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Quarterly Securities Report

(The second quarter of 147th Business Term)
for The Six-month Period and Three-month
Quarter Ended September 30, 2023

TAKEDA PHARMACEUTICAL COMPANY LIMITED
AND ITS SUBSIDIARIES

Index

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A. Company Information

I. Overview of Takeda

1. Key Consolidated Financial Data

	JPY (millions), unless otherwise indicated		
Term	Six-month period ended September 30, 2022	Six-month period ended September 30, 2023	For the year ended March 31, 2023
Revenue	1,974,771	2,101,707	4,027,478
<Three-month period ended September 30>	1,002,307	1,043,089	
Profit before tax	220,022	39,053	375,090
Net profit for the period	166,753	41,436	317,038
Net profit (loss) attributable to owners of the Company	166,756	41,365	317,017
<Three-month period ended September 30>	61,742	(48,030)	
Total comprehensive income for the period	1,163,590	824,964	911,574
Total equity	6,713,489	7,071,024	6,354,672
Total assets	14,588,847	14,871,889	13,957,750
Basic earnings (loss) per share (JPY)	107.62	26.51	204.29
<Three-month period ended September 30>	39.77	(30.68)	
Diluted earnings per share (JPY)	106.88	26.29	201.94
Ratio of equity attributable to owners of the Company to total assets (%)	46.0	47.5	45.5
Net cash from operating activities	305,234	291,305	977,156
Net cash used in investing activities	(121,920)	(327,109)	(607,102)
Net cash used in financing activities	(267,593)	(198,433)	(709,148)
Cash and cash equivalents at the end of the period	798,137	318,051	533,530

(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, 2022 and 2023 are based on the condensed interim consolidated financial statements prepared in accordance with IAS 34.

2. Business Overview

There has been no significant change in our business for the six-month period ended September 30, 2023.

As of September 30, 2023, Takeda consisted of 188 entities comprised of 171 consolidated subsidiaries (including partnerships), 16 associates accounted for using the equity method, and Takeda Pharmaceutical Company Limited. There has been no significant change in our group companies for the six-month period ended September 30, 2023.

II. Operating and Financial Review

1. Risk Factors

There were no new risk factors identified for the six-month period ended September 30, 2023 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, 2023 which was filed in Japan.

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

(1) Consolidated Financial Results (April 1 to September 30, 2023)

Billion JPY or percentage

	FY2022 H1	FY2023 H1	Change versus the same period of the previous fiscal year		
			AER		CER
			Amount of Change	% Change	% Change
Revenue	1,974.8	2,101.7	126.9	6.4 %	1.4 %
Cost of sales	(598.3)	(664.7)	(66.4)	11.1 %	6.0 %
Selling, general and administrative expenses	(480.2)	(501.1)	(20.9)	4.3 %	(0.8)%
Research and development expenses	(297.8)	(346.7)	(48.9)	16.4 %	9.6 %
Amortization and impairment losses on intangible assets associated with products	(273.6)	(369.7)	(96.0)	35.1 %	25.8 %
Other operating income	13.5	9.9	(3.6)	(26.7)%	(27.6)%
Other operating expenses	(83.4)	(110.2)	(26.9)	32.2 %	27.1 %
Operating profit	255.0	119.2	(135.7)	(53.2)%	(50.6)%
Finance income and (expenses), net	(33.6)	(81.8)	(48.2)	143.7 %	147.9 %
Share of profit (loss) of investments accounted for using the equity method	(1.4)	1.6	3.0	—	—
Profit before tax	220.0	39.1	(181.0)	(82.3)%	(79.8)%
Income tax (expenses) benefit	(53.3)	2.4	55.7	—	(86.0)%
Net profit for the period	166.8	41.4	(125.3)	(75.2)%	(77.8)%

In this section, when comparing results to the same period of the previous fiscal year, the amount of change and percentage change based on Actual Exchange Rates are presented in “AER” (which is presented in accordance with IFRS) and percentage change based on Constant Exchange Rate (which is a non-IFRS measure) is presented in “CER”. Please refer to Core Results (April 1 to September 30, 2023), Definition of Core financial measures and Constant Exchange Rate change, for the definition of “Constant Exchange Rate change”.

Revenue

Revenue for the six-month period ended September 30, 2023 was JPY 2,101.7 billion (JPY +126.9 billion and +6.4% AER, +1.4% CER). The increase is primarily attributable to favorable foreign exchange rates and growth from business momentum of our five key business areas (i.e. Gastroenterology (“GI”), Rare Diseases, Plasma-Derived Therapies (“PDT”) Immunology, Oncology, and Neuroscience), with the exception of Oncology which was impacted by generic erosion and intensified competition on certain products in the current period. In addition, revenue outside of our five key business areas decreased mainly due to lower revenue contribution from COVID-19 vaccines in Japan.

Revenue by Geographic Region

The following shows revenue by geographic region:

Billion JPY or percentage

Revenue:	FY2022 H1	FY2023 H1	Change versus the same period of the previous fiscal year		
			AER		CER
			Amount of Change	% Change	% Change
Japan	261.4	228.5	(32.8)	(12.6)%	(12.8)%
United States	1,032.5	1,104.8	72.2	7.0 %	0.1 %
Europe and Canada	409.0	460.0	51.0	12.5 %	3.4 %
Asia (excluding Japan)	105.7	123.3	17.6	16.6 %	14.4 %
Latin America	83.3	92.1	8.8	10.6 %	15.8 %
Russia/CIS	37.8	31.1	(6.7)	(17.8)%	(4.5)%
Other*1	45.1	62.0	16.9	37.4 %	44.0 %
Total	1,974.8	2,101.7	126.9	6.4 %	1.4 %

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

Revenue by Business Area

The following shows revenue by business area:

Billion JPY or percentage

Revenue:	FY2022 H1	FY2023 H1	Change versus the same period of the previous fiscal year		
			AER		CER
			Amount of Change	% Change	% Change
GI	546.4	596.9	50.5	9.2 %	3.0 %
Rare Diseases	362.2	381.0	18.7	5.2 %	1.9 %
Rare Hematology	155.7	152.7	(3.0)	(1.9)%	(5.7)%
Rare Genetics and Other	206.5	228.2	21.7	10.5 %	7.6 %
PDT Immunology	314.0	388.4	74.4	23.7 %	17.2 %
Oncology	225.3	225.2	(0.1)	(0.1)%	(3.0)%
Neuroscience	302.3	330.7	28.4	9.4 %	3.2 %
Other	224.6	179.6	(44.9)	(20.0)%	(23.1)%
Total	1,974.8	2,101.7	126.9	6.4 %	1.4 %

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

GI

In GI, revenue was JPY 596.9 billion (JPY +50.5 billion and +9.2% AER, +3.0% CER).

Sales of ENTYVIO (for ulcerative colitis (“UC”) and Crohn’s disease (“CD”)) were JPY 391.7 billion (JPY +45.1 billion and +13.0% AER, +5.8% CER). Sales in the U.S. were JPY 271.1 billion (JPY +27.3 billion and +11.2% AER). The increase was due to favorable foreign exchange rates and demand in the first line biologic inflammatory bowel disease (“IBD”) population primarily in UC. Sales in Europe and Canada were JPY 92.0 billion (JPY +13.2 billion and +16.7% AER). The increase was primarily due to favorable foreign exchange rates and new patient gains by an increased use of the subcutaneous formulation.

Sales of GATTEX/REVESTIVE (for short bowel syndrome) were JPY 58.9 billion (JPY +10.5 billion and +21.6% AER, +15.5% CER). The increase was primarily due to increased demand across all regions, expansion activities (infant indication label expansion and geographic expansion), and favorable exchange rates.

Sales of TAKECAB/VOCINTI (for acid-related diseases) were JPY 58.8 billion (JPY +4.1 billion and +7.5% AER, +6.9% CER). The increase was primarily due to increased sales in Japan and the Growth and Emerging Markets including Brazil and China.

Sales of DEXILANT (for acid reflux disease) were JPY 23.2 billion (JPY -14.8 billion and -39.0% AER, -43.1% CER). The decrease was due to the loss of exclusivity and the termination of the authorized generics program in the U.S.

Rare Diseases

In Rare Diseases, revenue was JPY 381.0 billion (JPY +18.7 billion and +5.2% AER, +1.9% CER).

Revenue of Rare Hematology was JPY 152.7 billion (JPY -3.0 billion and -1.9% AER, -5.7% CER).

Sales of FEIBA (for hemophilia A and B) were JPY 19.8 billion (JPY -1.5 billion and -7.0% AER, -10.7% CER). The decrease was primarily due to competition in Brazil.

Aggregate sales of plasma-derived human coagulation factor products, HEMOFIL (for hemophilia A), IMMUNATE (for hemophilia A), and IMMUNINE (for hemophilia B) were JPY 9.3 billion (JPY -1.3 billion and -12.5% AER, -16.4% CER). The decrease was primarily due to decreased sales in the Growth and Emerging Markets.

Sales of ADYNOVATE/ADYNOVI (for hemophilia A) were JPY 33.5 billion (JPY -0.9 billion and -2.7% AER, -6.5% CER). The decrease was primarily due to negative impacts from competition in the U.S.

Sales of VONVENDI (for von Willebrand disease) were JPY 7.4 billion (JPY +1.5 billion and +26.0% AER, +17.3% CER). The increase was primarily due to increased demand in the U.S.

Revenue of Rare Genetics and Other was JPY 228.2 billion (JPY +21.7 billion and +10.5% AER, +7.6% CER).

Sales of TAKHZYRO (for hereditary angioedema) were JPY 87.1 billion (JPY +14.3 billion and +19.6% AER, +13.1% CER). The continued growth was attributable to sustained launch momentum, expansion into new patient populations such as pediatrics, rising diagnosis rates, the growth of the prophylactic market, and favorable exchange rates.

Sales of LIVTENCITY (for post-transplant cytomegalovirus ("CMV") infection/disease) were JPY 8.3 billion (JPY +4.1 billion and +96.9% AER, +83.2% CER). The increase was primarily attributable to strong market penetration and successful launch performance in the U.S., complemented by continued geographical expansion in Europe.

Sales of enzyme replacement therapy ELAPRASE (for Hunter syndrome) were JPY 45.7 billion (JPY +3.3 billion and +7.7% AER, +6.3% CER). The increase was primarily due to strong demand in the Growth and Emerging Markets.

PDT Immunology

In PDT Immunology, revenue was JPY 388.4 billion (JPY +74.4 billion and +23.7% AER, +17.2% CER).

Aggregate sales of immunoglobulin products were JPY 309.2 billion (JPY +64.1 billion and +26.2% AER, +19.0% CER). 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, 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 (both primarily used for hypovolemia and hypoalbuminemia) were JPY 58.9 billion (JPY +7.2 billion and +13.9% AER, +10.9% CER). The increase was primarily driven by strong albumin demand in China.

Oncology

In Oncology, revenue was JPY 225.2 billion (JPY -0.1 billion and -0.1% AER, -3.0% CER).

Sales of VELCADE (for multiple myeloma) were JPY 2.9 billion (JPY -17.9 billion and -86.0% AER, -87.0% CER). The decrease was due to generic erosion in the U.S.

Sales of ADCETRIS (for malignant lymphomas) were JPY 54.3 billion (JPY +12.6 billion and +30.1% AER, +29.3% CER). The increase was led by strong growth in Growth and Emerging Markets.

Sales of ALUNBRIG (for small-cell lung cancer) were JPY 13.7 billion (JPY +4.0 billion and +41.2% AER, +36.2% CER). The increase benefited from strong demand across all regions.

Neuroscience

In Neuroscience, revenue was JPY 330.7 billion (JPY +28.4 billion and +9.4% AER, +3.2% CER).
Sales of VYVANSE/ELVANSE (for attention deficit hyperactivity disorder ("ADHD")) were JPY 226.3 billion (JPY +15.0 billion and +7.1% AER, +0.7% CER). Despite the growth of the adult market and favorable foreign exchange rates, these impacts were predominantly offset by multiple generic entrants in the U.S. starting from late August of this year.

Sales of ADDERALL XR (for ADHD) were JPY 22.6 billion (JPY +10.1 billion and +80.3% AER, +68.1% CER). The increase was primarily due to a shortage of generic versions of the instant release formulation marketed by competitors in the U.S.

Cost of Sales

Cost of Sales was JPY 664.7 billion (JPY +66.4 billion and +11.1% AER, +6.0% CER). The increase was primarily due to revenue growth in our five key business area with a change in product mix and the depreciation of Japanese yen as compared to the same period of the previous fiscal year. This was partially offset by a decrease in non-cash charges related to the unwind of the fair value step up on acquired inventories recognized in connection with the acquisition of Shire.

Selling, General and Administrative (SG&A) expenses

SG&A expenses were JPY 501.1 billion (JPY +20.9 billion and +4.3% AER, -0.8% CER). The increase was mainly due to the impact from the depreciation of Japanese yen.

Research and Development (R&D) expenses

R&D expenses were JPY 346.7 billion (JPY +48.9 billion and +16.4% AER, +9.6% CER). The increase was mainly due to various investments in pipeline programs and the impact from the depreciation of Japanese yen.

Amortization and Impairment Losses on Intangible Assets Associated with Products

Amortization and Impairment Losses on Intangible Assets Associated with Products was JPY 369.7 billion (JPY +96.0 billion and +35.1% AER, +25.8% CER). The increase was mainly due to an increase in impairment charges for certain assets related to in-process R&D and marketed products and an increase of amortization expenses due to the depreciation of Japanese yen. The JPY 115.8 billion impairment losses recorded in the current period primarily includes JPY 74.0 billion impairment charges for ALOFISEL (for complex Crohn's perianal fistulas) following topline results of phase 3 ADMIRE-CD II trial and JPY 28.5 billion impairment charges following a decision to voluntarily withdraw EXKIVITY (for non-small cell lung cancer) globally.

Other Operating Income

Other Operating Income was JPY 9.9 billion (JPY -3.6 billion and -26.7% AER, -27.6% CER).

Other Operating Expenses

Other Operating Expenses were JPY 110.2 billion (JPY +26.9 billion and +32.2% AER, +27.1% CER). The increase was primarily driven by increases in reserves and provisions, including for certain legal proceedings, and restructuring expenses.

Operating Profit

As a result of the above factors, Operating Profit was JPY 119.2 billion (JPY -135.7 billion and -53.2% AER, -50.6% CER).

Net Finance Expenses

Net Finance Expenses were JPY 81.8 billion (JPY +48.2 billion and +143.7% AER, +147.9% CER). The increase of Net Finance Expenses compared to the same period of the previous year was primarily due to a decrease in financial income reflecting gains from acquisitions of prior equity method companies and other income and gains recorded in the same period of the previous fiscal year.

Share of Profit of Investments Accounted for Using the Equity Method

Share of Profit of Investments Accounted for Using the Equity Method was JPY 1.6 billion (JPY +3.0 billion, compared to Share of Loss of Investments Accounted for Using the Equity Method of JPY 1.4 billion).

Income Tax (Expenses) Benefit

Income Tax Benefit was JPY 2.4 billion (JPY +55.7 billion, compared to Income Tax Expenses of JPY 53.3 billion, -86.0% CER). The increase was primarily due to a tax expense reduction of JPY 63.5 billion resulting from the reversal of the income taxes payable in excess of the settlement with Irish Revenue Commissioners with respect to a tax assessment related to the treatment of an acquisition break fee Shire received from AbbVie, Inc. (AbbVie) in 2014 as well as lower pretax earnings. These increases were partially offset by the tax charges from the write-down of deferred tax assets in the current period.

Net Profit for the Period

Net Profit for the Period was JPY 41.4 billion (JPY -125.3 billion and -75.2% AER, -77.8% CER).

Core Results (April 1 to September 30, 2023)

Definition of Core financial measures and Constant Exchange Rate change

Takeda uses the concept of Core financial measures for measuring financial performance. These measures are not defined by International Financial Reporting Standards (IFRS).

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.

Constant Exchange Rate (CER) 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

	FY2022 H1	FY2023 H1	Change versus the same period of the previous fiscal year		
			AER		CER
			Amount of Change	% change	% change
Core Revenue	1,974.8	2,101.7	126.9	6.4 %	1.4 %
Core Operating Profit	625.2	588.8	(36.4)	(5.8)%	(9.5)%
Core EPS (JPY)	288	261	(27)	(9.4)%	(14.4)%

Core Revenue

Core Revenue for the six-month period ended September 30, 2023 was JPY 2,101.7 billion (JPY +126.9 billion and +6.4% AER, +1.4% CER). There were no significant items unrelated to Takeda's core operations excluded from revenue in the current period or in the same period of the previous fiscal year, and, accordingly, Core Revenue for these periods is the same as Reported Revenue. Business momentum was led by Takeda's Growth and Launch Products* which totaled JPY 875.9 billion (JPY +143.1 billion and +19.5% AER, +12.7% CER).

* 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 (Takeda decided to voluntarily withdraw the product globally)
Other: QDENGA

Core Operating Profit

Core Operating Profit for the current period was JPY 588.8 billion (JPY -36.4 billion and -5.8% AER, -9.5% CER). The decrease was primarily due to a change in product mix and investments in various pipeline programs and data and technology.

Core EPS

Core EPS for the current period was JPY 261 (JPY -27 and -9.4% AER, -14.4% CER).

(2) Consolidated Financial Position

The amount of change from the previous fiscal year-end is presented based on Actual Exchange Rates.

Assets.

Total Assets as of September 30, 2023 were JPY 14,871.9 billion (JPY +914.1 billion). The increases of Goodwill, Property, Plant and Equipment, Inventories, and Intangible Assets (JPY +510.3 billion, JPY +202.9 billion, JPY +169.4 billion, and JPY +132.8 billion, respectively) were mainly due to the effect of foreign currency translation. These increases were partially offset by a decrease in Cash and Cash Equivalents (JPY -215.5 billion).

Liabilities.

Total Liabilities as of September 30, 2023 were JPY 7,800.9 billion (JPY +197.8 billion). Bonds and Loans were JPY 4,679.2 billion* (JPY +296.9 billion), which increased primarily due to the effect of foreign currency translation and the issuance of commercial paper. In addition, Other Financial Liabilities increased (JPY +162.6 billion) primarily due to increased lease liabilities in the U.S. These increases were partially offset by a decrease in Trade and Other Payables (JPY -228.2 billion) due to payments for the remaining upfront payment related to the acquisition of TAK-279 from Nimbus Therapeutics, LLC (Nimbus) and the exclusive license agreement with HUTCHMED (China) Limited (HUTCHMED).

* The carrying amount of Bonds was JPY 3,931.9 billion and Loans was JPY 747.4 billion as of September 30, 2023. 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 (USD 1,301 million)	June 2015	June 2025 ~ June 2045	194.8
Unsecured US dollar denominated senior notes (USD 3,000 million)	September 2016	September 2026	430.0
Unsecured Euro denominated senior notes (EUR 3,000 million)	November 2018	November 2026 ~ November 2030	472.0
Unsecured US dollar denominated senior notes (USD 2,250 million)	November 2018	November 2023 ~ November 2028	333.9
Hybrid bonds (subordinated bonds)	June 2019	June 2079	499.2
Unsecured US dollar denominated senior notes (USD 7,000 million)	July 2020	March 2030 ~ July 2060	1,036.7
Unsecured Euro denominated senior notes (EUR 3,600 million)	July 2020	July 2027 ~ July 2040	565.8
Unsecured JPY denominated senior bonds	October 2021	October 2031	249.5
Commercial paper	September 2023	December 2023	150.0
Total			3,931.9

Loans:

Name of Loan (Face Value if Denominated in Foreign Currency)	Execution	Maturity	Carrying Amount (Billion JPY)
Syndicated loans	April 2016	April 2026	100.0
Syndicated loans	April 2017	April 2027	113.5
Syndicated loans (USD 1,500 million)	April 2017	April 2027	223.4
Syndicated loans	April 2023	April 2030	100.0
Bilateral loans	March 2016 ~ March 2023	April 2024 ~ March 2029	210.0
Other			0.5
Total			747.4

On April 26, 2023, Takeda repaid JPY 100.0 billion in Syndicated Loans falling due and on the same day entered into new Syndicated Loans of JPY 100.0 billion maturing on April 26, 2030. Following this, Takeda redeemed USD 1,000 million of unsecured senior notes issued in September 2016 on their maturity date of September 23, 2023. Furthermore, Takeda had short term commercial paper drawings outstanding of JPY 150.0 billion as at September 30, 2023.

Equity.

Total Equity as of September 30, 2023 was JPY 7,071.0 billion (JPY +716.4 billion). The increase of Other Components of Equity (JPY +779.8 billion) was mainly due to fluctuation in currency translation adjustments reflecting the depreciation of Japanese yen. This increase was partially offset by a decrease in Retained Earnings (JPY -95.1 billion) mainly due to the decrease of JPY 140.1 billion related to dividends payments while Net Profit for the Period contributed to an increase.

Consolidated Cash Flows

	Billion JPY	
	FY2022 H1	FY2023 H1
Net cash from (used in) operating activities	305.2	291.3
Net cash from (used in) investing activities	(121.9)	(327.1)
Net cash from (used in) financing activities	(267.6)	(198.4)
Net increase (decrease) in cash and cash equivalents	(84.3)	(234.2)
Cash and cash equivalents at the beginning of the year	849.7	533.5
Effects of exchange rate changes on cash and cash equivalents	32.7	18.8
Cash and cash equivalents at the end of the period	798.1	318.1

The amount of change from the same period of the previous fiscal year is presented based on Actual Exchange Rates.

Net cash from operating activities

Net cash from operating activities for the current period was JPY 291.3 billion (JPY -13.9 billion). The decrease was due to unfavorable impacts from a lower net profit for the period adjusted for non-cash items and other adjustments, along with an increase in Income taxes paid. These were partially offset by a favorable net impact from Changes in assets and liabilities and other changes.

Net cash used in investing activities

Net cash used in investing activities was JPY 327.1 billion (JPY +205.2 billion). This increase was mainly due to an increase in Acquisition of intangible assets related to the acquisition of TAK-279 from Nimbus and the exclusive license agreement with HUTCHMED.

Net cash used in financing activities

Net cash used in financing activities was JPY 198.4 billion (JPY -69.2 billion). The decrease was mainly due to a net increase in commercial paper drawings of JPY 110.0 billion and the settlement of cross currency interest rate swaps related to bonds during

the current period. These were partially offset by the redemption of USD 1,000 million of unsecured senior notes issued in September 2016 on their maturity date of September 23, 2023.

(3) Research & Development Activities and Results

Research and development expenses for the six-month period ended September 30, 2023 were JPY 346.7 billion.

Takeda's R&D engine is focused on translating science into highly innovative, life-transformative 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 (Gastrointestinal and inflammation, neuroscience, oncology, and rare genetics and hematology). 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 mid- to 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 2023 are listed as follows:

R&D pipeline

Gastrointestinal and Inflammation

In Gastrointestinal and Inflammation, Takeda focuses on delivering innovative, life-changing therapeutics for patients with gastrointestinal diseases, including those of the liver as well as other immune-mediated inflammatory diseases. Takeda is maximizing the potential of our inflammatory bowel disease (IBD) franchise around ENTYVIO, including development of a subcutaneous formulation and expansion into other indications such as active chronic pouchitis. Takeda is also expanding its position with GATTEX/REVESTIVE to support further potential geographic expansion. Furthermore, Takeda is progressing a pipeline built through in-house discovery, partnerships and business development, exploring opportunities in inflammatory diseases (IBD, celiac disease, psoriasis, psoriatic arthritis, system lupus erythematosus, others), 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. TAK-279 is an example of an acquisition through business development of a late-stage, potential best-in-class oral allosteric tyrosine kinase 2 (TYK2) inhibitor with potential to treat multiple immune-mediated inflammatory diseases.

ENTYVIO / Generic name: vedolizumab

- In April 2023, Takeda announced that the U.S. Food and Drug Administration (FDA) accepted for review its Biologics License Application (BLA) resubmission for the investigational subcutaneous (SC) administration of ENTYVIO for maintenance therapy in adults with moderately to severely active ulcerative colitis (UC) after induction therapy with ENTYVIO intravenous (IV). The resubmission was intended to address FDA feedback in a December 2019 Complete Response Letter (CRL). Since receiving the CRL Takeda worked closely with the FDA to address the Agency's feedback; and this resubmission package included additional data collected to investigate the use of subcutaneous administration of ENTYVIO. The contents of the letter were unrelated to the IV formulation of ENTYVIO, the clinical safety and efficacy data, and conclusions from the pivotal VISIBLE 1 trial supporting the ENTYVIO SC BLA. VISIBLE 1 assessed the safety and efficacy of a SC formulation of ENTYVIO as maintenance therapy in 216 adult patients with moderately to severely active UC who achieved clinical response at week 6 following two doses of open-label ENTYVIO IV therapy at weeks 0 and 2. The primary endpoint was clinical remission at week 52, which was defined as a total Mayo score of ≤2 and no subscore >1. In September 2023, Takeda announced that the FDA approved a SC administration of ENTYVIO for maintenance therapy in adults with moderately to severely active UC after induction therapy with ENTYVIO IV.
- In September 2023, Takeda announced that the FDA accepted for review its BLA for the investigational SC administration of ENTYVIO for maintenance therapy in adults with moderately to severely active Crohn's disease (CD) after induction therapy with ENTYVIO IV. The BLA package is based on data from VISIBLE 2 trial that assessed the safety and efficacy of an SC formulation of ENTYVIO as maintenance therapy compared to placebo in 409 adult patients with moderately to severely active CD who achieved clinical response at week 6 following two doses of open-

label ENTYVIO IV therapy at weeks 0 and 2. The primary endpoint was clinical remission at week 52, which was defined as CD Activity Index (CDAI) score ≤150.

- In September 2023, Takeda announced that it received an approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) for a partial change to the marketing authorization status of ENTYVIO Pens for S.C. Injection 108 mg /Syringes for S.C. Injection 108 mg (ENTYVIO SC) as a maintenance therapy for moderate to severe active Crohn's disease (CD) with inadequate response to conventional treatment. This approval is based on the results of the MLN0002SC-3031 and MLN0002SC-3030 clinical trials, which are international Phase 3 trials that evaluated the efficacy and safety of ENTYVIO SC as a maintenance therapy in moderate to severe active CD.

ALOFISEL / Generic name: darvadstrocel

- In October 2023, Takeda announced that the Phase 3 ADMIRE-CD II study, assessing the efficacy and safety of ALOFISEL for the treatment of complex Crohn's Perianal Fistulas (CPF), did not meet its primary endpoint of combined remission at 24 weeks, based on topline data. The safety profile for darvadstrocel was consistent with prior studies and there were no new safety signals identified. Full results of the study will be presented at a future medical meeting or published in a peer-reviewed journal. ALOFISEL is approved in the European Union (EU), Israel, Switzerland, Serbia, United Kingdom and Japan based on positive data from the previously completed ADMIRE-CD study.

Development Code: TAK-279

- In September 2023, Takeda announced positive topline results from its randomized, double-blind, placebo-controlled, multiple-dose Phase 2b trial evaluating TAK-279, an investigational oral allosteric tyrosine kinase 2 (TYK2) inhibitor with next generation selectivity, in patients with active psoriatic arthritis. The study met its primary endpoint with a significantly greater proportion of patients treated once-daily with TAK-279 achieving at least a 20 percent improvement in signs and symptoms of disease (American College of Rheumatology 20 response [ACR20]) at week 12 compared to placebo, supporting its potential as a highly selective oral option for patients with psoriatic arthritis. The safety and tolerability profile of TAK-279 in the Phase 2b trial was consistent with previous TAK-279 clinical trials. Analysis of the results are ongoing, and Takeda plans to present clinical results at an upcoming medical meeting. Based on the Phase 2b results, Takeda intends to initiate a Phase 3 development program of TAK-279 in psoriatic arthritis. Takeda also intends to initiate a Phase 3 development program of TAK-279 in plaque psoriasis in FY2023 and plans to evaluate TAK-279 in systemic lupus erythematosus, Crohn's disease, ulcerative colitis and additional immune-mediated inflammatory diseases.

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

- In September 2023, Takeda announced that the U.S. Food and Drug Administration (FDA) accepted for review its New Drug Application (NDA) resubmission for TAK-721 (budesonide oral suspension) which is being investigated for the short-term treatment of eosinophilic esophagitis (EoE). The resubmission is intended to address previous FDA feedback to Takeda's original NDA submission.

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, danavorexton (TAK-925), etc.), rare epilepsies with soticlestat (TAK-935) and central nervous system (CNS) and somatic symptoms of Hunter Syndrome with pabinafusp alfa (TAK-141). Additionally, Takeda makes targeted investments to investigate well-defined segments of neuromuscular diseases, neurodegenerative diseases and movement disorders.

Oncology

In Oncology, we aspire to cure cancer, with inspiration from patients and innovation from everywhere. We are focused on: (1) building on our legacy in hematologic malignancies with marketed products (NINLARO, ADCETRIS, and ICLUSIG, etc.) and pipeline programs; (2) growing a solid tumor portfolio with marketed lung cancer product (ALUNBRIG), and development programs in other areas, including colorectal cancer with fruquinitinib (TAK-113); and (3) advancing a cutting-edge pipeline focused on the power of innate immunity.

CABOMETYX / Generic name: cabozantinib

- In August 2023, Takeda announced that, in the CONTACT-02 global phase 3 clinical trial, statistically significant difference in progression-free survival (PFS) was observed, demonstrating a clinically meaningful improvement. The CONTACT-02 trial compared the combination therapy of CABOMETYX and atezolizumab, an anti-PD-L1 (Programmed Death-Ligand 1) humanized monoclonal antibody, with a second novel hormonal therapy (either abiraterone and prednisone or enzalutamide) in patients with metastatic castration-resistant prostate cancer and measurable soft tissue disease who had received prior treatment with one form of hormonal therapy. The safety profiles of CABOMETYX and atezolizumab observed in this trial were consistent with their known safety profiles as monotherapies, and no new safety concerns were identified with the combination regimen. For the other primary endpoint of overall survival (OS) that occurred at the same time as the primary analysis of PFS, data were immature at this prespecified interim analysis. Therefore, the trial will continue to the next analysis of OS.

ADCETRIS / Generic name: brentuximab vedotin

- In October 2023, Takeda announced that the European Commission (EC) approved ADCETRIS in combination with doxorubicin, vinblastine and dacarbazine (AVD) to treat adult patients with previously untreated CD30+ Stage III Hodgkin lymphoma. The decision follows a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) in September, 2023. The approval is based on the results of the randomized Phase 3 ECHELON-1 trial designed to compare ADCETRIS plus AVD to doxorubicin, bleomycin, vinblastine, and dacarbazine (ABVD) as a therapy in adult patients with previously untreated Stage III or IV Hodgkin lymphoma. The trial met its primary endpoint of modified progression-free survival (PFS), as well as its key secondary endpoint of overall survival (OS), demonstrating a statistically significant improvement in OS in adult patients with previously untreated Stage III or IV classical Hodgkin lymphoma treated with ADCETRIS+AVD. The safety profile of ADCETRIS was consistent with previous studies, and no new safety signals were observed.

NINLARO / Generic name: ixazomib

- In September 2023, Takeda announced that it submitted a New Drug Application (NDA) to the Japanese Ministry of Health, Labour and Welfare (MHLW) for NINLARO capsules 0.5 mg as an additional dosage form of NINLARO (Capsules 2.3 mg/3 mg/4 mg). Aiming to achieve more appropriate dose adjustment in maintenance therapy for patients with multiple myeloma, Takeda filed this application to provide patients with a new treatment option (1.5 mg dose (0.5 mg/capsule x 3)) using a low-dose formulation of NINLARO.

EXKIVITY / Generic name: mobocertinib

- In October 2023, Takeda announced that, following discussions with the U.S. Food and Drug Administration (FDA), it will be working with the FDA towards a voluntary withdrawal of EXKIVITY in the U.S. for adult patients with epidermal growth factor receptor (EGFR) exon20 insertion mutation-positive (insertion+) locally advanced or metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on or after platinum-based chemotherapy. Takeda intends to similarly initiate voluntary withdrawal globally where EXKIVITY is approved and is working with regulators in other countries where it is currently available on next steps. This decision was based on the outcome of the Phase 3 EXCLAIM-2 confirmatory trial, which did not meet its primary endpoint and thus did not fulfill the confirmatory data requirements of the accelerated approval granted by the U.S. FDA nor the conditional marketing approvals granted in other countries. The EXCLAIM-2 trial was a Phase 3, multicenter, open-label study designed to investigate the safety and efficacy of EXKIVITY as a monotherapy versus platinum-based chemotherapy in first-line EGFR exon20 insertion+ locally advanced or metastatic NSCLC. No new safety signals were observed in the EXCLAIM-2 trial. Full data from the trial will be presented at an upcoming medical meeting or published in a peer-reviewed journal.

Development code: TAK-113 / Generic name: fruquintinib

- In May 2023, Takeda and HUTCHMED (China) Limited announced that the U.S. Food and Drug Administration (FDA) granted priority review of the New Drug Application (NDA) for fruquintinib, a highly selective and potent inhibitor of vascular endothelial growth factor receptors (VEGFR) -1, -2 and -3 for the treatment of adult patients with previously treated metastatic colorectal cancer (CRC). If approved, fruquintinib will be the first and only highly selective inhibitor of all three VEGF receptors approved in the U.S. for previously treated metastatic CRC. The NDA for fruquintinib includes results from the Phase 3 FRESCO-2 trial conducted in the US, Europe, Japan and Australia along with data from the Phase 3 FRESCO trial conducted in China. The Prescription Drug User Fee Act (PDUFA) goal date assigned by the FDA for this NDA is November 30, 2023.
- In June 2023, Takeda and HUTCHMED (China) Limited announced that the European Medicines Agency (EMA) validated and accepted for regulatory review the marketing authorization application (MAA) for fruquintinib for the treatment of adult patients with previously treated metastatic CRC. If approved, fruquintinib will be the first and only highly selective and potent inhibitor of VEGFR -1, -2 and -3 approved in the European Union (EU) for previously treated metastatic CRC. The MAA for fruquintinib includes results from the global Phase 3 FRESCO-2 clinical trial along with data from the Phase 3 FRESCO clinical trial.
- In June 2023, Takeda and HUTCHMED (China) Limited announced that results of the Phase 3 FRESCO-2 study evaluating fruquintinib in patients with previously treated metastatic CRC were published in *The Lancet*. FRESCO-2 is a global Phase 3 clinical trial (MRCT) conducted in the U.S., Europe, Japan and Australia investigating fruquintinib plus best supportive care (BSC) vs placebo plus BSC in patients with previously treated metastatic CRC. The FRESCO-2 study met its primary and key secondary endpoints, demonstrating that treatment with fruquintinib resulted in a statistically significant and clinically meaningful improvement in overall survival (OS) and progression-free survival (PFS), respectively. The safety profile of fruquintinib in FRESCO-2 was consistent with previously reported fruquintinib studies.
- In September 2023, Takeda announced that it submitted a New Drug Application (NDA) to the Japanese Ministry of Health, Labour and Welfare (MHLW) for fruquintinib for the treatment of previously treated metastatic colorectal cancer. The NDA for fruquintinib is based on the global Phase 3 FRESCO-2 clinical trial and the Phase 3 FRESCO clinical trial.

Rare Genetics and Hematology

In Rare Genetics and 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. 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 apadamtase alfa/cinaxadamtase alfa (TAK-755) for the treatment of immune thrombotic thrombocytopenic purpura (iTTP) and congenital thrombotic thrombocytopenic purpura (cTTP). In addition, Takeda aims to redefine the management of post-transplant cytomegalovirus (CMV) infection/disease with LIVTENCITY. Takeda commits to fulfilling our vision to deliver life-transforming medicines to patients with rare diseases.

Development code: TAK-755 / Generic name: apadamtase alfa/cinaxadamtase alfa

- In May 2023, Takeda announced that the U.S. Food and Drug Administration (FDA) accepted Takeda's Biologics License Application (BLA) for TAK-755, an enzyme replacement therapy for the treatment of congenital thrombotic thrombocytopenic purpura (cTTP), an ADAMTS13 deficiency disorder. The TAK-755 application was accepted by the FDA on May 16th and has been granted Priority Review. FDA also granted TAK-755 Rare Pediatric Disease (RPD) designation for cTTP. TAK-755 has previously received Fast Track Designation and Orphan Drug Designation in cTTP. The BLA is supported by the totality of the evidence provided by efficacy, pharmacokinetic, safety and tolerability data from the first randomized, controlled trial in cTTP, and supported by long-term safety and efficacy data from a continuation study. If approved, TAK-755 would be the first and only recombinant ADAMTS13 (rADAMTS13) replacement therapy for cTTP, a disorder with considerable unmet patient need. Takeda is also investigating the safety, efficacy and pharmacokinetics of TAK-755 treatment in immune-mediated TTP (iTTP).
- In June 2023, Takeda presented favorable interim results from a global pivotal Phase 3 randomized, controlled, open-label, crossover trial evaluating the safety and efficacy of TAK-755 replacement therapy for the prophylactic treatment of cTTP, and pharmacokinetics (PK) characteristics of TAK-755, as well as long-term data on TAK-755 prophylaxis from a Phase 3b continuation study at the International Society on Thrombosis and Haemostasis (ISTH) 2023 Congress. In the pivotal trial, no patient had an acute TTP event while receiving TAK-755 prophylactic treatment. TAK-755 also

reduced the incidence of thrombocytopenia by 60%, as compared to plasma-based therapy (hazard ratio [HR] 0.40; 95% confidence interval [CI]; 0.3- 0.7). Treatment-emergent adverse events (TEAEs) were reported in 10.3% of patients ages 12-68 receiving TAK-755 compared to 50% of patients receiving plasma-based therapy, demonstrating a favorable safety and tolerability profile with a potential safety advantage over plasma-based therapies. PK characteristics of ADAMTS13 after a single infusion (0-168 hours) were evaluated and compared to plasma-based therapy in 36 cTTP patients aged 12 and older. Patients receiving TAK-755 achieved a five-fold increase in their ADAMTS13 activity levels compared to those receiving plasma-based therapy (Cmax 100% activity for TAK-755 vs. 19% activity for plasma-based therapy) and lower variability (23.8% vs. 56% coefficient of variation [CV], respectively). Also, the results of an interim analysis of the Phase 3b continuation study, evaluating the safety and efficacy of long-term TAK-755 prophylaxis in 29 patients with cTTP, demonstrated a consistently favorable safety profile with TAK-755 prophylaxis and no development of neutralizing antibodies. Zero acute TTP events occurred during TAK-755 prophylaxis, and the incidence rates of subacute TTP events and TTP manifestations were comparable to those with TAK-755 prophylaxis in the pivotal study.

- In August 2023, Takeda announced that it filed an application for manufacturing and marketing approval for TAK-755 for the expected indication of cTTP with the Japanese Ministry of Health, Labour and Welfare (MHLW). The application is based on the interim analysis of the global Phase 3 clinical trial 281102 primarily focusing on patients with cTTP, including five Japanese individuals, and the Phase 3b continuation trial TAK-755-3002. In these trials, TAK-755 was evaluated for its efficacy and safety as a treatment for cTTP.

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

- In June 2023, 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 ADYNOVATE for dosage and administration. This approval will contribute driving personalized treatments by adjusting dosage and administration including dosing amount and intervals, depending on individual patient's clinical presentation and activity level. The approval is based primarily on the results of the global Phase 3 CONTINUATION study and Phase 3 PROPEL study conducted outside of Japan.

OBIZUR / Generic name: Susoctocog Alfa (recombinant)

- In June 2023, Takeda announced that it has submitted a marketing authorization application to the Japanese Ministry of Health, Labour and Welfare (MHLW) for Susoctocog Alfa (recombinant) for the control of bleeding in patients with acquired hemophilia A (AHA). The application is based primarily on a Japanese Phase 2/3 trial in adult Japanese patients with AHA and a Phase 2/3 trial conducted outside of Japan in non-Japanese adult patients with AHA.

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 for subcutaneous administration

- In April 2023, Takeda announced that the U.S. Food and Drug Administration (FDA) approved a supplemental biologics license application (sBLA) to expand the use of HYQVIA to treat primary immunodeficiency (PI) in children 2-16 years old. The FDA approval of HYQVIA for the treatment of PI in pediatric patients was based on evidence from a pivotal, prospective, open-label, non-controlled Phase 3 clinical trial that included 44 PI patients between the ages of 2 and 16. During the 12-month trial period, HYQVIA was shown to be efficacious with respect to the occurrence of acute serious bacterial infections (aSBIs), a primary endpoint. The mean aSBI rate per year was 0.04 and was statistically significantly lower (with an upper 1-sided 99% confidence interval of 0.21, $p<0.001$) than the predefined success rate of less than one aSBI per subject per year, favoring efficacy of HYQVIA treatment in pediatric subjects with PI diseases. Results from

the interim data analysis, where all subjects completed 12 months of participation (one year of observation period) in the study, indicated similar safety profiles to adults.

– In June 2023, Takeda announced full results from the pivotal Phase 3 ADVANCE-CIDP 1 clinical trial investigating HYQVIA as maintenance therapy in adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP). ADVANCE-CIDP 1 is a Phase 3, prospective, randomized, double-blind, multicenter, placebo-controlled study in which adults with stable CIDP on intravenous immunoglobulin (IVIG) were randomized 1:1 to be switched to HYQVIA (n=62) or placebo (n=70) and received their assigned treatment for six months or until relapse or study withdrawal. The primary endpoint was proportion of participants who experienced a relapse defined as worsening of CIDP symptoms as measured by Inflammatory Neuropathy Cause and Treatment (INCAT). Secondary endpoints included patient proportion experiencing functional worsening, time to relapse, change from pre-subcutaneous treatment baseline in Rasch-built Overall Disability Scale (R-ODS) centile score and safety. Results showed a clinically significant reduction in relapse rate with HYQVIA vs placebo (9.7% vs. 31.4%, respectively; p=0.0045) and other analysis showed delayed time to relapse with HYQVIA vs. placebo. Favorable data across other endpoints from the study and favorable tolerability were also observed. These findings were presented at the 2023 Peripheral Nerve Society (PNS) Annual Meeting in Denmark in June 2023, and simultaneously published in *the Journal of the Peripheral Nervous System* (JPNS).

CEPROTIN / Generic name: Human Dry Protein C Concentrate (Development code: TAK-662)

– In April 2023, 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 human dry protein C concentrate (TAK-662) for the treatment of venous thromboembolism and purpura fulminans caused by congenital protein C deficiency, as well as for the suppression of thrombi. The application is based primarily on a Phase 1/2 trial in Japanese patients with congenital protein C deficiency and two Phase 2/3 trials (IMAG-098 and 400101) outside of Japan in patients with congenital protein C deficiency. In these trials, TAK-662 demonstrated its efficacy and safety as a treatment for congenital protein C deficiency.

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

– In September 2023, Takeda announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) approved the use of CUVITRU in patients aged 2 years and older with agammaglobulinemia or hypogammaglobulinemia, disorders characterized by very low or absent levels of antibodies and an increased risk of serious recurring infection caused by primary immunodeficiency (PID) or secondary immunodeficiency (SID). The approval marks Takeda's first subcutaneous immunoglobulin (SCIG) therapy for patients in Japan. The approval is based on results from a Phase 3 clinical trial that evaluated the efficacy, safety, tolerability and pharmacokinetics of CUVITRU in Japanese patients with PID, as well as two Phase 2/3 clinical trials conducted in patients with PID in North America and Europe. Results from the clinical trial in 17 patients in Japan confirmed its efficacy and safety profile. No serious or severe adverse events were reported, and CUVITRU was well-tolerated. The most frequently reported adverse reactions were headache and injection site swelling in four patients (23.5%) and injection site erythema in three patients (17.6%) during CUVITRU treatment. Previously reported clinical trial results also confirmed the efficacy and safety of CUVITRU.

Vaccine

In Vaccines, Takeda is applying innovation to tackle some of the world's most challenging infectious diseases such as dengue (QDENGA (development code: 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.

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

– In July 2023, Takeda announced that it voluntarily withdrew the U.S. Biologics License Application (BLA) for TAK-003, following discussions with the U.S. Food and Drug Administration (FDA) on aspects of data collection, which cannot be addressed within the current BLA review cycle. The future plan for TAK-003 in the U.S. will be further evaluated given the need for travelers and those living in dengue-endemic areas of the U.S., such as Puerto Rico. The efficacy and safety profiles of TAK-003 have been demonstrated through a robust clinical trial program, including a 4.5-year Phase 3 study of over 20,000 children and adolescents living in eight dengue endemic areas. The study was designed per World Health Organization (WHO) guidance for a second-generation dengue vaccine, and it considered the

need to achieve high levels of subject retention and protocol compliance in endemic regions. The vaccine is approved in multiple endemic and non-endemic countries, with more approvals expected over the coming years.

- In October 2023, Takeda announced that the WHO Strategic Advisory Group of Experts on Immunization (SAGE) shared recommendations for use of QDENGA.
  SAGE made the following recommendations:
  - The vaccine to be considered for introduction in settings with high dengue disease burden and high transmission intensity to maximize the public health impact and minimize any potential risk in seronegative persons.
  - The vaccine to be introduced to children aged 6 to 16 years of age. Within this age range, the vaccine should be introduced about 1-2 years prior to the age-specific peak incidence of dengue-related hospitalizations. The vaccine should be administered in a 2-dose schedule with a 3-month interval between doses.
  - The vaccine introduction should be accompanied by a well-designed communication strategy and community engagement.

  SAGE reviewed data across 19 Phase 1, 2 and 3 trials with more than 28,000 children and adults, including the pivotal Phase 3 Tetravalent Immunization against Dengue Efficacy Study (TIDES) trial, which was designed according to the WHO's guidance for a second-generation dengue vaccine.
  The WHO will consider the SAGE recommendation and is expected to update its position paper on dengue vaccines to include final guidance on the use of QDENGA in public vaccination programs.

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 August 2023, Takeda announced that it entered into an exclusive licensing agreement with ImmunoGen, Inc. (ImmunoGen) to develop and commercialize mirvetuximab soravtansine-gynx (MIRV) for the Japanese market. MIRV is an intravenous injection antibody-drug conjugate (ADC), in which a microtubule inhibitor is linked to an anti-folate receptor-α (FRα) antibody. It is the first ADC developed for the treatment of ovarian cancer. MIRV is approved under accelerated approval in the U.S. for the treatment of adult patients with FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. MIRV was the first medicine to show a significant prolongation of overall survival (OS) compared with conventional chemotherapy for the treatment of platinum-resistant relapsed or refractory ovarian cancer in a phase 3 MIRASOL study, conducted outside of Japan.

3. Material Contracts

There were no material contracts executed during the three-month period ended September 30, 2023.

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, 2023)	Number of shares outstanding as of the filing date (October 30, 2023)	Stock exchange on which the Company is listed	Description
Common stock	1,582,373,225	1,582,373,225	Tokyo (Prime Market), Nagoya (Premier Market), Fukuoka, Sapporo, and New York	The number of shares per one unit of shares is 100 shares.
Total	1,582,373,225	1,582,373,225	—	—

(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 October 1, 2023 to the filing date of Quarterly Securities Report (October 30, 2023).

(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, 2023 to September 30, 2023 (Note1)	45	1,582,373	92	1,676,503	92	1,668,515

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

(5) Major shareholders

		As of September 30, 2023	
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	261,049	16.58
Custody Bank of Japan, Ltd. (Trust account)	8-12, Harumi 1-chome, Chuo-ku, Tokyo	85,912	5.46
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)	70,909	4.50
JP Morgan Chase Bank 385632 (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)	54,800	3.48
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)	32,706	2.08
JPMorgan Securities Japan Co., Ltd.	7-3, Marunouchi 2-chome, Chiyoda-ku, Tokyo	32,250	2.05
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)	24,752	1.57
SMBC Nikko Securities Inc.	3-1, Marunouchi 3-chome, Chiyoda-ku, Tokyo	21,879	1.39
SSBTC Client Omnibus Account (Standing proxy: The Hongkong and Shanghai Banking Corporation Limited Tokyo Branch	One Congress Street, Suite 1, Boston MA USA 02111 (11-1, Nihombashi 3-chome, Chuo-ku, Tokyo)	21,590	1.37
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)	20,711	1.32
Total		626,558	39.78

(6) Information on voting rights

1) Total number of shares

		As of September 30, 2023		
Classification	**Number of shares (Shares)**		**Number of voting rights (Units)**	**Description**
Shares without voting rights		—	—	—
Shares with restricted voting rights (Treasury stock and other)		—	—	—
Shares with restricted voting rights (Others)		—	—	—
Shares with full voting rights (Treasury stock and other)	(Treasury stock) Common stock	7,511,300	—	—
	(Crossholding stock) Common stock	287,000	—	—
Shares with full voting rights (Others)	Common stock	1,573,171,200	15,731,712	—
Shares less than one unit	Common stock	1,403,725	—	Shares less than one unit (100 shares)
Number of issued shares		1,582,373,225	—	—
Total number of voting rights		—	15,731,712	—

(Note1) "Shares with full voting rights (Others)" includes 3,630,200 (voting rights: 36,302) and 2,257,800 (voting rights: 22,578) of the shares held by the ESOP and BIP trust, respectively.

(Note2) "Shares less than one unit" includes 90 of the shares as the treasury stock, and 139 and 219 of the shares held by the ESOP and BIP trust, respectively.

(Note3) On July 7, 2023, Takeda conducted the disposal of 13,958,202 treasury shares based on the resolution made on June 9, 2023 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.

2) Treasury stock and other

		As of September 30, 2023			
Name of shareholders	**Address**	**Number of shares held under own name (Shares)**	**Number of shares held under the name of others (Shares)**	**Total shares held (Shares)**	**Percentage of total issued shares issued (%)**
(Treasury stock)					
Takeda Pharmaceutical Company Limited	1-1, Doshomachi 4-chome, Chuo-ku, Osaka	7,511,300	—	7,511,300	0.47
(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		7,798,300	—	7,798,300	0.49

(Note) In addition to 90 shared of the above treasury stock and shares less than one unit, 3,630,339 of the shares held by the ESOP trust and 2,258,019 of the shares held by the BIP trust are included in treasury stock on the condensed interim consolidated financial statements.

2. Members of the Board of Directors

No changes from the latest Annual Securities Report.

IV. Financial Information

Basis of Preparation of the Condensed Interim Consolidated Financial Statements

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

1. Condensed Interim Consolidated Financial Statements

(1) Condensed Interim Consolidated Statements of Profit or Loss

		JPY (millions, except per share data)			
		Six-month Period Ended September 30,		Three-month Period Ended September 30,	
	Note	2022	2023	2022	2023
Revenue	4	1,974,771	2,101,707	1,002,307	1,043,089
Cost of sales		(598,327)	(664,696)	(305,445)	(343,582)
Selling, general and administrative expenses		(480,214)	(501,065)	(248,734)	(252,952)
Research and development expenses		(297,752)	(346,687)	(154,145)	(183,946)
Amortization and impairment losses on intangible assets associated with products	5	(273,643)	(369,665)	(142,366)	(240,242)
Other operating income		13,476	9,874	7,997	5,670
Other operating expenses	6	(83,359)	(110,240)	(55,177)	(77,379)
Operating profit (loss)		254,953	119,230	104,438	(49,342)
Finance income		75,707	24,312	14,782	9,359
Finance expenses		(109,272)	(106,095)	(53,803)	(58,022)
Share of profit (loss) of investments accounted for using the equity method		(1,366)	1,607	(869)	2,025
Profit (loss) before tax		220,022	39,053	64,549	(95,980)
Income tax (expenses) benefit	7	(53,269)	2,382	(2,817)	48,009
Net profit (loss) for the period		166,753	41,436	61,732	(47,971)
Attributable to:					
Owners of the Company		166,756	41,365	61,742	(48,030)
Non-controlling interests		(3)	71	(10)	59
Net profit (loss) for the period		166,753	41,436	61,732	(47,971)
Earnings per share (JPY)					
Basic earnings (loss) per share	8	107.62	26.51	39.77	(30.68)
Diluted earnings (loss) per share	8	106.88	26.29	39.48	(30.68)

See accompanying notes to condensed interim consolidated financial statements.

(2) Condensed Interim Consolidated Statements of Comprehensive Income

	JPY (millions)			
	Six-month Period Ended September 30,		Three-month Period Ended September 30,	
	2022	2023	2022	2023
Net profit (loss) for the period	166,753	41,436	61,732	(47,971)
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	5,284	6,537	5,464	(7,654)
Remeasurement of defined benefit pension plans	13,395	2,644	2,862	2,954
	18,679	9,181	8,326	(4,701)
Items that may be reclassified subsequently to profit or loss:				
Exchange differences on translation of foreign operations	1,035,192	779,220	312,421	185,281
Cash flow hedges	(33,200)	(2,015)	(7,727)	9,006
Hedging cost	(22,749)	(2,579)	4,666	(10,438)
Share of other comprehensive loss of investments accounted for using the equity method	(1,085)	(279)	(445)	(88)
	978,158	774,347	308,915	183,761
Other comprehensive income for the period, net of tax	996,837	783,528	317,241	179,061
Total comprehensive income for the period	1,163,590	824,964	378,973	131,090
Attributable to:				
Owners of the Company	1,163,535	824,843	378,964	131,027
Non-controlling interests	55	121	9	62
Total comprehensive income for the period	1,163,590	824,964	378,973	131,090

See accompanying notes to condensed interim consolidated financial statements.

Translation for reference purpose only

(3) Condensed Interim Consolidated Statements of Financial Position

	Note	JPY (millions) As of March 31, 2023	As of September 30, 2023
ASSETS			
Non-current assets:			
Property, plant and equipment		1,691,229	1,894,136
Goodwill		4,790,723	5,301,017
Intangible assets		4,269,657	4,402,421
Investments accounted for using the equity method		99,174	103,112
Other financial assets		279,683	313,252
Other non-current assets		63,325	59,672
Deferred tax assets		366,003	336,211
Total non-current assets		11,559,794	12,409,822
Current assets:			
Inventories		986,457	1,155,866
Trade and other receivables		649,429	755,327
Other financial assets		20,174	15,756
Income taxes receivable		32,264	32,739
Other current assets		160,868	178,219
Cash and cash equivalents		533,530	318,051
Assets held for sale		15,235	6,108
Total current assets		2,397,956	2,462,066
Total assets		13,957,750	14,871,889
LIABILITIES AND EQUITY			
LIABILITIES			
Non-current liabilities:			
Bonds and loans	9	4,042,741	4,404,363
Other financial liabilities		534,269	574,874
Net defined benefit liabilities		127,594	134,953
Income taxes payable		24,558	4,025
Provisions		55,969	14,958
Other non-current liabilities		65,389	71,354
Deferred tax liabilities		270,620	228,719
Total non-current liabilities		5,121,138	5,433,247
Current liabilities:			
Bonds and loans	9	339,600	274,841
Trade and other payables		649,233	421,078
Other financial liabilities		185,537	307,543
Income taxes payable		232,377	130,218
Provisions		508,360	657,657
Other current liabilities		566,689	576,279
Liabilities held for sale		144	—
Total current liabilities		2,481,940	2,367,617
Total liabilities		7,603,078	7,800,864

Translation for reference purpose only

	Note	JPY (millions) As of March 31, 2023	As of September 30, 2023
EQUITY			
Share capital		1,676,345	1,676,503
Share premium		1,728,830	1,711,109
Treasury shares		(100,317)	(51,246)
Retained earnings		1,541,146	1,446,018
Other components of equity		1,508,119	2,287,969
Equity attributable to owners of the Company		6,354,122	7,070,352
Non-controlling interests		549	673
Total equity		6,354,672	7,071,024
Total liabilities and equity		13,957,750	14,871,889

See accompanying notes to condensed interim consolidated financial statements.

Translation for reference purpose only

(4) Condensed Interim Consolidated Statements of Changes in Equity

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

		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, 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			(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			(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.

Translation for reference purpose only

Six-month period ended September 30, 2023 (From April 1 to September 30, 2023)

		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, 2023		1,676,345	1,728,830	(100,317)	1,541,146	1,606,128	12,470	(87,352)	(23,127)	—	1,508,119	6,354,122	549	6,354,672
Net profit for the period					41,365						—	41,365	71	41,436
Other comprehensive income (loss)						778,851	6,577	(2,015)	(2,579)	2,644	783,478	783,478	50	783,528
Comprehensive income (loss) for the period		—	—	—	41,365	778,851	6,577	(2,015)	(2,579)	2,644	783,478	824,843	121	824,964
Transactions with owners:														
Issuance of new shares		158	158								—	315		315
Acquisition of treasury shares				(2,355)							—	(2,355)		(2,355)
Disposal of treasury shares			0	0							—	0		0
Dividends	10				(140,121)						—	(140,121)		(140,121)
Changes in ownership											—	—	3	3
Transfers from other components of equity					3,628		(985)			(2,644)	(3,628)	—		—
Share-based compensation			33,606								—	33,606		33,606
Exercise of share-based awards			(51,485)	51,426							—	(60)		(60)
Total transactions with owners		158	(17,721)	49,071	(136,493)	—	(985)	—	—	(2,644)	(3,628)	(108,613)	3	(108,611)
As of September 30, 2023		1,676,503	1,711,109	(51,246)	1,446,018	2,384,979	18,062	(89,367)	(25,706)	—	2,287,969	7,070,352	673	7,071,024

See accompanying notes to condensed interim consolidated financial statements.

Translation for reference purpose only

(5) Condensed Interim Consolidated Statements of Cash Flows

	Notes	JPY (millions) Six-month Period Ended September 30, 2022	2023
Cash flows from operating activities:			
Net profit for the period		166,753	41,436
Depreciation and amortization		326,110	354,197
Impairment losses		35,950	126,703
Equity-settled share-based compensation		29,335	33,977
Loss on sales and disposal of property, plant and equipment		145	304
Gain on divestment of business and subsidiaries		(640)	(294)
Change in fair value of financial assets and liabilities associated with contingent consideration arrangements, net		446	(150)
Finance (income) and expenses, net		33,565	81,783
Share of loss (profit) of investments accounted for using the equity method		1,366	(1,607)
Income tax expenses (benefit)		53,269	(2,382)
Changes in assets and liabilities:			
Increase in trade and other receivables		(5,915)	(73,081)
Increase in inventories		(15,778)	(77,938)
Decrease in trade and other payables		(137,260)	(49,679)
Increase (decrease) in provisions		(12,939)	17,163
Increase (decrease) in other financial liabilities		(48,068)	34,178
Other, net		(11,887)	(74,375)
Cash generated from operations		414,451	410,234
Income taxes paid		(115,432)	(129,040)
Tax refunds and interest on tax refunds received		6,215	10,111
Net cash from operating activities		305,234	291,305
Cash flows from investing activities:			
Interest received		1,456	5,102
Dividends received		2,415	147
Acquisition of property, plant and equipment		(71,423)	(83,804)
Proceeds from sales of property, plant and equipment		97	8,337
Acquisition of intangible assets		(67,562)	(255,476)
Acquisition of investments		(4,694)	(2,264)
Proceeds from sales and redemption of investments		18,400	631
Proceeds from sales of business, net of cash and cash equivalents divested		—	365
Other, net		(609)	(148)
Net cash used in investing activities		(121,920)	(327,109)

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	Notes	JPY (millions) Six-month Period Ended September 30, 2022	2023
Cash flows from financing activities:			
Net increase in short-term loans and commercial papers		—	110,000
Proceeds from issuance of bonds and long-term loans		—	100,000
Repayments of bonds and long-term loans		(26,900)	(246,091)
Proceeds from the settlement of cross currency interest rate swaps related to bonds		—	60,063
Acquisition of treasury shares		(26,929)	(2,326)
Interest paid		(52,719)	(49,711)
Dividends paid		(140,007)	(139,811)
Repayments of lease liabilities		(20,996)	(21,613)
Other, net		(42)	(8,943)
Net cash used in financing activities		(267,593)	(198,433)
Net decrease in cash and cash equivalents		(84,278)	(234,237)
Cash and cash equivalents at the beginning of the year		849,695	533,530
Effects of exchange rate changes on cash and cash equivalents		32,720	18,759
Cash and cash equivalents at the end of the period		798,137	318,051

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, 2023.

(2) Approval of Financial Statements

Takeda's condensed interim consolidated financial statements as of and for the six-month period ended September 30, 2023 were approved on October 30, 2023 by Representative Director, President & Chief Executive Officer ("CEO") Christophe Weber and Director & Chief Financial Officer Costa Saroukos.

(3) Functional 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 JPY 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, and the disclosure of contingent assets and liabilities. Actual results could differ from these estimates.

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

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 as of and for the fiscal year ended March 31, 2023.

As of September 30, 2023 and through the issuance date of this report, Takeda concluded there was no indication of goodwill impairment.

3. Material Accounting Policies

Material accounting policies adopted for the condensed interim consolidated financial statements are the same as those adopted for the consolidated financial statements as of and for the fiscal year ended March 31, 2023.

Takeda calculated income tax expenses for the six-month period ended September 30, 2023, based on the estimated average annual effective tax rate.

4. Operating Segment and Revenue Information

Takeda comprises a single operating segment and is engaged in the research, development, manufacturing, marketing and out-licensing of pharmaceutical products. This is consistent with how the financial information is viewed in allocating resources, measuring performance, and forecasting future periods by the CEO who is Takeda's Chief Operating Decision Maker.

(1) Disaggregation of Revenue Information

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

Revenue by Type of Good or Service

	JPY (millions)	
	Six-month Period Ended September 30,	
	2022	2023
Sales of pharmaceutical products	1,914,400	2,060,682
Out-licensing and service income	60,371	41,026
Total	1,974,771	2,101,707

	JPY (millions)	
	Three-month period ended September 30,	
	2022	2023
Sales of pharmaceutical products	975,506	1,026,882
Out-licensing and service income	26,801	16,208
Total	1,002,307	1,043,089

Revenue by Business Area and Product

	JPY (millions)	
	Six-month Period Ended September 30,	
	2022	2023
Gastroenterology:		
ENTYVIO	346,616	391,709
GATTEX/REVESTIVE	48,434	58,890
TAKECAB/VOCINTI [(1)]	54,695	58,779
DEXILANT	37,990	23,165
PANTOLOC/CONTROLOC [(2)]	22,206	22,882
ALOFISEL	1,135	1,527
Others	35,314	39,915
Total Gastroenterology	546,391	596,867
Rare Diseases:		
Rare Hematology:		
ADVATE	62,368	62,704
ADYNOVATE/ADYNOVI	34,397	33,484
FEIBA	21,295	19,809
VONVENDI	5,899	7,434
RECOMBINATE	6,175	5,992
Others	25,584	23,299
Total Rare Hematology	155,718	152,721

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	JPY (millions) Six-month Period Ended September 30,	
	2022	**2023**
Rare Genetics and Other:		
TAKHZYRO	72,827	87,092
ELAPRASE	42,414	45,671
REPLAGAL	34,308	36,205
VPRIV	23,339	24,330
LIVTENCITY	4,228	8,325
Others	29,392	26,626
Total Rare Genetics and Other	206,508	228,250
Total Rare Diseases	362,226	380,971
PDT Immunology:		
immunoglobulin	245,055	309,158
albumin	51,765	58,947
Others	17,157	20,274
Total PDT Immunology	313,977	388,379
Oncology:		
ADCETRIS	41,715	54,271
LEUPLIN/ENANTONE	53,657	48,778
NINLARO	48,819	46,343
ICLUSIG	23,216	27,011
ALUNBRIG	9,710	13,712
EXKIVITY	1,439	3,467
VELCADE	20,829	2,907
Others	25,906	28,674
Total Oncology	225,291	225,163
Neuroscience:		
VYVANSE/ELVANSE	211,235	226,269
TRINTELLIX	49,798	50,968
Others	41,281	53,464
Total Neuroscience	302,314	330,701
Other:		
AZILVA [(1)]	37,185	23,681
FOSRENOL	7,526	8,138
Others	179,860	147,809
Total Other	224,572	179,628
Total	1,974,771	2,101,707

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

Translation for reference purpose only

	JPY (millions) Three-month period ended September 30,	
	2022	2023
Gastroenterology:		
ENTYVIO	178,349	199,721
GATTEX/REVESTIVE	26,518	31,800
TAKECAB/VOCINTI [(1)]	27,057	28,947
DEXILANT	15,660	11,127
PANTOLOC/CONTROLOC [(2)]	10,869	11,723
ALOFISEL	517	661
Others	17,038	19,344
Total Gastroenterology	276,009	303,323
Rare Diseases:		
Rare Hematology:		
ADVATE	30,262	28,876
ADYNOVATE/ADYNOVI	16,886	16,117
FEIBA	10,761	7,957
VONVENDI	2,978	3,678
RECOMBINATE	2,954	2,963
Others	12,746	11,755
Total Rare Hematology	76,587	71,346
Rare Genetics and Other:		
TAKHZYRO	38,778	45,763
ELAPRASE	20,220	22,822
REPLAGAL	16,708	18,226
VPRIV	11,474	12,447
LIVTENCITY	2,014	4,264
Others	14,806	13,459
Total Rare Genetics and Other	103,999	116,980
Total Rare Diseases	180,586	188,326
PDT Immunology:		
immunoglobulin	133,233	163,574
albumin	29,774	28,160
Others	9,108	10,131
Total PDT Immunology	172,115	201,865
Oncology:		
ADCETRIS	21,751	27,151
LEUPLIN/ENANTONE	25,664	24,175
NINLARO	25,071	25,311
ICLUSIG	11,961	14,415
ALUNBRIG	5,167	7,088
EXKIVITY	737	1,335
VELCADE	4,348	1,090
Others	13,110	14,139
Total Oncology	107,809	114,704

	JPY (millions) Three-month period ended September 30,	
	2022	2023
Neuroscience:		
VYVANSE/ELVANSE	111,263	103,099
TRINTELLIX	28,364	26,649
Others	20,270	23,904
Total Neuroscience	159,897	153,652
Other:		
AZILVA [(1)]	17,629	5,008
FOSRENOL	3,325	3,975
Others	84,937	72,236
Total Other	105,891	81,219
Total	1,002,307	1,043,089

[(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 on the following geographic locations:

	JPY (millions) Six-month Period Ended September 30,	
	2022	2023
Japan	261,353	228,528
U.S.	1,032,526	1,104,762
Europe and Canada	408,964	459,968
Asia (excluding Japan)	105,718	123,276
Latin America	83,258	92,069
Russia/CIS	37,817	31,090
Other	45,135	62,014
Total	1,974,771	2,101,707

"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,	
	2022	2023
Japan	120,818	103,705
U.S.	531,468	550,372
Europe and Canada	203,391	235,631
Asia (excluding Japan)	59,622	62,448
Latin America	42,973	48,352
Russia/CIS	20,451	13,727
Other	23,583	28,855
Total	1,002,307	1,043,089

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

5. Amortization and impairment losses on intangible assets associated with products

The impairment losses recorded for the six-month period ended September 30, 2023 was JPY 115,750 million, which primarily include JPY 73,979 million impairment charges for ALOFISEL (for complex Crohn's perianal fistulas) following topline results of phase 3 ADMIRE-CD II trial and JPY 28,477 million impairment charges for EXKIVITY (for the treatment of non-small cell lung cancer) following a decision to initiate a voluntary withdrawal globally.

6. Other Operating Expenses

Other operating expenses were JPY 83,359 million and JPY 110,240 million for the six-month period ended September 30, 2022 and 2023, respectively. Other operating expenses included restructuring expenses such as reductions in the workforce and consolidation of sites and functions. The amount of the restructuring expenses were JPY 24,584 million and JPY 38,500 million for the six-month period ended September 30, 2022 and 2023, respectively. Included expenses for reserves related to pre-launch inventories were JPY 17,975 million and JPY 11,747 million for the six-month period ended September 30, 2022 and 2023, respectively. Others include expenses for legal provision related to certain legal proceedings, donation and contributions and certain impairment losses.

7. Income Tax Expenses

Shire received a tax assessment from the Irish Revenue Commissioners ("Irish Revenue") on November 28, 2018 for EUR 398 million. This assessment relates to the tax treatment of the USD 1,635 million break fee Shire received from AbbVie, Inc. ("AbbVie") in connection with the terminated offer to acquire Shire made by AbbVie in 2014. Shire was acquired by Takeda in January 2019. Takeda appealed the assessment to the Tax Appeals Commission ("TAC") and the appeal was heard by the TAC in late 2020. On July 30, 2021, Takeda received a ruling on the matter from the TAC, with the TAC ruling in favor of the Irish Revenue and recorded an income taxes payable for the case. Subsequently, on October 17, 2023, Takeda agreed with the Irish Revenue to settle the tax assessment for EUR 130 million including interest and without penalties, as a full and final settlement of all liabilities in relation to the receipt of the break fee. As a result, Takeda reversed its income taxes payable in excess of the settlement amount of EUR 130 million and recorded JPY 63,547 million reduction to tax expenses.

The effective tax rate for the six-month period ended September 30, 2023 was (6.1)% compared to 24.2% for the six-month period ended September 30, 2022, mainly due to the tax expense reduction described above. This was partially offset by the tax charges from the write-down of deferred tax assets for the six-month period ended September 30, 2023.

8. Earnings per Share

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

	Six-month Period Ended September 30,	
	2022	2023
Net profit for the period attributable to owners of the Company		
Net profit for the period attributable to owners of the Company (million JPY)	166,756	41,365
Net profit used for calculation of earnings per share (million JPY)	166,756	41,365
Weighted average number of ordinary shares outstanding during the period (thousands of shares) [basic]	1,549,479	1,560,613
Dilutive effect (thousands of shares)	10,723	12,706
Weighted average number of ordinary shares outstanding during the period (thousands of shares) [diluted]	1,560,202	1,573,319
Earnings per share		
Basic earnings per share (JPY)	107.62	26.51
Diluted earnings per share (JPY)	106.88	26.29

	Three-month Period Ended September 30,	
	2022	2023
Net profit for the period attributable to owners of the Company		
Net profit (loss) for the period attributable to owners of the Company (million JPY)	61,742	(48,030)
Net profit (loss) used for calculation of earnings per share (million JPY)	61,742	(48,030)
Weighted average number of ordinary shares outstanding during the period (thousands of shares) [basic]	1,552,407	1,565,296
Dilutive effect (thousands of shares)	11,326	—
Weighted average number of ordinary shares outstanding during the period (thousands of shares) [diluted]	1,563,733	1,565,296
Earnings per share		
Basic earnings (loss) per share (JPY)	39.77	(30.68)
Diluted earnings (loss) per share (JPY)	39.48	(30.68)

9. Bonds and Loans

(1) Bonds

During the six-month period ended September 30, 2023, Takeda redeemed the following bonds.

Instrument	Issuance	Redemption date	Principal Amount in contractual currency	Type of redemption
USD Unsecured Senior Notes	September 2016	September 23, 2023	USD1,000 million	Maturity redemption

(2) Loans

During the six-month period ended September 30, 2023, Takeda entered into the following borrowing.

Instrument	Execution	Maturity	Principal Amount in contractual currency
Syndicated loans	April 2023	April 2030	JPY 100,000 million

During the six-month period ended September 30, 2023, Takeda repaid the following borrowing.

Instrument	Execution	Repayment date	Principal Amount in contractual currency	Type of repayment
Syndicated loans	April 2016	April 26, 2023	JPY 100,000 million	Maturity repayment

10. Equity and Other Equity Items

(1) Disposal of treasury shares

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

During the six-month period ended September 30, 2023, the Company conducted the disposal of 13,958 thousand treasury shares under the LTIP for the Company Group employees overseas. The disposal of treasury shares resulted in a decrease in treasury shares of JPY 47,614 million.

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

(2) Dividends

Dividends declared and paid	Total dividends declared and paid JPY (millions)	Dividends per share (JPY)	Record date	Effective date
April 1, 2022 to September 30, 2022				
Q1 2022	140,365	90.00	March 31, 2022	June 30, 2022
April 1, 2023 to September 30, 2023				
Q1 2023	140,475	90.00	March 31, 2023	June 29, 2023

Dividends declared for which the effective date falls in after September 30, 2023 are as follows:

Dividends declared	Total dividends declared JPY (millions)	Dividends per share (JPY)	Record date	Effective date
Q3 2023	148,037	94.00	September 30, 2023	December 1, 2023

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.

	JPY (millions)			
As of September 30, 2023	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Financial assets measured at fair value through profit or loss				
Derivatives	—	8,338	7,321	15,659
Investments in convertible notes	—	—	10,785	10,785
Investments in debt instruments	—	—	1,113	1,113
Financial assets associated with contingent consideration arrangements	—	—	25,039	25,039
Derivatives for which hedge accounting is applied	—	64,683	—	64,683
Financial assets measured at fair value through OCI				
Trade and other receivables	—	84,152	—	84,152
Equity instruments	91,317	—	95,969	187,286
Total	91,317	157,173	140,227	388,717
Liabilities:				
Financial liabilities measured at fair value through profit or loss				
Derivatives	—	6,709	7,321	14,030
Financial liabilities associated with contingent consideration arrangements	—	—	8,481	8,481
Derivatives for which hedge accounting is applied	—	39,939	—	39,939
Total	—	46,648	15,802	62,450

(2) Valuation Techniques

The fair value of derivatives classified as Level 2 is measured based on Treasury management system valuation models or the Black-Scholes model, whose significant inputs are based on observable market data.

Derivatives classified as Level 3 include those recognized in connection with settlements of cash flows arising from differences between the fixed prices and floating market prices of renewable energy in a virtual power purchase agreement and those recognized in an agreement to offset the volatility of such cash flows. The fair value of derivatives in Level 3 is measured using the discounted cash flow method. The key assumptions taken into account include forecasted renewable energy prices and the expected generation of the renewable energy generating facility.

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 and other 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 5.0 times to 20.1 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, 2023. 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, 2023, 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, 2023. There were no other significant transfers between levels of the fair value hierarchy during the six-month period ended September 30, 2023.

(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 six-month period ended September 30, 2023. 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.

	JPY (millions)	
	Six-month Period Ended September 30, 2023	
	Financial assets associated with contingent consideration arrangements	**Equity instruments**
As of the beginning of the period	23,806	83,236
Changes recognized as finance income or finance expenses	(1,360)	—
Changes in fair value of financial assets measured at fair value through OCI and exchange differences on translation of foreign operations	2,594	14,093
Purchases	—	363
Sales	—	(1)
Transfers to Level 1	—	(5,008)
Acquisition from conversion of convertible notes	—	3,286
As of the end of the period	25,039	95,969

(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, 2023, the balance primarily relates to pre-existing contingent consideration arrangements from historical acquisitions.

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 six-month period ended September 30, 2023. 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, 2023
As of the beginning of the period	8,139
Changes in the fair value during the period	(121)
Foreign currency translation differences	463
As of the end of the period	8,481

(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, 2023	
	Carrying amount	Fair value
Bonds	3,781,851	3,306,007
Long-term loans	747,026	741,196

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

Not applicable.

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 147th fiscal year (from April 1, 2023 to March 31, 2024) at the meeting of the Board of Directors held on October 26, 2023.

(a)	Total amount of interim dividends	JPY 148,037,012,490
(b)	Interim dividend per share	JPY 94.00
(c)	Effective date/ Payment start date	December 1, 2023

B. Information on Guarantors of the Company

Not applicable.