

Quarterly Securities Report

(The third quarter of 146th Business Term)
for The Nine-month Period and Three-month
Quarter Ended December 31, 2022

TAKEDA PHARMACEUTICAL COMPANY LIMITED
AND ITS SUBSIDIARIES

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

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A. Company Information

I. Overview of Takeda

1. Key Consolidated Financial Data

Term	JPY (millions), unless otherwise indicated		
	Nine-month period ended December 31,	Nine-month period ended December 31,	For the year ended March 31,
	2021	2022	2022
Revenue	2,695,717	3,071,322	3,569,006
<Three-month period ended December 31>	901,294	1,096,551	
Profit before tax	356,618	327,175	302,571
Net profit for the period	241,541	285,903	230,166
Net profit attributable to owners of the Company	241,417	285,883	230,059
<Three-month period ended December 31>	57,770	119,127	
Total comprehensive income for the period	459,044	750,209	824,427
Total equity	5,331,822	6,176,498	5,683,523
Total assets	12,698,519	13,504,705	13,178,018
Basic earnings per share (JPY)	154.09	184.32	147.14
<Three-month period ended December 31>	36.91	76.63	
Diluted earnings per share (JPY)	153.03	182.65	145.87
Ratio of equity attributable to owners of the Company to total assets (%)	42.0	45.7	43.1
Net cash from (used in) operating activities	747,521	683,463	1,123,105
Net cash from (used in) investing activities	(172,487)	(168,610)	(198,125)
Net cash from (used in) financing activities	(826,465)	(702,548)	(1,070,265)
Cash and cash equivalents at the end of the period	724,341	685,141	849,695

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

(Note 2) The key consolidated financial data for the nine-month period ended December 31, 2021 and 2022 are based on the condensed interim consolidated financial statements prepared in accordance with IAS 34.

2. Business Overview

There has been no significant change in our business and our group companies for the nine-month period ended December 31, 2022.

As of December 31, 2022, Takeda consisted of 216 entities comprised of 197 consolidated subsidiaries (including partnerships), 18 associates accounted for using the equity method, and Takeda Pharmaceutical Company Limited.

Change in the major group companies for the nine-month period ended December 31, 2022 was as follows:

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

II. Operating and Financial Review

1. Risk Factors

There were no risk factors identified for the nine-month period ended December 31, 2022 as well as no significant changes in the risk factors compared to what we reported in our Annual Securities Report for the year ended March 31, 2022 which was filed in Japan.

This is based on our assessment as of the filing date of this Quarterly Securities Report (February 7, 2023).

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

(1) Consolidated Financial Results (April 1 to December 31, 2022)

	Billion JPY or percentage				
	FY2021 Q3YTD	FY2022 Q3YTD	Change versus the same period of the previous fiscal year		
				Actual % Change	CER % Change*1
Revenue	2,695.7	3,071.3	375.6	13.9 %	(0.7)%
Cost of sales	(798.5)	(934.3)	(135.8)	17.0 %	3.4 %
Selling, general and administrative expenses	(662.9)	(742.5)	(79.6)	12.0 %	(2.2)%
Research and development expenses	(382.5)	(472.4)	(89.9)	23.5 %	4.9 %
Amortization and impairment losses on intangible assets associated with products	(323.6)	(409.2)	(85.6)	26.4 %	5.4 %
Other operating income	34.3	16.7	(17.6)	(51.3)%	(54.4)%
Other operating expenses	(100.0)	(127.6)	(27.6)	27.6 %	8.6 %
Operating profit	462.5	401.9	(60.5)	(13.1)%	(20.3)%
Finance income and (expenses), net	(100.6)	(71.6)	29.0	(28.8)%	(31.6)%
Share of loss of investments accounted for using the equity method	(5.3)	(3.1)	2.1	(40.4)%	(58.1)%
Profit before tax	356.6	327.2	(29.4)	(8.3)%	(16.5)%
Income tax expenses	(115.1)	(41.3)	73.8	(64.1)%	(61.3)%
Net profit for the period	241.5	285.9	44.4	18.4 %	4.8 %

*1 Please refer to (ii) Core Results (April 1 to December 31, 2022), Definition of Core financial measures and Constant Exchange Rate change, for the definition.

Revenue. Revenue for the nine-month period ended December 31, 2022 was 3,071.3 billion JPY, an increase of 375.6 billion JPY, or 13.9% (CER % change: -0.7%), compared to the same period of the previous fiscal year. The increase is primarily attributable to growth from business momentum and favorable foreign exchange rates, offsetting the decrease of revenue in the current period due to the sale of a portfolio of diabetes products in Japan to Teijin Pharma Limited for 133.0 billion JPY, which was recorded as revenue in the same period of the previous fiscal year.

Revenue of our core therapeutic areas (i.e. Gastroenterology (“GI”), Rare Diseases, Plasma-Derived Therapies (“PDT”) Immunology, Oncology, and Neuroscience) increased by 522.1 billion JPY, or 23.6%, compared to the same period of the previous fiscal year, to 2,735.6 billion JPY. Each of our core therapeutic areas, except Oncology, contributed to positive revenue growth due to growth from business momentum and favorable foreign exchange rates. Generic erosion and intensified competition impacted certain Oncology products in the current period.

Revenue outside of our core therapeutic areas significantly decreased by 146.5 billion JPY, or 30.4%, compared to the same period of the previous fiscal year to 335.7 billion JPY, largely due to the aforementioned non-recurring 133.0 billion JPY selling price of the diabetes portfolio in Japan, which was recorded as revenue in the same period of the previous fiscal year.

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Revenue by Geographic Region

The following shows revenue by geographic region:

Revenue:	Billion JPY or percentage				
	FY2021 Q3YTD	FY2022 Q3YTD	Change versus the same period of the previous fiscal year		
			Actual % change	CER % change ^{*1}	
Japan ^{*2}	530.2	389.8	(140.4)	(26.5)%	(26.8)%
United States	1,297.0	1,621.8	324.8	25.0 %	2.6 %
Europe and Canada	541.0	632.4	91.4	16.9 %	7.9 %
Asia (excluding Japan)	139.8	169.0	29.3	20.9 %	6.5 %
Latin America	93.5	121.4	27.9	29.8 %	10.3 %
Russia/CIS	43.6	66.7	23.1	53.0 %	15.6 %
Other ^{*3}	50.6	70.2	19.6	38.7 %	43.4 %
Total	2,695.7	3,071.3	375.6	13.9 %	(0.7)%

*1 Please refer to Core Results (April 1 to December 31, 2022), Definition of Core financial measures and Constant Exchange Rate change, for the definition.

*2 The 133.0 billion JPY selling price of the sale of diabetes portfolio in Japan is included in the nine-month period ended December 31, 2021.

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

Revenue by Therapeutic Area

The following shows revenue by therapeutic area:

Revenue:	Billion JPY or percentage				
	FY2021 Q3YTD	FY2022 Q3YTD	Change versus the same period of the previous fiscal year		
			Actual % change	CER % change ^{*1}	
GI	665.7	857.5	191.8	28.8 %	11.1 %
Rare Diseases	462.9	553.6	90.7	19.6 %	5.0 %
Rare Hematology	211.6	232.6	21.1	10.0 %	(3.4)%
Rare Genetics and Other	251.3	321.0	69.6	27.7 %	12.2 %
PDT Immunology	363.2	502.4	139.2	38.3 %	17.6 %
Oncology	359.1	345.0	(14.1)	(3.9)%	(12.6)%
Neuroscience	362.6	477.1	114.5	31.6 %	10.2 %
Other ^{*2}	482.2	335.7	(146.5)	(30.4)%	(35.4)%
Total	2,695.7	3,071.3	375.6	13.9 %	(0.7)%

*1 Please refer to Core Results (April 1 to December 31, 2022), Definition of Core financial measures and Constant Exchange Rate change, for the definition.

*2 The 133.0 billion JPY selling price of the sale of diabetes portfolio in Japan is included in the nine-month period ended December 31, 2021.

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

- GI.* In Gastroenterology, revenue was 857.5 billion JPY, a year-on-year increase of 191.8 billion JPY, or 28.8% (CER % change: 11.1%). Growth was driven by Takeda's top-selling product ENTYVIO (for ulcerative colitis ("UC") and Crohn's disease ("CD")), with sales of 547.9 billion JPY and a year-on-year increase of 152.5 billion JPY, or 38.6%. Sales of ENTYVIO in the U.S. increased by 122.4 billion JPY, or 46.0%, to 388.3 billion JPY, driven by a continued increase in the first line biologic inflammatory bowel disease ("IBD") population both in UC and CD and favorable foreign exchange rates. Sales of ENTYVIO in Europe and Canada increased by 20.2 billion JPY, or 19.7%, to 122.4 billion JPY, supported by continued launches of the subcutaneous formulation and favorable foreign exchange rates. In the Growth and Emerging Markets, the increase in sales of ENTYVIO was led by growth in Brazil. Sales of GATTEX/REVESTIVE (for short bowel syndrome) were 78.2 billion JPY, an increase of 21.6 billion JPY, or 38.1%, primarily due to increased market penetration and new country launches, including Japan in August 2021, and favorable foreign exchange rates. Sales of DEXILANT (for acid reflux disease) were 55.1 billion JPY, an increase of 15.0 billion JPY, or 37.3% versus the same period of the previous fiscal year, due to the increased sales of authorized generics in the U.S. and favorable foreign exchange rates. Sales of TAKECAB/VOCINTI (for acid-related diseases) were 84.5 billion JPY, an increase of 6.2 billion JPY, or 7.9%, versus the same period of the previous fiscal year, primarily due to increased sales in China, partially offset by the decrease of sales in Japan, due to a negative impact associated with the market expansion re-pricing applied in April 2022, despite an increase in volume. Sales of PENTASA (for UC) were 7.3 billion JPY, a decrease of 8.5 billion JPY, or 53.7%, versus the same period of the previous fiscal year due to generic erosion in the U.S. from May 2022.
- Rare Diseases.* In Rare Diseases, revenue was 553.6 billion JPY, a year-on-year increase of 90.7 billion JPY, or 19.6% (CER % change: 5.0%).

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Revenue in Rare Hematology increased by 21.1 billion JPY, or 10.0% (CER % change: -3.4%), to 232.6 billion JPY. Sales of ADVATE (for hemophilia A), ADYNOVATE/ADYNOVI (for hemophilia A) and FEIBA (for hemophilia A and B) increased by 2.8 billion JPY or 3.1% to 92.1 billion JPY, 4.0 billion JPY or 8.7% to 49.9 billion JPY, and 3.6 billion JPY or 12.5% to 32.6 billion JPY, respectively, primarily due to favorable foreign exchange rates partially offset by negative impacts from competition in the U.S. Other Rare Hematology products in aggregate increased year-on-year, primarily due to additional indications, newly consolidated products, and favorable foreign exchange rates.

Revenue in Rare Genetics and Other was 321.0 billion JPY, a year-on-year increase of 69.6 billion JPY, or 27.7% (CER % change: 12.2%). Sales of TAKHZYRO (for hereditary angioedema) were 116.9 billion JPY, an increase of 38.5 billion JPY, or 49.0%, versus the same period of the previous fiscal year primarily due to expansion of the prophylactic market, continued geographic expansion and strong patient uptake as well as favorable foreign exchange rates. Sales of REPLAGAL (for Fabry disease) increased by 11.0 billion JPY, or 27.8%, to 50.6 billion JPY, primarily due to the succession to manufacturing and marketing rights in Japan by Takeda upon expiration of the relevant license agreement in February 2022. Sales of other enzyme replacement therapies ELAPRASE (for Hunter syndrome) and VPRIV (for Gaucher disease) increased by 7.3 billion JPY and 4.2 billion JPY, respectively, primarily due to favorable foreign exchange rates. Sales of LIVTENCITY (for post-transplant cytomegalovirus (“CMV”) infection/disease), which was first launched in the U.S. in December 2021, followed by several other countries, were 7.3 billion JPY in the current period.

- *PDT Immunology.* In Plasma-Derived Therapies (“PDT”) Immunology, revenue increased by 139.2 billion JPY, or 38.3% (CER % change: 17.6%) compared to the same period of the previous fiscal year, to 502.4 billion JPY. Aggregate sales of immunoglobulin products were 390.5 billion JPY, an increase of 112.2 billion JPY, or 40.3%, compared to the same period of the previous fiscal year. Sales of each of our three global immunoglobulin brands marked double digit percentage of revenue growth, due to continued strong demand globally and growing supply, especially in the U.S., where the pandemic pressure is now easing, as well as favorable foreign exchange rates. Those include GAMMAGARD LIQUID/KIOVIG (for the treatment of primary immunodeficiency (“PID”) and multifocal motor neuropathy (“MMN”)), and subcutaneous immunoglobulin therapies (CUVITRU and HYQVIA) which are growing due to their benefit to patients and convenience in administration compared to intravenous therapies. Aggregate sales of albumin products including HUMAN ALBUMIN and FLEXBUMIN (primarily used for hypovolemia and hypoalbuminemia) were 85.5 billion JPY, an increase of 24.0 billion JPY, or 39.1%, versus the same period of the previous fiscal year driven by strong albumin demand in the U.S. and in China and favorable exchange rates.
- *Oncology.* In Oncology, revenue was 345.0 billion JPY, a year-on-year decrease of 14.1 billion JPY, or 3.9% (CER % change: -12.6%), impacted by the rapid generic erosion of VELCADE (for multiple myeloma) sales in the U.S. Sales of VELCADE decreased by 59.7 billion JPY, or 70.7%, versus the same period of the previous fiscal year to 24.7 billion JPY predominantly due to multiple generic entrants in the U.S. starting in May 2022. Sales of NINLARO (for multiple myeloma) were 75.9 billion JPY, an increase of 5.2 billion JPY, or 7.3%, versus the same period of the previous fiscal year, aided by favorable foreign exchange rates, which were offset partially by intensified competition and decreased demand mainly in the U.S. Sales of ADCETRIS (for malignant lymphomas) were 65.8 billion JPY, an increase of 14.0 billion JPY, or 27.0%, versus the same period of the previous fiscal year, led by strong growth in countries such as Argentina, Italy and Japan. Sales of ICLUSIG (for leukemia) were 35.5 billion JPY, an increase of 8.8 billion JPY, or 33.1%, versus the same period of the previous fiscal year, due to steady growth in the U.S. and also aided by favorable foreign exchange rates. Sales of ALUNBRIG (for non-small cell lung cancer) were 15.8 billion JPY, an increase of 5.6 billion JPY, or 55.7%, benefiting from strong demand in European countries and the Growth and Emerging Markets such as China. Sales of ZEJULA (for ovarian cancer) were 9.8 billion JPY, an increase of 4.1 billion JPY, or 70.9%, primarily led by Japan where it was helped by a newly launched tablet formulation in June 2022, in addition to a capsule formulation. Sales of LEUPLIN/ENANTONE (for endometriosis, uterine fibroids, premenopausal breast cancer, prostatic cancer, etc.), an off-patent product, increased by 3.0 billion JPY, or 3.6%, versus the same period of the previous fiscal year to 85.2 billion JPY mainly due to favorable foreign exchange rates. Sales of EXKIVITY (for non-small cell lung cancer), which was first launched in the U.S. in September 2021, followed by several other countries, were 2.2 billion JPY in the current period.
- *Neuroscience.* In Neuroscience, revenue was 477.1 billion JPY, a year-on-year increase of 114.5 billion JPY, or 31.6% (CER % change: 10.2%). Sales of VYVANSE/ELVANSE (for attention deficit hyperactivity disorder (“ADHD”)) were 335.4 billion JPY, an increase of 90.5 billion JPY, or 36.9%, versus the same period of the previous fiscal year mainly driven by the growth of the adult market in the U.S., Europe and Canada and favorable foreign exchange rates. Sales of TRINTELLIX (for major depressive disorder (“MDD”)) were 79.7 billion JPY, an increase of 16.7 billion JPY, or 26.4%, versus the same period of the previous fiscal year, due to increasing prescriptions in the U.S. and Japan and favorable foreign exchange rates. Sales of INTUNIV (for ADHD) increased by 4.1 billion JPY, or 32.8%, versus the same period of the previous fiscal year, to 16.6 billion JPY driven by an increase of sales in Japan. Sales of ADDERALL XR (for ADHD) also increased, by 3.1 billion JPY or 19.6% versus the same period of the previous fiscal year, to 19.1 billion JPY mainly due to a shortage of generic versions of the instant release formulation marketed by competitors and favorable foreign exchange rates.

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Cost of Sales. Cost of Sales increased by 135.8 billion JPY, or 17.0% (CER % change: 3.4%), to 934.3 billion JPY. The increase was primarily due to the depreciation of the yen and a sales increase in our core therapeutic areas as compared to the same period of the previous fiscal year. The Cost of Sales Ratio increased by 0.8 pp compared to the same period of the previous fiscal year to 30.4%. The main reason for the increase in the Cost of Sales Ratio was the effect of the sale of a portfolio of diabetes products in Japan with the selling price of 133.0 billion JPY being recorded in revenue in the same period of the previous fiscal year.

Selling, General and Administrative (SG&A) expenses. SG&A expenses increased by 79.6 billion JPY, or 12.0% (CER % change: -2.2%) compared to the same period of the previous fiscal year, to 742.5 billion JPY, mainly due to the impact from the depreciation of the yen in the current period.

Research and Development (R&D) expenses. R&D expenses increased by 89.9 billion JPY, or 23.5% (CER % change: 4.9%) compared to the same period of the previous fiscal year, to 472.4 billion JPY, mainly due to the impact from the depreciation of the yen in the current period.

Amortization and Impairment Losses on Intangible Assets Associated with Products. Amortization and Impairment Losses on Intangible Assets Associated with Products increased by 85.6 billion JPY, or 26.4% (CER % change: 5.4%) compared to the same period of the previous fiscal year, to 409.2 billion JPY, mainly due to the impact from the depreciation of the yen in the current period and an increase in impairment charges for certain assets related to in-process R&D and marketed products.

Other Operating Income. Other Operating Income was 16.7 billion JPY, a decrease of 17.6 billion JPY, or 51.3% (CER % change: -54.4%), compared to the same period of the previous fiscal year primarily due to a change in fair value of financial assets and liabilities associated with contingent consideration arrangements recognized and certain settlement proceeds recorded in the same period of the previous fiscal year

Other Operating Expenses. Other Operating Expenses were 127.6 billion JPY, an increase of 27.6 billion JPY, or 27.6% (CER % change: 8.6%), compared to the same period of the previous fiscal year, primarily due to increases in reserves and provisions mainly for certain assets and pre-launch inventory during the current period, partially offset by a decrease in restructuring expenses attributable to the decrease in Shire integration costs.

Operating Profit. As a result of the above factors, Operating Profit decreased by 60.5 billion JPY, or 13.1% (CER % change: -20.3%) compared to the same period of the previous fiscal year to 401.9 billion JPY.

Net Finance Expenses. Net Finance Expenses were 71.6 billion JPY in the current period, a decrease of 29.0 billion JPY, or 28.8% (CER % change: -31.6%) compared to Net Finance Expenses of 100.6 billion JPY for the same period of the previous fiscal year. This decrease was mainly driven by a positive impact from the remeasurement of warrants to purchase stocks of companies held by Takeda as well as a gain on prior equity method investments related to the acquisitions of GammaDelta Therapeutics and Adaptate Biotherapeutics in April 2022.

Share of Loss of Investments Accounted for Using the Equity Method. Share of Loss of Investments Accounted for Using the Equity Method was 3.1 billion JPY, a decrease of 2.1 billion JPY, or 40.4% (CER % change: -58.1%), compared to the same period of the previous fiscal year.

Income Tax Expenses. Income Tax Expenses were 41.3 billion JPY, a decrease of 73.8 billion JPY, or 64.1% (CER % change: -61.3%), compared to the same period of the previous year. This decrease was primarily due to a tax charge of 64.6 billion JPY for tax and interest, net of 0.5 billion JPY of associated tax benefit, arising from tax assessment involving Irish taxation of the break fee Shire received from AbbVie in connection with the terminated offer to acquire Shire made by AbbVie in 2014 in the same period of the previous year as well as decreased tax charges for US international tax provisions and tax benefits from recognition of deferred tax assets in the current period. These decreases were partially offset by the tax benefits from internal entity restructuring transactions in the same period of the previous year.

Net Profit for the Period. Net Profit for the Period decreased by 44.4 billion JPY, or 18.4% (CER % change: 4.8%), compared to the same period of the previous fiscal year to 285.9 billion JPY.

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Core Results (April 1 to December 31, 2022)

Definition of Core financial measures and Constant Exchange Rate change

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

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

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

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

Results of Core Operations

	Billion JPY or percentage				
	FY2021 Q3YTD	FY2022 Q3YTD	Change versus the same period of the previous fiscal year		
				Actual % change	CER % change
Core Revenue	2,562.7	3,071.3	508.6	19.8 %	4.5 %
Core Operating Profit	757.9	954.7	196.7	26.0 %	9.7 %
Core EPS (yen)	333	456	123	37.0 %	17.1 %

Core Revenue for the nine-month period ended December 31, 2022 was 3,071.3 billion JPY, an increase of 508.6 billion JPY, or 19.8% (CER % change: 4.5%), compared to the same period of the previous fiscal year. Core revenue for the nine-month period ended December 31, 2021, was 2,562.7 billion JPY, which excluded the non-recurring 133.0 billion JPY selling price of the diabetes portfolio in Japan. There were no significant items unrelated to Takeda's core operations excluded from revenue in the current period, resulting in Core revenue for the current period being the same as Reported revenue at 3,071.3 billion JPY. Business momentum was led by Takeda's Growth and Launch Products* which totaled 1,199.6 billion JPY, a year-on-year increase of 350.7 billion JPY, or 41.3% (CER % change: 20.4%).

* Takeda's Growth and Launch Products

GI: ENTYVIO, ALOFISEL

Rare Diseases: TAKHZYRO, LIVTENCITY

PDT Immunology: Immunoglobulin products including GAMMAGARD LIQUID/KIOVIG, HYQVIA, and CUVITRU,

Albumin products including HUMAN ALBUMIN and FLEXBUMIN

Oncology: ALUNBRIG, EXKIVITY

Other: SPIKEVAX Intramuscular Injection, NUVAXOVID Intramuscular Injection

Core Operating Profit for the current period was 954.7 billion JPY, an increase of 196.7 billion JPY or 26.0% (CER % change: 9.7%) compared to the same period of the previous fiscal year driven by revenue growth in our core therapeutic areas and the depreciation of the yen in the current period.

Core EPS for the current period was 456 yen, an increase of 123 yen, or 37.0% (CER % change: 17.1%), compared to the same period of the previous fiscal year.

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(2) Consolidated Financial Position

Assets. Total Assets as of December 31, 2022 were 13,504.7 billion JPY, reflecting an increase of 326.7 billion JPY compared to the previous fiscal year-end. Goodwill and Property, Plant and Equipment increased by 283.2 billion JPY and 73.6 billion JPY respectively mainly due to the effect of foreign currency translation. In addition, Inventories increased by 74.1 billion JPY. These increases were partially offset by a decrease in Cash and Cash Equivalents of 164.6 billion JPY.

Liabilities. Total Liabilities as of December 31, 2022 were 7,328.2 billion JPY, reflecting a decrease of 166.3 billion JPY compared to the previous fiscal year-end. Trade and Other Payables and Deferred Tax Liabilities decreased by 135.2 billion JPY and 62.8 billion JPY, respectively. In addition, Bonds and Loans decreased by 58.5 billion JPY to 4,286.9 billion JPY* primarily due to the redemption of bonds partially offset by an increase due to the effect of foreign currency translation. These decreases were partially offset by an increase in Other Liabilities of 54.5 billion JPY.

* The carrying amount of Bonds was 3,565.0 billion JPY and Loans was 721.9 billion JPY as of December 31, 2022. Breakdown of Bonds and Loans carrying amount is as follows.

Bonds:

Name of Bond (Face Value if Denominated in Foreign Currency)	Issuance	Maturity	Carrying Amount (Billion JPY)
Unsecured US dollar denominated senior notes (1,301 million USD)	June 2015	June 2025 ~ June 2045	172.3
Unsecured US dollar denominated senior notes (4,000 million USD)	September 2016	September 2023 ~ September 2026	508.2
Unsecured Euro denominated senior notes (3,000 million EUR)	November 2018	November 2026 ~ November 2030	419.7
Unsecured US dollar denominated senior notes (2,250 million USD)	November 2018	November 2023 ~ November 2028	295.5
Hybrid bonds (subordinated bonds)	June 2019	June 2079	498.7
Unsecured US dollar denominated senior notes (7,000 million USD)	July 2020	March 2030 ~ July 2060	918.1
Unsecured Euro denominated senior notes (3,600 million EUR)	July 2020	July 2027 ~ July 2040	503.1
Unsecured JPY denominated senior bonds	October 2021	October 2031	249.4
Total			3,565.0

Loans:

Name of Loan (Face Value if Denominated in Foreign Currency)	Execution	Maturity	Carrying Amount (Billion JPY)
Syndicated loans	April 2016	April 2023 ~ April 2026	200.0
Syndicated loans	April 2017	April 2027	113.5
Syndicated loans (1,500 million USD)	April 2017	April 2027	197.8
Bilateral loans	March 2016 ~ April 2017	March 2023 ~ March 2026	210.0
Other			0.6
Total			721.9

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On April 23, 2022, Takeda redeemed 219 million USD of unsecured U.S. dollar-denominated senior notes issued in June 2015 in advance of their original maturity date of June 23, 2022. Following this, on October 27, 2022, Takeda redeemed 1,000 million USD of unsecured U.S. dollar-denominated senior notes issued in November 2018 in advance of their original maturity date of November 26, 2023. Furthermore, on November 21, 2022, Takeda redeemed 750 million EUR of unsecured floating rate senior notes issued in November 2018 on their maturity date.

Equity. Total Equity as of December 31, 2022 was 6,176.5 billion JPY, an increase of 493.0 billion JPY compared to the previous fiscal year-end. This was primarily resulted from an increase of 446.0 billion JPY in Other Components of Equity mainly due to fluctuation in currency translation adjustments reflecting the depreciation of yen and an increase in Retained Earnings of 28.0 billion JPY. The increase in Retained Earnings was primarily attributable to Net Profit for the Period largely offset by the dividends payments of 278.3 billion JPY.

Consolidated Cash Flows

	Billion JPY	
	FY2021 Q3YTD	FY2022 Q3YTD
Net cash from (used in) operating activities	747.5	683.5
Net cash from (used in) investing activities	(172.5)	(168.6)
Net cash from (used in) financing activities	(826.5)	(702.5)
Net increase (decrease) in cash and cash equivalents	(251.4)	(187.7)
Cash and cash equivalents at the beginning of the year	966.2	849.7
Effects of exchange rate changes on cash and cash equivalents	9.5	23.1
Cash and cash equivalents at the end of the period	724.3	685.1

Net cash from operating activities was 683.5 billion JPY for the current period compared to 747.5 billion JPY for the same period of the previous year. The decrease of 64.1 billion JPY was primarily driven by unfavorable impacts from changes in trade and other payables as well as trade and other receivables compared to the same period of the previous year. These were partially offset by a favorable impact from changes in provisions and higher net profit for the period adjusted for non-cash items and other adjustments reflecting sales increases in core therapeutic areas and favorable foreign exchange rates, while there was the decrease of cash from the sale of Japan diabetes portfolio in the same period of prior fiscal year.

Net cash used in investing activities was 168.6 billion JPY for the current period compared to 172.5 billion JPY for the same period of the previous year. This decrease of 3.9 billion JPY was mainly due to a decrease of 49.7 billion JPY in acquisition of business (net of cash and cash equivalents acquired), partially offset by an increase of 38.2 billion JPY in acquisition of intangible assets.

Net cash used in financing activities was 702.5 billion JPY for the current period compared to 826.5 billion JPY for the same period of the previous year. The decrease of 123.9 billion JPY was mainly due to a decrease in repayments of bonds and long-term loans, net of proceeds from issuance of bonds upon refinancing, of 104.1 billion JPY. In addition, there was a decrease in purchase of treasury shares of 25.6 billion JPY resulting from the higher share buybacks conducted in the same period of the previous year compared to the current period.

(3) Management Policy, Management Environment and Management Issues

There was no significant change in management policy, management environment and management issues for the nine-month period ended December 31, 2022.

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

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

Takeda's response to COVID-19 continues to focus on protecting the health and safety of our employees, our ability to ensure our medicines are available to patients who rely on them and playing our part to reduce transmission and support the communities where our employees live and work. While vaccines are becoming more broadly available, we continue to strictly adhere to local public health guidance across our geographies in addition to the internal protocols we have put in place, and monitor any potential impacts of the effects and evolution of COVID-19, including new variants, on our business activities.

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

Takeda's Operations in Ukraine and Russia

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

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

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

In the nine-month period ended December 31, 2022, revenue attributable to Russia/CIS represented 2.2% of Takeda's total consolidated revenue of 3,071.3 billion, as indicated in the Revenue by Region in II. Operating and Financial Review, 2. Analysis on Business Performance, Financial Position and Cash Flows, (1) Consolidated Financial Results (April 1 to December 31, 2022). There was no material financial impact on Takeda's financial results for the current period resulting from the crisis in these countries. However, depending on the future status of the crisis, our results of operations and financial conditions could be adversely affected.

(4) Research & Development Activities and Results

Research and development expenses for the nine-month period ended December 31, 2022 were 472.4 billion JPY.

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

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

Major progress on R&D events since April 2022 are listed as follows:

R&D pipeline

Oncology

In Oncology, Takeda endeavors to deliver novel medicines to patients with cancer worldwide through a commitment to breakthrough innovation and a passion for improving the lives of patients. Takeda focuses on three key areas in oncology: (1) building on its foundational expertise in hematologic malignancies through continued investment in lifecycle management programs for marketed products NINLARO, ADCETRIS, and ICLUSIG, as well as in pipeline assets in Multiple Myeloma, and other blood cancers; (2) further developing its portfolio in lung cancer with the marketed products ALUNBRIG, EXKIVITY, and development programs in targeted lung cancer populations; and (3) pursuing novel immuno-oncology targets and next-generation platforms (e.g., modakafusp alfa (TAK-573) and subasumstat (TAK-981)) harnessing the power of the innate immune system, internally and through external partnerships.

ADCETRIS / Generic name: brentuximab vedotin

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

VECTIBIX / Generic name: panitumumab

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

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

ICLUSIG / Generic name: ponatinib

- In November 2022, Takeda announced that the randomized, Phase 3 PhALLCON trial met its primary endpoint, demonstrating that adult patients with newly-diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) treated with ICLUSIG plus reduced-intensity chemotherapy achieved higher rates of minimal residual disease (MRD)-negative complete remission (CR) compared to imatinib. The PhALLCON study is the first Phase 3 randomized, international, open-label multicenter trial, and the only head-to-head study, evaluating the efficacy and safety of two tyrosine kinase inhibitor (TKIs) in combination with reduced-intensity chemotherapy as a frontline therapy for adult patients with newly diagnosed Ph+ ALL. In the trial, no new safety signals were observed.

EXKIVITY / Generic name: mobocertinib

- In January 2023, Takeda announced that EXKIVITY has been approved by the National Medical Products Administration (NMPA) of China for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) Exon20 insertion mutations, whose disease has progressed on or after platinum-based chemotherapy. EXKIVITY has shown clinically meaningful and durable responses in patients with locally advanced or metastatic EGFR Exon20 insertion+ NSCLC and is now the first and only treatment available for this patient population in China. EXKIVITY, an oral tyrosine kinase inhibitor designed to target Exon20 insertions, was reviewed as part of the NMPA's Breakthrough Therapy program. This approval is based on the results from the platinum-pretreated population in the Phase 1/2 trial of EXKIVITY. Full approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial.

Rare Genetics & Hematology

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

TAKHZYRO / Generic name: lanadelumab

- In April 2022, Takeda announced that the Phase 3 SPRING study evaluating the safety profile and pharmacokinetics of TAKHZYRO in patients 2 to <12 years of age is complete and has met its primary objectives. The safety profile was consistent with that seen in the clinical program for patients 12 years of age and older; there were no serious adverse events and no dropouts due to adverse events. The study also successfully reached the secondary objective evaluating the clinical activity/outcome of TAKHZYRO in preventing hereditary angioedema (HAE) attacks as well as characterizing the pharmacodynamics of TAKHZYRO in pediatric subjects 2 to <12 years of age.
- In July 2022, Takeda announced late-breaking data from the Phase 3 SPRING study presented at the European Academy of Allergy and Clinical Immunology (EAACI) Hybrid Congress 2022. The primary objective of the open-label, multicenter, Phase 3 (SPRING) study was to evaluate the safety and pharmacokinetics (PK) of TAKHZYRO in patients aged 2 to <12 years with HAE. Clinical outcomes (prevention of HAE attacks) were measured as a secondary objective. In this study, HAE patients received a dose of 150 mg every 4 weeks in patients 2 to <6 years and every 2 weeks in patients aged 6 to <12 years. TAKHZYRO reduced the rate of HAE attacks in children by a mean of 94.8% compared to baseline, from 1.84 attacks per month to 0.08 attacks during treatment. The majority of patients (76.2%) were attack-free during the 52-week treatment period with an average of 99.5% attack-free days. No deaths or serious treatment-emergent adverse events (TEAEs) were reported during the study, and no patients withdrew from the study due to TEAEs. These

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results are consistent with earlier studies with adult and adolescent patients. These data will be submitted to global regulatory authorities to evaluate a potential label expansion for TAKHZYRO to include the younger patient population.

- In October 2022, Takeda announced that the U.S. Food & Drug Administration (FDA) has accepted a supplemental Biologics License Application (sBLA) for the potential expanded use of TAKHZYRO for prophylaxis to prevent attacks of HAE in pediatric patients 2 to <12 years of age. The FDA has granted priority review of the application. If approved, TAKHZYRO could potentially become the first treatment of its kind for this population. The sBLA is based on data from the SPRING study, the open-label Phase 3 trial for HAE patients under the age of 12.

LIVTENCITY / Generic name: maribavir

- In April 2022, Takeda announced that it presented four company-sponsored abstracts on LIVTENCITY at the Tandem Transplantation & Cellular Therapy Meetings in Salt Lake City, Utah, and the 32nd European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in Lisbon, Portugal. The abstracts include an exploratory analysis of the Phase 3 SOLSTICE trial showing LIVTENCITY-treated patients with post-transplant cytomegalovirus (CMV) infections/disease had reductions in hospitalizations (34.8%; p=0.021) and length of hospital stay (53.8%; p=0.029), compared to those treated with conventional antiviral therapies. In addition, a post-hoc, sub-group analysis of the Phase 3 SOLSTICE trial showed shorter time to first confirmed CMV DNA level less than the lower limit of quantification (<LLOQ) with LIVTENCITY, compared to conventional antiviral therapies, which was consistent with previously reported findings.
- In November 2022, Takeda announced that the European Commission (EC) has granted Marketing Authorization for LIVTENCITY for the treatment of CMV infection and/or disease that is refractory (with or without resistance) to one or more prior therapies, including ganciclovir, valganciclovir, cidofovir or foscarnet, in adult patients who have undergone a hematopoietic stem cell transplant (HSCT) or solid organ transplant (SOT). The centralized marketing authorization is valid in all EU member states as well as in Iceland, Liechtenstein, Norway, and Northern Ireland, and was based on the Phase 3 SOLSTICE trial, which evaluated the safety and efficacy of LIVTENCITY versus conventional antiviral therapies (ganciclovir, valganciclovir, cidofovir or foscarnet) for the treatment of adult HSCT and SOT recipients with CMV infection refractory (with or without resistance) to prior therapies.
- In December 2022, Takeda announced that in the AURORA trial, a Phase 3, multicenter, randomized, double-blind, double-dummy, active-controlled study to assess the efficacy and safety of LIVTENCITY compared to valganciclovir for the treatment of CMV infection in HSCT recipients, LIVTENCITY demonstrated clinically meaningful efficacy in confirmed CMV viremia clearance, but did not meet its primary endpoint of non-inferiority vs. valganciclovir (maribavir 69.6% [190/273] vs. valganciclovir 77.4% [212/274]; adjusted difference, -7.7%; 95% CI: -14.98, -0.36), based on the prespecified non-inferiority margin of 7%. The primary endpoint was defined as the proportion of patients who achieved confirmed CMV viremia clearance (plasma CMV DNA <LLOQ; <137 IU/mL) after exclusively LIVTENCITY compared to valganciclovir at end of treatment phase (Week 8). At Week 16, the key secondary endpoint, 52.7% of patients treated with LIVTENCITY achieved a numerically higher maintenance effect of CMV viremia clearance and symptom control from Week 8 vs. 48.5% for valganciclovir. Sustained maintenance effect was observed with LIVTENCITY during post-treatment evaluations at Week 12 (LIVTENCITY 59.3%, valganciclovir 57.3%) and Week 20 (LIVTENCITY 43.2%, valganciclovir 42.3%). Study reaffirmed LIVTENCITY's favorable safety profile, given valganciclovir's higher incidence of treatment-emergent neutropenia (63.5% vs. 21.2% for LIVTENCITY) and higher rate of premature discontinuation of therapy due to neutropenia (17.5% vs. 4% for LIVTENCITY). Nausea (27.5%) and dysgeusia (25.6%) were the most common adverse events reported with LIVTENCITY. Takeda remains committed to the transplant community and is engaging with regulatory authorities to discuss AURORA study outcomes.

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

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

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FIRAZYR / Generic name: icatibant

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

Development code: TAK-611

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

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

- In December 2022, Takeda announced that it has received Orphan Drug Designation from the Japanese Ministry of Health, Labour and Welfare (MHLW) for TAK-755 for the expected indication of thrombotic thrombocytopenic purpura (TTP). As the first recombinant ADAMTS13 (rADAMTS13) drug targeting TTP, TAK-755 is developed globally for the treatment of congenital TTP (cTTP) and acquired (immune) TTP (iTTP).
- In January 2023, Takeda announced that the totality of evidence from a pre-planned interim analysis of a pivotal Phase 3 study supports the efficacy and safety of TAK-755 as enzyme replacement therapy for cTTP. The study evaluated TAK-755 compared to plasma-based therapies, which are the current standard of care (SoC), in a randomized cross-over study. The interim results showed that TAK-755 reduced the incidence of thrombocytopenia events by 60% (95% Confidence Interval, 30%-70%), an important marker of disease activity in cTTP, as compared to SoC. The proportion of subjects experiencing adverse events determined to be related to the treatment was substantially lower among subjects during treatment with TAK-755 (8.9%) compared to that while receiving SoC therapy (47.7%). Based on these data from the Phase 3 interim analysis, Takeda aims to seek marketing authorization for TAK-755 as the first rADAMTS13 replacement therapy for cTTP, a disorder with considerable unmet patient need.

Neuroscience

In Neuroscience, Takeda is focusing its R&D investments on potentially transformative treatments for neurological and neuromuscular diseases of high unmet need, and building its pipeline through a combination of in-house expertise and partnerships. By harnessing advances in disease biology understanding, translational tools, and innovative modalities, Takeda is primarily focusing on rare neurology, in particular, on potential investigative therapies for sleep-wake disorders such as narcolepsy and idiopathic hypersomnia with a franchise of orexin-2 receptor agonists (TAK-861, TAK-925, etc.), and rare epilepsies with soticlestat (TAK-935). Additionally, Takeda also makes targeted investments to investigate well-defined segments of neuromuscular diseases, neurodegenerative diseases and movement disorders.

Development code: TAK-994

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

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Gastroenterology (GI)

In Gastroenterology, Takeda focuses on delivering innovative, life-changing therapeutics for patients with gastrointestinal and liver diseases. Takeda is maximizing the potential of our inflammatory bowel disease (IBD) franchise around ENTYVIO, including development of a subcutaneous formulation and expanding into other indications such as active chronic pouchitis. Takeda is also expanding its position with GATTEX / REVESTIVE and ALOFISEL, which are in ongoing and planned Phase 3 trials to support further potential geographic expansion, including in the U.S. Furthermore, Takeda is progressing a pipeline built through partnerships exploring opportunities in IBD, celiac disease, select liver diseases, and motility disorders. Fazirsiran (TAK-999) is an example of an addition through partnership and a potential first-in-class RNAi for alpha-1 antitrypsin-deficiency associated liver disease in late-stage development.

Development code: TAK-999 / Generic name: fazirsiran

- In June 2022, Takeda and Arrowhead Pharmaceuticals Inc. announced that results from a Phase 2 clinical study (AROAAT-2002) of investigational fazirsiran for the treatment of liver disease associated with alpha-1 antitrypsin deficiency (AATD-LD) were published in *the New England Journal of Medicine* (NEJM) and presented in an oral presentation at The International Liver Congress 2022 - The Annual Meeting of the European Association for the Study of the Liver (EASL). Fazirsiran is a potential first-in-class investigational RNA interference (RNAi) therapy designed to reduce the production of mutant alpha-1 antitrypsin protein (Z-AAT) as a potential treatment for the rare genetic liver disease associated with AATD. Fazirsiran was granted Breakthrough Therapy Designation (BTD) in July 2021 and Orphan Drug Designation in February 2018 for the treatment of AATD from the U.S. Food and Drug Administration (FDA).
- In January 2023, Takeda and Arrowhead Pharmaceuticals Inc. announced topline results from the Phase 2 SEQUOIA clinical study of investigational fazirsiran. SEQUOIA is a placebo-controlled, multi-dose, Phase 2 study to determine the safety, tolerability, and pharmacodynamic effect of fazirsiran in 42 patients with AATD-LD. Patients receiving 25 mg, 100 mg, or 200 mg of fazirsiran who had baseline fibrosis (n=16) demonstrated a dose dependent mean reduction in serum Z-AAT concentration at Week 48 of 74%, 89%, and 94%, respectively. All three doses led to a dramatic reduction in total liver Z-AAT with a median reduction of 94% at the postbaseline liver biopsy visit. In addition, PAS-D globule burden, a histological measure of Z-AAT accumulation, was reduced from a baseline mean of 5.9 to a post baseline mean of 2.3 at the postbaseline liver biopsy visit. Improvement in portal inflammation was observed in 42% of patients while only 7% showed worsening. Also, 50% of patients achieved an improvement in fibrosis of at least one point by METAVIR stage. In contrast, by Week 48 patients receiving placebo who had baseline fibrosis (n=9) saw no meaningful changes from baseline in serum Z-AAT, a 26% increase in liver Z-AAT, no meaningful change in PAS-D globule burden, no placebo patients experienced an improvement in portal inflammation while 44% experienced worsening, and 22% of placebo patients experienced worsening while 38% experienced an improvement in fibrosis at the postbaseline liver biopsy visit. Fazirsiran has been well tolerated with treatment emergent adverse events reported to date generally well balanced between fazirsiran and placebo groups. There were no treatment-emergent adverse events leading to drug discontinuation, dose interruptions, or premature study withdrawals in any study group. Compared with placebo, no dose-dependent or clinically meaningful changes were observed in pulmonary function tests over 1 year with fazirsiran. The companies also provided an outline of a Phase 3 study that was co-developed by Takeda and Arrowhead and will be conducted by Takeda.

Development code: TAK-625 / Generic name: maralixibat chloride

- In December 2022, Takeda announced that it has received Orphan Drug Designation from the Japanese Ministry of Health, Labour and Welfare (MHLW) for maralixibat chloride for the expected indications of Alagille syndrome (ALGS) and progressive familial intrahepatic cholestasis (PFIC). Currently, there are no treatments approved for the treatment of ALGS or PFIC in Japan. Maralixibat is in Phase 3 clinical trials in Japan for the treatment of ALGS and PFIC.

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Plasma-Derived Therapies (PDT)

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

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

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

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

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

Vaccines

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.

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

- In May 2022, Takeda and Moderna, Inc. (Moderna) announced to transfer the marketing authorization in Japan for SPIKEVAX from Takeda to Moderna in Japan (Moderna Japan) as of August 1, 2022. Moderna Japan will assume responsibility for all SPIKEVAX activities, including import, local regulatory, development, quality assurance and commercialization. Takeda has agreed with Moderna that it will continue to provide distribution support under the current national vaccination campaign for Moderna COVID-19 vaccines for a transitional period.

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

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

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

- In June 2022, Takeda announced that TAK-003 demonstrated continued protection against dengue fever through four and a half years (54 months), with no important safety risks identified, in the pivotal Phase 3 Tetravalent Immunization against Dengue Efficacy Study (TIDES) trial, which was presented at the 8th Northern European Conference on Travel Medicine (NECTM8). Through four and a half years, TAK-003 demonstrated 84.1% vaccine efficacy (VE) (95% CI: 77.8, 88.6) against hospitalized dengue, with 85.9% VE (78.7, 90.7) in seropositive individuals and 79.3% VE (63.5, 88.2) in seronegative individuals. TAK-003 also demonstrated overall VE of 61.2% (95% CI: 56.0, 65.8) against virologically-confirmed dengue, with 64.2% VE (58.4, 69.2) in seropositive individuals and 53.5% VE (41.6, 62.9) in seronegative individuals. Observations of VE varied by serotype and remained consistent with previously reported results. TAK-003 was generally well tolerated, and there were no important safety risks identified. No evidence of disease enhancement was observed over the 54-month follow-up exploratory analysis.
- In August 2022, Takeda announced that its dengue vaccine, QDENGGA, was approved by the Indonesian National Agency for Drug and Food Control, Badan Pengawas Obat dan Makanan (BPOM), for the prevention of dengue disease caused by any serotype in individuals six years to 45 years of age. QDENGGA is the only dengue vaccine approved in Indonesia for use in individuals regardless of previous dengue exposure and without the need for pre-vaccination testing. The approval of QDENGGA is based on results through three years after vaccination from the ongoing Phase 3 TIDES trial.
- In October 2022, Takeda announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommended the approval of QDENGGA in Europe and in dengue-endemic countries participating in the parallel EU-M4all procedure. In December 2022, Takeda announced that the European Commission (EC) granted marketing authorization for QDENGGA for the prevention of dengue disease caused by any serotype in individuals from four years of age in the European Union (EU). EC’s approval was supported by results across 19 Phase 1, 2 and 3 trials with more than 28,000 children and adults, including four and a half years of follow-up data from the global, pivotal Phase 3 TIDES trial. Takeda continues to progress regulatory filings in other dengue-endemic countries in Asia and Latin America.
- In November 2022, Takeda announced that the U.S. Food and Drug Administration (FDA) has accepted and granted priority review of the Biologics License Application (BLA) for TAK-003. In the U.S., TAK-003 is being evaluated for the prevention of dengue disease caused by any dengue virus serotype in individuals 4 years through 60 years of age. TAK-003 BLA is supported by safety and efficacy data from the pivotal Phase 3 TIDES trial.

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Building a sustainable research platform / Enhancing R&D collaboration

In addition to our concentrated efforts to increase our in-house R&D capabilities, external partnerships with third-party partners are a key component of our strategy for enhancing our R&D pipeline. Our strategy to expand and diversify our external partnerships allows us to take part in research of a wide variety of new products and increases the chances that we will be able to take part in a major research-related breakthrough.

- In October 2022, Takeda, Zedira GmbH and Dr. Falk Pharma GmbH announced a collaboration and licensing agreement to develop ZED1227/TAK-227, a Phase 2b investigational therapy for the treatment of celiac disease. TAK-227 is a potential first-in-class therapy designed to prevent the immune response to gluten in celiac disease, a serious autoimmune disease where the ingestion of gluten leads to inflammation and damage to the small intestine. There are currently no approved therapies for the treatment of celiac disease. TAK-227 is a selective, oral small molecule designed to inhibit tissue transglutaminase (TG2), an enzyme that generates immunogenic gluten peptide fragments upon the breakdown of gluten in the stomach and intestinal tissue. TAK-227 targets the dysregulated transglutaminase to prevent mucosal damage in the small intestine by preventing the body's immune response to gluten, a disease process mediated by activation of gluten-specific T cells. Under the terms of the agreement, Takeda and Dr. Falk Pharma will conduct global clinical studies for TAK-227 in celiac disease. Takeda will receive an exclusive license to develop and commercialize TAK-227 in the United States and other territories outside of Europe, Canada, Australia and China.
- In December 2022, Takeda announced that it will acquire NDI-034858 from Nimbus Therapeutics, LLC. NDI-034858 is an oral, selective allosteric tyrosine kinase 2 (TYK2) inhibitor being evaluated for the treatment of multiple autoimmune diseases following successful recent Phase 2b results in psoriasis. When the transaction is complete, NDI-034858 will be known as TAK-279. Nimbus disclosed positive topline results from a Phase 2b study evaluating NDI-034858 in patients with moderate-to-severe plaque psoriasis. Takeda intends to present results from this Phase 2b study early in 2023. NDI-034858 is anticipated to enter Phase 3 in psoriasis in 2023. It is in an ongoing Phase 2b study in active psoriatic arthritis, and Takeda plans to investigate it for the treatment of inflammatory bowel disease (IBD) and other autoimmune diseases.
- In January 2023, Takeda announced that it has entered into an exclusive licensing agreement with HUTCHMED (China) Limited and its subsidiary HUTCHMED Limited, for the further development and commercialization of fruquintinib outside of mainland China, Hong Kong and Macau. Approved in China in 2018, fruquintinib is a highly selective and potent inhibitor of vascular endothelial growth factor receptors (VEGFR) -1, 2 and 3. Fruquintinib is orally administered and has the potential to be used across subtypes of refractory metastatic colorectal cancer (CRC), regardless of biomarker status. Positive results of FRESCO-2, the Phase 3 multi-regional clinical trial of fruquintinib in refractory metastatic CRC were presented at the European Society for Medical Oncology (ESMO) Congress in September 2022. FRESCO-2 met its primary endpoint of improving overall survival (OS) in patients with metastatic CRC and was generally well tolerated. The U.S. Food and Drug Administration (FDA) granted Fast Track designation for the development of fruquintinib for the treatment of patients with metastatic CRC in 2020. In December 2022, HUTCHMED initiated a rolling submission of a New Drug Application (NDA) for fruquintinib with the FDA, which is planned to be completed in the first half of 2023. This will be followed by planned submission of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) and a JNDA to the Japanese Ministry of Health, Labour and Welfare (MHLW).

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(5) Major Facilities

The following is a significant change in new facility construction for the nine-month period ended December 31, 2022.

Classification	Name or Subsidiaries' Company Name [Main Location]	Operating Segment	Details	Budget* ¹		Financing	Schedule	
				Total JPY (millions)	Paid JPY (millions)		Commencement	Completion
Construction	Takeda Pharmaceuticals U.S.A., Inc. [Cambridge, MA, U.S.A.]	Pharmaceuticals	Research and office	230,747* ²	—	Funds on hand/ Lease	January 2023	October 2026
Construction	Baxalta Belgium Manufacturing S.A. [Lessines, Belgium]	Pharmaceuticals	Manufacturing and warehouse	40,738	5,129	Funds on hand	February 2022	December 2024

*1 The budget is calculated based on the exchange rates as of December 31, 2022.

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

3. Material Contracts

The material contract entered into, amended or terminated during the three-month period ended December 31, 2022 is as follows:

Acquisition of Nimbus Lakshmi, Inc.

On December 13, 2022, we entered into a share purchase agreement with Nimbus Therapeutics, LLC (“Nimbus”) to acquire all of the capital stock of Nimbus Lakshmi, Inc. (“Lakshmi”), a wholly owned subsidiary of Nimbus, that owns or controls the intellectual property rights and other associated assets related to the allosteric TYK2 inhibitor known internally at Nimbus as “NDI-034858”. Under the terms of the agreement, we will pay Nimbus 4 billion USD upfront following the closing of the transaction, and two milestone payments of 1 billion USD each upon achieving annual net sales of 4 billion USD and 5 billion USD of products developed from the NDI-034858 program. The transaction is expected to be finalized before the end of the fiscal year ending March 31, 2023. Closing of the transaction is contingent on completion of review under antitrust laws, including the Hart-Scott-Rodino (HSR) Antitrust Improvements Act of 1976.

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III. Information on the Company

1. Information on the Company's Shares

(1) Total number of shares and other related information

1) Total number of shares

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

2) Number of shares issued

Class	Number of shares outstanding (As of December 31, 2022)	Number of shares outstanding as of the filing date (February 7, 2023)	Stock exchange on which the Company is listed	Description
Common stock	1,582,290,825	1,582,295,625	Tokyo (Prime Market), Nagoya (Premier Market), Fukuoka, Sapporo, and New York	The number of shares per one unit of shares is 100 shares.
Total	1,582,290,825	1,582,295,625	—	—

(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 February 1, 2023 to the filing date of Quarterly Securities Report (February 7, 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 October 1, 2022 to December 31, 2022 (Note1)	2	1,582,291	4	1,676,334	4	1,668,347

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

(Note2) The exercise of stock acquisition rights between January 1, 2023 to January 31, 2023 increased the number of shares issued by 5 thousand shares and the amount of share capital and legal capital surplus by 10 million JPY, respectively.

(5) Major shareholders

No information required in the 3rd quarter.

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(6) Information on voting rights

1) Total number of shares

Classification	As of December 31, 2022		
	Number of shares (Shares)	Number of voting rights (Units)	Description
Shares without voting rights	—	—	—
Shares with restricted voting rights (Treasury stock and other)	—	—	—
Shares with restricted voting rights (Others)	—	—	—
Shares with full voting rights (Treasury stock and other)	(Treasury stock) Common stock	21,466,200	—
	(Crossholding stock) Common stock	287,000	—
Shares with full voting rights (Others)	Common stock	1,559,215,900	15,592,159
Shares less than one unit	Common stock	1,321,725	—
			Shares less than one unit (100 shares)
Number of issued shares		1,582,290,825	—
Total number of voting rights		—	15,592,159

(Note1) "Shares with full voting rights (Others)" includes 3,981,600 (voting rights: 39,816) and 2,233,000 (voting rights: 22,330) of the shares held by the ESOP and BIP trust, respectively.

(Note2) "Shares less than one unit" includes 47 of the shares as the treasury stock, and 153 and 244 of the shares held by the ESOP and BIP trust, respectively.

2) Treasury stock and other

Name of shareholders	Address	As of December 31, 2022			
		Number of shares held under own name (Shares)	Number of shares held under the name of others (Shares)	Total shares held (Shares)	Percentage of total issued shares issued (%)
(Treasury stock)					
Takeda Pharmaceutical Company Limited	1-1, Doshomachi 4- chome, Chuo-ku, Osaka	21,466,200	—	21,466,200	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		21,753,200	—	21,753,200	1.37

(Note) In addition to the above treasury stock and shares less than one unit of 47 shares, 3,981,753 of the shares held by the ESOP trust and 2,233,244 of the shares held by the BIP trust are included in treasury stock on the condensed interim consolidated financial statements.

2. Members of the Board of Directors

No changes from the latest Annual Securities Report.

IV. Financial Information

Basis of Preparation of the Condensed Interim Consolidated Financial Statements

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

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1. Condensed Interim Consolidated Financial Statements

(1) Condensed Interim Consolidated Statements of Profit or Loss

	Note	JPY (millions, except per share data)			
		Nine-month Period Ended December 31,		Three-month Period Ended December 31,	
		2021	2022	2021	2022
Revenue	4	2,695,717	3,071,322	901,294	1,096,551
Cost of sales		(798,466)	(934,300)	(281,404)	(335,973)
Selling, general and administrative expenses		(662,932)	(742,513)	(231,078)	(262,299)
Research and development expenses		(382,459)	(472,381)	(128,378)	(174,629)
Amortization and impairment losses on intangible assets associated with products		(323,632)	(409,219)	(118,087)	(135,576)
Other operating income		34,269	16,676	14,734	3,200
Other operating expenses	5	(100,034)	(127,643)	(40,596)	(44,284)
Operating profit		462,463	401,943	116,484	146,990
Finance income		42,949	55,130	4,145	41,679
Finance expenses		(143,539)	(126,765)	(46,706)	(79,749)
Share of loss of investments accounted for using the equity method		(5,255)	(3,133)	(1,730)	(1,767)
Profit before tax		356,618	327,175	72,193	107,153
Income tax (expenses) benefit	6	(115,077)	(41,273)	(14,373)	11,996
Net profit for the period		241,541	285,903	57,820	119,149
Attributable to:					
Owners of the Company		241,417	285,883	57,770	119,127
Non-controlling interests		124	19	51	22
Net profit for the period		241,541	285,903	57,820	119,149
Earnings per share (JPY)					
Basic earnings per share	7	154.09	184.32	36.91	76.63
Diluted earnings per share	7	153.03	182.65	36.68	75.86

See accompanying notes to condensed interim consolidated financial statements.

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(2) Condensed Interim Consolidated Statements of Comprehensive Income

	JPY (millions)			
	Nine-month Period Ended December 31,		Three-month Period Ended December 31,	
	2021	2022	2021	2022
Net profit for the period	241,541	285,903	57,820	119,149
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	(5,951)	730	(10,220)	(4,554)
Remeasurement of defined benefit pension plans	(2,912)	12,977	(1,210)	(418)
	(8,862)	13,707	(11,430)	(4,972)
Items that may be reclassified subsequently to profit or loss:				
Exchange differences on translation of foreign operations	206,582	481,206	139,883	(553,986)
Cash flow hedges	13,958	(17,584)	2,406	15,616
Hedging cost	5,969	(12,107)	185	10,642
Share of other comprehensive income (loss) of investments accounted for using the equity method	(145)	(915)	(108)	170
	226,365	450,599	142,365	(527,558)
Other comprehensive income (loss) for the period, net of tax	217,503	464,306	130,935	(532,531)
Total comprehensive income for the period	459,044	750,209	188,756	(413,381)
Attributable to:				
Owners of the Company	458,887	750,193	188,689	(413,341)
Non-controlling interests	157	16	66	(40)
Total comprehensive income for the period	459,044	750,209	188,756	(413,381)

See accompanying notes to condensed interim consolidated financial statements.

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(3) Condensed Interim Consolidated Statements of Financial Position

	Note	JPY (millions)	
		As of March 31, 2022	As of December 31, 2022
ASSETS			
Non-current assets:			
Property, plant and equipment	8	1,582,800	1,656,416
Goodwill		4,407,749	4,690,949
Intangible assets		3,818,544	3,765,757
Investments accounted for using the equity method		96,579	94,426
Other financial assets		233,554	275,043
Other non-current assets		82,611	66,774
Deferred tax assets		362,539	359,393
Total non-current assets		10,584,376	10,908,758
Current assets:			
Inventories		853,167	927,286
Trade and other receivables		696,644	707,318
Other financial assets		25,305	41,467
Income taxes receivable		27,733	72,554
Other current assets		141,099	154,824
Cash and cash equivalents		849,695	685,141
Assets held for sale		—	7,356
Total current assets		2,593,642	2,595,946
Total assets		13,178,018	13,504,705
LIABILITIES AND EQUITY			
LIABILITIES			
Non-current liabilities:			
Bonds and loans	10	4,141,418	3,914,884
Other financial liabilities		468,943	503,542
Net defined benefit liabilities		145,847	132,809
Income taxes payable		21,634	25,152
Provisions		52,199	59,628
Other non-current liabilities		67,214	66,701
Deferred tax liabilities		451,511	388,681
Total non-current liabilities		5,348,764	5,091,397
Current liabilities:			
Bonds and loans	10	203,993	372,019
Trade and other payables		516,297	381,109
Other financial liabilities		196,071	180,575
Income taxes payable		200,918	188,779
Provisions		443,502	473,194
Other current liabilities		584,949	639,959
Liabilities held for sale		—	1,173
Total current liabilities		2,145,730	2,236,809
Total liabilities		7,494,495	7,328,206

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JPY (millions)

		JPY (millions)	
	Note	As of March 31, 2022	As of December 31, 2022
<u>EQUITY</u>			
Share capital	11	1,676,263	1,676,334
Share premium	11	1,708,873	1,712,036
Treasury shares	11	(116,007)	(100,314)
Retained earnings		1,479,716	1,507,720
Other components of equity		934,173	1,380,202
Equity attributable to owners of the company		5,683,019	6,175,978
Non-controlling interests		504	520
Total equity		5,683,523	6,176,498
Total liabilities and equity		13,178,018	13,504,705

See accompanying notes to condensed interim consolidated financial statements.

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(4) Condensed Interim Consolidated Statements of Changes in Equity

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

JPY (millions)														
Equity attributable to owners of the Company														
Other components of equity														
	Note	Share capital	Share premium	Treasury shares	Retained earnings	Exchange differences on translation of foreign operations	Changes in fair value of financial assets measured at fair value through other comprehensive income	Cash flow hedges	Hedging cost	Remeasurements of defined benefit pension plans	Total other components of equity	Total equity attributable to owners of the Company	Non-controlling interests	Total equity
As of April 1, 2021		1,668,145	1,688,424	(59,552)	1,509,906	400,798	41,983	(68,075)	(8,592)	—	366,114	5,173,037	4,140	5,177,177
Net profit for the period					241,417							241,417	124	241,541
Other comprehensive income (loss)						206,337	(5,883)	13,958	5,969	(2,912)	217,470	217,470	33	217,503
Comprehensive income (loss) for the period		—	—	—	241,417	206,337	(5,883)	13,958	5,969	(2,912)	217,470	458,887	157	459,044
Transactions with owners:														
Issuance of new shares	11	8,118	14,036									22,154		22,154
Acquisition of treasury shares				(54,451)								(54,451)		(54,451)
Disposal of treasury shares			(0)	1								1		1
Dividends	11				(284,246)							(284,246)		(284,246)
Changes in ownership					(2,143)							(2,143)	(3,804)	(5,948)
Transfers from other components of equity					1,992		(4,904)			2,912	(1,992)	—		—
Share-based compensation			32,057									32,057		32,057
Exercise of share-based awards			(36,955)	22,989								(13,966)		(13,966)
Total transactions with owners		8,118	9,138	(31,461)	(284,397)	—	(4,904)	—	—	2,912	(1,992)	(300,594)	(3,804)	(304,399)
As of December 31, 2021		1,676,263	1,697,562	(91,013)	1,466,926	607,135	31,196	(54,116)	(2,623)	—	581,592	5,331,330	493	5,331,822

See accompanying notes to condensed interim consolidated financial statements.

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Nine-month period ended December 31, 2022 (From April 1 to December 31, 2022)

JPY (millions)														
Equity attributable to owners of the Company														
	Note	Other components of equity											Total equity	
		Share capital	Share premium	Treasury shares	Retained earnings	Exchange differences on translation of foreign operations	Changes in fair value of financial assets measured at fair value through other comprehensive income	Cash flow hedges	Hedging cost	Remeasurements of defined benefit pension plans	Total other components of equity	Total equity attributable to owners of the Company		Non-controlling interests
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					285,883						—	285,883	19	285,903
Other comprehensive income (loss)						480,326	698	(17,584)	(12,107)	12,977	464,310	464,310	(4)	464,306
Comprehensive income (loss) for the period		—	—	—	285,883	480,326	698	(17,584)	(12,107)	12,977	464,310	750,193	16	750,209
Transactions with owners:														
Issuance of new shares		71	71								—	142		142
Acquisition of treasury shares	11		(5)	(27,056)							—	(27,062)		(27,062)
Disposal of treasury shares			0	1							—	1		1
Dividends	11				(278,321)						—	(278,321)		(278,321)
Transfers from other components of equity					22,402		(9,424)			(12,977)	(22,402)	—		—
Share-based compensation			45,823								—	45,823		45,823
Exercise of share-based awards	11		(42,727)	42,749							—	22		22
Total transactions with owners		71	3,162	15,693	(255,919)	—	(9,424)	—	—	(12,977)	(22,402)	(259,395)	—	(259,395)
As of December 31, 2022		1,676,334	1,712,036	(100,314)	1,507,720	1,468,588	13,341	(83,486)	(18,242)	—	1,380,202	6,175,978	520	6,176,498

See accompanying notes to condensed interim consolidated financial statements.

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(5) Condensed Interim Consolidated Statements of Cash Flows

	Notes	JPY (millions)	
		Nine-month Period Ended	
		December 31,	
		2021	2022
Cash flows from operating activities:			
Net profit for the period		241,541	285,903
Depreciation and amortization		430,877	502,990
Impairment losses		14,666	41,969
Equity-settled share-based compensation		32,057	45,823
Loss (gain) on sales and disposal of property, plant and equipment		258	(161)
Gain on divestment of business and subsidiaries		(1,095)	(959)
Change in fair value of financial assets and liabilities associated with contingent consideration arrangements, net		(9,683)	4,323
Finance (income) and expenses, net		100,589	71,635
Share of loss of investments accounted for using the equity method		5,255	3,133
Income tax expenses		115,077	41,273
Changes in assets and liabilities:			
Decrease in trade and other receivables		82,243	6,856
Increase in inventories		(39,268)	(34,240)
Decrease in trade and other payables		(1,797)	(144,971)
Increase (decrease) in provisions		(70,098)	11,605
Decrease in other financial liabilities		(51,158)	(7,906)
Other, net		(858)	21,258
Cash generated from operations		848,607	848,529
Income taxes paid		(107,224)	(173,363)
Tax refunds and interest on tax refunds received		6,138	8,297
Net cash from operating activities		747,521	683,463
Cash flows from investing activities:			
Interest received		2,468	2,792
Dividends received		2,598	3,234
Acquisition of property, plant and equipment		(87,673)	(104,888)
Proceeds from sales of property, plant and equipment		412	80
Acquisition of intangible assets		(46,541)	(84,721)
Acquisition of investments		(7,600)	(5,441)
Proceeds from sales and redemption of investments		16,065	20,553
Acquisition of businesses, net of cash and cash equivalents acquired		(49,672)	—
Proceeds from sales of business, net of cash and cash equivalents divested		2,138	—
Other, net		(4,683)	(219)
Net cash used in investing activities		(172,487)	(168,610)

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	Notes	JPY (millions)	
		Nine-month Period Ended December 31,	
		2021	2022
Cash flows from financing activities:			
Net decrease in short-term loans and commercial papers		(2)	—
Proceeds from issuance of bonds and long-term loans		249,334	—
Repayments of bonds and long-term loans		(635,047)	(281,585)
Acquisition of treasury shares		(52,538)	(26,929)
Interest paid		(84,917)	(86,563)
Dividends paid		(273,024)	(268,997)
Repayments of lease liabilities		(29,904)	(32,510)
Other, net		(366)	(5,964)
Net cash used in financing activities		(826,465)	(702,548)
Net decrease in cash and cash equivalents		(251,430)	(187,695)
Cash and cash equivalents at the beginning of the year		966,222	849,695
Effects of exchange rate changes on cash and cash equivalents		9,549	23,141
Cash and cash equivalents at the end of the period		724,341	685,141

See accompanying notes to condensed interim consolidated financial statements.

Notes to Condensed Interim Consolidated Financial Statements

1. Reporting Entity

Takeda Pharmaceutical Company Limited (the “Company”) is a public company incorporated in Japan. The Company and its subsidiaries (collectively, “Takeda”) is a global, values-based, R&D-driven biopharmaceutical company with a diverse portfolio, engaged primarily in the research, development, production and global commercialization of pharmaceutical products. Takeda’s principal pharmaceutical products include medicines in the following key business areas: gastroenterology (“GI”), rare diseases, Plasma-Derived Therapies (“PDT”) immunology, oncology, and neuroscience.

2. Basis of Preparation

(1) Compliance

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

The condensed interim consolidated financial statements do not contain all the information required in consolidated financial statements as of the end of a fiscal year. Therefore, the condensed interim consolidated financial statements should be used with the consolidated financial statements as of and for the fiscal year ended March 31, 2022.

(2) Approval of Financial Statements

Takeda’s condensed interim consolidated financial statements as of and for the period ended December 31, 2022 were approved on February 7, 2023 by Representative Director, President & Chief Executive Officer (“CEO”) Christophe Weber and Director & Chief Financial Officer Costa Saroukos.

(3) Functional Currency and Presentation Currency

The condensed interim consolidated financial statements are presented in Japanese yen (“JPY”), which is the functional currency of the Company. All financial information presented in JPY has been rounded to the nearest million, except when otherwise indicated. In tables with rounded figures, sums may not add up due to rounding.

(4) Use of Judgments, Estimates and Assumptions

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

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

The condensed interim consolidated financial statements are prepared based on the same judgments and estimations as well as the accounting estimates and assumptions applied and described in Takeda’s consolidated financial statements for the fiscal year ended March 31, 2022.

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

3. Significant Accounting Policies

Significant accounting policies adopted for the condensed interim consolidated financial statements are the same as those adopted for the consolidated financial statements of the fiscal year ended March 31, 2022.

Takeda calculated income tax expenses for the nine-month period ended December 31, 2022, based on the estimated average annual effective tax rate.

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4. Operating Segment and Revenue Information

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

(1) Disaggregation of Revenue Information

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

Revenue by Type of Good or Service

	JPY (millions)	
	Nine-month Period Ended December 31,	
	2021	2022
Sales of pharmaceutical products	2,485,164	2,982,909
Out-licensing and service income	210,552	88,414
Total	2,695,717	3,071,322

	JPY (millions)	
	Three-month period ended December 31,	
	2021	2022
Sales of pharmaceutical products	873,882	1,068,509
Out-licensing and service income	27,412	28,042
Total	901,294	1,096,551

Revenue by Therapeutic Area and Product

	JPY (millions)	
	Nine-month Period Ended December 31,	
	2021	2022
Gastroenterology:		
ENTYVIO	395,373	547,888
TAKECAB/VOCINTI ⁽¹⁾	78,373	84,540
GATTEX/REVESTIVE	56,635	78,213
DEXILANT	40,136	55,106
PANTOLOC/CONTROLOC ⁽²⁾	30,068	33,777
ALOFISEL	1,353	1,984
Others	63,745	56,007
Total Gastroenterology	665,683	857,515
Rare Diseases:		
Rare Hematology:		
ADVATE	89,315	92,092
ADYNOVATE/ADYNOVI	45,873	49,860
FEIBA	28,978	32,593
RECOMBINATE	9,586	9,667
Others	37,840	48,433
Total Rare Hematology	211,592	232,645
Rare Genetics and Other:		
TAKHZYRO	78,425	116,880
ELAPRASE	57,714	65,002
REPLAGAL	39,568	50,559

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	JPY (millions)	
	Nine-month Period Ended December 31,	
	2021	2022
VPRIV	32,171	36,330
LIVTENCITY	190	7,312
Others	43,239	44,871
Total Rare Genetics and Other	251,305	320,954
Total Rare Diseases	462,897	553,600
PDT Immunology:		
immunoglobulin	278,309	390,483
albumin	61,490	85,508
Others	23,448	26,426
Total PDT Immunology	363,247	502,418
Oncology:		
VELCADE	84,459	24,735
LEUPLIN/ENANTONE	82,215	85,182
NINLARO	70,747	75,939
ADCETRIS	51,786	65,785
ICLUSIG	26,687	35,529
ALUNBRIG	10,127	15,764
EXKIVITY	444	2,250
Others	32,631	39,770
Total Oncology	359,096	344,953
Neuroscience:		
VYVANSE/ELVANSE	244,994	335,449
TRINTELLIX	63,030	79,699
Others	54,607	61,994
Total Neuroscience	362,630	477,141
Other:		
AZILVA ⁽¹⁾	60,057	56,590
LOTRIGA	24,753	13,328
Others ⁽³⁾	397,354	265,777
Total Other	482,163	335,695
Total	2,695,717	3,071,322

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

⁽²⁾ Generic name: pantoprazole

⁽³⁾ The figure for the nine-month period ended December 31, 2021 includes the 133,043 million JPY selling price on sales of four diabetes products (NESINA, LIOVEL, INISYNC and ZAFATEK) in Japan to Teijin Pharma Limited recorded as revenue. As Takeda transferred only the assets, marketing rights and, eventually, marketing authorization associated with the pharmaceutical products which do not entail transfer of employees or associated contracts, Takeda applied IFRS 15 to the transaction and recorded the selling price in revenue.

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	JPY (millions)	
	Three-month period ended December 31,	
	2021	2022
Gastroenterology:		
ENTYVIO	139,465	201,272
TAKECAB/VOCINTI ⁽¹⁾	29,261	29,845
GATTEX/REVESTIVE	19,800	29,779
DEXILANT	14,432	17,115
PANTOLOC/CONTROLOC ⁽²⁾	10,207	11,571
ALOFISEL	554	849
Others	22,874	20,693
Total Gastroenterology	236,594	311,124
Rare Diseases:		
Rare Hematology:		
ADVATE	28,027	29,724
ADYNOVATE/ADYNOVI	15,906	15,464
FEIBA	8,804	11,299
RECOMBINATE	3,288	3,491
Others	13,981	16,950
Total Rare Hematology	70,005	76,928
Rare Genetics and Other:		
TAKHZYRO	30,895	44,053
ELAPRASE	22,901	22,589
REPLAGAL	13,635	16,251
VPRIV	11,182	12,990
LIVTENCITY	190	3,084
Others	14,033	15,479
Total Rare Genetics and Other	92,835	114,446
Total Rare Diseases	162,839	191,374
PDT Immunology:		
immunoglobulin	96,992	145,428
albumin	19,746	33,743
Others	8,481	9,269
Total PDT Immunology	125,219	188,440
Oncology:		
VELCADE	29,350	3,905
LEUPLIN/ENANTONE	28,362	31,525
NINLARO	24,942	27,120
ADCETRIS	17,644	24,070
ICLUSIG	8,826	12,312
ALUNBRIG	3,888	6,053
EXKIVITY	208	811
Others	12,159	13,865
Total Oncology	125,380	119,662
Neuroscience:		
VYVANSE/ELVANSE	85,714	124,213
TRINTELLIX	22,980	29,901
Others	20,218	20,713
Total Neuroscience	128,912	174,827

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	JPY (millions)	
	Three-month period ended December 31,	
	2021	2022
Other:		
AZILVA ⁽¹⁾	19,704	19,405
LOTRIGA	8,690	2,819
Others ⁽³⁾	93,955	88,900
Total Other	122,350	111,124
Total	901,294	1,096,551

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

⁽²⁾ Generic name: pantoprazole

(2) Geographic Information

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

	JPY (millions)	
	Nine-month Period Ended December 31,	
	2021	2022
Japan	530,245	389,843
U.S.	1,297,020	1,621,772
Europe and Canada	540,978	632,403
Asia (excluding Japan)	139,770	169,024
Latin America	93,545	121,425
Russia/CIS	43,582	66,700
Other	50,577	70,156
Total	2,695,717	3,071,322

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

	JPY (millions)	
	Three-month period ended December 31,	
	2021	2022
Japan	139,377	128,490
U.S.	458,644	589,246
Europe and Canada	187,007	223,438
Asia (excluding Japan)	50,063	63,306
Latin America	32,174	38,167
Russia/CIS	18,494	28,882
Other	15,536	25,021
Total	901,294	1,096,551

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

5. Other Operating Expenses

Other operating expenses was 100,034 million JPY and 127,643 million JPY for the nine-month period ended December 31, 2021 and 2022, 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 59,102 million JPY and 38,473 million JPY for the nine-month period ended December 31, 2021 and 2022, respectively. Other operating expenses also included 12,395 million JPY and 18,984 million JPY of pre-launch inventory write-offs for the nine-month period ended December 31, 2021 and 2022, respectively. In addition, other operating expenses for the nine-month period ended December 31, 2022 included 14,796 million JPY write-off of option fees Takeda paid as part of collaboration agreements.

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6. Income Tax Expenses

The effective tax rate for the nine-month period ended December 31, 2022 was 12.6% compared to 32.3% for the nine-month period ended December 31, 2021, mainly due to a tax charge of 64.6 billion JPY for tax and interest, net of 0.5 billion JPY of associated tax benefit, arising from tax assessment involving Irish taxation of the break fee Shire received from AbbVie in connection with the terminated offer to acquire Shire made by AbbVie in 2014 for the nine-month period ended December 31, 2021 as well as decreased tax charges for US international tax provisions and tax benefits from recognition of deferred tax assets for the nine-month period ended December 31, 2022. These were partially offset by the tax benefits from internal entity restructuring transactions for the nine-month period ended December 31, 2021.

7. Earnings Per Share

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

	Nine-month Period Ended December 31,	
	2021	2022
Net profit for the period attributable to owners of the Company		
Net profit for the period attributable to owners of the Company (million JPY)	241,417	285,883
Net profit used for calculation of earnings per share (million JPY)	241,417	285,883
Weighted average number of ordinary shares outstanding during the period (thousands of shares) [basic]	1,566,730	1,550,992
Dilutive effect (thousands of shares)	10,886	14,243
Weighted average number of ordinary shares outstanding during the period (thousands of shares) [diluted]	1,577,616	1,565,235
Earnings per share		
Basic earnings per share (JPY)	154.09	184.32
Diluted earnings per share (JPY)	153.03	182.65

	Three-month Period Ended December 31,	
	2021	2022
Net profit for the period attributable to owners of the Company		
Net profit for the period attributable to owners of the Company (million JPY)	57,770	119,127
Net profit used for calculation of earnings per share (million JPY)	57,770	119,127
Weighted average number of ordinary shares outstanding during the period (thousands of shares) [basic]	1,565,162	1,554,524
Dilutive effect (thousands of shares)	9,758	15,892
Weighted average number of ordinary shares outstanding during the period (thousands of shares) [diluted]	1,574,920	1,570,416
Earnings per share		
Basic earnings per share (JPY)	36.91	76.63
Diluted earnings per share (JPY)	36.68	75.86

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8. Property, Plant and Equipment

In June 2022, the Company entered into a lease agreement for research and development and office space of a to be constructed building in Cambridge, Massachusetts, with an expected lease term starting in 2025. The base lease term is for 15 years, after which the Company has the option to renew the lease twice for 10 years each at market rates. In addition to payment obligations related to its share of operating expenses, utilities and taxes, the Company will have a base lease term payment obligation of 196,154 million JPY (1,486 million USD) to be paid over the course of the base lease term. Under certain conditions, the Company has the ability to terminate the lease agreement prior to the building being constructed.

9. Collaborations, Licensing Arrangements, and Other Asset Acquisitions

Takeda is a party to certain collaborations, in-licensing agreements, out-licensing arrangements and other asset acquisitions.

Collaborations, in-licensing arrangements, and other asset acquisitions

These agreements generally provide for commercialization rights to a product or products being developed by the partner, and in exchange, often resulted in an up-front payment being paid upon execution of the agreement and resulted in an obligation that may require Takeda to make future development, regulatory approval, or commercial milestone payments as well as sales-based royalty payments. In some of these arrangements, Takeda and the licensee are both actively involved in the development and commercialization of the licensed products and have exposure to risks and rewards that are dependent on its commercial success. Other asset acquisitions are acquisitions of legal entities that do not qualify as business combinations under IFRS3. These acquisitions include acquisitions of entities where the value of these acquired entities largely consists of the rights to a single product or group of products.

There were no significant updates on the out-licensing agreements, the collaborations, in-licensing arrangements and other asset acquisitions disclosed in the consolidated financial statements as of and for the year ended March 31, 2022 except for the below contract.

Nimbus Therapeutics, LLC (“Nimbus”)

In December 2022, Takeda entered into an agreement to acquire all shares of Nimbus Lakshmi, Inc., a wholly-owned subsidiary of Nimbus. Through this transaction, Takeda will acquire NDI-034858, an oral, selective allosteric tyrosine kinase 2 (TYK2) inhibitor being evaluated for the treatment of multiple autoimmune diseases following successful recent Phase 2b results in psoriasis. When the transaction is complete, NDI-034858 will be known as TAK-279. Under the terms of the agreement, Takeda will pay Nimbus 4 billion USD upfront following the closing of the transaction, and two milestone payments of 1 billion USD each upon achieving annual net sales of 4 billion USD and 5 billion USD of products developed from the NDI-034858 program. The transaction is expected to be finalized before the end of the fiscal year ending March 31, 2023. Closing of the transaction is contingent on completion of review under antitrust laws, including the Hart-Scott-Rodino (HSR) Antitrust Improvements Act of 1976.

10. Bonds and Loans

Bonds

During the nine-month period ended December 31, 2022, Takeda redeemed the following bonds.

Instrument	Issuance	Redemption date	Type of redemption	Principal Amount in contractual currency
USD Unsecured Senior Notes	June 2015	April 23, 2022	Early redemption	219 million USD
USD Unsecured Senior Notes	November 2018	October 27, 2022	Early redemption	1,000 million USD
EUR Unsecured Senior Notes	November 2018	November 21, 2022	Maturity redemption	750 million EUR

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11. Equity and Other Equity Items

(1) Issuance of shares and disposal of treasury shares

During the nine months period ended December 31, 2021, the Company issued 3,874 thousand shares of common stock under the Long Term Incentive Plan for the Company Group employees overseas. The issuance of these shares resulted in an increase in share capital of 7,138 million JPY and share premium of 7,138 million JPY.

During the nine months period ended December 31, 2022, the Company conducted the disposal of 8,091 thousand treasury shares under the Long Term Incentive Plan for the Company Group employees overseas. The disposal of treasury shares resulted in a decrease in treasury shares of 27,599 million JPY.

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

(2) Acquisition of treasury shares

During the nine-month period ended December 31, 2022, Takeda acquired 6,908 thousand shares of its common stock for 24,993 million JPY in accordance with the resolution on the acquisition of its own shares at the Board of Directors Meeting held on October 28, 2021. Including its own shares acquired during the fiscal year ended March 31, 2022, Takeda acquired a total of 29,377 thousand shares of its common stock for 99,966 million JPY, and the acquisition in accordance with the resolution was completed.

(3) Dividends

Dividends declared and paid	Total dividends declared and paid JPY (millions)	Dividends per share (JPY)	Basis date	Effective date
April 1, 2021 to December 31, 2021				
Q1 2021	141,859	90.00	March 31, 2021	June 30, 2021
Q3 2021	142,387	90.00	September 30, 2021	December 1, 2021
April 1, 2022 to December 31, 2022				
Q1 2022	140,365	90.00	March 31, 2022	June 30, 2022
Q3 2022	140,474	90.00	September 30, 2022	December 1, 2022

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12. 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 December 31, 2022	JPY (millions)			
	Level 1	Level 2	Level 3	Total
Assets:				
Financial assets measured at fair value through profit or loss				
Derivatives	—	4,868	5,949	10,818
Investments in convertible notes	—	—	8,602	8,602
Investments in debt instruments	—	—	1,063	1,063
Financial assets associated with contingent consideration arrangements	—	—	22,662	22,662
Derivatives for which hedge accounting is applied	—	84,549	—	84,549
Financial assets measured at fair value through OCI				
Trade and other receivables	—	92,727	—	92,727
Equity instruments	82,170	—	77,844	160,014
Total	82,170	182,144	116,121	380,435
Liabilities:				
Financial liabilities measured at fair value through profit or loss				
Derivatives	—	37,454	5,949	43,404
Financial liabilities associated with contingent consideration arrangements	—	—	7,763	7,763
Derivatives for which hedge accounting is applied	—	10,274	—	10,274
Total	—	47,729	13,712	61,441

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(2) Valuation Techniques

The fair value of derivatives in 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 3.7 times to 11.2 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 nine-month period ended December 31, 2022. These transfers resulted from the investments in the companies whose shares were previously not listed on an equity or stock exchange and had no recent observable active trades in the shares. During the nine-month period ended December 31, 2022, the companies listed their equity shares on an exchange and are currently actively traded in the market. As the equity shares have a published price quotation in an active market, the fair value measurement was transferred from Level 3 to Level 1 on the fair value hierarchy during the nine-month period ended December 31, 2022. There were no other significant transfers between levels of the fair value hierarchy during the nine-month period ended December 31, 2022.

(4) Level 3 fair values

Takeda invests in equity instruments mainly for research collaboration. The following table shows a reconciliation from the opening balances to the closing balances for Level 3 financial asset fair values for the period ended December 31, 2022. The disclosure related to Level 3 financial liabilities which are financial liabilities associated with contingent consideration arrangements are included in (5) Financial liabilities associated with contingent consideration arrangements. There are no significant changes in fair value during the changes in certain assumptions which influence the fair value measurement for Level 3 financial assets.

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	JPY (millions)	
	Nine-month Period Ended December 31, 2022	
	Financial assets associated with contingent consideration arrangements	Equity instruments
As of the beginning of the period	26,852	64,263
Changes recognized as finance income or finance expenses	811	—
Changes in fair value of financial assets associated with contingent consideration due to other elements than time value	(3,886)	—
Changes in fair value of financial assets measured at fair value through OCI and exchange differences on translation of foreign operations	2,607	5,836
Settled and received during the period	(3,722)	—
Purchases	—	6,680
Transfers to Level 1	—	(1,711)
Acquisition from conversion of convertible notes	—	1,368
Transfers from investments accounted for using the equity method	—	2,245
Transfers to investments accounted for using the equity method	—	(837)
As of the end of the period	<u>22,662</u>	<u>77,844</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 December 31, 2022, the balance primarily relates to pre-existing contingent consideration arrangements from Shire's historical acquisition.

The pre-existing contingent consideration arrangements acquired from Shire through Shire's historical acquisitions is due upon the achievement of certain milestones related to the development, regulatory, first commercial sale and other sales milestones of products at various stages of development and marketing. The fair value of financial liabilities associated with contingent consideration arrangements could increase or decrease due to changes in certain assumptions which underpin the fair value measurements. The assumptions include probability of milestones being achieved.

The fair value of financial liabilities associated with contingent consideration arrangements are classified as Level 3 in the fair value hierarchy. The following table shows a reconciliation from the opening balances to the closing balances for financial liabilities associated with contingent consideration arrangements for the period ended December 31, 2022. There are no significant changes in fair value during the changes in significant assumptions which influence the fair value measurement for financial liabilities associated with contingent consideration arrangements.

	JPY (millions)
	Nine-month Period Ended December 31, 2022
As of the beginning of the period	5,844
Changes in the fair value during the period	2,058
Settled during the period	(728)
Foreign currency translation differences	589
As of the end of the period	<u>7,763</u>

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(6) Financial instruments not measured at fair value

The carrying amount and fair value of financial instruments that are not measured at fair value in the condensed interim consolidated statements of financial position are as follows. Fair value information is not provided for financial instruments, if the carrying amount is a reasonable estimate of fair value due to the relatively short period of maturity of these instruments.

	JPY (millions)	
	As of December 31, 2022	
	Carrying amount	Fair value
Bonds	3,565,012	3,194,262
Long-term loans	721,635	718,173

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.

13. Subsequent Events

Not applicable.

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2. Others

Interim Dividend

In accordance with the provision of Article 29 of the Articles of Incorporation of the Company, Takeda made the following resolution on an interim dividend for the 146th fiscal year (from April 1, 2022 to March 31, 2023) at the meeting of the Board of Directors held on October 27, 2022, and paid the interim dividend.

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

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B. Information on Guarantors of the Company

Not applicable.