

# **Quarterly Securities Report**

(The first quarter of 145th Business Term)  
for The Three-month Period Ended June 30, 2021

TAKEDA PHARMACEUTICAL COMPANY LIMITED  
AND ITS SUBSIDIARIES

## Table of Contents

### Index

	<u>Page</u>
<u>[Cover]</u>	<u>1</u>
<b>A. Company Information</b>	
<b><u>I. Overview of Takeda</u></b>	<b>2</b>
<u>1. Key Consolidated Financial Data</u>	2
<u>2. Business Overview</u>	3
<b><u>II. Operating and Financial Review</u></b>	<b>4</b>
<u>1. Risk Factors</u>	4
<u>2. Analysis on Business Performance, Financial Position and Cash Flows</u>	4
<u>3. Material Contracts</u>	19
<b><u>III. Information on the Company</u></b>	<b>20</b>
<u>1. Information on the Company's Shares</u>	20
<u>2. Members of the Board of Directors</u>	22
<b><u>IV. Financial Information</u></b>	<b>23</b>
<u>1. Condensed Interim Consolidated Financial Statements</u>	24
<u>2. Others</u>	43
<b><u>B. Information on Guarantors of the Company</u></b>	<b>44</b>

## Table of Contents

### **[Cover]**

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## [Table of Contents](#)

### A. Company Information

#### I. Overview of Takeda

##### 1. Key Consolidated Financial Data

Term	JPY (millions), unless otherwise indicated		
	Three-month period ended June 30,	Three-month period ended June 30,	For the year ended March 31,
	2020	2021	2021
Revenue	801,850	949,603	3,197,812
Profit before tax	130,291	222,978	366,235
Net profit for the period	82,519	137,726	376,171
Net profit attributable to owners of the Company	82,511	137,684	376,005
Total comprehensive income for the period	97,258	197,005	697,416
Total equity	4,690,764	5,238,643	5,177,177
Total assets	12,613,852	12,657,234	12,912,293
Basic earnings per share (JPY)	52.93	87.96	240.72
Diluted earnings per share (JPY)	52.69	87.45	238.96
Ratio of equity attributable to owners of the Company to total assets (%)	37.2	41.4	40.1
Net cash from (used in) operating activities	145,861	166,858	1,010,931
Net cash from (used in) investing activities	662	(70,445)	393,530
Net cash from (used in) financing activities	(192,765)	(411,038)	(1,088,354)
Cash and cash equivalents at the end of the period	589,787	654,920	966,222

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

(Note 2) The key consolidated financial data for the three-month period ended June 30, 2020 and 2021 are based on the condensed interim consolidated financial statements prepared in accordance with IAS 34.

## **2. Business Overview**

There has been no significant change in our business for the three-month period ended June 30, 2021.

Changes in number of our group companies were as follows:

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

As a result, as of June 30, 2021, Takeda consisted of 253 entities comprised of 231 consolidated subsidiaries (including partnerships), 21 associates accounted for using the equity method, and Takeda Pharmaceutical Company Limited.

## [Table of Contents](#)

### II. Operating and Financial Review

#### 1. Risk Factors

For the three-month period ended June 30, 2021, there were no unusual changes in our business performance, financial position, and cash flows, as well as no significant changes in the risk factors compared to what we reported in our Annual Securities Report for the year ended March 31, 2021 which was filed in Japan.

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

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

##### (1) Consolidated Financial Results (April 1 to June 30, 2021):

	Billion JPY or percentage			
	FY2020Q1	FY2021Q1	Change versus the same period of the previous fiscal year	
Revenue	801.9	949.6	147.8	18.4 %
Cost of sales	(238.1)	(241.3)	(3.2)	1.3 %
Selling, general and administrative expenses	(202.4)	(219.8)	(17.5)	8.6 %
Research and development expenses	(106.8)	(122.5)	(15.7)	14.7 %
Amortization and impairment losses on intangible assets associated with products	(104.2)	(102.8)	1.4	(1.4)%
Other operating income	63.7	11.1	(52.6)	(82.6)%
Other operating expenses	(46.8)	(25.8)	21.0	(44.9)%
Operating profit	167.3	248.6	81.3	48.6 %
Finance income and (expenses), net	(27.2)	(25.2)	2.0	(7.4)%
Share of loss of investments accounted for using the equity method	(9.8)	(0.4)	9.4	(96.3)%
Profit before tax	130.3	223.0	92.7	71.1 %
Income tax expenses	(47.8)	(85.3)	(37.5)	78.5 %
Net profit for the period	82.5	137.7	55.2	66.9 %

**Revenue.** Revenue for the three-month period ended June 30, 2021 was 949.6 billion JPY, an increase of 147.8 billion JPY, or 18.4%, compared to the same period of the previous fiscal year. Excluding the impact from fluctuations in foreign exchange rates, which was calculated by translating revenue of the three-month period ended June 30, 2021 using corresponding exchange rates in the same period of the previous fiscal year, the increase in revenue was 14.3%. In April 2021, Takeda completed the sale of a portfolio of diabetes products in Japan to Teijin Pharma Limited for 133.0 billion JPY, which was recorded as revenue and accounted for 16.6 percentage points ("pp") of the increase in revenue. Excluding this selling price from revenue for the three-month period ended June 30, 2021, the increase was 1.8%.

Each of our core therapeutic areas (i.e. Gastroenterology ("GI"), Rare Diseases, Plasma-Derived Therapies ("PDT") Immunology, Oncology, and Neuroscience) contributed to positive revenue growth; however, Rare Diseases and PDT Immunology would have declined if not for the positive impact of the depreciation of the yen. Intensified competition, generic erosion, and shipment timing impacted some products in these two areas. Overall, the global spread of COVID-19 did not have a material effect on our revenue for the three-month period ended June 30, 2021.

Revenue outside of our core therapeutic areas increased by 101.8 billion JPY, or 72.8%, compared to the same period of the previous fiscal year to 241.6 billion JPY, largely due to the 133.0 billion JPY selling price of the diabetes portfolio in Japan, offsetting the impact from divestitures.

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

- *GI.* In Gastroenterology, revenue was 210.5 billion JPY, a year-on-year increase of 23.6 billion JPY, or 12.6%. Growth was driven by Takeda's top-selling product ENTYVIO (for ulcerative colitis ("UC") and Crohn's disease ("CD")), with

## Table of Contents

sales of 125.4 billion JPY, a year-on-year increase of 24.1 billion JPY, or 23.9%. Sales in the U.S. increased by 12.2 billion JPY, or 17.1%, to 83.7 billion JPY and sales in Europe and Canada increased by 8.6 billion JPY, or 35.6%, to 32.7 billion JPY, due to an increase in demand. In the Growth and Emerging Markets, the increase in sales was primarily driven by Brazil and China. Sales of TAKECAB (for acid-related diseases) were 24.3 billion JPY, an increase of 4.1 billion JPY, or 20.1%, versus the same period of the previous fiscal year. This increase was driven by the expansion of new prescriptions in the Japanese market due to TAKECAB's efficacy in reflux esophagitis and the prevention of recurrence of gastric and duodenal ulcers during low-dose aspirin administration. Sales of AMITIZA (for chronic constipation) decreased by 4.1 billion JPY, or 65.8%, to 2.1 billion JPY, due to generic entrants in the U.S. in January 2021.

- *Rare Diseases*. In Rare Diseases, revenue was 155.5 billion JPY, a slight year-on-year increase of 0.5 billion JPY, or 0.3%.

Revenue in Rare Metabolic increased by 4.3 billion JPY, or 10.9%, compared to the same period of the previous fiscal year to 44.3 billion JPY. Sales of enzyme replacement therapies REPLAGAL (for Fabry disease), VPRIV (for Gaucher disease) and ELAPRASE (for Hunter syndrome) increased due to higher demand coupled with the positive impact of the depreciation of the yen.

Revenue in Rare Hematology decreased by 4.6 billion JPY, or 5.9%, to 72.2 billion JPY. Sales of ADVATE decreased by 3.0 billion JPY, or 8.9%, to 30.7 billion JPY. Sales of ADYNOVATE increased by 0.1 billion JPY, or 0.6%, to 15.4 billion JPY, helped by the positive impact of the depreciation of the yen. Both products were impacted by the competitive landscape in the hemophilia A non-inhibitors market in the U.S. FEIBA sales decreased by 1.5 billion JPY, or 11.3%, to 11.4 billion JPY.

Revenue in Hereditary Angioedema ("HAE") was 39.0 billion JPY, a year-on-year increase of 0.7 billion JPY, or 1.8%. Sales of TAKHZYRO were 25.5 billion JPY, an increase of 2.2 billion JPY, or 9.6%, versus the same period of the previous fiscal year primarily due to new launches including prefilled syringe administration in Europe. Sales of FIRAZYR decreased by 1.2 billion JPY, or 15.1%, to 6.9 billion JPY, primarily due to the continued impact of generic entrants in the U.S.

- *PDT Immunology*. In Plasma-Derived Therapies ("PDT") Immunology, revenue increased by 1.9 billion JPY, or 1.8%, compared to the same period of the previous fiscal year to 107.2 billion JPY. Aggregate sales of immunoglobulin products were 81.6 billion JPY, a decrease of 3.5 billion JPY, or 4.1%, compared to the same period of the previous fiscal year. In particular, GAMMAGARD LIQUID (for the treatment of primary immunodeficiency ("PID") and multifocal motor neuropathy ("MMN")) decreased in sales mainly due to shipment timing, as the last three-month period of the previous fiscal year saw higher sales. On the other hand, CUVITRU, a SCIG (subcutaneous immunoglobulin) therapy continued to mark double digit growth. Aggregate sales of albumin products including HUMAN ALBUMIN and FLEXBUMIN (primarily used for hypovolemia and hypoalbuminemia) were 17.8 billion JPY, an increase of 4.8 billion JPY, or 36.8%, versus the same period of the previous fiscal year driven by the resolution of the temporary supply interruption impacting HUMAN ALBUMIN for release in China which impacted the second half of the previous fiscal year.
- *Oncology*. In Oncology, revenue was 121.4 billion JPY, a year-on-year increase of 13.4 billion JPY, or 12.4%. Sales of VELCADE (for multiple myeloma) increased by 5.9 billion JPY, or 24.6% versus the same period of the previous fiscal year to 30.1 billion JPY. While royalty income outside the U.S. decreased by 0.3 billion JPY, or 30.8%, due to continued generic erosion, sales in the U.S. increased by 6.3 billion JPY, or 27.3%, versus the same period of the previous fiscal year, reflecting a rebound in demand after lower sales in the same period of the prior year when prescribers favored orally administered products over infusions or injections, as a result of the COVID-19 outbreak. Sales of NINLARO (for multiple myeloma) were 24.4 billion JPY, an increase of 1.4 billion JPY, or 6.3%, versus the same period of the previous fiscal year. NINLARO's convenient profile as an orally administered treatment led to a temporary increase in demand in light of the spread of COVID-19, especially in the first few months of the previous fiscal year, because its administration reduced some of the logistical burden for patients visiting a hospital, clinic or physician's office to get an infusion or injection. This benefit has since normalized in the U.S.; however, there have been strong demand increases in other countries, particularly in China. Sales of ADCETRIS (for malignant lymphomas) increased by 2.1 billion JPY, or 14.2% versus the same period of the previous fiscal year to 17.2 billion JPY, led by strong growth in sales in the Growth and Emerging Markets, particularly in China where it was approved in May 2020. Sales of LEUPLIN/ENANTONE (generic name: leuprorelin) (for endometriosis, uterine fibroids, premenopausal breast cancer, prostatic cancer, etc.), an off-patented product, decreased by 1.2 billion JPY, or 4.3%, versus the same period of the previous fiscal year to 26.2 billion JPY mainly due to generic erosion and competition in Japan.
- *Neuroscience*. In Neuroscience, revenue was 113.4 billion JPY, a year-on-year increase of 6.6 billion JPY, or 6.1%. Sales of VYVANSE/ELVANSE (for attention deficit hyperactivity disorder ("ADHD")) were 79.2 billion JPY, an increase of 13.2 billion JPY, or 20.0%, versus the same period of the previous fiscal year. VYVANSE/ELVANSE has been negatively affected by COVID-19 during the course of the pandemic, most notably during periods when stay-at-home

## Table of Contents

restrictions have been in place reducing patient visits, subsequent diagnoses and creating temporary discontinuation of medication. The trend has been fluctuating throughout 2020 and into 2021; however, when comparing the three-month period of the current fiscal year with the same period of the previous fiscal year, there has been a positive impact from increasing prescriptions. Sales of TRINTELLIX (for major depressive disorder (“MDD”)) were 17.9 billion JPY, an increase of 1.0 billion JPY, or 5.9%, versus the same period of the previous fiscal year, primarily due increasing market penetration in Japan. The increase of these products was partially offset by the decrease of other neuroscience products such as REMINYL (for Alzheimer's disease) and ADDERALL XR (for ADHD), attributable to the continued impact of competition from generic products.

### Revenue by Geographic Region:

Revenue:	Billion JPY; percentages are portion of total revenue			
	FY2020Q1		FY2021Q1	
Japan <sup>*1</sup>	144.0	18.0 %	259.0	27.3 %
United States	402.6	50.2 %	412.2	43.4 %
Europe and Canada	157.6	19.6 %	178.7	18.8 %
Asia (excluding Japan)	36.9	4.6 %	40.3	4.2 %
Latin America	30.8	3.8 %	30.1	3.2 %
Russia/CIS	13.0	1.6 %	12.3	1.3 %
Other <sup>*2</sup>	16.9	2.1 %	17.0	1.8 %
Total	801.9	100.0 %	949.6	100.0 %

\*1 The 133.0 billion JPY selling price of the sale of diabetes portfolio in Japan is included in the three-month period ended June 30, 2021.

\*2 Other includes the Middle East, Oceania and Africa.

**Cost of Sales.** Cost of Sales increased by 3.2 billion JPY, or 1.3%, to 241.3 billion JPY and the Cost of Sales Ratio decreased by 4.3pp compared to the same period of the previous fiscal year to 25.4%. The increase was primarily due to the depreciation of the yen during the current period as compared to same period of the previous fiscal year, however, this increase was partially offset by a 15.4 billion JPY decrease in non-cash charges related to the unwind of the fair value step up on acquired inventory recognized in connection with the acquisition of Shire plc (the "Shire Acquisition"). The main reason for the decrease in the Cost of Sales Ratio was the effect of the sale of a portfolio of diabetes products in Japan with the selling price of 133.0 billion JPY being recorded in revenue.

**Selling, General and Administrative (SG&A) expenses.** SG&A expenses increased by 17.5 billion JPY, or 8.6%, to 219.8 billion JPY compared to the same period of the previous fiscal year, mainly due to the impact from the depreciation of the yen in the current period.

**Research and Development (R&D) expenses.** R&D expenses increased by 15.7 billion JPY, or 14.7%, to 122.5 billion JPY compared to the same period of the previous fiscal year, mainly due to further investment in prioritized new molecular entities as well as the impact from the depreciation of the yen in the current period.

**Amortization and Impairment Losses on Intangible Assets Associated with Products.** Amortization and Impairment Losses on Intangible Assets Associated with Products decreased by 1.4 billion JPY, or 1.4%, to 102.8 billion JPY compared to the same period of the previous fiscal year.

**Other Operating Income.** Other Operating Income was 11.1 billion JPY, a decrease of 52.6 billion JPY, or 82.6%, compared to the same period of the previous fiscal year, mainly driven by a 60.2 billion JPY revaluation gain recorded in the same period of the previous fiscal year triggered by an update to previously recognized liabilities for pipeline compound SHP647 and certain associated rights ("SHP647"), to reflect management's decision to terminate the clinical trial program following the European Commission's decision in May 2020 to release Takeda's obligation to divest SHP647.

**Other Operating Expenses.** Other Operating Expenses were 25.8 billion JPY, a decrease of 21.0 billion JPY, or 44.9%, compared to the same period of the previous fiscal year. This is mainly attributable to a 18.6 billion JPY loss recognized in the same period of the previous year from changes in the fair value of contingent consideration assets from the divestment of XIIDRA. There was also a 8.1 billion JPY decrease in restructuring expenses mainly attributable to lower Shire integration costs. A negative impact of the valuation reserve for pre-launch inventories by 4.5 billion JPY partially offset this decrease.



## Table of Contents

**Operating Profit.** As a result of the above factors, Operating Profit increased by 81.3 billion JPY, or 48.6% compared to the same period of the previous fiscal year to 248.6 billion JPY.

**Net Finance Expenses.** Net Finance Expenses were 25.2 billion JPY in the current period, a decrease of 2.0 billion JPY compared to the same period of the previous fiscal year. The decrease is mainly due to a gain on prior equity method investments related to the acquisition of Maverick Therapeutics, Inc. in April 2021, partially offset by the negative impact from remeasurement of the warrant to purchase stocks of a company held by Takeda.

**Share of Loss of Investments Accounted for Using the Equity Method.** Share of Loss of Investments Accounted for Using the Equity Method was 0.4 billion JPY, a decrease of 9.4 billion JPY compared to the same period of the previous fiscal year. This was mainly due to Takeda's shareholding ratio of impairment loss recognized by Teva Takeda Pharma Ltd. for the same period of the previous fiscal year resulting from the reassessment of the recoverable amount of relevant assets triggered by the decision to divest a part of its generics business and a manufacturing plant.

**Income Tax Expenses.** Income Tax Expenses were 85.3 billion JPY, an increase of 37.5 billion JPY compared to the same period of the previous year. This increase was primarily due to a tax charge of 62.7 billion JPY for tax and interest, net of 0.5 billion JPY of associated tax benefit, arising from tax assessment involving Irish taxation of the break fee Shire received from AbbVie in connection with the terminated offer to acquire Shire made by AbbVie in 2014 as well as higher pretax earnings in the current period. These increases were partially offset by the tax benefits from internal entity restructuring transactions in the current period and a decrease in unitary tax on overseas subsidiaries in the current period versus the same period of the previous year.

**Net Profit for the Period.** Net Profit for the Period increased by 55.2 billion JPY, compared to the same period of the previous fiscal year to 137.7 billion JPY.

**Underlying Results (April 1 to June 30, 2021)**

***Definition of Core and Underlying Growth***

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

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

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

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

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

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

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

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

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

***Underlying Results***

**FY2021Q1**

Underlying Revenue Growth	+3.8%
Underlying Core Operating Profit Growth	-2.1%
Underlying Core Operating Profit Margin	30.5%
Underlying Core EPS Growth	+3.9%

***Underlying Revenue Growth*** was 3.8% compared to the same three-month period of the previous fiscal year. Underlying revenue attributable to Takeda's 14 global brands\* grew by 6.8%, despite a decline of GAMMAGARD LIQUID/KIOVIG.

\* Takeda's 14 global brands

GI: ENTYVIO, GATTEX/REVESTIVE, ALOFISEL

Rare Diseases: NATPARA/NATPAR, ADYNOVATE/ADYNOVI, TAKHZYRO, ELAPRASE, VPRIV

PDT Immunology: GAMMAGARD LIQUID/KIOVIG, HYQVIA, CUVITRU, HUMAN ALUBUMIN/FLEXBUMIN

Oncology: NINLARO, ALUNBRIG

## Table of Contents

### **Underlying Revenue Growth by Therapeutic Area**

GI	+7.9%
Rare Diseases	-3.4%
Rare Metabolic	+6.6%
Rare Hematology	-9.4%
Hereditary Angioedema	-1.7%
PDT Immunology	-1.8%
Oncology	+8.9%
Neuroscience	+2.9%
Other	+9.0%
Total	+3.8%

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

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

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

***Underlying Core Operating Profit Growth*** was -2.1% over the same three-month period of the previous fiscal year, reflecting increase in R&D investment.

Core Operating Profit for the current period, which excludes items unrelated to Takeda's core operations such as the sale of a portfolio of diabetes products in Japan, was 248.9 billion JPY.

***Underlying Core Operating Profit Margin*** for the current period was 30.5%

***Underlying Core EPS Growth*** for the current period was 3.9%.

## [Table of Contents](#)

### (2) Consolidated Financial Position

**Assets.** Total Assets as of June 30, 2021 were 12,657.2 billion JPY, reflecting a decrease of 255.1 billion JPY compared to the previous fiscal year-end. Cash and Cash Equivalents decreased by 311.3 billion JPY, and Intangible Assets decreased by 52.7 billion JPY mainly due to amortization. These decreases were partially offset by an increase in Trade and Other Receivables of 44.2 billion JPY and an increase in Inventories of 25.3 billion JPY.

**Liabilities.** Total Liabilities as of June 30, 2021 were 7,418.6 billion JPY, reflecting a decrease of 316.5 billion JPY compared to the previous fiscal year-end. Bonds and Loans decreased by 229.5 billion JPY to 4,405.9 billion JPY\* primarily as a result of the repayment of loans and the redemption of bonds. In addition, Provisions decreased by 63.8 billion JPY.

\* The carrying amount of Bonds was 3,524.0 billion JPY and Loans was 881.9 billion JPY as of June 30, 2021. Breakdown of Bonds and Loans carrying amount is as follows.

#### Bonds:

<b>Name of Bond (Face Value if Denominated in Foreign Currency)</b>	<b>Issuance</b>	<b>Maturity</b>	<b>Carrying Amount (Billion JPY)</b>
Unsecured US dollar denominated senior notes (1,520 million USD)	June 2015	June 2022 ~ June 2045	167.9
Unsecured US dollar denominated senior notes (5,500 million USD)	September 2016	September 2023 ~ September 2026	578.8
Unsecured Euro denominated senior notes (5,250 million EUR)	November 2018	November 2022 ~ November 2030	685.8
Unsecured US dollar denominated senior notes (3,250 million USD)	November 2018	November 2023 ~ November 2028	357.1
Hybrid bonds (subordinated bonds)	June 2019	June 2079	497.6
Unsecured US dollar denominated senior notes (7,000 million USD)	July 2020	March 2030 ~ July 2060	767.7
Unsecured Euro denominated senior notes (3,600 million EUR)	July 2020	July 2027 ~ July 2040	469.1
Total			<u>3,524.0</u>

#### Loans:

<b>Name of Loan (Face Value if Denominated in Foreign Currency)</b>	<b>Execution</b>	<b>Maturity</b>	<b>Carrying Amount (Billion JPY)</b>
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	165.4
Japan Bank for International Cooperation (1,700 million USD)	January 2019	December 2025	187.8
Bilateral loans	March 2016 ~ April 2017	March 2023 ~ March 2026	210.0
Other			5.1
Total			<u>881.9</u>

On May 17, 2021, Takeda redeemed the remaining 200 million USD of unsecured U.S. dollar-denominated senior notes issued in July 2017 in advance of their original maturity date of January 18, 2022. Following this, on June 11, 2021, Takeda prepaid 2,000 million USD of the Japan Bank for International Cooperation loan amount of 3,700 million USD (that was entered into on December 3, 2018) in advance of its original maturity date of December 11, 2025.

## [Table of Contents](#)

**Equity.** Total Equity as of June 30, 2021 was 5,238.6 billion JPY, an increase of 61.5 billion JPY compared to the previous fiscal year-end. This was mainly due to a 59.0 billion JPY increase in Other Components of Equity primarily as a result of fluctuation in currency translation adjustments reflecting the depreciation of the yen.

### Consolidated Cash Flow

	Billion JPY	
	FY2020Q1	FY2021Q1
Net cash from (used in) operating activities	145.9	166.9
Net cash from (used in) investing activities	0.7	(70.4)
Net cash from (used in) financing activities	(192.8)	(411.0)
Net increase (decrease) in cash and cash equivalents	(46.2)	(314.6)
Cash and cash equivalents at the beginning of the year	637.6	966.2
Effects of exchange rate changes on cash and cash equivalents	(1.6)	3.3
Cash and cash equivalents at the end of the period	589.8	654.9

**Net cash from operating activities** was 166.9 billion JPY for the current period compared to 145.9 billion JPY for the same period of the previous year. The increase of 21.0 billion JPY was driven by higher net profit for the period adjusted for non-cash items and other adjustments, including the income relating to the release from the obligation to divest the pipeline compound SHP 647 and certain associated rights in the same period of the previous year. It was partially offset by a decrease in provisions and an increase in inventories.

**Net cash used in investing activities** was 70.4 billion JPY for the current period compared to the net cash from investing activities of 0.7 billion JPY for the same period of the previous year. This increase in net cash used of 71.1 billion JPY was mainly due to a decrease of 44.0 billion JPY in proceeds from sales and redemption of investments and an increase of 27.5 billion JPY in acquisition of business, net of cash and cash equivalents acquired.

**Net cash used in financing activities** was 411.0 billion JPY for the current period compared to 192.8 billion JPY for the same period of the previous year. This increase in net cash used of 218.3 billion JPY was mainly due to an increase in repayments of bonds and long-term loans of 232.9 billion JPY partially offset by the favorable impact from short-term loans and commercial papers of 10.0 billion JPY.

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

There was no significant change in management policy, management environment and management issues for the three-month period ended June 30, 2021.

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

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

It has been more than a year since the COVID-19 pandemic began, and Takeda continues to respond and provide industry support in a number of ways. While vaccines are becoming more broadly available, we continue to strictly adhere to local public health guidance across our geographies in addition to the existing protocols we have had in place over the past year, and monitor any potential impacts of effects of COVID-19 on our business activities.

In monitoring demand for our products, we have seen limited impact to date as many of our medicines are for severe chronic or life-threatening diseases, without the requirement of a hospital elective procedure. In terms of our global supply chain, based on current assessments, we have not yet seen, nor do we anticipate, any material potential supply distribution issues due to the COVID-19 outbreak.

Since the COVID-19 pandemic began, we have continued voluntary suspensions of certain business activities, including business travel, attending industry events, and holding company-sponsored events. However, and in accordance with local guidelines, we are slowly easing some of these restrictions in some geographies with high rates of vaccinations and low new infection rates. In addition, our field force are resuming a small number of face-to-face engagements with customers, with the majority of all interactions still virtual. Where we are engaging face-to-face, it is only with the agreement of healthcare providers and employees follow strict infection prevention protocols set out by both Takeda and any additional public health and customer requirements.

In the early stages of the global pandemic, we placed a temporary pause on the initiation of the majority of new clinical trial studies. At the same time, for studies already ongoing, we temporarily paused the activation of new study sites and new patient enrollment with a small number of exceptions. This was a short-term action and we have resumed most of our trial activities during the previous fiscal year.

As we continue to monitor developments in the financial markets, we currently do not anticipate any material liquidity or funding-related issues.

#### **(ii) Takeda's Initiatives to Mitigate the Impact of COVID-19**

Guided by our values, Takeda's response to COVID-19 continues to focus on protecting the health and safety of our employees, our ability to ensure our medicines are available to patients who rely on them and playing our part to reduce transmission and support the communities where our employees live and work.

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

- We spent several months evaluating new ways of working to ensure we consider the long-term effects of virtual and hybrid working on our overall people experience and to build an exceptional working environment in a "post-COVID-19" world. Now we are rolling out a new hybrid working model in parts of Takeda. It will never be a "one-size-fits-all" approach. Instead, we have created core principles, global guidelines and toolkits to help Takeda leaders and managers determine and implement new hybrid working models for their teams post-COVID.
- Takeda has undertaken a number of efforts to help the world respond to COVID-19. One example is to bring COVID-19 vaccines to Japan through two partnerships. The first partnership is with Novavax, for the development, manufacturing and commercialization of its COVID-19 vaccine candidate NVX CoV2373 (development code in Japan: TAK-019) in Japan. The second partnership is with Moderna and the Government of Japan's Ministry of Health Labour & Welfare (MHLW) to import and distribute its mRNA COVID-19 vaccine (development code in Japan: TAK-919) in Japan. In May 2021, Takeda obtained approval from the MHLW for TAK-919 following positive interim results in Takeda's Phase 1/2 immunogenicity and safety clinical trial, and has since commenced distribution in Japan. Takeda initially entered a three-way agreement with Moderna and MHLW to distribute 50 million doses of TAK-919 in Japan, and in July 2021, Takeda announced an additional three-way agreement to import and distribute an additional 50 million doses from as early as the beginning of 2022, totaling 100 million doses between the two agreements. The agreement of July 2021 includes the potential to secure and supply vaccines corresponding to COVID-19 variants or booster products, should they be successfully developed by Moderna and licensed by the MHLW.

## [Table of Contents](#)

### **(iii) FY2021 Q1 financial impact from COVID-19**

Overall, the global spread of COVID-19 did not have a material effect on our financials for the three-month period ended June 30, 2021. Over the course of the pandemic, there have been adverse effects due to COVID-19 observed in certain therapeutic areas, especially in Neuroscience during periods when stay-at-home restrictions have been in place, reducing patient visits to medical care providers. This was notable especially in the same period of the previous fiscal year when transmission of COVID-19 rapidly expanded across the countries where we operate. The trend has fluctuated since then, and we have not yet seen a full recovery to pre-COVID-19 levels, however, a certain number of our life-saving medicines have shown resilience and have grown even under such an environment.

## Table of Contents

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

Research and development expenses for the three-month period ended June 30, 2021 were 122.5 billion JPY.

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

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

#### **R&D pipeline**

##### **Oncology**

In Oncology, Takeda endeavors to deliver novel medicines to patients with cancer worldwide through a commitment to breakthrough innovation and a passion for improving the lives of patients. Takeda focuses on three key areas in oncology: (1) building on its foundational expertise in hematologic malignancies through continued investment in lifecycle management programs for marketed products NINLARO, ADCETRIS, and ICLUSIG, as well as in pipeline assets in Multiple Myeloma, Acute Myeloid Leukemia, Myelodysplastic Syndromes, and other blood cancers; (2) further developing its portfolio in lung cancer with the marketed product ALUNBRIG and development programs in targeted lung cancer populations; and (3) pursuing novel immuno-oncology targets and next-generation platforms with external partners as well as exploring innovative cell therapies.

##### *NINLARO / Generic name: ixazomib*

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

##### *ICLUSIG / Generic name: ponatinib*

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

##### *ALUNBRIG / Generic name: brigatinib*

- In June 2021, Takeda announced that ALUNBRIG can be used for first-line treatment of patients with non-small cell lung cancer (NSCLC) who are ALK fusion gene positive (ALK-positive) as determined by the companion



## Table of Contents

diagnostic ALK fusion protein kit, Ventana OptiView ALK (D5F3) ("Ventana") in Japan. Ventana, developed by Roche Diagnostics, which uses as its assay principle the immunohistochemical staining method (IHC method), received an additional indication through a partial change of the drug's manufacturing and marketing approval to include its use to ALUNBRIG. The additional approval of ALUNBRIG for the indication of Ventana, in addition to the Fluorescence *In Situ* Hybridization (FISH) diagnostic, will provide a wider range of ALK-positive NSCLC patients with the opportunity to be treated with ALUNBRIG.

*Development code: TAK-788 / Generic name: mobocertinib*

- In April 2021, Takeda announced that the U.S. Food and Drug Administration (FDA) granted priority review for the New Drug Application (NDA) of mobocertinib for the treatment of adult patients with epidermal growth factor receptor (EGFR) Exon20 insertion mutation-positive (insertion+) metastatic non-small cell lung cancer (mNSCLC), as detected by an FDA-approved test, who have received prior platinum-based chemotherapy. Mobocertinib is the first oral therapy specifically designed to selectively target EGFR Exon20 insertion mutations. The NDA for mobocertinib is primarily based on results from the Phase 1/2 trial, which is evaluating the safety and efficacy of oral mobocertinib in patients with mNSCLC. The application was submitted under the FDA's accelerated approval program. Prescription Drug User Fee Act (PDUFA) target action date is set for October 26, 2021.
- In May 2021, Takeda announced updated data from the Phase 1/2 trial of mobocertinib in patients with epidermal growth factor receptor (EGFR) Exon20 insertion mutation-positive (insertion+) metastatic non-small cell lung cancer (mNSCLC) who received prior platinum-based chemotherapy. The results showed mobocertinib continued to demonstrate clinically meaningful benefit after over a year of follow up and were presented at the virtual 57th American Society of Clinical Oncology (ASCO) Annual Meeting. Results showed a median overall survival (OS) of 24 months with a median follow up of 14 months, and responses were observed across diverse EGFR Exon20 insertion variants. Other key data points such as confirmed objective response rate (ORR), a median duration of response (DoR) and a disease control rate (DCR), remained consistent with previously reported data. The safety profile observed was manageable and consistent with previous findings.
- In July 2021, Takeda announced that Center for Drug Evaluation (CDE) of the National Medical Products Administration of China (NMPA) has accepted the New Drug Application (NDA) for mobocertinib and granted priority review for this Class-1 innovative drug, for the treatment of adult patients with non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) Exon20 insertion mutations.

### **Rare Genetics & Hematology**

In Rare Genetics & Hematology, Takeda focuses on hereditary angioedema to transform the treatment paradigm, including through TAKHZYRO, and on rare hematology and rare metabolic diseases, with the aim to deliver functional cures in a select group of diseases using novel modalities and platforms.

*TAKHZYRO / Generic name: lanadelumab*

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

## Table of Contents

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

- In June 2021, Takeda announced that the U.S. Food & Drug Administration (FDA) has accepted the supplemental Biologics License Application (sBLA) for VONVENDI for the prophylactic treatment to prevent or reduce the frequency of bleeding episodes in adults (age 18 and older) with von Willebrand disease (VWD). The FDA has provided an anticipated Prescription Drug User Fee Act (PDUFA) action date of January 28, 2022.

### *Development code: TAK-620 / Generic name: maribavir*

- In May 2021, Takeda announced that the U.S. Food & Drug Administration (FDA) accepted a New Drug Application (NDA), granting priority review, for maribavir for the treatment of CMV infections that are refractory with or without resistance (R/R), in solid organ transplant (SOT) or hematopoietic cell transplant (HCT) recipients. The application is based on the pivotal Phase 3 TAK-620-303 (SOLSTICE) trial. Maribavir has been granted Orphan Drug Designation by the FDA for treatment of clinically significant CMV viremia and disease in at-risk patients. The FDA has also granted maribavir Breakthrough Therapy Designation as a treatment for CMV infection and disease in transplant patients resistant or refractory to prior therapy.
- In June 2021, Takeda announced the results from a new subgroup analysis of SOT recipients in the Phase 3 TAK-620-303 (SOLSTICE) trial, for the investigational drug maribavir, at the American Transplant Congress (ATC) 2021 Virtual Connect. More than twice (55.6%, 79/142) as many SOT recipients with R/R CMV infection at baseline treated with maribavir achieved confirmed CMV viremia clearance at Study Week 8 (end of treatment phase) compared to those treated with conventional antiviral therapies (26.1%, 18/69) (investigator assigned treatment; IAT consists of one or a combination of ganciclovir, valganciclovir, foscarnet or cidofovir) (adjusted difference [95% CI]: 30.5% [17.3, 43.6]). The results presented showed consistent efficacy in SOT recipients receiving maribavir in heart, lung and kidney transplants.

## **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 (e.g., narcolepsy, Amyotrophic Lateral Sclerosis, Huntington's disease and other ataxias), as well as making targeted investments to potentially address well-defined segments of neurodegenerative diseases (e.g., Parkinson's Disease).

### *Development code: TAK-994*

- In July 2021, Takeda announced that the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation (BTD) to TAK-994, its Phase 2 investigational oral orexin agonist, which is designed to selectively target orexin 2 receptors. TAK-994 is currently being studied in an ongoing Phase 2 (TAK-994-1501) study for the treatment of excessive daytime sleepiness (EDS) in patients with narcolepsy type 1 (NT1), a chronic neurological disorder that alters the sleep-wake cycle. The TAK-994 BTD was based, in part, on early phase and preliminary clinical data that indicates Takeda's investigational oral orexin agonist may demonstrate substantially improved objective and subjective measurements of daytime wakefulness in NT1 patients.

## **Gastroenterology (GI)**

In Gastroenterology, Takeda focuses on delivering innovative, life-changing therapeutics for patients with gastroenterology and liver diseases. Takeda is maximizing the potential of our inflammatory bowel disease (IBD) franchise around ENTYVIO and ALOFISEL, expanding our position in specialty GI with GATTEX / REVESTIVE and progressing a pipeline built through partnerships exploring opportunities in motility disorders, celiac disease, and select liver diseases.

### *GATTEX / REVESTIVE / Generic name: teduglutide*

- In June 2021, Takeda announced that it obtained approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) to manufacture and market REVESTIVE 3.8 mg for subcutaneous injection as a treatment for short bowel

## [Table of Contents](#)

syndrome. The approval is mainly based on the results of several trials conducted overseas, as well as Phase 3 clinical trials (SHP633-302, SHP633-305, SHP633-306, and SHP633-307) conducted in pediatric and adult patients in Japan.

### **Plasma-Derived Therapies (PDT)**

Takeda created a dedicated PDT business unit with a focus to manage the business end-to-end, from plasma collection to manufacturing and commercialization. In PDT, we maximize the therapeutic value of PDT for patients with rare and complex diseases through innovation across the product life cycle. The dedicated R&D organization in PDT is charged with identifying new targeted therapies and optimizing efficiencies of current product manufacturing. PDT focuses on developing products which are essential for effectively treating patients with a variety of rare, life-threatening, chronic and genetic diseases across the world.

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

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

### **Vaccines**

In Vaccines, Takeda is applying innovation to tackle some of the world’s most challenging infectious diseases such as dengue, COVID-19, zika, and norovirus. To support the expansion of our pipeline and the development of our programs, we have entered into partnerships with government organizations in Japan and the U.S., and leading global institutions. Such partnerships have been essential in building the critical capabilities that will be necessary to deliver on our programs and realize their full potential.

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

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

## Table of Contents

- In July 2021, Takeda announced an additional agreement with Moderna and the Government of Japan’s Ministry of Health, Labour and Welfare (MHLW) to import and distribute an additional 50 million doses of COVID-19 Vaccine Moderna Intramuscular Injection in Japan from as early as the beginning of 2022. This agreement includes the potential to secure and supply vaccines corresponding to COVID-19 variants or booster products, should they be successfully developed by Moderna and licensed by the MHLW. Takeda will import and distribute the totaling 100 million doses including the additional 50 million doses in 2022 and 50 million doses announced in October, 2020.
- In July 2021, Takeda announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) accepted the change in age indication in the package insert for COVID-19 Vaccine Moderna Intramuscular Injection to expand to 12 years of age and older. This change is based on the results of Moderna's Phase 2/3 study conducted in 3,732 subjects aged 12 to 17 years in the United States. The serum neutralizing antibody titer and neutralizing antibody titer response rate 28 days after the second vaccination of adolescents (12 to 17 years old), which are the primary endpoints, showed non-inferiority to young adults (18 to 25 years old) in the overseas phase 3 study (mRNA-1273-P301 study). Additionally, the results indicating a high preventive effect at the vaccine efficacy rate 2 weeks after the second vaccination, which was set as a secondary endpoint. No significant safety concerns were reported, as was the case with the results of clinical studies in patients aged 18 years or older.

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

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

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

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

- In July 2021, Takeda and PeptiDream Inc. announced an expansion of its research collaboration and exclusive license agreement, announced in December 2020, to create peptide-drug conjugates (PDCs) for several central nervous system (CNS) targets, which play important roles in chronic neurodegenerative diseases. This new collaboration expands the use of the TfR1 binding peptide ligands for CNS targets associated with neurodegeneration allowing Takeda to conjugate the peptides with therapeutic cargoes optimized to cross the blood-brain barrier (BBB). A significant challenge to the development of effective medicines for neurodegenerative diseases is the ability to deliver therapeutic molecules across the BBB into the brain. Peptide carriers that bind to TfR1 when conjugated to various therapeutic payloads facilitate the transport of the payload across the BBB into the brain, and thereby significantly improve functional benefit. This TfR1 BBB shuttle approach has the potential to accelerate the development of therapies for which BBB penetration remains challenging. This approach may also enable broad brain region biodistribution that is frequently needed to effectively treat many neurodegenerative diseases for which few, if any, effective drugs currently exist.
- In July 2021, Takeda and Frazier Healthcare Partners announced a collaboration to launch HilleVax, Inc. (HilleVax), a biopharmaceutical company to develop and commercialize Takeda’s norovirus vaccine candidate. Takeda has

## [Table of Contents](#)

granted a license to HilleVax for the exclusive development and commercialization rights to its norovirus vaccine candidate, HIL-214 (formerly TAK-214), worldwide outside of Japan, in exchange for upfront consideration, as well as future cash milestones and royalties on net sales. Takeda will retain commercialization rights in Japan and HilleVax will integrate certain Japan development activities into its global development. HIL-214, which is a virus-like particle (VLP) based vaccine candidate, completed a randomized, placebo-controlled Phase 2b field efficacy study in 4,712 adult subjects in which HIL-214 was well-tolerated and demonstrated clinical proof of concept in preventing moderate-to-severe cases of acute gastroenteritis from norovirus infection.<sup>1</sup> To date, the candidate has been studied in nine human clinical trials with safety data from over 4,500 subjects and immunogenicity data from over 2,000 subjects.

### **3. Material Contracts**

On June 11, 2021, Takeda prepaid 2.0 billion USD of the Japan Bank for International Cooperation loan amount of 3.7 billion USD (that was entered into on December 3, 2018) in advance of its original maturity date of December 11, 2025.

## [Table of Contents](#)

### III. Information on the Company

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

##### (1) Total number of shares and other related information

###### 1) Total number of shares

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

###### 2) Number of shares issued

Class	Number of shares outstanding (As of June 30, 2021)	Number of shares outstanding as of the filing date (August 6, 2021)	Stock exchange on which the Company is listed	Description
Common stock	1,578,378,220	1,582,252,525	Tokyo, Nagoya (both listed on the first section), Fukuoka, Sapporo, New York	The number of shares per one unit of shares is 100 shares.
Total	1,578,378,220	1,582,252,525	—	—

(Note1) The Company's American Depositary Shares (ADS) are listed on the New York Stock Exchange.

(Note2) Based on the resolution on July 8, 2021, new stocks were issued through third party allotment on July 26, 2021. Due to the issuance, the number of shares outstanding increased by 3,874,305 shares to 1,582,252,525 shares.

(Note3) The number of shares outstanding as of the filing date does not include newly issued shares exercised by stock acquisition rights from August 1, 2021 to the filing date of Quarterly Securities Report (August 6, 2021).

##### (2) Status of stock acquisition rights

###### 1) Contents of stock option plans

Not applicable.

###### 2) Status of other stock acquisition rights

Not applicable.

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

Not applicable.

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

Date	Change in the total number of issued shares (Thousand of shares)	Balance of the total number of issued shares (Thousand of shares)	Change in share capital JPY (millions)	Balance of share capital JPY (millions)	Change in capital reserve JPY (millions)	Balance of capital reserve JPY (millions)
From April 1, 2021 to June 30, 2021 (Note) 1, 2, and 3	1,990	1,578,378	980	1,669,125	6,899	1,661,137

(Note1) 10 thousand shares out of the increase in the total number of issued shares were due to exercise of stock acquisition rights.

(Note2) 1,462 thousand shares out of increase in the total number of issued shares were due the share exchange where Nihon Pharmaceutical Co., Ltd. would be Takeda's wholly-owned subsidiary effective April 1, 2021.

## Table of Contents

(Note3) 518 thousand shares out of the increase in the total number of issued shares were due to the issuance of new stocks through third party allotment.

Price of issuing stocks: 3,730 JPY Amount of capitalization per share: 1,865 JPY

Allottee: The Master Trust Bank of Japan, Ltd (trust account for Stock grant ESOP)

(Note4) Based on the resolution on July 8, 2021, new stocks were issued through third party allotment on July 26, 2021. Due to the issuance, the number of issued shares increased by 3,874 thousand shares and the amount of share capital and legal capital surplus increased by 7,138 million JPY, respectively.

(Note5) There was no increase in the total number of issued shares, share capital or capital reserve due to the exercise of stock acquisition rights from July 1, 2021 to July 31, 2021.

(5) Major shareholders

No information required in the 3rd quarter.

(6) Information on voting rights

1) Total number of shares

Classification	As of June 30, 2021			Description
	Number of shares (Shares)	Number of voting rights (Units)		
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)	173,500	—	—
	Common stock			
Shares with full voting rights (Others)	(Crossholding stock)	287,000	—	—
	Common stock			
Shares with full voting rights (Others)	Common stock	1,576,987,200	15,769,872	—
Shares less than one unit	Common stock	930,520	—	Shares less than one unit (100 shares)
Number of issued shares		1,578,378,220	—	—
Total number of voting rights		—	15,769,872	—

(Note1) "Shares with full voting rights (Others)" includes 7,143,700 (voting rights: 71,437) and 2,320,400 (voting rights: 23,204) of the shares held by the ESOP and BIP trust, respectively.

(Note2) "Shares less than one unit" includes 86 of the shares as the treasury stock, and 103 and 102 of the shares held by the ESOP and BIP trust, respectively.

## Table of Contents

### 2) Treasury stock and other

<b>As of June 30, 2021</b>					
<b>Name of shareholders</b>	<b>Address</b>	<b>Number of shares held under own name (Shares)</b>	<b>Number of shares held under the name of others (Shares)</b>	<b>Total shares held (Shares)</b>	<b>Percentage of total issued shares issued (%)</b>
<b>(Treasury stock)</b>					
Takeda Pharmaceutical Company Limited	1-1, Doshomachi 4-chome, Chuo-ku, Osaka	173,500	—	173,500	0.01
<b>(Crossholding stock)</b>					
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		<u>460,500</u>	<u>—</u>	<u>460,500</u>	<u>0.03</u>

(Note) In addition to the above treasury stock and shares less than one unit of 86 shares, 7,143,803 of the shares held by the ESOP trust and 2,320,502 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.



## [Table of Contents](#)

### **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).

[Table of Contents](#)

**1. Condensed Interim Consolidated Financial Statements**

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

	Note	JPY (millions, except per share data)	
		Three-month Period Ended June 30,	
		2020	2021
Revenue	4	801,850	949,603
Cost of sales		(238,078)	(241,264)
Selling, general and administrative expenses		(202,374)	(219,843)
Research and development expenses		(106,821)	(122,480)
Amortization and impairment losses on intangible assets associated with products		(104,250)	(102,824)
Other operating income	5	63,732	11,118
Other operating expenses	6	(46,774)	(25,758)
Operating profit		167,285	248,552
Finance income		19,611	45,851
Finance expenses		(46,846)	(71,068)
Share of loss of investments accounted for using the equity method	7	(9,759)	(357)
Profit before tax		130,291	222,978
Income tax expenses	13	(47,772)	(85,252)
Net profit for the period		82,519	137,726
Attributable to:			
Owners of the Company		82,511	137,684
Non-controlling interests		8	43
Net profit for the period		82,519	137,726
Earnings per share (JPY)			
Basic earnings per share	8	52.93	87.96
Diluted earnings per share	8	52.69	87.45

See accompanying notes to condensed interim consolidated financial statements.

[Table of Contents](#)

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

	<b>JPY (millions)</b>	
	<b>Three-month Period Ended June 30,</b>	
	<b>2020</b>	<b>2021</b>
Net profit for the period	82,519	137,726
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	25,518	15,877
Remeasurement of defined benefit pension plans	(2,286)	(57)
	23,232	15,819
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	1,997	28,280
Cash flow hedges	(5,126)	12,948
Hedging cost	(5,357)	2,230
Share of other comprehensive income (loss) of investments accounted for using the equity method	(7)	2
	(8,493)	43,460
Other comprehensive income for the period, net of tax	14,739	59,279
Total comprehensive income for the period	97,258	197,005
Attributable to:		
Owners of the Company	97,183	196,956
Non-controlling interests	75	49
Total comprehensive income for the period	97,258	197,005

See accompanying notes to condensed interim consolidated financial statements.

[Table of Contents](#)

(3) Condensed Interim Consolidated Statements of Financial Position

		<b>JPY (millions)</b>	
		<b>As of March 31, 2021</b>	<b>As of June 30, 2021</b>
	<b>Note</b>		
<b><u>ASSETS</u></b>			
Non-current assets:			
Property, plant and equipment		1,453,917	1,452,172
Goodwill		4,033,917	4,058,935
Intangible assets		3,909,106	3,856,432
Investments accounted for using the equity method		112,468	115,751
Other financial assets		235,882	258,908
Other non-current assets		100,341	95,022
Deferred tax assets		353,769	343,557
Total non-current assets		<u>10,199,400</u>	<u>10,180,777</u>
Current assets:			
Inventories		753,881	779,148
Trade and other receivables		783,091	827,253
Other financial assets		36,598	29,930
Income taxes receivable		29,623	31,704
Other current assets		122,789	133,307
Cash and cash equivalents		966,222	654,920
Assets held for sale	9	20,689	20,195
Total current assets		<u>2,712,893</u>	<u>2,476,458</u>
Total assets		<u><u>12,912,293</u></u>	<u><u>12,657,234</u></u>
<b><u>LIABILITIES AND EQUITY</u></b>			
<b><u>LIABILITIES</u></b>			
Non-current liabilities:			
Bonds and loans	10	4,613,218	4,381,589
Other financial liabilities		517,677	496,546
Net defined benefit liabilities		158,857	160,871
Income taxes payable		33,690	29,006
Provisions		38,748	35,970
Other non-current liabilities		56,898	58,768
Deferred tax liabilities		542,852	549,059
Total non-current liabilities		<u>5,961,940</u>	<u>5,711,809</u>
Current liabilities:			
Bonds and loans	10	22,153	24,272
Trade and other payables		343,838	320,645
Other financial liabilities		248,053	233,170
Income taxes payable	13	145,203	200,926
Provisions		471,278	410,300
Other current liabilities		542,651	517,468
Total current liabilities		<u>1,773,176</u>	<u>1,706,782</u>
Total liabilities		<u><u>7,735,116</u></u>	<u><u>7,418,591</u></u>

[Table of Contents](#)

JPY (millions)

	Note	As of March 31, 2021	As of June 30, 2021
<b><u>EQUITY</u></b>			
Share capital		1,668,145	1,669,125
Share premium		1,688,424	1,682,504
Treasury shares		(59,552)	(42,344)
Retained earnings		1,509,906	1,503,811
Other components of equity		366,114	425,163
Equity attributable to owners of the company		5,173,037	5,238,258
Non-controlling interests		4,140	385
Total equity		5,177,177	5,238,643
Total liabilities and equity		12,912,293	12,657,234

See accompanying notes to condensed interim consolidated financial statements.

[Table of Contents](#)

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

Three-month period ended June 30, 2020 (From April 1 to June 30, 2020)

JPY (millions)															
Equity attributable to owners of the Company															
	Note	Other components of equity										Total	Total	Non-controlling interests	Total equity
		Share capital	Share premium	Treasury shares	Retained earnings	Exchange differences on translation of foreign operations	Changes in fair value of financial assets measured at fair value through other comprehensive income	Cash flow hedges	Hedging cost	Remeasurements of defined benefit pension plans	Total				
As of April 1, 2020		1,668,123	1,680,287	(87,463)	1,369,972	91,848	22,891	(22,730)	555	—	92,564	4,723,483	4,003	4,727,486	
Net profit for the period					82,511						—	82,511	8	82,519	
Other comprehensive income (loss)						1,957	25,484	(5,126)	(5,357)	(2,286)	14,672	14,672	67	14,739	
Comprehensive income (loss) for the period		—	—	—	82,511	1,957	25,484	(5,126)	(5,357)	(2,286)	14,672	97,183	75	97,258	
Transaction with owners:															
Issuance of new shares		22	22								—	44		44	
Acquisition of treasury shares				(2,132)							—	(2,132)		(2,132)	
Disposal of treasury shares			(0)	0							—	0		0	
Dividends	11				(141,858)						—	(141,858)	(77)	(141,935)	
Transfers from other components of equity					19,429		(21,715)			2,286	(19,429)	—		—	
Share-based compensation			10,043								—	10,043		10,043	
Exercise of share-based awards			(28,878)	28,878							—	(0)		(0)	
Total transactions with owners		22	(18,813)	26,746	(122,429)	—	(21,715)	—	—	2,286	(19,429)	(133,903)	(77)	(133,980)	
As of June 30, 2020		1,668,145	1,661,474	(60,717)	1,330,054	93,805	26,660	(27,856)	(4,802)	—	87,807	4,686,763	4,001	4,690,764	

See accompanying notes to condensed interim consolidated financial statements.

## Table of Contents

Three-month period ended June 30, 2021 (From April 1 to June 30, 2021)

JPY (millions)														
Equity attributable to owners of the Company					Other components of equity									
	Note	Share capital	Share premium	Treasury shares	Retained earnings	Exchange differences on translation of foreign operations	Changes in fair value of financial assets measured at fair value through other comprehensive income	Cash flow hedges	Hedging cost	Remeasurements of defined benefit pension plans	Total	Total	Non-controlling interests	Total equity
As of April 1, 2021		1,668,145	1,688,424	(59,552)	1,509,906	400,798	41,983	(68,075)	(8,592)	—	366,114	5,173,037	4,140	5,177,177
Net profit for the period					137,684						—	137,684	43	137,726
Other comprehensive income (loss)						28,208	15,944	12,948	2,230	(57)	59,272	59,272	7	59,279
Comprehensive income (loss) for the period		—	—	—	137,684	28,208	15,944	12,948	2,230	(57)	59,272	196,956	49	197,005
Transaction with owners:														
Issuance of new shares		980	6,898								—	7,878		7,878
Acquisition of treasury shares				(4,464)							—	(4,464)		(4,464)
Disposal of treasury shares			(0)	0							—	0		0
Dividends	11				(141,859)						—	(141,859)		(141,859)
Changes in ownership					(2,143)						—	(2,143)	(3,804)	(5,948)
Transfers from other components of equity					224		(281)			57	(224)	—		—
Share-based compensation			8,547								—	8,547		8,547
Exercise of share-based awards			(21,365)	21,671							—	307		307
Total transactions with owners		980	(5,919)	17,208	(143,779)	—	(281)	—	—	57	(224)	(131,734)	(3,804)	(135,539)
As of June 30, 2021		1,669,125	1,682,504	(42,344)	1,503,811	429,006	57,646	(55,126)	(6,362)	—	425,163	5,238,258	385	5,238,643

See accompanying notes to condensed interim consolidated financial statements.

[Table of Contents](#)

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

	Notes	JPY (millions)	
		Three-month Period Ended June 30,	
		2020	2021
<b>Cash flows from operating activities:</b>			
Net profit for the period		82,519	137,726
Depreciation and amortization		141,587	142,948
Impairment losses		7,458	53
Equity-settled share-based compensation		10,043	8,547
Change in estimate of liabilities related to SHP647	5	(60,179)	—
Loss on sales and disposal of property, plant and equipment		300	94
Gain on divestment of business and subsidiaries		(365)	(365)
Change in fair value of financial assets and liabilities associated with contingent consideration arrangements, net	6	19,297	(934)
Finance (income) and expenses, net		27,235	25,216
Share of loss of investments accounted for using the equity method		9,759	357
Income tax expenses		47,772	85,252
<b>Changes in assets and liabilities:</b>			
Increase in trade and other receivables		(25,845)	(41,835)
Increase in inventories		(4,367)	(21,009)
Decrease in trade and other payables		(23,153)	(24,854)
Increase (decrease) in provisions		2,177	(65,217)
Increase (decrease) in other financial liabilities		685	(7,985)
Other, net		(37,579)	(35,236)
Cash generated from operations		197,344	202,760
Income taxes paid		(51,483)	(35,902)
Net cash from operating activities		145,861	166,858
<b>Cash flows from investing activities:</b>			
Interest received		308	349
Dividends received		177	139
Acquisition of property, plant and equipment		(23,135)	(29,838)
Proceeds from sales of property, plant and equipment		26	79
Acquisition of intangible assets		(17,342)	(12,454)
Acquisition of investments		(3,517)	(3,251)
Proceeds from sales and redemption of investments		44,437	483
Acquisition of businesses, net of cash and cash equivalents acquired		—	(27,549)
Proceeds from sales of business, net of cash and cash equivalents divested		—	2,138
Other, net		(292)	(543)
Net cash from (used in) investing activities		662	(70,445)



## [Table of Contents](#)

	Notes	JPY (millions)	
		Three-month Period Ended June 30,	
		2020	2021
Cash flows from financing activities:			
Net increase (decrease) in short-term loans and commercial papers		(10,000)	1
Repayments of bonds and long-term loans		(9,979)	(242,919)
Acquisition of treasury shares		(2,132)	(2,542)
Interest paid		(30,207)	(23,218)
Dividends paid		(133,115)	(132,032)
Repayments of lease liabilities		(7,213)	(10,328)
Other, net		(119)	—
Net cash used in financing activities		<u>(192,765)</u>	<u>(411,038)</u>
Net decrease in cash and cash equivalents		(46,242)	(314,625)
Cash and cash equivalents at the beginning of the year (Consolidated statements of financial position)		637,614	966,222
Effects of exchange rate changes on cash and cash equivalents		(1,585)	3,324
Cash and cash equivalents at the end of the period (Consolidated statements of financial position)		<u>589,787</u>	<u>654,920</u>

See accompanying notes to condensed interim consolidated financial statements.

## Notes to Condensed Interim Consolidated Financial Statements

### 1. Reporting Entity

Takeda Pharmaceutical Company Limited (the “Company”) is a public company incorporated in Japan. The Company and its subsidiaries (collectively, “Takeda”) is a global, values-based, R&D-driven biopharmaceutical company with an innovative portfolio, engaged primarily in the research, development, production and global commercialization of pharmaceutical products. Our intent is to translate science into highly innovative life transforming medicines. Takeda has grown both organically and through acquisitions, completing a series of major transactions that have resulted in growth in our areas of therapeutic, geographic and pipeline focus. Takeda’s principal pharmaceutical products include medicines in the following key business areas: gastroenterology (“GI”), rare diseases, Plasma-Derived Therapies (“PDT”), oncology, and neuroscience.

### 2. Basis of Preparation

#### (1) Compliance

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

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

#### (2) Approval of Financial Statements

Takeda’s condensed interim consolidated financial statements as of and for the period ended June 30, 2021 were approved on August 6, 2021 by Representative Director, President & Chief Executive Officer (“CEO”) Christophe Weber and Director & Chief Financial Officer Costa Saroukos.

#### (3) Functional Currency and Presentation Currency

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

#### (4) Use of Judgments, Estimates and Assumptions

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

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

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

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

### 3. Significant Accounting Policies

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

Takeda calculated income tax expenses for the three-month period ended June 30, 2021, based on the estimated average annual effective tax rate.

## [Table of Contents](#)

### 4. Operating Segment and Revenue Information

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

#### (1) Disaggregation of Revenue Information

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

##### *Revenue by Type of Good or Service*

	JPY (millions)	
	Three-month Period Ended June 30,	
	2020	2021
Sales of pharmaceutical products	783,791	791,911
Out-licensing and service income	18,059	157,692
<b>Total</b>	<b>801,850</b>	<b>949,603</b>

##### *Revenue by Therapeutic Area and Product*

	JPY (millions)	
	Three-month Period Ended June 30,	
	2020	2021
<b>Gastroenterology:</b>		
ENTYVIO	101,224	125,370
TAKECAB-F <sup>(1)</sup>	20,214	24,268
GATTEX/REVESTIVE	17,474	18,123
DEXILANT	13,609	10,788
PANTOLOC/CONTROLOC <sup>(2)</sup>	9,177	10,446
ALOFISEL	11	388
Others	25,219	21,123
<b>Total Gastroenterology</b>	<b>186,928</b>	<b>210,505</b>
<b>Rare Diseases:</b>		
<b>Rare Metabolic:</b>		
ELAPRASE	17,637	18,599
REPLAGAL	12,193	14,050
VPRIV	9,343	10,452
NATPARA/NATPAR	734	1,150
<b>Total Rare Metabolic</b>	<b>39,907</b>	<b>44,251</b>
<b>Rare Hematology:</b>		
ADVATE	33,652	30,663
ADYNOVATE/ADYNOVI	15,280	15,373
FEIBA	12,859	11,402
RECOMBINATE	3,721	3,688
Others	11,243	11,073
<b>Total Rare Hematology</b>	<b>76,755</b>	<b>72,199</b>
<b>Hereditary Angioedema:</b>		
TAKHZYRO	23,245	25,469
FIRAZYR	8,095	6,873
Other	6,981	6,675
<b>Total Hereditary Angioedema</b>	<b>38,321</b>	<b>39,017</b>

## Table of Contents

	JPY (millions)	
	Three-month Period Ended June 30,	
	2020	2021
Total Rare Diseases	154,983	155,467
PDT Immunology:		
Immunoglobulin	85,106	81,608
Albumin	12,979	17,759
Others	7,179	7,831
Total PDT Immunology	105,264	107,197
Oncology:		
VELCADE	24,181	30,129
LEUPLIN/ENANTONE	27,400	26,213
NINLARO	22,931	24,370
ADCETRIS	15,090	17,228
ICLUSIG	9,233	10,369
ALUNBRIG	2,017	3,113
Others	7,121	9,961
Total Oncology	107,973	121,382
Neuroscience:		
VYVANSE/ELVANSE	66,009	79,212
TRINTELLIX	16,880	17,868
Others	23,968	16,332
Total Neuroscience	106,857	113,411
Other:		
AZILVA-F <sup>(1)</sup>	20,855	22,646
LOTRIGA	8,065	7,826
Others <sup>(3)</sup>	110,925	211,169
Total Other	139,845	241,641
Total	801,850	949,603

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

<sup>(2)</sup> Generic name: pantoprazole

<sup>(3)</sup> The figure for the three-month period ended June 30, 2020 includes the revenue of Takeda Consumer Healthcare Company Limited, which was divested on March 31, 2021.

The figure for the three-month period ended June 30, 2021 includes the 133,043 million JPY selling price on sales of four diabetes products (NESINA, LIOVEL, INISYNC and ZAFATEK) in Japan to Teijin Pharma Limited recorded as revenue. As Takeda transferred only the assets, marketing rights and, eventually, marketing authorization associated with the pharmaceutical products which do not entail transfer of employees or associated contracts, Takeda applied IFRS 15 to the transaction and recorded the selling price in revenue.

## [Table of Contents](#)

### (2) Geographic Information

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

	JPY (millions)	
	Three-month Period Ended June 30,	
	2020	2021
Japan	144,045	258,963
U.S.	402,606	412,220
Europe and Canada	157,559	178,742
Asia (excluding Japan)	36,879	40,292
Latin America	30,774	30,059
Russia/CIS	13,044	12,336
Other	16,943	16,991
Total	801,850	949,603

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

### 5. Other Operating Income

Other Operating Income for the three-month period ended June 30, 2020 was 63,732 million JPY, including 60,179 million JPY revaluation gain triggered by an update to previously recognized liabilities for pipeline compound SHP647 and certain associated rights ("SHP647") to reflect a change in expected future costs, such as program termination costs, to reflect management's decision to terminate the clinical trial program following the European Commission's decision in May 2020 to release Takeda's obligation to divest SHP647.

Other Operating Income for the three-month period ended June 30, 2021 was 11,118 million JPY, including a compensation for damages from a litigation.

### 6. Other Operating Expenses

Other operating expenses was 46,774 million JPY and 25,758 million JPY for the three-month period ended June 30, 2020 and 2021, respectively.

Restructuring expenses such as reductions in the workforce and consolidation of sites included in other operating expenses were 23,902 million JPY and 15,827 million JPY for the three-month period ended June 30, 2020 and 2021, respectively. Restructuring expenses for the three-month period ended June 30, 2020 and three-month period ended June 30, 2021 included Shire integration costs related to the acquisition of Shire plc.

Other operating expenses also included 924 million JPY of the reversal of pre-launch inventory write-offs and 3,582 million JPY of pre-launch inventory write-offs for the three-month period ended June 30, 2020 and 2021, respectively.

In addition, for the three-month period ended June 30, 2020, Takeda recorded 18,562 million JPY loss from changes in the fair value of financial assets associated with contingent consideration arrangements driven by the impact of Novartis' withdrawal of the Marketing Authorisation Application in Europe for Xiidra (dry eye medication), which Takeda sold to Novartis in July 2019 (Note 12).

## [Table of Contents](#)

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

Share of loss of investments accounted for using the equity method for the three-month period ended June 30, 2020 included a loss of 10,124 million JPY related to Takeda's shareholding ratio of the impairment loss recognized by Teva Takeda Pharma Ltd., a business venture of Takeda and Teva Pharmaceutical Industries Ltd., which operates the long listed products business and the generics business.

The impairment loss was recorded resulting from the reassessment of the recoverable amount of relevant assets triggered by the decision to divest a part of its generics business and a manufacturing plant.

### 8. Earnings Per Share

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

	Three-month Period Ended June 30,	
	2020	2021
Net profit for the period attributable to owners of the Company		
Net profit for the period attributable to owners of the Company (million JPY)	82,511	137,684
Net profit used for calculation of earnings per share (million JPY)	82,511	137,684
Weighted average number of ordinary shares outstanding during the period (thousands of shares) [basic]	1,558,969	1,565,249
Dilutive effect (thousands of shares)	7,151	9,177
Weighted average number of ordinary shares outstanding during the period (thousands of shares) [diluted]	1,566,120	1,574,426
Earnings per share		
Basic earnings per share (JPY)	52.93	87.96
Diluted earnings per share (JPY)	52.69	87.45

### 9. Disposal Groups Held for Sale

The disposal groups held for sale as of March 31, 2021 and June 30, 2021 consisted mainly of a group of assets and liabilities such as related to a portfolio of non-core prescription pharmaceutical assets sold in China. As of June 30, 2021, the corresponding assets such as goodwill and intangible assets were 20,195 million JPY.

## [Table of Contents](#)

### 10. Bonds and Loans

#### (1) Bonds

During the three-month period ended June 30, 2021, Takeda redeemed the following bonds in advance of the original maturity dates.

<b>Instrument</b>	<b>Issuance</b>	<b>Redemption date</b>	<b>Principal Amount in contractual currency</b>
USD Unsecured Senior Notes	July 2017	May 17, 2021	200 million USD

#### (2) Loans

During the three-month period ended June 30, 2021, Takeda prepaid the following borrowings in advance of the original maturity dates.

<b>Instrument</b>	<b>Issuance</b>	<b>Repayment date</b>	<b>Principal Amount in contractual currency</b>
USD Japan Bank for International Cooperation 2019	January 2019	June 11, 2021	2,000 million USD

### 11. Equity and Other Equity Items

#### Dividends

	<b>Total dividends declared and paid JPY (millions)</b>	<b>Dividends per share (JPY)</b>	<b>Basis date</b>	<b>Effective date</b>
Three-month period ended June 30, 2020 (April 1, 2020 to June 30, 2020)	141,858	90.00	March 31, 2020	June 25, 2020
Three-month period ended June 30, 2021 (April 1, 2021 to June 30, 2021)	141,859	90.00	March 31, 2021	June 30, 2021

## [Table of Contents](#)

### 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. 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.

As of June 30, 2021	JPY (millions)			
	Level 1	Level 2	Level 3	Total
Assets:				
Financial assets measured at fair value through profit or loss				
Derivatives	—	53,118	—	53,118
Investments in convertible notes	—	—	10,358	10,358
Investments in debt instruments	—	—	1,052	1,052
Financial assets associated with contingent consideration arrangements	—	—	26,572	26,572
Derivatives for which hedge accounting is applied	—	1,547	—	1,547
Financial assets measured at fair value through OCI				
Equity instruments	114,303	—	56,979	171,282
<b>Total</b>	<b>114,303</b>	<b>54,665</b>	<b>94,961</b>	<b>263,929</b>
Liabilities:				
Financial liabilities measured at fair value through profit or loss				
Derivatives	—	17,495	—	17,495
Financial liabilities associated with contingent consideration arrangements	—	—	30,633	30,633
Other	—	—	2,704	2,704
Derivatives for which hedge accounting is applied	—	54,378	—	54,378
<b>Total</b>	<b>—</b>	<b>71,873</b>	<b>33,337</b>	<b>105,210</b>

#### (2) Valuation Techniques

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

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

Equity instruments and investments in debt instruments are not held for trading. If equity instruments or investments in debt instruments are quoted in an active market, the fair value is based on price quotations at the period-end-date. If equity instruments or investments in debt instruments are not quoted in an active market, the fair value is calculated utilizing an adjusted net assets book value method or multiples of EBITDA approach based on available information as of each period-end-date and company comparable. The principal input that is not observable and utilized for the calculation of the fair value of equity instruments and investments in debt instruments classified as Level 3 is the EBITDA rate used for the EBITDA multiples approach, which ranges from 7.7 times to 9.7 times.

Financial assets and liabilities associated with contingent consideration arrangements are valued at fair value at the time of the divestiture or the acquisition date of business combination. When the contingent consideration arrangement meets the definition of a financial asset or liability, it is subsequently re-measured to fair value at each closing date. The determination of the fair value is based on models such as scenario-based methods and discounted cash flows. The key



## Table of Contents

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.

The joint venture net written option, included in other Level 3 liabilities above is valued at fair value, and subsequently re-measured to fair value at each closing date. The determination of the fair value is based on the Monte Carlo Simulation model. The key assumptions include probability weighting, estimated earnings and assumed market participant discount rates that are taken into account for the fair value.

### (3) Transfers between levels

Takeda recognizes transfers between levels of the fair value hierarchy, at the end of the reporting period during which the change has occurred. There were transfers from Level 3 to Level 1 recorded in the three-month period ended June 30, 2021. These transfers resulted from the investments in the companies whose shares were previously not listed on an equity or stock exchange and had no recent observable active trades in the shares. During the three-month period ended June 30, 2021, the companies listed their equity shares on an exchange and are currently actively traded in the market. As the equity shares have a published price quotation in an active market, the fair value measurement was transferred from Level 3 to Level 1 on the fair value hierarchy during the three-month period ended June 30, 2021. There were no other transfers between levels of the fair value hierarchy during the three-month period ended June 30, 2021.

### (4) Level 3 fair values

Takeda invests in equity instruments mainly for research collaboration. The following table shows a reconciliation from the opening balances to the closing balances for Level 3 financial asset fair values for the period ended June 30, 2021. The disclosure related to the Level 3 financial liabilities which are financial liabilities associated with contingent consideration arrangements are included in (5) Financial liabilities associated with contingent consideration arrangements. There are no significant changes in fair value during the changes in certain assumptions which influence the fair value measurement for level 3 financial assets.

	JPY (millions)	
	Three-month Period Ended June 30, 2021	
	Financial assets associated with contingent consideration arrangements	Equity instruments
As of the beginning of the period	25,446	52,468
Changes recognized as finance income	219	—
Changes in fair value of financial assets associated with contingent consideration due to other elements than time value	877	—
Changes in fair value of financial assets measured at fair value through OCI and exchange differences on translation of foreign operations	29	18,499
Purchases	—	3,466
Transfers to Level 1	—	(16,164)
Transfers to investments accounted for using the equity method	—	(1,290)
As of the end of the period	26,572	56,979

## Table of Contents

### (5) Financial liabilities associated with contingent consideration arrangements

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

As of June 30, 2021, the balance primarily relates to pre-existing contingent consideration arrangements from Shire's historical acquisition.

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

The fair value of financial liabilities associated with contingent consideration arrangements are classified as Level 3 in the fair value hierarchy.

#### 1) Changes in the Fair Value of financial liabilities associated with contingent consideration arrangements

	<b>JPY (millions)</b>
	<b>Three-month Period Ended</b>
	<b>June 30, 2021</b>
As of the beginning of the period	27,770
Additions arising from business combinations	3,017
Changes in the fair value during the period	106
Settled during the period	(220)
Foreign currency translation differences	(40)
As of the end of the period	<u>30,633</u>

#### 2) Sensitivity analysis

The following sensitivity analysis represents effect on the fair value of financial liabilities associated with contingent consideration arrangements from changes in major assumptions:

	<b>JPY (millions)</b>	
	<b>Change in assumption</b>	<b>Impact</b>
Probability of technical milestones being achieved	Increase by 5%	3,959
	Decrease by 5%	(3,954)
Discount rate	Increase by 0.5%	(1,161)
	Decrease by 0.5%	1,178

## Table of Contents

### (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:

	<b>JPY (millions)</b>	
	<b>As of June 30, 2021</b>	
	<b>Carrying amount</b>	<b>Fair value</b>
Bonds	3,524,000	3,800,933
Long-term loans	881,791	878,958

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. Commitments and Contingent Liabilities**

#### *Irish Revenue Commissioners assessment*

Shire received a tax assessment from the Irish Revenue Commissioners on November 28, 2018 for 398 million EUR. This assessment relates to the tax treatment of a 1,635 million USD break fee Shire received from AbbVie, Inc. (“AbbVie”) in connection with the terminated offer to acquire Shire made by AbbVie in 2014. Takeda appealed the assessment to the Tax Appeals Commission (“TAC”) and the appeal was heard by the TAC in late 2020. On July 30, 2021 (IST), Takeda received a ruling on the matter from the TAC, with the TAC ruling in favor of Irish Revenue Commissioners. While Takeda intends to appeal the TAC ruling and continues to assert that the AbbVie break fee is not subject to Irish tax, Takeda has recorded a tax provision for 472 million EUR in current liabilities as income taxes payable, representing the 398 million EUR tax liability asserted by Irish Revenue Commissioners plus accrued interest for the three-month period ended June 30, 2021.

#### *Litigation*

Takeda is involved in various legal and administrative proceedings. There were no significant updates during the three-month period ended June 30, 2021 except for the matters below.

#### *Intellectual property*

##### **ADYNOVATE**

On December 5, 2016, Bayer Healthcare LLC (“Bayer”) filed a lawsuit in the U.S. District Court for the District of Delaware against Baxalta Incorporated and Baxalta US Inc. (collectively “Baxalta”), which are now subsidiaries of Takeda, and Nektar Therapeutics (“Nektar”) filed alleging infringement of U.S. Patent No. 9,364,520 in connection with the sales of ADYNOVATE [antihemophilic factor (recombinant), PEGylated]. The case was tried before a jury beginning on January 28, 2019. The jury found in favor of Bayer determining that the patent is infringed. The jury further awarded damages in the amount of 155.2 million USD. Takeda has filed an appeal with the Court of Appeals of the Federal Circuit (CAFC) in September 2019. The CAFC upheld the District Court’s decision on March 1, 2021. The Appeal Mandate was issued on April 7, 2021. On May 14, 2021, Takeda settled this litigation and related pending litigations. The settlement allows both Baxalta and Bayer to continue selling their respective products. Takeda also made a payment in settlement of these cases but the settlement had no material impact on Takeda’s condensed interim consolidated statements of profit or loss as Takeda had established a provision against this case as of March 31, 2021.

##### **NINLARO**

Takeda received a paragraph IV notice letter from Sun Pharmaceutical Industries Limited (“Sun”) on January 17, 2020. Sun alleged that U.S. Patent numbers 7,442,830, 8,859,504, and 9,175,017 are invalid, unenforceable, and/or will not be infringed. Takeda filed a complaint against Sun in the U.S. District Court for the District of Delaware on February 27, 2020. On June 18, 2021, Takeda entered into a settlement agreement with Sun. The impact of the settlement was not material to Takeda’s condensed interim consolidated statements of profit or loss.

## [Table of Contents](#)

### **14. Subsequent Events**

On July 9, 2021, Takeda provided a notice of redemption to the holders of 1,500 million EUR in unsecured senior notes issued in November 2018 in advance of their original maturity date of November 21, 2022. The redemption date of the unsecured senior notes will be August 10, 2021.

The impact from the accelerated debt prepayment on the consolidated statements of profit or loss is not expected to be material.

## Table of Contents

### **2. Others**

Not applicable.

[Table of Contents](#)

**B. Information on Guarantors of the Company**

Not applicable.