

Quarterly Securities Report

(The second quarter of 146th Business Term)
for The Six-month Period and Three-month
Quarter Ended September 30, 2022

TAKEDA PHARMACEUTICAL COMPANY LIMITED
AND ITS SUBSIDIARIES

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[Document Filed]	Quarterly Securities Report
[Applicable Law]	Article 24-4-7, paragraph 1 of the Financial Instruments and Exchange Act of Japan
[Filed with]	Director, Kanto Local Finance Bureau
[Filing Date]	November 4, 2022
[Fiscal period]	The second quarter of 146th Business Term (from July 1, 2022 to September 30, 2022)
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A. Company Information

I. Overview of Takeda

1. Key Consolidated Financial Data

Term	JPY (millions), unless otherwise indicated		
	Six-month period ended September 30,	Six-month period ended September 30,	For the year ended March 31,
	2021	2022	2022
Revenue	1,794,423	1,974,771	3,569,006
<Three-month period ended September 30>	844,819	1,002,307	
Profit before tax	284,425	220,022	302,571
Net profit for the period	183,721	166,753	230,166
Net profit attributable to owners of the Company	183,648	166,756	230,059
<Three-month period ended September 30>	45,964	61,742	
Total comprehensive income for the period	270,288	1,163,590	824,427
Total equity	5,324,361	6,713,489	5,683,523
Total assets	12,560,273	14,588,847	13,178,018
Basic earnings per share (JPY)	117.08	107.62	147.14
<Three-month period ended September 30>	29.24	39.77	
Diluted earnings per share (JPY)	116.40	106.88	145.87
Ratio of equity attributable to owners of the Company to total assets (%)	42.4	46.0	43.1
Net cash from (used in) operating activities	400,011	305,234	1,123,105
Net cash from (used in) investing activities	(103,349)	(121,920)	(198,125)
Net cash from (used in) financing activities	(658,405)	(267,593)	(1,070,265)
Cash and cash equivalents at the end of the period	607,881	798,137	849,695

(Note 1) All amounts shown are rounded to the nearest million JPY.

(Note 2) The key consolidated financial data for the six-month period ended September 30, 2021 and 2022 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 and our group companies for the six-month period ended September 30, 2022.

As of September 30, 2022, Takeda consisted of 220 entities comprised of 201 consolidated subsidiaries (including partnerships), 18 associates accounted for using the equity method, and Takeda Pharmaceutical Company Limited.

Change in the major group companies was as follows:

During the three-month period ended September 30, 2022 Takeda deconsolidated Baxalta GmbH due to the merger into Takeda Pharmaceuticals International AG, a consolidated subsidiary.

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II. Operating and Financial Review

1. Risk Factors

For the six-month period ended September 30, 2022, 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, 2022 which was filed in Japan.

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

(1) Consolidated Financial Results (April 1 to September 30, 2022)

	Billion JPY or percentage				
	FY2021 H1	FY2022 H1	Change versus the same period of the previous fiscal year		
				Actual % Change	CER % Change*1
Revenue	1,794.4	1,974.8	180.3	10.1 %	(2.3)%
Cost of sales	(517.1)	(598.3)	(81.3)	15.7 %	3.9 %
Selling, general and administrative expenses	(431.9)	(480.2)	(48.4)	11.2 %	(1.4)%
Research and development expenses	(254.1)	(297.8)	(43.7)	17.2 %	1.4 %
Amortization and impairment losses on intangible assets associated with products	(205.5)	(273.6)	(68.1)	33.1 %	13.2 %
Other operating income	19.5	13.5	(6.1)	(31.0)%	(36.9)%
Other operating expenses	(59.4)	(83.4)	(23.9)	40.2 %	22.0 %
Operating profit	346.0	255.0	(91.0)	(26.3)%	(30.7)%
Finance income and (expenses), net	(58.0)	(33.6)	24.5	(42.2)%	(35.2)%
Share of loss of investments accounted for using the equity method	(3.5)	(1.4)	2.2	(61.3)%	(76.7)%
Profit before tax	284.4	220.0	(64.4)	(22.6)%	(29.2)%
Income tax expenses	(100.7)	(53.3)	47.4	(47.1)%	(44.1)%
Net profit for the period	183.7	166.8	(17.0)	(9.2)%	(21.1)%

*1 Please refer to (ii) Core Results (April 1 to September 30, 2022), Definition of Core financial measures and Constant Exchange Rate change, for the definition.

Revenue. Revenue for the six-month period ended September 30, 2022 was 1,974.8 billion JPY, an increase of 180.3 billion JPY, or 10.1% (CER % change: -2.3%), compared to the same period of the previous fiscal year. The increase is primarily attributable to growth from business momentum and favorable foreign exchange rates, offsetting the decrease of revenue in the current period due to the sale of a portfolio of diabetes products in Japan to Teijin Pharma Limited for 133.0 billion JPY, which was recorded as revenue in the same period of the previous fiscal year.

Revenue of our core therapeutic areas (i.e. Gastroenterology (“GI”), Rare Diseases, Plasma-Derived Therapies (“PDT”) Immunology, Oncology, and Neuroscience) increased by 315.6 billion JPY, or 22.0%, compared to the same period of the previous fiscal year, to 1,750.2 billion JPY. Each of our core therapeutic areas, except Oncology, contributed to positive revenue growth due to growth from business momentum and favorable foreign exchange rates. Generic erosion and intensified competition impacted certain Oncology products in the current period.

Revenue outside of our core therapeutic areas significantly decreased by 135.2 billion JPY, or 37.6%, compared to the same period of the previous fiscal year to 224.6 billion JPY, largely due to the aforementioned non-recurring 133.0 billion JPY selling price of the diabetes portfolio in Japan recorded as revenue in the same period of the previous fiscal year.

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Revenue by Geographic Region

The following shows revenue by geographic region:

Revenue:	Billion JPY or percentage				
	FY2021 H1	FY2022 H1	Change versus the same period of the previous fiscal year		
				Actual % change	CER % change ^{*1}
Japan ^{*2}	390.9	261.4	(129.5)	(33.1)%	(33.4)%
United States	838.4	1,032.5	194.1	23.2 %	3.2 %
Europe and Canada	354.0	409.0	55.0	15.5 %	8.3 %
Asia (excluding Japan)	89.7	105.7	16.0	17.8 %	3.8 %
Latin America	61.4	83.3	21.9	35.7 %	18.7 %
Russia/CIS	25.1	37.8	12.7	50.7 %	19.6 %
Other ^{*3}	35.0	45.1	10.1	28.8 %	36.7 %
Total	1,794.4	1,974.8	180.3	10.1 %	(2.3)%

*1 Please refer to Core Results (April 1 to September 30, 2022), Definition of Core financial measures and Constant Exchange Rate change, for the definition.

*2 The 133.0 billion JPY selling price of the sale of diabetes portfolio in Japan is included in the six-month period ended September 30, 2021.

*3 Other includes the Middle East, Oceania and Africa.

Revenue by Therapeutic Area

The following shows revenue by therapeutic area:

Revenue:	Billion JPY or percentage				
	FY2021 H1	FY2022 H1	Change versus the same period of the previous fiscal year		
				Actual % change	CER % change ^{*1}
GI	429.1	546.4	117.3	27.3 %	11.7 %
Rare Diseases	300.1	362.2	62.2	20.7 %	8.3 %
Rare Hematology	141.6	155.7	14.1	10.0 %	(1.5)%
Rare Genetics and Other	158.5	206.5	48.0	30.3 %	17.0 %
PDT Immunology	238.0	314.0	75.9	31.9 %	14.2 %
Oncology	233.7	225.3	(8.4)	(3.6)%	(11.5)%
Neuroscience	233.7	302.3	68.6	29.3 %	10.6 %
Other ^{*2}	359.8	224.6	(135.2)	(37.6)%	(41.1)%
Total	1,794.4	1,974.8	180.3	10.1 %	(2.3)%

*1 Please refer to Core Results (April 1 to September 30, 2022), Definition of Core financial measures and Constant Exchange Rate change, for the definition.

*2 The 133.0 billion JPY selling price of the sale of diabetes portfolio in Japan is included in the six-month period ended September 30, 2021.

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

- GI.** In Gastroenterology, revenue was 546.4 billion JPY, a year-on-year increase of 117.3 billion JPY, or 27.3% (CER % change: 11.7%). Growth was driven by Takeda's top-selling product ENTYVIO (for ulcerative colitis ("UC") and Crohn's disease ("CD")), with sales of 346.6 billion JPY and a year-on-year increase of 90.7 billion JPY, or 35.4%. Sales of ENTYVIO in the U.S. increased by 72.5 billion JPY, or 42.3%, to 243.8 billion JPY, driven by a continued increase in the first line biologic inflammatory bowel disease ("IBD") population both in UC and CD and favorable foreign exchange rates. Sales of ENTYVIO in Europe and Canada increased by 12.2 billion JPY, or 18.3%, to 78.8 billion JPY, supported by continued launches of the subcutaneous formulation. In the Growth and Emerging Markets, the increase in sales of ENTYVIO was led by growth in Brazil. Sales of DEXILANT (for acid reflux disease) were 38.0 billion JPY, an increase of 12.3 billion JPY, or 47.8% versus the same period of the previous fiscal year, due to the increased sales of authorized generics in the U.S. Sales of GATTEX/REVESTIVE (for short bowel syndrome) were 48.4 billion JPY, an increase of 11.6 billion JPY, or 31.5%, primarily due to increased market penetration and new country launches, including Japan in August 2021. Sales of TAKECAB/VOCINTI (for acid-related diseases) were 54.7 billion JPY, an increase of 5.6 billion JPY, or 11.4%, versus the same period of the previous fiscal year, primarily due to increased sales in China. In Japan, sales were 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, despite a negative impact associated with the market expansion re-pricing applied in April 2022. Sales of PENTASA (for UC) were 4.7 billion JPY, a decrease of 5.3 billion JPY, or 53.2%, versus the same period of the previous fiscal year due to generic erosion in the U.S. from May 2022.

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- *Rare Diseases.* In Rare Diseases, revenue was 362.2 billion JPY, a year-on-year increase of 62.2 billion JPY, or 20.7% (CER % change: 8.3%).

Revenue in Rare Hematology increased by 14.1 billion JPY, or 10.0% (CER % change: -1.5%), to 155.7 billion JPY. Sales of ADVATE (for hemophilia A), ADYNOVATE/ADYNOVI (for hemophilia A) and FEIBA (for hemophilia A and B) increased by 1.1 billion JPY or 1.8% to 62.4 billion JPY, 4.4 billion JPY or 14.8% to 34.4 billion JPY, and 1.1 billion JPY or 5.6% to 21.3 billion JPY, respectively, primarily due to favorable foreign exchange rates partially offset by negative impacts from competition in the U.S.

Revenue in Rare Genetics and Other was 206.5 billion JPY, a year-on-year increase of 48.0 billion JPY, or 30.3% (CER % change: 17.0%). Sales of TAKHZYRO (for hereditary angioedema) were 72.8 billion JPY, an increase of 25.3 billion JPY, or 53.2%, versus the same period of the previous fiscal year primarily due to expansion of the prophylactic market, continued geographic expansion and strong patient uptake as well as favorable foreign exchange rates. Sales of REPLAGAL (for Fabry disease) increased by 8.4 billion JPY, or 32.3%, to 34.3 billion JPY, primarily due to the succession to manufacturing and marketing rights in Japan by Takeda upon expiration of the relevant license agreement in February 2022. Sales of other enzyme replacement therapies ELAPRASE (for Hunter syndrome) and VPRIV (for Gaucher disease) increased by 7.6 billion JPY and 2.4 billion JPY, respectively, primarily due to increased sales in Growth and Emerging Markets. Sales of LIVTENCITY (for post-transplant cytomegalovirus (“CMV”) infection/disease), which was launched in the U.S. in December 2021, were 4.2 billion JPY in the current period.

- *PDT Immunology.* In Plasma-Derived Therapies (“PDT”) Immunology, revenue increased by 75.9 billion JPY, or 31.9% (CER % change: 14.2%) compared to the same period of the previous fiscal year, to 314.0 billion JPY. Aggregate sales of immunoglobulin products were 245.1 billion JPY, an increase of 63.7 billion JPY, or 35.2%, compared to the same period of the previous fiscal year. Sales of each of our three global immunoglobulin brands marked double digit percentage of revenue growth, due to continued strong demand globally and growing supply, especially in the U.S., where the pandemic pressure is now easing, as well as favorable foreign exchange rates. Those include GAMMAGARD LIQUID/KIOVIG (for the treatment of primary immunodeficiency (“PID”) and multifocal motor neuropathy (“MMN”)), and subcutaneous immunoglobulin therapies (CUVITRU and HYQVIA) which are growing due to their benefit to patients and convenience in administration compared to intravenous therapies. Aggregate sales of albumin products including HUMAN ALBUMIN and FLEXBUMIN (primarily used for hypovolemia and hypoalbuminemia) were 51.8 billion JPY, an increase of 10.0 billion JPY, or 24.0%, versus the same period of the previous fiscal year driven by strong albumin demand in Europe and in Growth and Emerging Markets.
- *Oncology.* In Oncology, revenue was 225.3 billion JPY, a year-on-year decrease of 8.4 billion JPY, or 3.6% (CER % change: -11.5%), impacted by the rapid generic erosion of VELCADE (for multiple myeloma) sales in the U.S. Sales of VELCADE decreased by 34.3 billion JPY, or 62.2%, versus the same period of the previous fiscal year to 20.8 billion JPY predominantly due to multiple generic entrants in the U.S. starting in May 2022. Sales of NINLARO (for multiple myeloma) were 48.8 billion JPY, an increase of 3.0 billion JPY, or 6.6%, versus the same period of the previous fiscal year, aided by favorable foreign exchange rates, which were offset partially by intensified competition and decreased demand mainly in the U.S. Sales of ADCETRIS (for malignant lymphomas) were 41.7 billion JPY, an increase of 7.6 billion JPY, or 22.2%, versus the same period of the previous fiscal year, led by strong growth in countries such as Italy and China. Sales of ICLUSIG (for leukemia) were 23.2 billion JPY, an increase of 5.4 billion JPY, or 30.0%, versus the same period of the previous fiscal year, due to steady growth in the U.S. and also aided by favorable foreign exchange rates. Sales of ALUNBRIG (for non-small cell lung cancer) were 9.7 billion JPY, an increase of 3.5 billion JPY, or 55.6%, benefitting from strong demand in the Growth and Emerging Markets and in Europe. Sales of EXKIVITY (for non-small cell lung cancer), which launched in the U.S. in September 2021, were 1.4 billion JPY in the current period.
- *Neuroscience.* In Neuroscience, revenue was 302.3 billion JPY, a year-on-year increase of 68.6 billion JPY, or 29.3% (CER % change: 10.6%). Sales of VYVANSE/ELVANSE (for attention deficit hyperactivity disorder (“ADHD”)) were 211.2 billion JPY, an increase of 52.0 billion JPY, or 32.6%, versus the same period of the previous fiscal year mainly driven by the growth of the adult market in the U.S. and favorable foreign exchange rates. Sales of TRINTELLIX (for major depressive disorder (“MDD”)) were 49.8 billion JPY, an increase of 9.7 billion JPY, or 24.3%, versus the same period of the previous fiscal year, due to increasing prescriptions in the U.S. and in Japan. Sales of INTUNIV (for ADHD) increased by 3.0 billion JPY, or 39.9%, versus the same period of the previous fiscal year, to 10.5 billion JPY driven by an increase of sales in Japan. Sales of ADDERALL XR (for ADHD) also increased, by 2.9 billion JPY or 30.1% versus the same period of the previous fiscal year, to 12.5 billion JPY mainly due to sales increases in the U.S.

Cost of Sales. Cost of Sales increased by 81.3 billion JPY, or 15.7% (CER % change: 3.9%), to 598.3 billion JPY. The increase was primarily due to the depreciation of the yen and a sales increase in our core therapeutic areas as compared to the same period of the previous fiscal year. The Cost of Sales Ratio increased by 1.5 pp compared to the same period of the previous fiscal year to 30.3%. The main reason for the increase 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 in the same period of the previous fiscal year.

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Selling, General and Administrative (SG&A) expenses. SG&A expenses increased by 48.4 billion JPY, or 11.2% (CER % change: -1.4%) compared to the same period of the previous fiscal year, to 480.2 billion JPY, 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 43.7 billion JPY, or 17.2% (CER % change: 1.4%) compared to the same period of the previous fiscal year, to 297.8 billion JPY, mainly due to 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 68.1 billion JPY, or 33.1% (CER % change: 13.2%) compared to the same period of the previous fiscal year, to 273.6 billion JPY, mainly due to the impact from the depreciation of the yen in the current period and an increase in impairment charges for certain assets related to in-process R&D and marketed products.

Other Operating Income. Other Operating Income was 13.5 billion JPY, a decrease of 6.1 billion JPY, or 31.0% (CER % change: -36.9%), compared to the same period of the previous fiscal year primarily due to a 8.4 billion JPY change in fair value of financial assets and liabilities associated with contingent consideration arrangements recognized in the same period of the previous fiscal year

Other Operating Expenses. Other Operating Expenses were 83.4 billion JPY, an increase of 23.9 billion JPY, or 40.2% (CER % change: 22.0%), compared to the same period of the previous fiscal year, primarily due to increases in reserves and provisions during the current period, including a 12.9 billion JPY increase of valuation reserve for pre-launch inventory, partially offset by a decrease in restructuring expenses attributable to the decrease in Shire integration costs.

Operating Profit. As a result of the above factors, Operating Profit decreased by 91.0 billion JPY, or 26.3% (CER % change: -30.7%) compared to the same period of the previous fiscal year to 255.0 billion JPY.

Net Finance Expenses. Net Finance Expenses were 33.6 billion JPY in the current period, a decrease of 24.5 billion JPY, or 42.2% (CER % change: -35.2%) compared to Net Finance Expenses of 58.0 billion JPY for the same period of the previous fiscal year. Included in the current period are a gain on prior equity method investments related to the acquisitions of GammaDelta Therapeutics and Adaptate Biotherapeutics in April 2022 as well as a derivative gain on the warrant to purchase stocks of a company that went public in May 2022 recorded in the current period.

Share of Loss of Investments Accounted for Using the Equity Method. Share of Loss of Investments Accounted for Using the Equity Method was 1.4 billion JPY, a decrease of 2.2 billion JPY, or 61.3% (CER % change: -76.7%), compared to the same period of the previous fiscal year.

Income Tax Expenses. Income Tax Expenses were 53.3 billion JPY, a decrease of 47.4 billion JPY, or 47.1% (CER % change: -44.1%), compared to the same period of the previous year. This decrease was primarily due to a tax charge of 63.7 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 in the same period of the previous year as well as tax benefits from recognition of deferred tax assets in the current period. These decreases were partially offset by the tax benefits from internal entity restructuring transactions in the same period of the previous year and tax charges from legal entity restructuring in the current period.

Net Profit for the Period. Net Profit for the Period decreased by 17.0 billion JPY, or 9.2% (CER % change: -21.1%), compared to the same period of the previous fiscal year to 166.8 billion JPY.

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Core Results (April 1 to September 30, 2022)

Definition of Core financial measures and Constant Exchange Rate change

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.

CER (Constant Exchange Rate) change eliminates the effect of foreign exchange rates from year-over-year comparisons by translating Reported or Core results for the current period using corresponding exchange rates in the same period of the previous fiscal year.

Results of Core Operations

	Billion JPY or percentage				
	FY2021 H1	FY2022 H1	Change versus the same period of the previous fiscal year		
				Actual % change	CER % change
Core Revenue	1,661.4	1,974.8	313.4	18.9 %	5.5 %
Core Operating Profit	485.7	625.2	139.4	28.7 %	14.5 %
Core EPS (yen)	214	288	74	34.6 %	15.8 %

Core Revenue for the six-month period ended September 30, 2022 was 1,974.8 billion JPY, an increase of 313.4 billion JPY, or 18.9% (CER % change: 5.5%), compared to the same period of the previous fiscal year. Core revenue for the six-month period ended September 30, 2021, was 1,661.4 billion JPY, which excluded the non-recurring 133.0 billion JPY selling price of the diabetes portfolio in Japan. There were no significant items unrelated to Takeda's core operations excluded from revenue in the current period, resulting in Core revenue for the current period being the same as Reported revenue at 1,974.8 billion JPY. Business momentum was led by Takeda's Growth and Launch Products* which totaled 759.8 billion JPY, a year-on-year increase of 205.3 billion JPY, or 37.0% (CER % change: 19.2%).

- * Takeda's Growth and Launch Products
 - GI: ENTYVIO, ALOFISEL
 - Rare Diseases: TAKHZYRO, LIVTENCITY
 - PDT Immunology: Immunoglobulin products including GAMMAGARD LIQUID/KIOVIG, HYQVIA, and CUVITRU,
Albumin products including HUMAN ALBUMIN and FLEXBUMIN
 - Oncology: ALUNBRIG, EXKIVITY
 - Other: SPIKEVAX Intramuscular Injection, NUVAXOVID Intramuscular Injection

Core Operating Profit for the current period was 625.2 billion JPY, an increase of 139.4 billion JPY or 28.7% (CER % change: 14.5%) compared to the same period of the previous fiscal year driven by revenue growth in our core therapeutic areas and the depreciation of the yen in the current period.

Core EPS for the current period was 288 yen, an increase of 74 yen, or 34.6% (CER % change: 15.8%), compared to the same period of the previous fiscal year.

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(2) Consolidated Financial Position

Assets. Total Assets as of September 30, 2022 were 14,588.8 billion JPY, reflecting an increase of 1,410.8 billion JPY compared to the previous fiscal year-end. Goodwill, Intangible Assets, and Property, Plant and Equipment increased by 586.9 billion JPY, 368.5 billion JPY, and 177.5 billion JPY respectively mainly due to the effect of foreign currency translation. In addition, Inventories increased by 100.3 billion JPY.

Liabilities. Total Liabilities as of September 30, 2022 were 7,875.4 billion JPY, reflecting an increase of 380.9 billion JPY compared to the previous fiscal year-end. Bonds and Loans increased by 391.2 billion JPY to 4,736.6 billion JPY* primarily due to the effect of foreign currency translation and Provisions increased by 56.1 billion JPY. These increases were partially offset by a decrease in Trade and Other Payables of 127.7 billion JPY.

* The carrying amount of Bonds was 3,996.3 billion JPY and Loans was 740.3 billion JPY as of September 30, 2022. 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 (1,301 million USD)	June 2015	June 2025 ~ June 2045	188.1
Unsecured US dollar denominated senior notes (4,000 million USD)	September 2016	September 2023 ~ September 2026	553.5
Unsecured Euro denominated senior notes (3,750 million EUR)	November 2018	November 2022 ~ November 2030	529.6
Unsecured US dollar denominated senior notes (3,250 million USD)	November 2018	November 2023 ~ November 2028	466.9
Hybrid bonds (subordinated bonds)	June 2019	June 2079	498.5
Unsecured US dollar denominated senior notes (7,000 million USD)	July 2020	March 2030 ~ July 2060	1,003.0
Unsecured Euro denominated senior notes (3,600 million EUR)	July 2020	July 2027 ~ July 2040	507.3
Unsecured JPY denominated senior bonds	October 2021	October 2031	249.4
Total			3,996.3

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	216.1
Bilateral loans	March 2016 ~ April 2017	March 2023 ~ March 2026	210.0
Other			0.7
Total			740.3

On April 23, 2022, Takeda redeemed 219 million USD of unsecured U.S. dollar-denominated senior notes issued in June 2015 in advance of their original maturity date of June 23, 2022.

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Equity. Total Equity as of September 30, 2022 was 6,713.5 billion JPY, an increase of 1,030.0 billion JPY compared to the previous fiscal year-end. This was primarily resulted from an increase of 977.0 billion JPY in Other Components of Equity mainly due to fluctuation in currency translation adjustments reflecting the depreciation of yen and an increase in Retained Earnings of 50.5 billion JPY. The increase in Retained Earnings was primarily attributable to Net Profit for the Period partially offset by the dividends payments of 138.2 billion JPY.

Consolidated Cash Flows

	Billion JPY	
	FY2021 H1	FY2022 H1
Net cash from (used in) operating activities	400.0	305.2
Net cash from (used in) investing activities	(103.3)	(121.9)
Net cash from (used in) financing activities	(658.4)	(267.6)
Net increase (decrease) in cash and cash equivalents	(361.7)	(84.3)
Cash and cash equivalents at the beginning of the year	966.2	849.7
Effects of exchange rate changes on cash and cash equivalents	3.4	32.7
Cash and cash equivalents at the end of the period	607.9	798.1

Net cash from operating activities was 305.2 billion JPY for the current period compared to 400.0 billion JPY for the same period of the previous year. The decrease of 94.8 billion JPY was primarily driven by a decrease in trade and other payables. This unfavorable impact was partially offset by higher net profit for the period adjusted for non-cash items and other adjustments reflecting sales increases in core therapeutic areas and favorable foreign exchange rates largely offset by the decrease of cash from the sale of Japan diabetes portfolio in the same period of prior fiscal year.

Net cash used in investing activities was 121.9 billion JPY for the current period compared to 103.3 billion JPY for the same period of the previous year. This increase of 18.6 billion JPY was mainly due to an increase of 42.4 billion JPY in acquisition of intangible assets and an increase of 10.8 billion JPY in acquisition of property, plant and equipment, partially offset by a decrease of 27.5 billion JPY in acquisition of business (net of cash and cash equivalents acquired).

Net cash used in financing activities was 267.6 billion JPY for the current period compared to 658.4 billion JPY for the same period of the previous year. The decrease of 390.8 billion JPY was mainly due to a decrease in repayments of bonds and long-term loans of 414.2 billion JPY, partially offset by an increase in purchase of treasury shares of 24.4 billion JPY resulting from the share buybacks conducted in the current period.

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(3) Management Policy, Management Environment and Management Issues

There was no significant change in management policy, management environment and management issues for the six-month period ended September 30, 2022.

Takeda's initiatives to mitigate the impact of COVID-19 and Takeda's operations in Ukraine and Russia are as follows.

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

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. While vaccines are becoming more broadly available, we continue to strictly adhere to local public health guidance across our geographies in addition to the internal protocols we have put in place, and monitor any potential impacts of the effects and evolution of COVID-19, including new variants, on our business activities.

Takeda is manufacturing NUVAXOVID Intramuscular Injection, a novel recombinant protein-based COVID-19 vaccine which was licensed, with manufacturing technologies transferred, from Novavax, at its Hikari facility and has been distributing it in Japan since May 2022. Also, Takeda will continue to provide distribution support in bringing an mRNA COVID-19 vaccine, SPIKEVAX Intramuscular Injection, to Japan through its partnership with Moderna.

Takeda's Operations in Ukraine and Russia

Our commitment to patients, regardless of where they live, and to our people is unwavering and is even more important in times of crisis. Takeda is making every effort to protect our colleagues in Ukraine and to continue to supply patients in Ukraine and in the region with much needed treatments.

Takeda discontinued activities in Russia that are not essential to maintaining the supply of medicines to patients and providing ongoing support to our employees. This includes suspending all new investments, suspending advertising and promotion, not initiating new clinical trials and stopping enrollment of new patients in ongoing clinical trials. Our focus only on essential activities is consistent with our values and ethical responsibility to our patients in Ukraine, Russia and the region who depend on our treatments. This commitment notwithstanding, we are adhering to all international sanctions imposed on Russia.

We will be increasing our humanitarian relief efforts, including monetary and medicine donations to benefit people affected by the conflict in Ukraine, and we will continue to assess new ways to provide support as we look to meet the needs of patients across the region.

In the six-month period ended September 30, 2022, revenue attributable to Russia/CIS represented 1.9% of Takeda's total consolidated revenue of 1,974.8 billion, as indicated in the Revenue by Region in II. Operating and Financial Review, 2. Analysis on Business Performance, Financial Position and Cash Flows, (1) Consolidated Financial Results (April 1 to September 30, 2022). There was no material financial impact on Takeda's financial results for the current period resulting from the crisis in these countries. However, depending on the future status of the crisis, our results of operations and financial conditions could be adversely affected.

(4) Research & Development Activities and Results

Research and development expenses for the six-month period ended September 30, 2022 were 297.8 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, including via our acquisition of Shire, we are working to harness the potential of cell and gene therapies by investing in new capabilities and next-generation platforms internally and through a network of partnerships. We are embracing data and digital technologies to improve the quality of innovation and accelerate execution.

Takeda's pipeline is positioned to support both the near-term and long-term sustained growth of the company. Once first approval of a product is achieved, Takeda R&D is equipped to support geographic expansions of such approval and approvals in 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 2022 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, 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 (e.g., modakafusp alfa (TAK-573) and subasumstat (TAK-981)) harnessing the power of the innate immune system, internally and through external partnerships.

ADCETRIS / Generic name: brentuximab vedotin

- In May 2022, Takeda announced that it received an approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) for a partial change in approved items of the manufacturing and marketing approval of ADCETRIS as a first-line treatment for CD30-positive Hodgkin lymphoma in pediatric patients.
- In May 2022, Takeda and Seagen Inc. announced the overall survival (OS) data from the Phase 3 ECHELON-1 clinical trial of an ADCETRIS plus chemotherapy combination. The data was presented in an oral session at the 59th American Society of Clinical Oncology (ASCO) Annual Meeting and at the 27th European Hematology Association (EHA) Annual Meeting. Data from the ECHELON-1 trial demonstrated a statistically significant improvement in OS in adult patients with previously untreated Stage III or IV classical Hodgkin lymphoma treated with ADCETRIS plus doxorubicin, vinblastine and dacarbazine (A+AVD) vs. doxorubicin, bleomycin, vinblastine, and dacarbazine (ABVD). With approximately six years median follow up (73 months), patients receiving A+AVD had a 41 percent reduction in the risk of death (hazard ratio [HR] 0.59; 95% confidence interval [CI]: 0.396 to 0.879), with an estimated OS rate (95% CI) of 93.9% (91.6, 95.5) at 6 years. The safety profile of ADCETRIS was consistent with previous studies, and no new safety signals were observed.

VECTIBIX / Generic name: panitumumab

- In June 2022, Takeda announced the data from the PARADIGM, a Phase 3 clinical trial of VECTIBIX in chemotherapy-naive Japanese patients with unresectable advanced recurrent colorectal cancer with wild-type *RAS* gene, was presented at the Plenary Session of the American Society of Clinical Oncology (ASCO) Annual Meeting. PARADIGM is the first prospective trial to evaluate appropriate treatment options for metastatic colorectal cancer patients with wild-type *RAS* gene and left-side primary tumor (descending colon, sigmoid colon, and rectum). The results of the trial showed that the mFOLFOX6 + VECTIBIX combination provides a statistically significant improvement in overall survival (OS) over the mFOLFOX6 + bevacizumab combination in patients with a left-sided primary tumor or regardless of tumor locations (median OS for left-sided tumors: 37.9 vs. 34.3, HR=0.82 [95.798% CI: 0.68-0.99], p=0.031, overall median OS: 36.2

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vs. 31.3, HR=0.84 [95% CI: 0.72-0.98], p=0.030). The safety profile of VECTIBIX administration in this study was similar to clinical study results previously published.

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 genetics and others, 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 like pabinafusp alfa for Hunter Syndrome. In addition, Takeda aims to redefine the management of post-transplant cytomegalovirus (CMV) infection/disease with LIVTENCITY. 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 April 2022, Takeda announced that the Phase 3 SPRING study evaluating the safety profile and pharmacokinetics of TAKHZYRO in patients 2 to <12 years of age is complete and has met its primary objectives. The safety profile was consistent with that seen in the clinical program for patients 12 years of age and older; there were no serious adverse events and no dropouts due to adverse events. The study also successfully reached the secondary objective evaluating the clinical activity/outcome of TAKHZYRO in preventing hereditary angioedema (HAE) attacks as well as characterizing the pharmacodynamics of TAKHZYRO in pediatric subjects 2 to <12 years of age.
- In July 2022, Takeda announced late-breaking data from the Phase 3 SPRING study presented at the European Academy of Allergy and Clinical Immunology (EAACI) Hybrid Congress 2022. The primary objective of the open-label, multicenter, Phase 3 (SPRING) study was to evaluate the safety and pharmacokinetics (PK) of TAKHZYRO in patients aged 2 to <12 years with HAE. Clinical outcomes (prevention of HAE attacks) were measured as a secondary objective. In this study, HAE patients received a dose of 150 mg every 4 weeks in patients 2 to <6 years and every 2 weeks in patients aged 6 to <12 years. TAKHZYRO reduced the rate of HAE attacks in children by a mean of 94.8% compared to baseline, from 1.84 attacks per month to 0.08 attacks during treatment. The majority of patients (76.2%) were attack-free during the 52-week treatment period with an average of 99.5% attack-free days. No deaths or serious treatment-emergent adverse events (TEAEs) were reported during the study, and no patients withdrew from the study due to TEAEs. These results are consistent with earlier studies with adult and adolescent patients. These data will be submitted to global regulatory authorities to evaluate a potential label expansion for TAKHZYRO to include the younger patient population.
- In October 2022, Takeda announced that the U.S. Food & Drug Administration (FDA) has accepted a supplemental Biologics License Application (sBLA) for the potential expanded use of TAKHZYRO for prophylaxis to prevent attacks of hereditary angioedema (HAE) in pediatric patients 2 to <12 years of age. The FDA has granted priority review of the application. If approved, TAKHZYRO could potentially become the first treatment of its kind for this population. The sBLA is based on data from the SPRING study, the open-label Phase 3 trial for HAE patients under the age of 12.

LIVTENCITY / Generic name: maribavir

- In April 2022, Takeda announced that it presented four company-sponsored abstracts on LIVTENCITY at the Tandem Transplantation & Cellular Therapy Meetings in Salt Lake City, Utah, and the 32nd European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in Lisbon, Portugal. The abstracts include an exploratory analysis of the Phase 3 SOLSTICE trial showing LIVTENCITY-treated patients with post-transplant cytomegalovirus (CMV) infections/disease had reductions in hospitalizations (34.8%; p=0.021) and length of hospital stay (53.8%; p=0.029), compared to those treated with conventional antiviral therapies. In addition, a post-hoc, sub-group analysis of the Phase 3 SOLSTICE trial showed shorter time to first confirmed CMV DNA level less than the lower limit of quantification (<LLOQ) with LIVTENCITY, compared to conventional antiviral therapies, which was consistent with previously reported findings.
- In September 2022, Takeda announced the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended the approval of maribavir for the treatment of cytomegalovirus (CMV) infection

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and/or disease that are refractory (with or without resistance) to one or more prior therapies, including ganciclovir, valganciclovir, cidofovir or foscarnet in adult patients who have undergone a hematopoietic stem cell transplant (HSCT) or solid organ transplant (SOT). The European Commission (EC) will consider the CHMP positive opinion and decide upon potential marketing authorization in the coming months. If approved, maribavir would be the first inhibitor of CMV-specific UL97 protein kinase in the European Union (EU) for this indication. The positive opinion from the CHMP was based on the Phase 3 SOLSTICE trial, which evaluated the safety and efficacy of maribavir versus conventional antiviral therapies (one or more of ganciclovir, valganciclovir, foscarnet or cidofovir) for the treatment of patients with refractory CMV infection, with or without resistance.

ADYNOVATE/ADYNOVI / Generic name: antihemophilic factor (recombinant), PEGylated

- In June 2022, Takeda announced that it submitted a Supplemental New Drug Application (sNDA) of ADYNOVATE for a partial change in approved items of the manufacturing and marketing approval, which is for dosage and administration in prophylaxis use in Japan. The application is based primarily on the results of the global Phase 3 clinical trials, CONTINUATION study and PROPEL study.

FIRAZYR / Generic name: icatibant

- In August 2022, Takeda announced that it received an approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) for a partial change in approved items of the manufacturing and marketing approval for FIRAZYR as a treatment for pediatric patients two years of age or older with hereditary angioedema (HAE). The approval is based primarily on a Japanese Phase 3 open-label trial and a Phase 3 open-label trial outside of Japan evaluating the safety, efficacy and pharmacokinetics of subcutaneous administration of FIRAZYR in pediatric HAE patients aged between two and 18 years.

Development code: TAK-611

- In June 2022, Takeda announced that it has received Orphan Drug Designation from the Japanese Ministry of Health, Labour and Welfare (MLHW) for its recombinant human arylsulfatase A (rhASA) TAK-611 for the expected indication of Metachromatic Leukodystrophy (MLD). Currently, there are no treatments indicated for MLD in Japan. TAK-611 is an rhASA for enzyme replacement therapy for MLD, and global Phase 2b studies and other studies are ongoing.

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-861, TAK-925, etc.), and rare epilepsies with soticlestat (TAK-935). Additionally, Takeda also makes targeted investments to investigate well-defined segments of neuromuscular diseases, neurodegenerative diseases and movement disorders.

Development code: TAK-994

- In June 2022, Takeda decided not to proceed with further development activities of TAK-994 following an assessment of the benefit/risk profile. After a safety signal had emerged in Phase 2 studies of TAK-994 (TAK-994-1501 study and TAK-994-1504 study), in October 2021, Takeda had decided to stop both Phase 2 studies early.

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, a needle free device, and expanding into other indications such as active chronic pouchitis. Takeda is also expanding its position with GATTEX / REVESTIVE and ALOFISEL, which are in ongoing and planned Phase 3 trials to support further potential geographic expansion, including in the U.S. Furthermore, Takeda is progressing

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a pipeline built through partnerships exploring opportunities in IBD, celiac disease, select liver diseases, and motility disorders. Fazirsiran (TAK-999) is an example of an addition through partnership and a potential first-in-class RNAi for alpha-1 antitrypsin-deficiency associated liver disease in late-stage development.

Development code: TAK-999 / Generic name: fazirsiran

- In June 2022, Takeda and Arrowhead Pharmaceuticals Inc. announced that results from a Phase 2 clinical study (AROAAT-2002) of investigational fazirsiran for the treatment of liver disease associated with alpha-1 antitrypsin deficiency (AATD) were published in the New England Journal of Medicine (NEJM) and presented in an oral presentation at The International Liver Congress 2022 - The Annual Meeting of the European Association for the Study of the Liver (EASL). Fazirsiran is a potential first-in-class investigational RNA interference (RNAi) therapy designed to reduce the production of mutant alpha-1 antitrypsin protein (Z-AAT) as a potential treatment for the rare genetic liver disease associated with AATD. Fazirsiran was granted Breakthrough Therapy Designation (BTD) in July 2021 and Orphan Drug Designation in February 2018 for the treatment of AATD from the U.S. Food and Drug Administration (FDA).

Plasma-Derived Therapies (PDT)

Takeda has 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 (e.g. hypersialylated Immunoglobulin (hsIgG)) that would add to our diversified commercial portfolio of more than 20 therapeutic products distributed worldwide.

HYQVIA / Generic name: Immunoglobulin (IG) Infusion 10% (Human) w/ Recombinant Human Hyaluronidase

- In July 2022, Takeda announced that ADVANCE-1, a randomized, placebo-controlled, double-blind Phase 3 clinical trial evaluating HYQVIA for the maintenance treatment of chronic inflammatory demyelinating polyradiculoneuropathy (CIDP), met its primary endpoint. The pivotal ADVANCE-1 clinical trial evaluated the efficacy, safety and tolerability of HYQVIA in 132 adult patients with CIDP who had been on a stable dosing regimen of intravenous immunoglobulin (IVIG) therapy for at least three months prior to infusion. Analysis of the primary endpoint shows that HYQVIA, when administered at the same dose and dosing interval as the patient's previous IVIG, reduced CIDP relapse as compared to placebo [9.7% vs 31.4%, respectively; p-value = 0.0045], as measured by Inflammatory Neuropathy Cause and Treatment (INCAT). The majority of patients in the study received a four-week dosing regimen of HYQVIA. Of the 62 patients treated with HYQVIA, the majority of treatment-related adverse events were reported as mild or moderate. No new safety risks were reported with HYQVIA. The safety profile of HYQVIA in CIDP will be further supported by data from the ongoing ADVANCE-3 clinical trial, the longest extension study of its kind with up to six years of follow-up data on some participants. Upon full data analyses, Takeda intends to submit applications for HYQVIA to regulatory authorities in the United States and European Union in fiscal year 2022.

CUVITRU / Generic name: Immunoglobulin (IG) Infusion 20% (Human)

- In October 2022, Takeda announced that it submitted a New Drug Application (NDA) to the Japanese Ministry of Health, Labour and Welfare (MHLW) for manufacturing and marketing approval of a subcutaneous injection of 20% human immunoglobulin for the expected indications of agammaglobulinemia and hypogammaglobulinemia. The application is based primarily on a Phase 3 trial in Japanese patients with primary immunodeficiency syndrome (PID) and two Phase 2/3 trials outside of Japan in patients with PID. In these trials, the subcutaneous injection of 20% human immunoglobulin demonstrated its efficacy and safety as a treatment for patients with agammaglobulinemia or hypogammaglobulinemia.

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Vaccines

In Vaccines, Takeda is applying innovation to tackle some of the world's most challenging infectious diseases such as dengue (TAK-003), COVID-19 (NUVAXOVID), and zika (TAK-426). 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 2022, Takeda and Moderna, Inc. (Moderna) announced to transfer the marketing authorization in Japan for SPIKEVAX from Takeda to Moderna in Japan (Moderna Japan) as of August 1, 2022. Moderna Japan will assume responsibility for all SPIKEVAX activities, including import, local regulatory, development, quality assurance and commercialization. Takeda has agreed with Moderna that it will continue to provide distribution support under the current national vaccination campaign for Moderna COVID-19 vaccines for a transitional period.

NUVAXOVID Intramuscular Injection / Development code: NVX-CoV2373 (Japanese development code: TAK-019)

- In April 2022, Takeda announced that it has received manufacturing and marketing approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) for NUVAXOVID Intramuscular Injection (NUVAXOVID), a novel recombinant protein-based COVID-19 vaccine, for primary and booster immunization in individuals aged 18 and older. The approval is based on interim results from a Phase 1/2 study conducted by Takeda in Japan and several studies conducted by Novavax, including two pivotal Phase 3 clinical trials in the U.K., the U.S. and Mexico, Phase 1/2 studies in Australia and the U.S., as well as safety and efficacy data from outside of Japan which was subsequently submitted for review. Interim results from the Phase 1/2 study in Japan were positive and consistent with previously reported clinical trial results. No serious adverse events were reported in the NUVAXOVID treatment group, and the vaccine candidate was well-tolerated. Additionally, studies conducted by Novavax, including Phase 1/2 studies conducted in Australia and the U.S. as well as a Phase 2 study conducted in South Africa, evaluated safety and efficacy of booster immunization. In these studies, subjects received a booster dose 6 months after primary immunization, and compared to pre-booster levels, a significant elevation of antibody titer was observed without major safety concerns.
- In May 2022, Takeda announced that NUVAXOVID Intramuscular Injection (NUVAXOVID) has been designated as “special vaccination” status in Japan for primary (first and second dosing) and booster (third dosing) immunization following the revision of laws and regulations for COVID-19 vaccines specified under the Preventive Vaccination Law. NUVAXOVID is stored at refrigerated temperature of 2-8°C, like many other medicines and vaccines, which enables transportation and storage with conventional vaccine supply chain.

Development code: TAK-003 / Generic name: Dengue tetravalent vaccine [live,attenuated]

- In June 2022, Takeda announced that TAK-003 demonstrated continued protection against dengue fever through four and a half years (54 months), with no important safety risks identified, in the pivotal Phase 3 Tetravalent Immunization against Dengue Efficacy Study (TIDES) trial, which was presented at the 8th Northern European Conference on Travel Medicine (NECTM8). Through four and a half years, TAK-003 demonstrated 84.1% vaccine efficacy (VE) (95% CI: 77.8, 88.6) against hospitalized dengue, with 85.9% VE (78.7, 90.7) in seropositive individuals and 79.3% VE (63.5, 88.2) in seronegative individuals. TAK-003 also demonstrated overall VE of 61.2% (95% CI: 56.0, 65.8) against virologically-confirmed dengue, with 64.2% VE (58.4, 69.2) in seropositive individuals and 53.5% VE (41.6, 62.9) in seronegative individuals. Observations of VE varied by serotype and remained consistent with previously reported results. TAK-003 was generally well tolerated, and there were no important safety risks identified. No evidence of disease enhancement was observed over the 54-month follow-up exploratory analysis.
- In August 2022, Takeda announced that its dengue vaccine, QDENGAs, was approved by the Indonesian National Agency for Drug and Food Control, Badan Pengawas Obat dan Makanan (BPOM), for the prevention of dengue disease caused by any serotype in individuals six years to 45 years of age. QDENGAs is the only dengue vaccine approved in Indonesia for use in individuals regardless of previous dengue exposure and without the need for pre-vaccination testing. The approval of QDENGAs is based on results through three years after vaccination from the ongoing Phase 3 TIDES

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trial.

*QDenga is the approved brand name of TAK-003 in Indonesia.

- In October 2022, Takeda announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommended the approval of Takeda’s dengue vaccine candidate, TAK-003, for the prevention of dengue disease caused by any serotype in individuals four years of age and older in Europe and in dengue-endemic countries participating in the parallel EU-M4all procedure. The final step in the path to approval in Europe is Marketing Authorization from the EMA, which is expected in the coming months. Regulatory reviews will also progress in dengue-endemic countries in Latin America and Asia. CHMP’s positive opinion was supported by results across five Phase 1, 2 and 3 trials with more than 28,000 children and adults. This includes four and a half years of follow-up data from the global, pivotal Phase 3 TIDES trial, consistent with the World Health Organization’s (WHO) recommendation to obtain three to five years of follow-up data after the completion of a primary dengue vaccination in order to most accurately assess safety and efficacy.

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 October 2022, Takeda, Zedira GmbH and Dr. Falk Pharma GmbH announced a collaboration and licensing agreement to develop ZED1227/TAK-227, a Phase 2b investigational therapy for the treatment of celiac disease. TAK-227 is a potential first-in-class therapy designed to prevent the immune response to gluten in celiac disease, a serious autoimmune disease where the ingestion of gluten leads to inflammation and damage to the small intestine. There are currently no approved therapies for the treatment of celiac disease. TAK-227 is a selective, oral small molecule designed to inhibit tissue transglutaminase (TG2), an enzyme that generates immunogenic gluten peptide fragments upon the breakdown of gluten in the stomach and intestinal tissue. TAK-227 targets the dysregulated transglutaminase to prevent mucosal damage in the small intestine by preventing the body’s immune response to gluten, a disease process mediated by activation of gluten-specific T cells. Under the terms of the agreement, Takeda and Dr. Falk Pharma will conduct global clinical studies for TAK-227 in celiac disease. Takeda will receive an exclusive license to develop and commercialize TAK-227 in the United States and other territories outside of Europe, Canada, Australia and China.

(5) Major Facilities

The following is an significant change in new facility construction for the six-month period ended September 30, 2022.

Classification	Name or Subsidiaries’ Company Name [Main Location]	Operating Segment	Details	Budget* ¹		Financing	Schedule	
				Total JPY (millions)	Paid JPY (millions)		Commencement	Completion
Construction	Takeda Pharmaceuticals U.S.A., Inc. [Cambridge, MA, U.S.A.]	Pharmaceuticals	Research and office	252,103* ²	—	Funds on hand/ Lease	January 2023	October 2026
Construction	Baxalta Belgium Manufacturing S.A. [Lessines, Belgium]	Pharmaceuticals	Manufacturing and warehouse	41,085	3,249	Funds on hand	February 2022	December 2024

*1 The budget is calculated based on the exchange rates as of September 30, 2022.

*2 It includes a lease term payment obligation expected to start in 2025 based on a lease agreement we entered.

3. Material Contracts

There were no material contracts executed during the three-month period ended September 30, 2022.

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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 September 30, 2022)	Number of shares outstanding as of the filing date (November 4, 2022)	Stock exchange on which the Company is listed	Description
Common stock	1,582,288,725	1,582,290,825	Tokyo (Prime Market), Nagoya (Premier Market), Fukuoka, Sapporo, and New York	The number of shares per one unit of shares is 100 shares.
Total	1,582,288,725	1,582,290,825	—	—

(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 shares issued upon exercise of stock acquisition rights from November 1, 2022 to the filing date of Quarterly Securities Report (November 4, 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, 2022 to September 30, 2022	26	1,582,289	52	1,676,330	52	1,668,342

(Note1) The increases are due to the exercise of stock acquisition rights.

(Note2) The exercise of stock acquisition rights between October 1, 2022 to October 31, 2022 increased the number of shares issued by 2 thousand shares and the amount of share capital and legal capital surplus by 4 million JPY, respectively.

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(5) Major shareholders

		As of September 30, 2022	
Name	Address	Number of Shares Held (Thousands of Shares)	Percentage of Total Number of Shares Issued (Excluding Treasury Stocks) (%)
The Master Trust Bank of Japan, Ltd. (Trust account)	11-3, Hamamatsucho 2-chome, Minato-ku, Tokyo	261,229	16.74
Custody Bank of Japan, Ltd. (Trust account)	8-12, Harumi 1-chome, Chuo-ku, Tokyo	92,313	5.91
The Bank of New York Mellon as depositary bank for depositary receipt holders (Standing proxy: Sumitomo Mitsui Banking Corporation)	240 Greenwich Street, 8th Floor West, New York, NY 10286 U.S.A. (1-2, Marunouchi 1-chome, Chiyoda-ku, Tokyo)	64,730	4.15
JPMorgan Securities Japan Co., Ltd.	7-3, Marunouchi 2-chome, Chiyoda-ku, Tokyo	37,735	2.42
Nippon Life Insurance Company (Standing proxy: The Master Trust Bank of Japan, Ltd.)	6-6, Marunouchi 1-chome, Chiyoda-ku, Tokyo (11-3, Hamamatsucho 2-chome, Minato-ku, Tokyo)	29,447	1.89
State Street Bank West Client-Treaty 505234 (Standing proxy: Settlement & Clearing Services Department, Mizuho Bank, Ltd.)	1776 Heritage Drive, North Quincy, MA 02171, U.S.A. (15-1, Konan 2-chome, Minato-ku, Tokyo)	29,023	1.86
JP Morgan Chase Bank 385781 (Standing proxy: Settlement & Clearing Services Department, Mizuho Bank, Ltd.)	25 Bank Street, Canary Wharf, London, E14 5JP, United Kingdom (15-1, Konan 2-chome, Minato-ku, Tokyo)	20,305	1.30
Takeda Science Foundation	3-6, Doshomachi 2-chome, Chuo-ku, Osaka	17,912	1.15
SSBTC CLIENT OMNIBUS ACCOUNT (Standing proxy: Custody Business Department, Tokyo branch, The Hongkong and Shanghai Banking Corporation Limited)	One Lincoln Street, Boston, MA, U.S.A. 02111 (11-1, Nihonbashi 3-Chome, Chuo-ku, Tokyo)	17,794	1.14
State Street Bank and Trust Company 505225 (Standing proxy: Settlement & Clearing Services Department, Mizuho Bank, Ltd.)	P. O. Box 351 Boston MA 02101, U.S.A. (15-1, Konan 2-chome, Minato-ku, Tokyo)	15,895	1.02
Total		586,382	37.57

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(6) Information on voting rights

1) Total number of shares

Classification	As of September 30, 2022		
	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	21,465,000	—
	(Crossholding stock) Common stock	287,000	—
Shares with full voting rights (Others)	Common stock	1,559,214,300	15,592,143
Shares less than one unit	Common stock	1,322,425	—
			Shares less than one unit (100 shares)
Number of issued shares	1,582,288,725	—	—
Total number of voting rights	—	15,592,143	—

(Note1) "Shares with full voting rights (Others)" includes 3,982,500 (voting rights: 39,825) and 2,233,000 (voting rights: 22,330) of the shares held by the ESOP and BIP trust, respectively.

(Note2) "Shares less than one unit" includes 169 and 244 of the shares held by the ESOP and BIP trust, respectively.

(Note3) On July 7, 2022, Takeda conducted the disposal of 8,091,236 treasury shares based on the resolution made on June 10, 2022 by Christophe Weber, Representative Director and Chief Executive Officer, for the purpose of providing the Company's ADS to group employees overseas under the long-term incentive plan. Shares of common stock disposed were converted to the Company's ADS and provided to the employees.

2) Treasury stock and other

Name of shareholders	Address	As of September 30, 2022			
		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	21,465,000	—	21,465,000	1.36
(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		21,752,000	—	21,752,000	1.37

(Note) In addition to the above treasury stock, 3,982,669 of the shares held by the ESOP trust and 2,233,244 of the shares held by the BIP trust are included in treasury stock on the condensed interim consolidated financial statements.

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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).

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1. Condensed Interim Consolidated Financial Statements

(1) Condensed Interim Consolidated Statements of Profit or Loss

	Note	JPY (millions, except per share data)			
		Six-month Period Ended September 30,		Three-month Period Ended September 30,	
		2021	2022	2021	2022
Revenue	4	1,794,423	1,974,771	844,819	1,002,307
Cost of sales		(517,061)	(598,327)	(275,797)	(305,445)
Selling, general and administrative expenses		(431,854)	(480,214)	(212,011)	(248,734)
Research and development expenses		(254,081)	(297,752)	(131,600)	(154,145)
Amortization and impairment losses on intangible assets associated with products		(205,545)	(273,643)	(102,721)	(142,366)
Other operating income		19,535	13,476	8,417	7,997
Other operating expenses	5	(59,438)	(83,359)	(33,680)	(55,177)
Operating profit		345,979	254,953	97,427	104,438
Finance income		46,912	75,707	6,864	14,782
Finance expenses		(104,940)	(109,272)	(39,676)	(53,803)
Share of loss of investments accounted for using the equity method		(3,525)	(1,366)	(3,168)	(869)
Profit before tax		284,425	220,022	61,447	64,549
Income tax expenses	6	(100,704)	(53,269)	(15,452)	(2,817)
Net profit for the period		183,721	166,753	45,994	61,732
Attributable to:					
Owners of the Company		183,648	166,756	45,964	61,742
Non-controlling interests		73	(3)	31	(10)
Net profit for the period		183,721	166,753	45,994	61,732
Earnings per share (JPY)					
Basic earnings per share	7	117.08	107.62	29.24	39.77
Diluted earnings per share	7	116.40	106.88	29.08	39.48

See accompanying notes to condensed interim consolidated financial statements.

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(2) Condensed Interim Consolidated Statements of Comprehensive Income

	JPY (millions)			
	Six-month Period Ended September 30,		Three-month Period Ended September 30,	
	2021	2022	2021	2022
Net profit for the period	183,721	166,753	45,994	61,732
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	4,269	5,284	(11,607)	5,464
Remeasurement of defined benefit pension plans	(1,702)	13,395	(1,644)	2,862
	2,568	18,679	(13,252)	8,326
Items that may be reclassified subsequently to profit or loss:				
Exchange differences on translation of foreign operations	66,700	1,035,192	38,420	312,421
Cash flow hedges	11,553	(33,200)	(1,396)	(7,727)
Hedging cost	5,785	(22,749)	3,555	4,666
Share of other comprehensive income of investments accounted for using the equity method	(37)	(1,085)	(39)	(445)
	84,000	978,158	40,540	308,915
Other comprehensive income for the period, net of tax	86,568	996,837	27,289	317,241
Total comprehensive income for the period	270,288	1,163,590	73,283	378,973
Attributable to:				
Owners of the Company	270,198	1,163,535	73,242	378,964
Non-controlling interests	90	55	41	9
Total comprehensive income for the period	270,288	1,163,590	73,283	378,973

See accompanying notes to condensed interim consolidated financial statements.

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(3) Condensed Interim Consolidated Statements of Financial Position

	Note	JPY (millions)	
		As of March 31, 2022	As of September 30, 2022
ASSETS			
Non-current assets:			
Property, plant and equipment	8	1,582,800	1,760,327
Goodwill		4,407,749	4,994,632
Intangible assets		3,818,544	4,187,055
Investments accounted for using the equity method		96,579	96,872
Other financial assets		233,554	328,894
Other non-current assets		82,611	80,699
Deferred tax assets		362,539	394,752
Total non-current assets		10,584,376	11,843,231
Current assets:			
Inventories		853,167	953,450
Trade and other receivables		696,644	759,894
Other financial assets		25,305	31,932
Income taxes receivable		27,733	40,642
Other current assets		141,099	155,636
Cash and cash equivalents		849,695	798,137
Assets held for sale		—	5,925
Total current assets		2,593,642	2,745,616
Total assets		13,178,018	14,588,847
LIABILITIES AND EQUITY			
LIABILITIES			
Non-current liabilities:			
Bonds and loans	9	4,141,418	4,168,417
Other financial liabilities		468,943	548,344
Net defined benefit liabilities		145,847	136,318
Income taxes payable		21,634	27,483
Provisions		52,199	67,028
Other non-current liabilities		67,214	70,302
Deferred tax liabilities		451,511	465,746
Total non-current liabilities		5,348,764	5,483,638
Current liabilities:			
Bonds and loans	9	203,993	568,228
Trade and other payables		516,297	388,616
Other financial liabilities		196,071	113,079
Income taxes payable		200,918	189,568
Provisions		443,502	484,742
Other current liabilities		584,949	646,698
Liabilities held for sale		—	788
Total current liabilities		2,145,730	2,391,720
Total liabilities		7,494,495	7,875,358

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JPY (millions)

		JPY (millions)	
	Note	As of March 31, 2022	As of September 30, 2022
<u>EQUITY</u>			
Share capital	10	1,676,263	1,676,330
Share premium	10	1,708,873	1,695,544
Treasury shares	10	(116,007)	(100,313)
Retained earnings		1,479,716	1,530,200
Other components of equity		934,173	1,911,167
Equity attributable to owners of the company		5,683,019	6,712,929
Non-controlling interests		504	560
Total equity		5,683,523	6,713,489
Total liabilities and equity		13,178,018	14,588,847

See accompanying notes to condensed interim consolidated financial statements.

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(4) Condensed Interim Consolidated Statements of Changes in Equity

Six-month period ended September 30, 2021 (From April 1 to September 30, 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 other components of equity	Total equity attributable to owners of the Company	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					183,648							183,648	73	183,721
Other comprehensive income (loss)						66,578	4,337	11,553	5,785	(1,702)	86,551	86,551	17	86,568
Comprehensive income (loss) for the period		—	—	—	183,648	66,578	4,337	11,553	5,785	(1,702)	86,551	270,198	90	270,288
Transactions with owners:														
Issuance of new shares	10	8,118	14,036									22,154		22,154
Acquisition of treasury shares				(4,468)								(4,468)		(4,468)
Disposal of treasury shares			(0)	1								1		1
Dividends	10				(141,859)							(141,859)		(141,859)
Changes in ownership					(2,143)							(2,143)	(3,804)	(5,948)
Transfers from other components of equity					1,599		(3,301)			1,702	(1,599)	—		—
Share-based compensation			20,972									20,972		20,972
Exercise of share-based awards			(36,938)	22,982								(13,956)		(13,956)
Total transactions with owners		8,118	(1,931)	18,515	(142,404)	—	(3,301)	—	—	1,702	(1,599)	(119,300)	(3,804)	(123,104)
As of September 30, 2021		1,676,263	1,686,493	(41,037)	1,551,150	467,376	43,019	(56,522)	(2,807)	—	451,066	5,323,935	426	5,324,361

See accompanying notes to condensed interim consolidated financial statements.

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Six-month period ended September 30, 2022 (From April 1 to September 30, 2022)

JPY (millions)														
Equity attributable to owners of the Company														
	Note	Other components of equity										Non-controlling interests	Total equity	
		Share capital	Share premium	Treasury shares	Retained earnings	Exchange differences on translation of foreign operations	Changes in fair value of financial assets measured at fair value through other comprehensive income	Cash flow hedges	Hedging cost	Remeasurements of defined benefit pension plans	Total other components of equity			Total equity attributable to owners of the Company
As of April 1, 2022		1,676,263	1,708,873	(116,007)	1,479,716	984,141	22,068	(65,901)	(6,135)	—	934,173	5,683,019	504	5,683,523
Effect of hyperinflation					(1,960)	4,121					4,121	2,161		2,161
Restated opening balance		1,676,263	1,708,873	(116,007)	1,477,756	988,263	22,068	(65,901)	(6,135)	—	938,294	5,685,180	504	5,685,684
Net profit for the period					166,756						—	166,756	(3)	166,753
Other comprehensive income (loss)						1,034,071	5,262	(33,200)	(22,749)	13,395	996,779	996,779	58	996,837
Comprehensive income (loss) for the period		—	—	—	166,756	1,034,071	5,262	(33,200)	(22,749)	13,395	996,779	1,163,535	55	1,163,590
Transactions with owners:														
Issuance of new shares		67	67								—	133		133
Acquisition of treasury shares	10		(5)	(27,051)							—	(27,057)		(27,057)
Disposal of treasury shares			0	0							—	1		1
Dividends	10				(138,217)						—	(138,217)		(138,217)
Transfers from other components of equity					23,906		(10,510)			(13,395)	(23,906)	—		—
Share-based compensation			29,335								—	29,335		29,335
Exercise of share-based awards	10		(42,725)	42,745							—	19		19
Total transactions with owners		67	(13,329)	15,694	(114,311)	—	(10,510)	—	—	(13,395)	(23,906)	(135,786)	—	(135,786)
As of September 30, 2022		1,676,330	1,695,544	(100,313)	1,530,200	2,022,333	16,819	(99,101)	(28,884)	—	1,911,167	6,712,929	560	6,713,489

See accompanying notes to condensed interim consolidated financial statements.

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(5) Condensed Interim Consolidated Statements of Cash Flows

	Notes	JPY (millions)	
		Six-month Period Ended September 30,	
		2021	2022
Cash flows from operating activities:			
Net profit for the period		183,721	166,753
Depreciation and amortization		283,595	326,110
Impairment losses		1,489	35,950
Equity-settled share-based compensation		20,972	29,335
Loss on sales and disposal of property, plant and equipment		219	145
Gain on divestment of business and subsidiaries		(730)	(640)
Change in fair value of financial assets and liabilities associated with contingent consideration arrangements, net		(8,099)	446
Finance (income) and expenses, net		58,028	33,565
Share of loss of investments accounted for using the equity method		3,525	1,366
Income tax expenses		100,704	53,269
Changes in assets and liabilities:			
Increase in trade and other receivables		(55,190)	(5,915)
Increase in inventories		(24,965)	(15,778)
Decrease in trade and other payables		(9,043)	(137,260)
Decrease in provisions		(63,512)	(12,939)
Increase (decrease) in other financial liabilities		1,023	(48,068)
Other, net		(17,856)	(11,887)
Cash generated from operations		473,883	414,451
Income taxes paid		(78,707)	(115,432)
Tax refunds and interest on tax refunds received		4,835	6,215
Net cash from operating activities		400,011	305,234
Cash flows from investing activities:			
Interest received		2,126	1,456
Dividends received		142	2,415
Acquisition of property, plant and equipment		(60,601)	(71,423)
Proceeds from sales of property, plant and equipment		389	97
Acquisition of intangible assets		(25,182)	(67,562)
Acquisition of investments		(3,591)	(4,694)
Proceeds from sales and redemption of investments		10,070	18,400
Acquisition of businesses, net of cash and cash equivalents acquired		(27,549)	—
Proceeds from sales of business, net of cash and cash equivalents divested		2,138	—
Other, net		(1,292)	(609)
Net cash used in investing activities		(103,349)	(121,920)

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	Notes	JPY (millions)	
		Six-month Period Ended September 30,	
		2021	2022
Cash flows from financing activities:			
Net decrease in short-term loans and commercial papers		(1)	—
Repayments of bonds and long-term loans		(441,072)	(26,900)
Acquisition of treasury shares		(2,542)	(26,929)
Interest paid		(52,668)	(52,719)
Dividends paid		(141,573)	(140,007)
Repayments of lease liabilities		(20,536)	(20,996)
Other, net		(13)	(42)
Net cash used in financing activities		(658,405)	(267,593)
Net decrease in cash and cash equivalents		(361,743)	(84,278)
Cash and cash equivalents at the beginning of the year		966,222	849,695
Effects of exchange rate changes on cash and cash equivalents		3,402	32,720
Cash and cash equivalents at the end of the period		607,881	798,137

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 a diverse portfolio, engaged primarily in the research, development, production and global commercialization of pharmaceutical products. Takeda’s principal pharmaceutical products include medicines in the following key business areas: gastroenterology (“GI”), rare diseases, Plasma-Derived Therapies (“PDT”) immunology, 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, 2022.

(2) Approval of Financial Statements

Takeda’s condensed interim consolidated financial statements as of and for the period ended September 30, 2022 were approved on November 4, 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, 2022.

Although the COVID-19 pandemic could potentially impact business activities within Takeda, 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 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, 2022.

Takeda calculated income tax expenses for the six-month period ended September 30, 2022, based on the estimated average annual effective tax rate.

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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)	
	Six-month Period Ended September 30,	
	2021	2022
Sales of pharmaceutical products	1,611,282	1,914,400
Out-licensing and service income	183,141	60,371
Total	1,794,423	1,974,771

	JPY (millions)	
	Three-month period ended September 30,	
	2021	2022
Sales of pharmaceutical products	819,371	975,506
Out-licensing and service income	25,448	26,801
Total	844,819	1,002,307

Revenue by Therapeutic Area and Product

	JPY (millions)	
	Six-month Period Ended September 30,	
	2021	2022
Gastroenterology:		
ENTYVIO	255,908	346,616
TAKECAB/VOCINTI ⁽¹⁾	49,111	54,695
GATTEX/REVESTIVE	36,835	48,434
DEXILANT	25,704	37,990
PANTOLOC/CONTROLOC ⁽²⁾	19,861	22,206
ALOFISEL	798	1,135
Others	40,871	35,314
Total Gastroenterology	429,088	546,391
Rare Diseases:		
Rare Hematology:		
ADVATE	61,289	62,368
ADYNOVATE/ADYNOVI	29,967	34,397
FEIBA	20,174	21,295
RECOMBINATE	6,298	6,175
Others	23,860	31,484
Total Rare Hematology	141,587	155,718
Rare Genetics and Other:		
TAKHZYRO	47,530	72,827
ELAPRASE	34,813	42,414
REPLAGAL	25,933	34,308

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	JPY (millions)	
	Six-month Period Ended September 30,	
	2021	2022
VPRIV	20,988	23,339
LIVTENCITY	—	4,228
Others	29,206	29,392
Total Rare Genetics and Other	158,470	206,508
Total Rare Diseases	300,057	362,226
PDT Immunology:		
immunoglobulin	181,317	245,055
albumin	41,744	51,765
Others	14,967	17,157
Total PDT Immunology	238,028	313,977
Oncology:		
VELCADE	55,109	20,829
LEUPLIN/ENANTONE	53,853	53,657
NINLARO	45,805	48,819
ADCETRIS	34,142	41,715
ICLUSIG	17,861	23,216
ALUNBRIG	6,239	9,710
EXKIVITY	236	1,439
Others	20,472	25,906
Total Oncology	233,716	225,291
Neuroscience:		
VYVANSE/ELVANSE	159,280	211,235
TRINTELLIX	40,050	49,798
Others	34,389	41,281
Total Neuroscience	233,719	302,314
Other:		
AZILVA ⁽¹⁾	40,352	37,185
LOTRIGA	16,063	10,509
Others ⁽³⁾	303,398	176,878
Total Other	359,814	224,572
Total	1,794,423	1,974,771

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

⁽²⁾ Generic name: pantoprazole

⁽³⁾ The figure for the six-month period ended September 30, 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.

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	JPY (millions)	
	Three-month period ended September 30,	
	2021	2022
Gastroenterology:		
ENTYVIO	130,538	178,349
TAKECAB/VOCINTI ⁽¹⁾	24,843	27,057
GATTEX/REVESTIVE	18,712	26,518
DEXILANT	14,916	15,660
PANTOLOC/CONTROLOC ⁽²⁾	9,415	10,869
ALOFISEL	411	517
Others	19,748	17,038
Total Gastroenterology	218,583	276,009
Rare Diseases:		
Rare Hematology:		
ADVATE	30,626	30,262
ADYNOVATE/ADYNOVI	14,594	16,886
FEIBA	8,772	10,761
RECOMBINATE	2,610	2,954
Others	12,786	15,725
Total Rare Hematology	69,388	76,587
Rare Genetics and Other:		
TAKHZYRO	22,061	38,778
ELAPRASE	16,214	20,220
REPLAGAL	11,883	16,708
VPRIV	10,537	11,474
LIVTENCITY	—	2,014
Others	14,507	14,806
Total Rare Genetics and Other	75,202	103,999
Total Rare Diseases	144,591	180,586
PDT Immunology:		
immunoglobulin	99,709	133,233
albumin	23,985	29,774
Others	7,137	9,108
Total PDT Immunology	130,831	172,115
Oncology:		
VELCADE	24,980	4,348
LEUPLIN/ENANTONE	27,640	25,664
NINLARO	21,435	25,071
ADCETRIS	16,914	21,751
ICLUSIG	7,492	11,961
ALUNBRIG	3,125	5,167
EXKIVITY	236	737
Others	10,511	13,110
Total Oncology	112,335	107,809
Neuroscience:		
VYVANSE/ELVANSE	80,068	111,263
TRINTELLIX	22,182	28,364
Others	18,058	20,270
Total Neuroscience	120,307	159,897

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Other:		
AZILVA ⁽¹⁾	17,706	17,629
LOTRIGA	8,236	2,096
Others ⁽³⁾	92,230	86,166
Total Other	118,173	105,891
Total	844,819	1,002,307

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

⁽²⁾ Generic name: pantoprazole

(2) Geographic Information

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

	JPY (millions)	
	Six-month Period Ended September 30,	
	2021	2022
Japan	390,868	261,353
U.S.	838,376	1,032,526
Europe and Canada	353,970	408,964
Asia (excluding Japan)	89,706	105,718
Latin America	61,372	83,258
Russia/CIS	25,088	37,817
Other	35,041	45,135
Total	1,794,423	1,974,771

“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 September 30,	
	2021	2022
Japan	131,906	120,818
U.S.	426,156	531,468
Europe and Canada	175,228	203,391
Asia (excluding Japan)	49,414	59,622
Latin America	31,312	42,973
Russia/CIS	12,752	20,451
Other	18,050	23,583
Total	844,819	1,002,307

“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 Expenses

Other operating expenses was 59,438 million JPY and 83,359 million JPY for the six-month period ended September 30, 2021 and 2022, respectively.

Restructuring expenses such as reductions in the workforce and consolidation of sites included in other operating expenses were 39,623 million JPY and 24,584 million JPY for the six-month period ended September 30, 2021 and 2022, respectively. Restructuring expenses for the six-month period ended September 30, 2021 were mainly comprised of Shire integration costs related to the acquisition of Shire plc.

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Other operating expenses also included 5,107 million JPY and 17,975 million JPY of pre-launch inventory write-offs for the six-month period ended September 30, 2021 and 2022, respectively.

6. Income Tax Expenses

The effective tax rate for the six-month period ended September 30, 2022 was 24.2% compared to 35.4% for the six-month period ended September 30, 2021, mainly due to a tax charge of 63.7 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 for the six-month period ended September 30, 2021 as well as tax benefits from recognition of deferred tax assets for the six-month period ended September 30, 2022. These were partially offset by the tax benefits from internal entity restructuring transactions for the six-month period ended September 30, 2021 and tax charges from legal entity restructuring for the six-month period ended September 30, 2022.

7. Earnings Per Share

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

	Six-month Period Ended September 30,	
	2021	2022
Net profit for the period attributable to owners of the Company		
Net profit for the period attributable to owners of the Company (million JPY)	183,648	166,756
Net profit used for calculation of earnings per share (million JPY)	183,648	166,756
Weighted average number of ordinary shares outstanding during the period (thousands of shares) [basic]	1,568,498	1,549,479
Dilutive effect (thousands of shares)	9,296	10,723
Weighted average number of ordinary shares outstanding during the period (thousands of shares) [diluted]	1,577,794	1,560,202
Earnings per share		
Basic earnings per share (JPY)	117.08	107.62
Diluted earnings per share (JPY)	116.40	106.88

	Three-month Period Ended September 30,	
	2021	2022
Net profit for the period attributable to owners of the Company		
Net profit for the period attributable to owners of the Company (million JPY)	45,964	61,742
Net profit used for calculation of earnings per share (million JPY)	45,964	61,742
Weighted average number of ordinary shares outstanding during the period (thousands of shares) [basic]	1,571,786	1,552,407
Dilutive effect (thousands of shares)	8,635	11,326
Weighted average number of ordinary shares outstanding during the period (thousands of shares) [diluted]	1,580,421	1,563,733
Earnings per share		
Basic earnings per share (JPY)	29.24	39.77
Diluted earnings per share (JPY)	29.08	39.48

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8. Property, Plant and Equipment

In June 2022, the Company entered into a lease agreement for research and development and office space of a to be constructed building in Cambridge, Massachusetts, with an expected lease term starting in 2025. The base lease term is for 15 years, after which the Company has the option to renew the lease twice for 10 years each at market rates. In addition to payment obligations related to its share of operating expenses, utilities and taxes, the Company will have a base lease term payment obligation of 214,308 million JPY (1,486 million USD) to be paid over the course of the base lease term. Under certain conditions, the Company has the ability to terminate the lease agreement prior to the building being constructed.

9. Bonds and Loans

Bonds

During the six-month period ended September 30, 2022, 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	June 2015	April 23, 2022	219 million USD

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10. Equity and Other Equity Items

(1) Issuance of shares and disposal of treasury shares

During the six months period ended September 30, 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.

During the six months period ended September 30, 2022, the Company conducted the disposal of 8,091 thousand treasury shares under the Long Term Incentive Plan for the Company Group employees overseas. The disposal of treasury shares resulted in a decrease in treasury shares of 27,599 million JPY.

The shares of the Company common stock and treasury shares were converted into the Company's American Depositary Shares and settled with employees.

(2) Acquisition of treasury shares

During the six-month period ended September 30, 2022, Takeda acquired 6,908 thousand shares of its common stock for 24,993 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. Including its own shares acquired during the fiscal year ended March 31, 2022, Takeda acquired a total of 29,377 thousand shares of its common stock for 99,966 million JPY, and the acquisition in accordance with the resolution was completed.

(3) Dividends

Dividends declared and paid	Total dividends declared and paid JPY (millions)	Dividends per share (JPY)	Basis date	Effective date
April 1, 2021 to September 30, 2021				
Q1 2021	141,859	90.00	March 31, 2021	June 30, 2021
April 1, 2022 to September 30, 2022				
Q1 2022	140,365	90.00	March 31, 2022	June 30, 2022

Dividends declared for which the effective date falls in after September 30, 2022 are as follows:

Dividends declared	Total dividends declared JPY (millions)	Dividends per share (JPY)	Basis date	Effective date
Q3 2022	140,474	90.00	September 30, 2022	December 1, 2022

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11. 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.

As of September 30, 2022	JPY (millions)			
	Level 1	Level 2	Level 3	Total
Assets:				
Financial assets measured at fair value through profit or loss				
Derivatives	—	38,167	—	38,167
Investments in convertible notes	—	—	11,399	11,399
Investments in debt instruments	—	—	1,063	1,063
Financial assets associated with contingent consideration arrangements	—	—	28,208	28,208
Derivatives for which hedge accounting is applied	—	94,871	—	94,871
Financial assets measured at fair value through OCI				
Trade receivables	—	26,643	—	26,643
Equity instruments	76,490	—	81,007	157,497
Total	76,490	159,681	121,678	357,848
Liabilities:				
Financial liabilities measured at fair value through profit or loss				
Derivatives	—	1,574	—	1,574
Financial liabilities associated with contingent consideration arrangements	—	—	7,904	7,904
Derivatives for which hedge accounting is applied	—	13,496	—	13,496
Total	—	15,070	7,904	22,974

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(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 the invoiced amount.

Equity investments and investments in debt instruments are not held for trading. If equity instruments or investments in debt instruments are quoted in an active market, the fair value is based on price quotations at the period-end-date. If equity instruments or investments in debt instruments are not quoted in an active market, the fair value is calculated utilizing an adjusted book value per share method or EBITDA multiples approach based on available information as of each period-end-date and comparable companies. 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 2.7 times to 13.1 times.

Financial assets and liabilities associated with contingent consideration arrangements are measured 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 at 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 six-month period ended September 30, 2022. 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 six-month period ended September 30, 2022, 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 six-month period ended September 30, 2022. There were no other transfers between levels of the fair value hierarchy during the six-month period ended September 30, 2022.

(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 September 30, 2022. The disclosure related to 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.

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	JPY (millions)	
	Six-month Period Ended September 30, 2022	
	Financial assets associated with contingent consideration arrangements	Equity instruments
As of the beginning of the period	26,852	64,263
Changes recognized as finance income or finance expenses	534	—
Changes in fair value of financial assets measured at fair value through OCI and exchange differences on translation of foreign operations	4,544	10,589
Settled and received during the period	(3,722)	—
Purchases	—	5,090
Transfers to Level 1	—	(1,711)
Acquisition from conversion of convertible notes	—	1,368
Transfers from investments accounted for using the equity method	—	2,245
Transfers to investments accounted for using the equity method	—	(837)
As of the end of the period	<u>28,208</u>	<u>81,007</u>

(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 financial liabilities associated with contingent consideration arrangements is re-measured based on risk-adjusted future cash flows discounted using an appropriate discount rate.

As of September 30, 2022, the balance primarily relates to pre-existing contingent consideration arrangements from Shire's historical acquisition.

The pre-existing contingent consideration arrangements 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 financial liabilities associated with contingent consideration arrangements 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 September 30, 2022. There are no significant changes in fair value during the changes in significant assumptions which influence the fair value measurement for financial liabilities associated with contingent consideration arrangements.

	JPY (millions)
	Six-month Period Ended September 30, 2022
As of the beginning of the period	5,844
Changes in the fair value during the period	1,492
Settled during the period	(549)
Foreign currency translation differences	1,117
As of the end of the period	<u>7,904</u>

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(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 September 30, 2022	
	Carrying amount	Fair value
Bonds	3,996,349	3,575,359
Long-term loans	740,024	738,532

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.

12. Subsequent Events

On October 27, 2022, Takeda redeemed 1,000 million USD in unsecured U.S. dollar-denominated senior notes issued in November 2018 in advance of their original maturity date of November 26, 2023. The impact from the accelerated debt prepayment on the consolidated statements of profit or loss was not material.

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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 146th fiscal year (from April 1, 2022 to March 31, 2023) at the meeting of the Board of Directors held on October 27, 2022.

(a)	Total amount of interim dividends	140,474,135,250 JPY
(b)	Interim dividend per share	90.00 JPY
(c)	Effective date/ Payment start date	December 1, 2022

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B. Information on Guarantors of the Company

Not applicable.