

Quarterly Securities Report

(The first quarter of 147th Business Term)
for The Three-month Period Ended June 30, 2023

TAKEDA PHARMACEUTICAL COMPANY LIMITED
AND ITS SUBSIDIARIES

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A. Company Information

I. Overview of Takeda

1. Key Consolidated Financial Data

Term	JPY (millions), unless otherwise indicated		
	Three-month period ended June 30,	Three-month period ended June 30,	For the year ended March 31,
	2022	2023	2023
Revenue	972,465	1,058,618	4,027,478
Profit before tax	155,473	135,033	375,090
Net profit for the period	105,021	89,406	317,038
Net profit attributable to owners of the Company	105,014	89,395	317,017
Total comprehensive income for the period	784,617	693,874	911,574
Total equity	6,317,383	6,921,668	6,354,672
Total assets	14,065,426	14,792,738	13,957,750
Basic earnings per share (JPY)	67.94	57.51	204.29
Diluted earnings per share (JPY)	67.56	57.12	201.94
Ratio of equity attributable to owners of the Company to total assets (%)	44.9	46.8	45.5
Net cash from (used in) operating activities	84,241	92,400	977,156
Net cash from (used in) investing activities	(94,714)	(266,530)	(607,102)
Net cash from (used in) financing activities	(215,717)	(57,778)	(709,148)
Cash and cash equivalents at the end of the period	645,991	316,380	533,530

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

(Note 2) The key consolidated financial data for the three-month period ended June 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 three-month period ended June 30, 2023.

As of June 30, 2023, Takeda consisted of 193 entities comprised of 175 consolidated subsidiaries (including partnerships), 17 associates accounted for using the equity method, and Takeda Pharmaceutical Company Limited. There has been no significant change in our group companies for the three-month period ended June 30, 2023.

II. Operating and Financial Review

1. Risk Factors

There were no risk factors identified for the three-month period ended June 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 June 30, 2023)

	Billion JPY or percentage				
	FY2022 Q1	FY2023 Q1	Change versus the same period of the previous fiscal year		
			AER		CER
			Amount of Change	% Change	% Change
Revenue	972.5	1,058.6	86.2	8.9 %	3.7 %
Cost of sales	(292.9)	(321.1)	(28.2)	9.6 %	4.6 %
Selling, general and administrative expenses	(231.5)	(248.1)	(16.6)	7.2 %	1.9 %
Research and development expenses	(143.6)	(162.7)	(19.1)	13.3 %	6.6 %
Amortization and impairment losses on intangible assets associated with products	(131.3)	(129.4)	1.9	(1.4)%	(8.1)%
Other operating income	5.5	4.3	(1.2)	(22.4)%	(22.0)%
Other operating expenses	(28.2)	(32.9)	(4.7)	16.8 %	10.0 %
Operating profit	150.5	168.6	18.1	12.0 %	10.0 %
Finance income and (expenses), net	5.5	(33.1)	(38.6)	—	—
Share of loss of investments accounted for using the equity method	(0.5)	(0.4)	0.1	(15.9)%	(51.6)%
Profit before tax	155.5	135.0	(20.4)	(13.1)%	(14.0)%
Income tax expenses	(50.5)	(45.6)	4.8	(9.6)%	(11.2)%
Net profit for the period	105.0	89.4	(15.6)	(14.9)%	(15.4)%

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 June 30, 2023), Definition of Core financial measures and Constant Exchange Rate change, for the definition of “Constant Exchange Rate change”.

Revenue

Revenue for the three-month period ended June 30, 2023 was JPY 1,058.6 billion (JPY +86.2 billion and +8.9% AER, +3.7% 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.

Revenue by Geographic Region

The following shows revenue by geographic region:

	Billion JPY or percentage				
	FY2022 Q1	FY2023 Q1	Change versus the same period of the previous fiscal year		
			AER		CER
Revenue:			Amount of Change	% Change	% Change
Japan	140.5	124.8	(15.7)	(11.2)%	(11.3)%
United States	501.1	554.4	53.3	10.6 %	2.9 %
Europe and Canada	205.6	224.3	18.8	9.1 %	2.8 %
Asia (excluding Japan)	46.1	60.8	14.7	32.0 %	29.6 %
Latin America	40.3	43.7	3.4	8.5 %	13.9 %
Russia/CIS	17.4	17.4	(0.0)	(0.0)%	0.1 %
Other* ¹	21.6	33.2	11.6	53.9 %	56.4 %
Total	972.5	1,058.6	86.2	8.9 %	3.7 %

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

Revenue by Business Area

The following shows revenue by business area:

	Billion JPY or percentage				
	FY2022 Q1	FY2023 Q1	Change versus the same period of the previous fiscal year		
			AER		CER
Revenue:			Amount of Change	% Change	% Change
GI	270.4	293.5	23.2	8.6 %	2.7 %
Rare Diseases	181.6	192.6	11.0	6.1 %	2.0 %
Rare Hematology	79.1	81.4	2.2	2.8 %	(1.7)%
Rare Genetics and Other	102.5	111.3	8.8	8.5 %	4.9 %
PDT Immunology	141.9	186.5	44.7	31.5 %	24.3 %
Oncology	117.5	110.5	(7.0)	(6.0)%	(8.6)%
Neuroscience	142.4	177.0	34.6	24.3 %	17.2 %
Other	118.7	98.4	(20.3)	(17.1)%	(20.3)%
Total	972.5	1,058.6	86.2	8.9 %	3.7 %

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

GI

In GI, revenue was JPY 293.5 billion (JPY +23.2 billion and +8.6% AER, +2.7% CER).

Sales of ENTYVIO (for ulcerative colitis (“UC”) and Crohn’s disease (“CD”)) were JPY 192.0 billion (JPY +23.7 billion and +14.1% AER, +7.1% CER). Sales in the U.S. were JPY 134.3 billion (JPY +16.4 billion and +13.9% AER). The increase was due to demand in the first line biologic inflammatory bowel disease (“IBD”) population both in UC and CD and favorable foreign exchange rates. Sales in Europe and Canada were JPY 44.0 billion (JPY +5.1 billion and +13.2% AER). The increase was primarily due to continued launches of the subcutaneous formulation, new patient gains and favorable foreign exchange rates.

Sales of GATTEX/REVESTIVE (for short bowel syndrome) were JPY 27.1 billion (JPY +5.2 billion and +23.6% AER, +17.0% CER). The increase was primarily due to increased demand across all regions and favorable foreign exchange rates.

Sales of TAKECAB/VOCINTI (for acid-related diseases) were JPY 29.8 billion (JPY +2.2 billion and +7.9% AER, +7.6% CER). The increase was primarily due to increased sales in China.

Sales of DEXILANT (for acid reflux disease) were JPY 12.0 billion (JPY -10.3 billion and -46.1% AER, -48.8% 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 192.6 billion (JPY +11.0 billion and +6.1% AER, +2.0% CER).

Revenue of Rare Hematology was JPY 81.4 billion (JPY +2.2 billion and +2.8% AER, -1.7% CER).

Sales of ADVATE (for hemophilia A) were JPY 33.8 billion (JPY +1.7 billion and +5.4% AER, +0.6% CER). The increase was due to favorable foreign exchange rates.

Sales of FEIBA (for hemophilia A and B) were JPY 11.9 billion (JPY +1.3 billion and +12.5% AER, +7.2% CER). The increase was primarily due to the favorable timing of shipments in the U.S. and favorable foreign exchange rates.

Aggregate sales of plasma-derived human coagulation factor products, HEMOFIL (for hemophilia A), IMMUNATE (for hemophilia A), and IMMUNINE (for hemophilia B) were JPY 4.2 billion (JPY -1.2 billion and -21.7% AER, -23.3% CER). The decrease was primarily due to decreased sales in the Growth and Emerging Markets.

Revenue of Rare Genetics and Other was JPY 111.3 billion (JPY +8.8 billion and +8.5% AER, +4.9% CER).

Sales of TAKHZYRO (for hereditary angioedema) were JPY 41.3 billion (JPY +7.3 billion and +21.4% AER, +14.7% CER). The increase was primarily due to continued strong demand across all regions and favorable foreign exchange rates.

Sales of LIVTENCITY (for post-transplant cytomegalovirus (“CMV”) infection/disease) were JPY 4.1 billion (JPY +1.8 billion and +83.4% AER, +70.7% CER). The increase was primarily due to continued patient uptake in the U.S. and Europe and Canada.

Sales of FIRAZYR (for hereditary angioedema) were JPY 5.5 billion (JPY -1.2 billion and -18.3% AER, -20.2% CER). The decrease was primarily due to the loss of exclusivity in the U.S. and Europe.

PDT Immunology

In PDT Immunology, revenue was JPY 186.5 billion (JPY +44.7 billion and +31.5% AER, +24.3% CER).

Aggregate sales of immunoglobulin products were JPY 145.6 billion (JPY +33.8 billion and +30.2% AER, +22.5% 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, especially in the U.S., as well as favorable foreign exchange rates. Those include GAMMAGARD LIQUID/KIOVIG (for the treatment of primary immunodeficiency (“PID”) and multifocal motor neuropathy (“MMN”)), and subcutaneous immunoglobulin therapies (CUVITRU and HYQVIA) which are growing due to their benefit to patients and convenience in administration compared to intravenous therapies.

Aggregate sales of albumin products including HUMAN ALBUMIN and FLEXBUMIN (primarily used for hypovolemia and hypoalbuminemia) were JPY 30.8 billion (JPY +8.8 billion and +40.0% AER, +36.0% CER). The increase was primarily driven by strong albumin demand in China.

Oncology

In Oncology, revenue was JPY 110.5 billion (JPY -7.0 billion and -6.0% AER, -8.6% CER).

Sales of VELCADE (for multiple myeloma) were JPY 1.8 billion (JPY -14.7 billion and -89.0% AER, -89.8% CER). The decrease was primarily due to multiple generic entrants in the U.S. starting in May 2022.

Sales of ADCETRIS (for malignant lymphomas) were JPY 27.1 billion (JPY +7.2 billion and +35.8% AER, +35.3% CER). The increase was led by strong growth in Growth and Emerging Markets.

Neuroscience

In Neuroscience, revenue was JPY 177.0 billion (JPY +34.6 billion and +24.3% AER, +17.2% CER).

Sales of VYVANSE/ELVANSE (for attention deficit hyperactivity disorder (“ADHD”)) were JPY 123.2 billion (JPY +23.2 billion and +23.2% AER, +16.0% CER). The increase was mainly due to the growth of the adult market, including an impact from a shortage of generic versions of the instant release formulation of ADDERALL in the U.S., and favorable foreign exchange rates.

Sales of ADDERALL XR (for ADHD) were JPY 13.5 billion (JPY +7.3 billion and +117.7% AER, +100.8% CER). The increase was mainly due to a shortage of generic versions of the instant release formulation marketed by competitors in the U.S. and favorable foreign exchange rates.

Cost of Sales

Cost of Sales was JPY 321.1 billion (JPY +28.2 billion and +9.6% AER, +4.6% CER). The increase was primarily due to the depreciation of Japanese yen and revenue growth in our five key business areas 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 248.1 billion (JPY +16.6 billion and +7.2% AER, +1.9% 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 162.7 billion (JPY +19.1 billion and +13.3% AER, +6.6% CER). The increase was mainly due to the impact from the depreciation of Japanese yen and various investments including those for advancement of pipeline in the current period.

Amortization and Impairment Losses on Intangible Assets Associated with Products

Amortization and Impairment Losses on Intangible Assets Associated with Products was JPY 129.4 billion (JPY -1.9 billion and -1.4% AER, -8.1% CER). The decrease was mainly due to a decrease in impairment charges for certain assets related to in-process R&D and marketed products, partially offset by the increase of amortization expenses due to the depreciation of Japanese yen.

Other Operating Income

Other Operating Income was JPY 4.3 billion (JPY -1.2 billion and -22.4% AER, -22.0% CER).

Other Operating Expenses

Other Operating Expenses were JPY 32.9 billion (JPY +4.7 billion and +16.8% AER, +10.0% CER). The increase was primarily due to an increased valuation reserve for pre-launch inventory and the write-off of a certain asset related to a collaboration agreement booked during the current period.

Operating Profit

As a result of the above factors, Operating Profit was JPY 168.6 billion (JPY +18.1 billion and +12.0% AER, +10.0% CER).

Net Finance Expenses

Net Finance Expenses were JPY 33.1 billion (JPY +38.6 billion, compared to Net Finance Income of JPY 5.5 billion in the same period of the previous fiscal year). The change was primarily attributable to a decrease in Finance Income reflecting gains from acquisitions of prior equity method companies and other income recorded in the same period of the previous fiscal year.

Share of Loss of Investments Accounted for Using the Equity Method

Share of Loss of Investments Accounted for Using the Equity Method was JPY 0.4 billion (JPY -0.1 billion and -15.9% AER, -51.6% CER).

Income Tax Expenses

Income Tax Expenses were JPY 45.6 billion (JPY -4.8 billion, -9.6% AER, -11.2% CER). The decrease was primarily due to a decrease in Profit Before Tax.

Net Profit for the Period

Net Profit for the Period was JPY 89.4 billion (JPY -15.6 billion and -14.9% AER, -15.4% CER).

Core Results (April 1 to June 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 Q1	FY2023 Q1	Change versus the same period of the previous fiscal year		
			AER		CER
			Amount of Change	% change	% change
Core Revenue	972.5	1,058.6	86.2	8.9 %	3.7 %
Core Operating Profit	319.1	326.3	7.3	2.3 %	(2.0)%
Core EPS (JPY)	145	150	5	3.5 %	0.3 %

Core Revenue

Core Revenue for the three-month period ended June 30, 2023 was JPY 1,058.6 billion (JPY +86.2 billion and +8.9% AER, +3.7% 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 424.1 billion (JPY +79.9 billion and +23.2% AER, +16.2% 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
- Other: QDENGGA

Core Operating Profit

Core Operating Profit for the current period was JPY 326.3 billion (JPY +7.3 billion and +2.3% AER, -2.0% CER). The increase on an AER basis was due to the depreciation of the yen in the current period, while the decline on a CER basis was due to a change in product mix resulted in higher cost of sales ratio and increased investment in R&D and data and technology.

Core EPS

Core EPS for the current period was JPY 150 (JPY +5 and +3.5% AER, +0.3% CER).

(2) Consolidated Financial Position

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

Assets.

Total Assets as of June 30, 2023 were JPY 14,792.7 billion (JPY +835.0 billion). The increases of Goodwill, Intangible Assets, and Property, Plant and Equipment (JPY +391.4 billion, JPY +244.4 billion, and JPY +104.1 billion, respectively) were mainly due to the effect of foreign currency translation. In addition, Trade and Other Receivables increased (JPY +143.5 billion). These increases were partially offset by a decrease in Cash and Cash Equivalents (JPY -217.1 billion).

Liabilities.

Total Liabilities as of June 30, 2023 were JPY 7,871.1 billion (JPY +268.0 billion). Bonds and Loans were JPY 4,747.1 billion* (JPY +364.8 billion), which increased primarily due to the effect of foreign currency translation and the issuance of commercial paper in June 2023. This increase was partially offset by a decrease in Trade and Other Payables (JPY -208.3 billion).

* The carrying amount of Bonds was JPY 4,006.3 billion and Loans was JPY 740.8 billion as of June 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 (1,301 million USD)	June 2015	June 2025 ~ June 2045	188.9
Unsecured US dollar denominated senior notes (4,000 million USD)	September 2016	September 2023 ~ September 2026	560.2
Unsecured Euro denominated senior notes (3,000 million EUR)	November 2018	November 2026 ~ November 2030	467.9
Unsecured US dollar denominated senior notes (2,250 million USD)	November 2018	November 2023 ~ November 2028	324.0
Hybrid bonds (subordinated bonds)	June 2019	June 2079	499.1
Unsecured US dollar denominated senior notes (7,000 million USD)	July 2020	March 2030 ~ July 2060	1,006.0
Unsecured Euro denominated senior notes (3,600 million EUR)	July 2020	July 2027 ~ July 2040	560.8
Unsecured JPY denominated senior bonds	October 2021	October 2031	249.4
Commercial paper	June 2023	September 2023	150.0
Total			4,006.3

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 (1,500 million USD)	April 2017	April 2027	216.8
Syndicated loans	April 2023	April 2030	100.0
Bilateral loans	March 2016 ~ March 2023	April 2024 ~ March 2029	210.0
Other			0.5
Total			740.8

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. Furthermore, Takeda had short term commercial paper drawings outstanding of JPY 150.0 billion as at June 30, 2023.

Equity.

Total Equity as of June 30, 2023 was JPY 6,921.7 billion (JPY +567.0 billion). The increase of Other Components of Equity (JPY +604.7 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 -51.0 billion) mainly due to the decrease of JPY 140.1 billion related to dividends payments despite recording Net Profit for the Period.

Consolidated Cash Flows

	Billion JPY	
	FY2022 Q1	FY2023 Q1
Net cash from (used in) operating activities	84.2	92.4
Net cash from (used in) investing activities	(94.7)	(266.5)
Net cash from (used in) financing activities	(215.7)	(57.8)
Net increase (decrease) in cash and cash equivalents	(226.2)	(231.9)
Cash and cash equivalents at the beginning of the year	849.7	533.5
Effects of exchange rate changes on cash and cash equivalents	22.5	14.8
Cash and cash equivalents at the end of the period	646.0	316.4

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

Net cash from operating activities

Net cash from operating activities for the current period was JPY 92.4 billion (JPY +8.2 billion). This increase was primarily due to a favorable impact from changes in trade and other payables and other financial liabilities in addition to a higher net profit for the period adjusted for non-cash items and other adjustments. These were partially offset by an unfavorable impact from changes in trade and other receivables and an increase in income taxes paid.

Net cash used in investing activities

Net cash used in investing activities was JPY 266.5 billion (JPY +171.8 billion). This increase was mainly due to an increase in acquisition of intangible assets related to the acquisition of TAK-279 from Nimbus Therapeutics, LLC (Nimbus) and the exclusive license agreement with HUTCHMED (China) Limited (HUTCHMED).

Net cash used in financing activities

Net cash used in financing activities was JPY 57.8 billion (JPY -157.9 billion). The decrease was mainly due to a net increase in commercial paper drawings of JPY 110.0 billion during the current period.

(3) Research & Development Activities and Results

Research and development expenses for the three-month period ended June 30, 2023 were JPY 162.7 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, and ALOFISEL which is currently in Phase 3 trial to support further potential geographic expansion in the U.S. 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 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 is intended to address FDA feedback in a December 2019 Complete Response Letter (CRL). Since receiving the CRL Takeda has worked closely with the FDA to address the Agency's feedback; this resubmission package includes 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 vedolizumab intravenous 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 . Takeda expects a decision from the FDA by the end of 2023.

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 products (ALUNBRIG and EXKIVITY), and development programs in other areas, including colorectal cancer with fruquintinib (TAK-113); and (3) advancing a cutting-edge pipeline focused on the power of innate immunity.

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 Phase 3 FRESCO-2 trial along with data from the Phase 3 FRESCO 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 multi-regional 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.

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 (C_{max} 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.

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% fSC1g (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 (aSBI), 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.

Vaccine

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

QDENG / 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.

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.

3. Material Contracts

There were no material contracts executed during the three-month period ended June 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 June 30, 2023)	Number of shares outstanding as of the filing date (August 1, 2023)	Stock exchange on which the Company is listed	Description
Common stock	1,582,327,925	1,582,346,225	Tokyo (Prime Market), Nagoya (Premier Market), Fukuoka, Sapporo, and New York	The number of shares per one unit of shares is 100 shares.
Total	1,582,327,925	1,582,346,225	—	—

(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 on the filing date of Quarterly Securities Report (August 1, 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 April 1, 2023 to June 30, 2023 (Note1)	32	1,582,328	66	1,676,411	66	1,688,423

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

(5) Major shareholders

No information required in the 1st quarter.

(6) Information on voting rights

1) Total number of shares

Classification	As of June 30, 2023		
	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)	—	—	—
	(Treasury stock)		
	Common stock	21,468,600	—
Shares with full voting rights (Treasury stock and other)	(Crossholding stock)		
	Common stock	287,000	—
Shares with full voting rights (Others)	Common stock	1,559,223,300	15,592,233
			Shares less than one unit (100 shares)
Shares less than one unit	Common stock	1,349,025	—
Number of issued shares		1,582,327,925	—
Total number of voting rights		—	15,592,233

(Note1) "Shares with full voting rights (Others)" includes 3,710,200 (voting rights: 37,102) and 2,491,900 (voting rights: 24,919) of the shares held by the ESOP and BIP trust, respectively.

(Note2) "Shares less than one unit" includes 2 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

Name of shareholders	Address	As of June 30, 2023			
		Number of shares held under own name (Shares)	Number of shares held under the name of others (Shares)	Total shares held (Shares)	Percentage of total issued shares issued (%)
(Treasury stock)					
Takeda Pharmaceutical Company Limited	1-1, Doshomachi 4- chome, Chuo-ku, Osaka	21,468,600	—	21,468,600	1.36
(Crossholding stock)					
Amato Pharmaceutical Products, Ltd.	5-3, Shinsenri Higashi- machi 1-chome, Toyonaka-city, Osaka	275,000	—	275,000	0.02
Watanabe Chemical, Co., Ltd.	6-1, Hiranomachi 3- chome, Chuo-ku, Osaka-city, Osaka	12,000	—	12,000	0.00
Total		21,755,600	—	21,755,600	1.37

(Note) In addition to 2 shared of the above treasury stock and shares less than one unit, 3,710,339 of the shares held by the ESOP trust and 2,492,119 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

	Note	JPY (millions, except per share data)	
		Three-month Period Ended June 30,	
		2022	2023
Revenue	4	972,465	1,058,618
Cost of sales		(292,882)	(321,114)
Selling, general and administrative expenses		(231,480)	(248,113)
Research and development expenses		(143,607)	(162,741)
Amortization and impairment losses on intangible assets associated with products		(131,277)	(129,423)
Other operating income		5,479	4,251
Other operating expenses		(28,182)	(32,907)
Operating profit		150,515	168,571
Finance income		60,925	26,455
Finance expenses		(55,469)	(59,575)
Share of loss of investments accounted for using the equity method		(497)	(418)
Profit before tax		155,473	135,033
Income tax expenses		(50,452)	(45,627)
Net profit for the period		105,021	89,406
Attributable to:			
Owners of the Company		105,014	89,395
Non-controlling interests		7	11
Net profit for the period		105,021	89,406
Earnings per share (JPY)			
Basic earnings per share	5	67.94	57.51
Diluted earnings per share	5	67.56	57.12

See accompanying notes to condensed interim consolidated financial statements.

(2) Condensed Interim Consolidated Statements of Comprehensive Income

	JPY (millions)	
	Three-month Period Ended June 30,	
	2022	2023
Net profit for the period	105,021	89,406
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	(180)	14,192
Remeasurement of defined benefit pension plans	10,533	(310)
	10,354	13,881
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	722,771	593,939
Cash flow hedges	(25,473)	(11,021)
Hedging cost	(27,415)	7,859
Share of other comprehensive income of investments accounted for using the equity method	(641)	(191)
	669,242	590,586
Other comprehensive income for the period, net of tax	679,596	604,467
Total comprehensive income for the period	784,617	693,874
Attributable to:		
Owners of the Company	784,571	693,816
Non-controlling interests	46	58
Total comprehensive income for the period	784,617	693,874

See accompanying notes to condensed interim consolidated financial statements.

(3) Condensed Interim Consolidated Statements of Financial Position

		JPY (millions)	
		As of March 31, 2023	As of June 30, 2023
	Note		
<u>ASSETS</u>			
Non-current assets:			
Property, plant and equipment		1,691,229	1,795,315
Goodwill		4,790,723	5,182,128
Intangible assets		4,269,657	4,514,084
Investments accounted for using the equity method		99,174	100,421
Other financial assets		279,683	293,108
Other non-current assets		63,325	60,143
Deferred tax assets		366,003	375,522
Total non-current assets		<u>11,559,794</u>	<u>12,320,721</u>
Current assets:			
Inventories		986,457	1,083,374
Trade and other receivables		649,429	792,895
Other financial assets		20,174	52,229
Income taxes receivable		32,264	32,586
Other current assets		160,868	179,884
Cash and cash equivalents		533,530	316,380
Assets held for sale		15,235	14,670
Total current assets		<u>2,397,956</u>	<u>2,472,017</u>
Total assets		<u><u>13,957,750</u></u>	<u><u>14,792,738</u></u>
<u>LIABILITIES AND EQUITY</u>			
<u>LIABILITIES</u>			
Non-current liabilities:			
Bonds and loans	6	4,042,741	4,330,254
Other financial liabilities		534,269	495,494
Net defined benefit liabilities		127,594	137,108
Income taxes payable		24,558	4,807
Provisions		55,969	59,504
Other non-current liabilities		65,389	72,612
Deferred tax liabilities		270,620	269,549
Total non-current liabilities		<u>5,121,138</u>	<u>5,369,328</u>
Current liabilities:			
Bonds and loans	6	339,600	416,860
Trade and other payables		649,233	440,924
Other financial liabilities		185,537	313,882
Income taxes payable		232,377	242,756
Provisions		508,360	527,773
Other current liabilities		566,689	559,547
Liabilities held for sale		144	—
Total current liabilities		<u>2,481,940</u>	<u>2,501,741</u>
Total liabilities		<u><u>7,603,078</u></u>	<u><u>7,871,069</u></u>

JPY (millions)

	Note	As of March 31, 2023	As of June 30, 2023
<u>EQUITY</u>			
Share capital		1,676,345	1,676,411
Share premium		1,728,830	1,741,937
Treasury shares		(100,317)	(100,255)
Retained earnings		1,541,146	1,490,097
Other components of equity		1,508,119	2,112,861
Equity attributable to owners of the Company		6,354,122	6,921,052
Non-controlling interests		549	617
Total equity		6,354,672	6,921,668
Total liabilities and equity		13,957,750	14,792,738

See accompanying notes to condensed interim consolidated financial statements.

(4) Condensed Interim Consolidated Statements of Changes in Equity
 Three-month period ended June 30, 2022 (From April 1 to June 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					105,014						—	105,014	7	105,021
Other comprehensive income (loss)						722,137	(225)	(25,473)	(27,415)	10,533	679,557	679,557	39	679,596
Comprehensive income (loss) for the period		—	—	—	105,014	722,137	(225)	(25,473)	(27,415)	10,533	679,557	784,571	46	784,617
Transactions with owners:														
Issuance of new shares		14	14								—	29		29
Acquisition of treasury shares			(5)	(27,045)							—	(27,050)		(27,050)
Dividends	7				(138,218)						—	(138,218)		(138,218)
Transfers from other components of equity					15,213		(4,679)			(10,533)	(15,213)	—		—
Share-based compensation			12,292								—	12,292		12,292
Exercise of share-based awards			(13,838)	13,867							—	30		30
Total transactions with owners		14	(1,537)	(13,177)	(123,005)	—	(4,679)	—	—	(10,533)	(15,213)	(152,918)	—	(152,918)
As of June 30, 2022		1,676,277	1,707,336	(129,184)	1,459,764	1,710,399	17,163	(91,375)	(33,549)	—	1,602,638	6,316,832	551	6,317,383

See accompanying notes to condensed interim consolidated financial statements.

Three-month period ended June 30, 2023 (From April 1 to June 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					89,395						—	89,395	11	89,406
Other comprehensive income (loss)						593,692	14,201	(11,021)	7,859	(310)	604,421	604,421	47	604,467
Comprehensive income (loss) for the period		—	—	—	89,395	593,692	14,201	(11,021)	7,859	(310)	604,421	693,816	58	693,874
Transactions with owners:														
Issuance of new shares		66	66								—	132		132
Acquisition of treasury shares				(2,350)							—	(2,350)		(2,350)
Disposal of treasury shares			0	0							—	0		0
Dividends	7				(140,122)						—	(140,122)		(140,122)
Changes in ownership											—	—	9	9
Transfers from other components of equity					(322)		12			310	322	—		—
Share-based compensation			15,467								—	15,467		15,467
Exercise of share-based awards			(2,425)	2,412							—	(13)		(13)
Total transactions with owners		66	13,108	62	(140,444)	—	12	—	—	310	322	(126,886)	9	(126,877)
As of June 30, 2023		1,676,411	1,741,937	(100,255)	1,490,097	2,199,820	26,682	(98,373)	(15,268)	—	2,112,861	6,921,052	617	6,921,668

See accompanying notes to condensed interim consolidated financial statements.

(5) Condensed Interim Consolidated Statements of Cash Flows

	Notes	JPY (millions)	
		Three-month Period Ended June 30,	
		2022	2023
Cash flows from operating activities:			
Net profit for the period		105,021	89,406
Depreciation and amortization		158,283	171,501
Impairment losses		14,238	7,829
Equity-settled share-based compensation		12,292	15,442
Loss on sales and disposal of property, plant and equipment		7	326
Gain on divestment of business and subsidiaries		(320)	(147)
Change in fair value of financial assets and liabilities associated with contingent consideration arrangements, net		136	44
Finance (income) and expenses, net		(5,456)	33,120
Share of loss of investments accounted for using the equity method		497	418
Income tax expenses		50,452	45,627
Changes in assets and liabilities:			
Increase in trade and other receivables		(17,970)	(90,373)
Increase in inventories		(9,118)	(28,589)
Decrease in trade and other payables		(97,123)	(34,656)
Decrease in provisions		(20,106)	(22,583)
Increase (decrease) in other financial liabilities		(44,152)	25,254
Other, net		(41,583)	(67,640)
Cash generated from operations		105,097	144,980
Income taxes paid		(24,945)	(55,907)
Tax refunds and interest on tax refunds received		4,090	3,327
Net cash from operating activities		84,241	92,400
Cash flows from investing activities:			
Interest received		470	2,322
Dividends received		138	147
Acquisition of property, plant and equipment		(42,125)	(45,957)
Proceeds from sales of property, plant and equipment		34	11
Acquisition of intangible assets		(56,251)	(223,280)
Acquisition of investments		(2,933)	(674)
Proceeds from sales and redemption of investments		6,178	543
Proceeds from sales of business, net of cash and cash equivalents divested		—	372
Other, net		(224)	(15)
Net cash used in investing activities		(94,714)	(266,530)

	Notes	JPY (millions)	
		Three-month Period Ended June 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		(26,804)	(100,088)
Acquisition of treasury shares		(26,929)	(2,326)
Interest paid		(22,770)	(19,815)
Dividends paid		(128,873)	(130,746)
Repayments of lease liabilities		(10,325)	(10,546)
Other, net		(17)	(4,257)
Net cash used in financing activities		(215,717)	(57,778)
Net decrease in cash and cash equivalents		(226,190)	(231,908)
Cash and cash equivalents at the beginning of the year		849,695	533,530
Effects of exchange rate changes on cash and cash equivalents		22,485	14,759
Cash and cash equivalents at the end of the period		645,991	316,380

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 three-month period ended June 30, 2023 were approved on August 1, 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.

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 for the fiscal year ended March 31, 2023.

Takeda calculated income tax expenses for the three-month period ended June 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)	
	Three-month Period Ended June 30,	
	2022	2023
Sales of pharmaceutical products	938,894	1,033,800
Out-licensing and service income	33,571	24,818
Total	972,465	1,058,618

Revenue by Business Area and Product

	JPY (millions)	
	Three-month Period Ended June 30,	
	2022	2023
Gastroenterology:		
ENTYVIO	168,267	191,988
TAKECAB/VOCINTI ⁽¹⁾	27,638	29,832
GATTEX/REVESTIVE	21,916	27,091
DEXILANT	22,330	12,038
PANTOLOC/CONTROLOC ⁽²⁾	11,337	11,158
ALOFISEL	617	866
Others	18,276	20,571
Total Gastroenterology	270,382	293,543
Rare Diseases:		
Rare Hematology:		
ADVATE	32,106	33,828
ADYNOVATE/ADYNOVI	17,511	17,366
FEIBA	10,534	11,853
VONVENDI	2,921	3,755
RECOMBINATE	3,221	3,029
Others	12,838	11,544
Total Rare Hematology	79,131	81,375
Rare Genetics and Other:		
TAKHZYRO	34,049	41,329
ELAPRASE	22,194	22,850
REPLAGAL	17,601	17,979
VPRIV	11,865	11,883
LIVTENCITY	2,214	4,061
Others	14,586	13,167
Total Rare Genetics and Other	102,510	111,269
Total Rare Diseases	181,640	192,645

	JPY (millions)	
	Three-month Period Ended June 30,	
	2022	2023
PDT Immunology:		
immunoglobulin	111,822	145,584
albumin	21,991	30,787
Others	8,049	10,143
Total PDT Immunology	141,862	186,514
Oncology:		
ADCETRIS	19,964	27,121
LEUPLIN/ENANTONE	27,993	24,603
NINLARO	23,748	21,031
ICLUSIG	11,256	12,596
ALUNBRIG	4,544	6,623
EXKIVITY	702	2,132
VELCADE	16,481	1,816
Others	12,795	14,535
Total Oncology	117,482	110,458
Neuroscience:		
VYVANSE/ELVANSE	99,972	123,170
TRINTELLIX	21,434	24,319
Others	21,012	29,560
Total Neuroscience	142,418	177,049
Other:		
AZILVA ⁽¹⁾	19,556	18,673
FOSRENOL	4,201	4,163
Others	94,923	75,573
Total Other	118,681	98,409
Total	972,465	1,058,618

⁽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)	
	Three-month Period Ended June 30,	
	2022	2023
Japan	140,534	124,823
U.S.	501,058	554,390
Europe and Canada	205,573	224,338
Asia (excluding Japan)	46,096	60,827
Latin America	40,285	43,717
Russia/CIS	17,366	17,364
Other	21,552	33,159
Total	972,465	1,058,618

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

5. Earnings Per Share

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

	Three-month Period Ended June 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)	105,014	89,395
Net profit used for calculation of earnings per share (million JPY)	105,014	89,395
Weighted average number of ordinary shares outstanding during the period (thousands of shares) [basic]	1,545,706	1,554,419
Dilutive effect (thousands of shares)	8,645	10,621
Weighted average number of ordinary shares outstanding during the period (thousands of shares) [diluted]	1,554,350	1,565,041
Earnings per share		
Basic earnings per share (JPY)	67.94	57.51
Diluted earnings per share (JPY)	67.56	57.12

6. Bonds and Loans

Loans

During the three-month period ended June 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 three-month period ended June 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

7. Equity and Other Equity Items

Dividends

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

8. Financial Instruments

(1) Fair Value Measurements

Derivative and non-derivative financial instruments measured at fair value are categorized in the following three-tier fair value hierarchy that reflects the significance of the inputs in making the measurements. Level 1 is defined as observable inputs, such as quoted prices in active markets for an identical asset or liability. Level 2 is defined as inputs other than quoted prices in active markets within Level 1 that are directly or indirectly observable. Level 3 is defined as unobservable inputs.

As of June 30, 2023	JPY (millions)			
	Level 1	Level 2	Level 3	Total
Assets:				
Financial assets measured at fair value through profit or loss				
Derivatives	—	5,792	6,236	12,028
Investments in convertible notes	—	—	12,717	12,717
Investments in debt instruments	—	—	1,113	1,113
Financial assets associated with contingent consideration arrangements	—	—	25,830	25,830
Derivatives for which hedge accounting is applied	—	78,821	—	78,821
Financial assets measured at fair value through OCI				
Trade and other receivables	—	105,025	—	105,025
Equity instruments	102,795	—	87,136	189,931
Total	102,795	189,638	133,033	425,465
Liabilities:				
Financial liabilities measured at fair value through profit or loss				
Derivatives	—	31,711	6,236	37,947
Financial liabilities associated with contingent consideration arrangements	—	—	8,627	8,627
Derivatives for which hedge accounting is applied	—	32,843	—	32,843
Total	—	64,554	14,863	79,417

(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 4.4 times to 15.8 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 three-month period ended June 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 three-month period ended June 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 three-month period ended June 30, 2023. There were no other significant transfers between levels of the fair value hierarchy during the three-month period ended June 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 three-month period ended June 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)	
	Three-month Period Ended June 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	(201)	—
Changes in fair value of financial assets measured at fair value through OCI and exchange differences on translation of foreign operations	2,226	8,477
Purchases	—	297
Sales	—	(1)
Transfers to Level 1	—	(4,873)
As of the end of the period	<u>25,830</u>	<u>87,136</u>

(5) Financial liabilities associated with contingent consideration arrangements

Financial liabilities associated with contingent consideration arrangements represent consideration related to business combinations or license agreements that are payable only upon future events such as the achievement of development milestones and sales targets, including pre-existing contingent consideration arrangements of the companies that are acquired by Takeda. At each reporting date, the fair value of financial liabilities associated with contingent consideration arrangements is re-measured based on risk-adjusted future cash flows discounted using an appropriate discount rate.

As of June 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 three-month period ended June 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) Three-month Period Ended June 30, 2023
As of the beginning of the period	8,139
Changes in the fair value during the period	28
Foreign currency translation differences	460
As of the end of the period	<u>8,627</u>

(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 June 30, 2023	
	Carrying amount	Fair value
Bonds	3,856,305	3,472,858
Long-term loans	740,472	738,618

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.

9. Subsequent Events

Not applicable.

2. Others

Not applicable.

B. Information on Guarantors of the Company

Not applicable.