory write-offs for the nine-month period ended December 31, 2020 and 2021, respectively.

In addition, for the nine-month period ended December 31, 2020, Takeda recorded 18,666 million JPY loss from changes in the fair value of financial assets associated with contingent consideration arrangements driven by the impact of Novartis' withdrawal of the Marketing Authorisation Application in Europe for Xiidra (dry eye medication), which Takeda sold to Novartis in July 2019 (Note 14).

## 7. Share of Loss of Investments Accounted for Using the Equity Method

Share of loss of investments accounted for using the equity method for the nine-month period ended December 31, 2020 included a loss of 14,861 million JPY related to Takeda's shareholding ratio of the impairment loss recognized by Teva Takeda Pharma Ltd., a business venture of Takeda and Teva Pharmaceutical Industries Ltd., which operates the long listed products business and the generics business.

The impairment loss was recorded resulting from the reassessment of the recoverable amount of relevant assets triggered by the decision 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.

## 8. Income Tax Expenses

The effective tax rate for the nine-month period ended December 31, 2021 was 32.3% compared to 23.9% for the nine-month period ended December 31, 2020. This increase was primarily due to a tax charge of 64.6 billion JPY for tax and interest, net of 0.5 billion JPY of associated tax benefit, arising from tax assessment involving Irish taxation of the break fee Shire received from AbbVie in connection with the terminated offer to acquire Shire made by AbbVie in 2014. This increase was partially offset by an increase in tax credits and a decrease in unitary tax on overseas subsidiaries in the current period versus the same period of the previous year.

## 9. Earnings Per Share

The basis for calculating basic and diluted earnings per share (attributable to owners) is as follows:

| | Nine-month Period Ended December 31, | |
|---|---|---|
| | 2020 | 2021 |
| Net profit for the period attributable to owners of the Company | | |
| Net profit for the period attributable to owners of the Company (million JPY) | 178,907 | 241,417 |
| Net profit used for calculation of earnings per share (million JPY) | 178,907 | 241,417 |
| Weighted average number of ordinary shares outstanding during the period (thousands of shares) [basic] | 1,561,600 | 1,566,730 |
| Dilutive effect (thousands of shares) | 11,623 | 10,886 |
| Weighted average number of ordinary shares outstanding during the period (thousands of shares) [diluted] | 1,573,223 | 1,577,616 |
| Earnings per share | | |
| Basic earnings per share (JPY) | 114.57 | 154.09 |
| Diluted earnings per share (JPY) | 113.72 | 153.03 |

| | Three-month Period Ended December 31, | |
|---|---|---|
| | 2020 | 2021 |
| Net profit for the period attributable to owners of the Company | | |
| Net profit for the period attributable to owners of the Company (million JPY) | 92,359 | 57,770 |
| Net profit used for calculation of earnings per share (million JPY) | 92,359 | 57,770 |
| Weighted average number of ordinary shares outstanding during the period (thousands of shares) [basic] | 1,563,356 | 1,565,162 |
| Dilutive effect (thousands of shares) | 12,346 | 9,758 |
| Weighted average number of ordinary shares outstanding during the period (thousands of shares) [diluted] | 1,575,702 | 1,574,920 |
| Earnings per share | | |
| Basic earnings per share (JPY) | 59.08 | 36.91 |
| Diluted earnings per share (JPY) | 58.61 | 36.68 |

## 10. Trade and Other Receivables

In December 2021, Takeda put in place a program to sell certain trade receivables to a select group of banks on a non-recourse basis. Under this program, trade receivables sold are derecognized at the point of sale when the risks and rewards of ownership have been transferred.

Trade receivables due from customers that Takeda has the option to factor are classified as investments in debt instruments measured at fair value through other comprehensive income ("FVTOCI") since they are held to collect and sell. As of December 31, 2021, trade receivables measured at FVTOCI were 41,247 million JPY.

## 11. Disposal Groups Held for Sale

The disposal groups held for sale as of March 31, 2021 and December 31, 2021 consisted of a group of assets and liabilities such as related to a portfolio of non-core prescription pharmaceutical assets sold in China. As of December 31, 2021, the corresponding assets such as goodwill and intangible assets were 20,203 million JPY.

## 12. Bonds and Loans

(1) Bonds

During the nine-month period ended December 31, 2021, the Company issued unsecured bonds as outlined below.

Unsecured Senior Bonds

| | |
|---|---|
| Issue Amount | 250,000 million JPY |
| Coupon | 0.400% per annum |
| Issue Price | 100% of the principle amount |
| Maturity Date | October 14, 2031 |

During the nine-month period ended December 31, 2021, Takeda redeemed the following bonds in advance of the original maturity dates.

| Instrument | Issuance | Redemption date | Principal Amount in contractual currency |
|---|---|---|---|
| USD Unsecured Senior Notes | July 2017 | May 17, 2021 | 200 million USD |
| 2018 EUR Unsecured Senior Notes - fixed rate | November 2018 | August 10, 2021 | 1,500 million EUR |

(2) Loans

During the nine-month period ended December 31, 2021, Takeda prepaid the following borrowings in advance of the original maturity dates.

| Instrument | Issuance | Repayment date | Principal Amount in contractual currency |
|---|---|---|---|
| USD Japan Bank for International Cooperation 2019 | January 2019 | June 11, 2021 | 2,000 million USD |
| USD Japan Bank for International Cooperation 2019 | January 2019 | December 13, 2021 | 1,700 million USD |

## 13. Equity and Other Equity Items

(1) Issuance of shares

During the nine-month period ended December 31, 2021, the Company issued 3,874 thousand shares of common stock under the Long Term Incentive Plan for the Company Group employees overseas. The issuance of these shares resulted in an increase in share capital of 7,138 million JPY and share premium of 7,138 million JPY. The shares of the Company common stock were converted into the Company's American Depositary Shares and settled with employees.

(2) Acquisition of treasury shares

During the nine-month period ended December 31, 2021, Takeda acquired 15,336 thousand shares of its common stock for 49,980 million JPY in accordance with the resolution on the acquisition of its own shares at the Board of Directors Meeting held on October 28, 2021.

(3) Dividends

| Dividends declared and paid | Total dividends declared and paid JPY (millions) | Dividends per share (JPY) | Basis date | Effective date |
|---|---|---|---|---|
| April 1, 2020 to December 31, 2020 | | | | |
| Q1 2020 | 141,858 | 90.00 | March 31, 2020 | June 25, 2020 |
| Q3 2020 | 141,860 | 90.00 | September 30, 2020 | December 1, 2020 |
| April 1, 2021 to December 31, 2021 | | | | |
| Q1 2021 | 141,859 | 90.00 | March 31, 2021 | June 30, 2021 |
| Q3 2021 | 142,387 | 90.00 | September 30, 2021 | December 1, 2021 |

## 14. Financial Instruments

(1) Fair Value Measurements

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.

| | JPY (millions) | | | |
|---|---|---|---|---|
| As of December 31, 2021 | Level 1 | Level 2 | Level 3 | Total |
| Assets: | | | | |
| Financial assets measured at fair value through profit or loss | | | | |
| Derivatives | — | 37,687 | — | 37,687 |
| Investments in convertible notes | — | — | 10,779 | 10,779 |
| Investments in debt instruments | — | — | 1,052 | 1,052 |
| Financial assets associated with contingent consideration arrangements | — | — | 27,640 | 27,640 |
| Derivatives for which hedge accounting is applied | — | 13,307 | — | 13,307 |
| Financial assets measured at fair value through OCI | | | | |
| Trade receivables | — | 41,247 | — | 41,247 |
| Equity instruments | 82,572 | — | 57,010 | 139,583 |
| Total | 82,572 | 92,242 | 96,482 | 271,296 |
| | | | | |
| Liabilities: | | | | |
| Financial liabilities measured at fair value through profit or loss | | | | |
| Derivatives | — | 2,841 | — | 2,841 |
| Financial liabilities associated with contingent consideration arrangements | — | — | 20,237 | 20,237 |
| Derivatives for which hedge accounting is applied | — | 33,557 | — | 33,557 |
| Total | — | 36,398 | 20,237 | 56,635 |

(2) 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.

The fair value of the investment in convertible notes is measured using techniques such as the discounted cash flow and option pricing models.

The fair value of trade receivables, which are due from customers that Takeda has the option to factor, are measured based on invoiced amount.

Equity instruments 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 5.7 times to 10.2 times.

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 Note (5) Financial liabilities associated with contingent consideration arrangements.

(3) 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 nine-month period ended December 31, 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 nine-month period ended December 31, 2021, the companies listed their 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 nine-month period ended December 31, 2021. There were no other transfers between levels of the fair value hierarchy during the nine-month period ended December 31, 2021.

(4) Level 3 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 period ended December 31, 2021. The disclosure related to the Level 3 financial liabilities which are financial liabilities associated with contingent consideration arrangements are included in (5) 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) Nine-month Period Ended December 31, 2021 | |
|---|---|---|
| | Financial assets associated with contingent consideration arrangements | Equity instruments |
| As of the beginning of the period | 25,446 | 52,468 |
| Changes recognized as finance income | 665 | — |
| Changes in fair value of financial assets associated with contingent consideration due to other elements than time value | 545 | — |
| Changes in fair value of financial assets measured at fair value through OCI and exchange differences on translation of foreign operations | 984 | 20,692 |
| Purchases | — | 7,113 |
| Sales | — | (299) |
| Transfers to Level 1 | — | (21,674) |
| Transfers to investments accounted for using the equity method | — | (1,290) |
| As of the end of the period | 27,640 | 57,010 |

(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 December 31, 2021, the balance primarily relates to pre-existing contingent consideration arrangements from Shire's historical acquisition. 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. 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. The following table shows a reconciliation from the opening balances to the closing balances for financial liabilities associated with contingent consideration arrangements for the period ended December 31, 2021. There are no significant changes in fair value during the changes in certain assumptions which influence the fair value measurement for financial liabilities associated with contingent consideration arrangements.

| | JPY (millions) Nine-month Period Ended December 31, 2021 |
|---|---|
| As of the beginning of the period | 27,770 |
| Additions arising from business combinations | 6,110 |
| Changes in the fair value during the period | (8,567) |
| Settled during the period | (5,941) |
| Foreign currency translation differences | 865 |
| As of the end of the period | 20,237 |

(6) 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 condensed interim consolidated statements of financial position are as follows. 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 December 31, 2021 | |
| | Carrying amount | Fair value |
| Bonds | 3,653,673 | 3,890,646 |
| Long-term loans | 701,203 | 697,514 |

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.

## 15. Commitments and Contingent Liabilities

***Irish Revenue Commissioners assessment***

Shire received a tax assessment from the Irish Revenue Commissioners on November 28, 2018 for 398 million EUR. This assessment relates to the tax treatment of 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 appealed the assessment to the Tax Appeals Commission ("TAC") and the appeal was heard by the TAC in late 2020. On July 30, 2021 (IST), Takeda received a ruling on the matter from the TAC, with the TAC ruling in favor of Irish Revenue Commissioners. While Takeda intends to appeal the TAC ruling and continues to assert that the AbbVie break fee is not subject to Irish tax, Takeda has recorded a tax provision for 488 million EUR in current liabilities as income taxes payable, representing the 398 million EUR tax liability asserted by Irish Revenue Commissioners plus accrued interest for the nine-month period ended December 31, 2021.

***Litigation***

Takeda is involved in various legal and administrative proceedings. There were no significant updates during the nine-month period ended December 31, 2021 except for the matters below.

*Intellectual property*

**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 condensed interim 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 condensed interim consolidated statements of profit or loss.

## 16. Subsequent Events

On January 28, 2022, Takeda provided a notice of redemption to the holders of 1,500 million USD in unsecured U.S. dollar-denominated senior notes issued in September 2016 in advance of their original maturity date of September 23, 2023. The redemption date of the unsecured senior notes will be March 24, 2022. The impact from the accelerated debt prepayment on the consolidated statements of profit or loss is not expected to be material.

**2. Others**

*Interim Dividend*

In accordance with the provision of Article 29 of the Articles of Incorporation of the Company, Takeda made the following resolution on an interim dividend for the 145th fiscal year (from April 1, 2021 to March 31, 2022) at the meeting of the Board of Directors held on October 28, 2021, and paid the interim dividend.

| | | |
|---|---|---|
| (a) | Total amount of interim dividends | 142,387,003,440 JPY |
| (b) | Interim dividend per share | 90.00 JPY |
| (c) | Effective date/ Payment start date | December 1, 2021 |

## B. Information on Guarantors of the Company

Not applicable.