

A solid red vertical bar on the left side of the page.

Takeda Quarterly Financial Report

For the Quarter Ended June 30, 2022

Table of Contents

Financial Highlights	3
<u>Selected Financial Results</u>	3
<u>Revenue by Region</u>	4
Recent Developments	5
<u>Pipeline and R&D Activities</u>	5
Analysis of results of operations, financial position, and cash flow	9
<u>Results of Operations (Reported)</u>	9
<u>Results of Operations (Core Results)</u>	13
<u>Consolidated Financial Position</u>	14
<u>Consolidated Cash Flow</u>	15
<u>Outlook for the Fiscal Year Ending March 31, 2023</u>	16
<u>Other</u>	18
Condensed Interim Consolidated Financial Statements	19
(1) <u>Condensed Interim Consolidated Statements of Profit or Loss</u>	19
(2) <u>Condensed Interim Consolidated Statements of Comprehensive Income</u>	20
(3) <u>Condensed Interim Consolidated Statements of Financial Position</u>	21
(4) <u>Condensed Interim Consolidated Statements of Changes in Equity</u>	23
(5) <u>Condensed Interim Consolidated Statements of Cash Flows</u>	25
(6) <u>Other Information</u>	26
Supplementary Information	27
1. <u>Pipeline</u>	28
• <u>I. Clinical Development Activities</u>	28
• <u>II. Recent Progress in stage</u>	35
• <u>III. Discontinued projects</u>	35
• <u>IV. Main Research & Development collaborations</u>	36
2. <u>Supplementary Revenue Information</u>	42
• <u>Revenue by region</u>	42
◦ <u>Year to date</u>	42
◦ <u>Quarterly</u>	43
• <u>Product Sales Analysis</u>	44
◦ <u>Year to date</u>	44
• <u>Product Sales Analysis (Reported & Core CER Change)</u>	46
• <u>Product Forecast</u>	48
Financial Appendix	

Financial Highlights

Selected Financial Results

Takeda uses certain non-IFRS measures to supplement the analysis of results of operations under International Financial Reporting Standards ("IFRS"). Refer to "[Financial Appendix](#)" for the definition and reconciliations of non-IFRS Measures.

Results of Operation

(JPY millions)	Three-month period Ended June 30,		Change versus the same period of the previous fiscal year		
	2021	2022	JPY	Actual % Change	CER % Change
Revenue	949,603	972,465	22,861	2.4 %	(6.8)%
Operating profit	248,552	150,515	(98,037)	(39.4)%	(42.2)%
Profit before tax	222,978	155,473	(67,505)	(30.3)%	(33.7)%
Net profit for the period	137,726	105,021	(32,705)	(23.7)%	(28.7)%
Basic earnings per share (yen)	87.96	67.94	(20.02)	(22.8)%	(27.8)%

Core Results

Results of Core Operations

(JPY billions)	Three-month period Ended June 30,		Change versus the same period of the previous fiscal year		
	2021	2022		Actual % change	CER % change
Core Revenue	816.6	972.5	155.9	19.1 %	8.3 %
Core Operating Profit	248.9	319.1	70.1	28.2 %	17.0 %
Core EPS (yen)	113	145	32	28.5 %	15.8 %

Leverage

(JPY billions)	As of	
	March 31, 2022	June 30, 2022
	Net debt	(3,233.8)
Adjusted EBITDA	1,168.0	1,244.3
Net debt/Adjusted EBITDA ratio	2.8 x	2.8 x

Consolidated Cash Flows

(JPY millions)	Three-month period Ended June 30,		Change versus the same period of the previous fiscal year	
	2021	2022	JPY	%
Cash flows from (used in) operating activities	166,858	84,241	(82,617)	(49.5) %
Cash flows from (used in) investing activities	(70,445)	(94,714)	(24,268)	34.4
Cash flows from (used in) financing activities	(411,038)	(215,717)	195,321	(47.5) %

Free Cash Flow

(JPY billions)	Three-month period Ended June 30,		Change versus the same period of the previous fiscal year	
	2021	2022	JPY	%
Free Cash Flow	129.9	42.6	(87.3)	(67.2) %

Consolidated Financial Position

(JPY millions)	As of		Change versus the previous fiscal year-end	
	March 31, 2022	June 30, 2022	JPY	%
Non-current Assets	10,584,376	11,515,911	931,535	8.8 %
Current Assets	2,593,642	2,549,515	(44,128)	(1.7) %
Total Assets	13,178,018	14,065,426	887,408	6.7 %
Non-current Liabilities	5,348,764	5,581,101	232,336	4.3 %
Current Liabilities	2,145,730	2,166,942	21,212	1.0 %
Total Liabilities	7,494,495	7,748,043	253,548	3.4 %
Equity	5,683,523	6,317,383	633,859	11.2 %
Total liabilities and equity	13,178,018	14,065,426	887,408	6.7 %

Forecast and Management Guidance

*Forecast**

(JPY billions)	FY2021 (Actual)	FY2022 (Forecast)	Change over the previous year	
Reported:				
Revenue	3,569.0	3,690.0	121.0	3.4 %
Operating profit	460.8	520.0	59.2	12.8 %
Profit before tax	302.6	411.0	108.4	35.8 %
Net profit for the year (attributable to owners of the Company)	230.1	292.0	61.9	26.9 %
EPS (JPY)	147.14	188.13	40.99	27.9 %
Non-IFRS Measures				
Core Operating Profit	955.2	1,100.0	144.8	15.2 %
Core EPS (JPY)	425	484	—	14.0 %
Free cash flow (including announced divestitures)	943.7	600.0 - 700.0		
Dividends per share (Yen)	180	180	—	—

*Refer to *Analysis of Results of Operations, Financial Position, and Cash Flow "Outlook for the Fiscal Year Ending March 31, 2023"* for details.

Management Guidance

	FY2022 Management Guidance Core Growth at CER*
Core Revenue Growth	Low-single-digit growth
Core Operating Profit Growth	High-single-digit growth
Core EPS Growth	High-single-digit growth

*Refer to "[Financial Appendix](#)" for the definition and reconciliations of core financial measures and CER (Constant Exchange Rate).

Revenue by Region

		JPY (millions)						
		Period Ended June 30, 2022						
	Japan	United States	Europe and Canada	Asia (excluding Japan)	Latin America	Russia/CIS	Other	Total
2021	258,963	412,220	178,742	40,292	30,059	12,336	16,991	949,603
2022	140,534	501,058	205,573	46,096	40,285	17,366	21,552	972,465
Change versus the previous year	JPY (118,428)	88,838	26,831	5,804	10,226	5,030	4,561	22,861
	% (45.7)%	21.6 %	15.0 %	14.4 %	34.0 %	40.8 %	26.8 %	2.4 %

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

Recent Developments

Pipeline and R&D Activities

Research and development expenses for the three-month period ended June 30, 2022 were 143.6 billion JPY.

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

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

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

R&D pipeline

Oncology

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

ADCETRIS / Generic name: brentuximab vedotin

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

VECTIBIX / Generic name: panitumumab

- In June 2022, Takeda announced the data from the PARADIGM, a Phase 3 clinical trial of VECTIBIX in chemotherapy-naïve Japanese patients with unresectable advanced recurrent colorectal cancer with wild-type *RAS* gene, was presented at the Plenary Session of the American Society of Clinical Oncology (ASCO) Annual Meeting. PARADIGM is the first prospective trial to evaluate appropriate treatment options for metastatic colorectal cancer patients with wild-type *RAS* gene and left-side primary tumor (descending colon, sigmoid colon, and rectum). The results of the trial showed that the mFOLFOX6 + VECTIBIX combination provides a statistically significant

improvement in overall survival (OS) over the mFOLFOX6 + bevacizumab combination in patients with a left-sided primary tumor or regardless of tumor locations (median OS for left-sided tumors: 37.9 vs. 34.3, HR=0.82 [95.798% CI: 0.68-0.99], p=0.031, overall median OS: 36.2 vs. 31.3, HR=0.84 [95% CI: 0.72-0.98], p=0.030). The safety profile of VECTIBIX administration in this study was similar to clinical study results previously published.

Rare Genetics & Hematology

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

Rare Genetics & Hematology

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

Neuroscience

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

Development code: TAK-994

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

Gastroenterology (GI)

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

Development code: TAK-999 / Generic name: fazirsiran

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

Plasma-Derived Therapies (PDT)

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

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

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

Vaccines

In Vaccines, Takeda is applying innovation to tackle some of the world's most challenging infectious diseases such as dengue (TAK-003), COVID-19 (NUVAXOVID), and zika (TAK-426). To support the expansion of our pipeline and the development of our programs, we have entered into partnerships with government organizations in Japan and the U.S., and leading global institutions. Such partnerships have been essential in building the critical capabilities that will be necessary to deliver on our programs and realize their full potential.

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

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

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

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

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

- In June 2022, Takeda announced that TAK-003 demonstrated continued protection against dengue fever through four and a half years (54 months), with no important safety risks identified, in the pivotal Phase 3 Tetravalent Immunization against Dengue Efficacy Study (TIDES) trial, which was presented at the 8th Northern European Conference on Travel Medicine (NECTM8). Through four and a half years, TAK-003 demonstrated 84.1% vaccine efficacy (VE) (95% CI: 77.8, 88.6) against hospitalized dengue, with 85.9% VE (78.7, 90.7) in seropositive individuals and 79.3% VE (63.5, 88.2) in seronegative individuals. TAK-003 also demonstrated overall VE of 61.2% (95% CI: 56.0, 65.8) against virologically-confirmed dengue, with 64.2% VE (58.4, 69.2) in seropositive individuals and 53.5% VE (41.6, 62.9) in seronegative individuals. Observations of VE varied by serotype and remained consistent with previously reported results. TAK-003 was generally well tolerated, and there were no important safety risks identified. No evidence of disease enhancement was observed over the 54-month follow-up exploratory analysis.

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.

Analysis of Results of Operations, Financial Position, and Cash Flow

Results of Operations (Reported)

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

	Billion JPY or percentage				
	FY2021 Q1	FY2022 Q1	Change versus the same period of the previous fiscal year		
				Actual % Change	CER % Change ^{*1}
Revenue	949.6	972.5	22.9	2.4 %	(6.8)%
Cost of sales	(241.3)	(292.9)	(51.6)	21.4 %	11.3 %
Selling, general and administrative expenses	(219.8)	(231.5)	(11.6)	5.3 %	(4.4)%
Research and development expenses	(122.5)	(143.6)	(21.1)	17.2 %	4.4 %
Amortization and impairment losses on intangible assets associated with products	(102.8)	(131.3)	(28.5)	27.7 %	12.5 %
Other operating income	11.1	5.5	(5.6)	(50.7)%	(52.5)%
Other operating expenses	(25.8)	(28.2)	(2.4)	9.4 %	(6.2)%
Operating profit	248.6	150.5	(98.0)	(39.4)%	(42.2)%
Finance income and (expenses), net	(25.2)	5.5	30.7	—	—
Share of loss of investments accounted for using the equity method	(0.4)	(0.5)	(0.1)	39.3 %	(2.0)%
Profit before tax	223.0	155.5	(67.5)	(30.3)%	(33.7)%
Income tax expenses	(85.3)	(50.5)	34.8	(40.8)%	(41.7)%
Net profit for the period	137.7	105.0	(32.7)	(23.7)%	(28.7)%

*1 Refer to "[Financial Appendix](#)" for the definition and reconciliations of CER (Constant Exchange Rate).

Revenue. Revenue for the three-month period ended June 30, 2022 was 972.5 billion JPY, an increase of 22.9 billion JPY, or 2.4% (CER % change: -6.8%), compared to the same period of the previous fiscal year. The increase is primarily attributable to growth from business momentum and favorable foreign exchange rates, offsetting the decrease of revenue in the current period due to sale of a portfolio of diabetes products in Japan to Teijin Pharma Limited for 133.0 billion JPY, which was recorded as revenue in the same period of the previous fiscal year.

Revenue of our core therapeutic areas (i.e. Gastroenterology (“GI”), Rare Diseases, Plasma-Derived Therapies (“PDT”) Immunology, Oncology, and Neuroscience) increased by 145.8 billion JPY, or 20.6%, compared to the same period of the previous fiscal year, to 853.8 billion JPY. Each of our core therapeutic areas, except Oncology, contributed to positive revenue growth due to growth from business momentum and favorable foreign exchange rates. Generic erosion and intensified competition impacted certain Oncology products in the current period.

Revenue outside of our core therapeutic areas significantly decreased by 123.0 billion JPY, or 50.9%, compared to the same period of the previous fiscal year to 118.7 billion JPY, largely due to the aforementioned non-recurring 133.0 billion JPY selling price of the diabetes portfolio in Japan recorded as revenue in the same period of the previous fiscal year.

Revenue by Geographic Region

The following shows revenue by geographic region:

Revenue:	Billion JPY or percentage				
	FY2021 Q1	FY2022 Q1	Change versus the same period of the previous fiscal year		
			Actual % change	CER % change ^{*1}	
Japan ^{*2}	259.0	140.5	(118.4)	(45.7)%	(45.9)%
United States	412.2	501.1	88.8	21.6 %	5.4 %
Europe and Canada	178.7	205.6	26.8	15.0 %	9.3 %
Asia (excluding Japan)	40.3	46.1	5.8	14.4 %	2.9 %
Latin America	30.1	40.3	10.2	34.0 %	16.7 %
Russia/CIS	12.3	17.4	5.0	40.8 %	24.7 %
Other ^{*3}	17.0	21.6	4.6	26.8 %	34.2 %
Total	949.6	972.5	22.9	2.4 %	(6.8)%

*1 Refer to "[Financial Appendix](#)" for the definition and reconciliations of CER (Constant Exchange Rate).

*2 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.

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

Revenue by Therapeutic Area

The following shows revenue by therapeutic area:

Revenue:	Billion JPY or percentage				
	FY2021 Q1	FY2022 Q1	Change versus the same period of the previous fiscal year		
			Actual % change	CER % change ^{*1}	
GI	210.5	270.4	59.9	28.4 %	15.4 %
Rare Diseases	155.5	181.6	26.2	16.8 %	7.3 %
Rare Hematology	72.2	79.1	6.9	9.6 %	0.7 %
Rare Genetics and Other	83.3	102.5	19.2	23.1 %	13.1 %
PDT Immunology	107.2	141.9	34.7	32.3 %	18.0 %
Oncology	121.4	117.5	(3.9)	(3.2)%	(10.1)%
Neuroscience	113.4	142.4	29.0	25.6 %	10.7 %
Other ^{*2}	241.6	118.7	(123.0)	(50.9)%	(52.9)%
Total	949.6	972.5	22.9	2.4 %	(6.8)%

*1 Refer to "[Financial Appendix](#)" for the definition and reconciliations of CER (Constant Exchange Rate).

*2 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.

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 270.4 billion JPY, a year-on-year increase of 59.9 billion JPY, or 28.4% (CER % change: 15.4%). Growth was driven by Takeda's top-selling product ENTYVIO (for ulcerative colitis ("UC") and Crohn's disease ("CD")), with sales of 168.3 billion JPY and a year-on-year increase of 42.9 billion JPY, or 34.2%. Sales of ENTYVIO in the U.S. increased by 34.2 billion JPY, or 40.9%, to 117.9 billion JPY driven by continued increase in the first line biologic inflammatory bowel disease ("IBD") population both in UC and CD. Sales headwinds of ENTYVIO associated with COVID-19 experienced in the previous quarter ended March 31, 2022 have been gradually improved in the current period and shipment timing has been largely resolved. Sales of ENTYVIO in Europe and Canada increased by 6.2 billion JPY, or 18.8%, to 38.9 billion JPY. In the Growth and Emerging Markets, the increase in sales of ENTYVIO was led by growth in Brazil. Sales of DEXILANT (for acid reflux disease) were 22.3 billion JPY, an increase of 11.5 billion JPY, or 107.0% versus the same period of the previous fiscal year, due to the increased sales of authorized generics in the U.S. Sales of TAKECAB/VOCINTI (for acid-related diseases) were 27.6 billion JPY, an increase of 3.4 billion JPY, or 13.9%, versus the same period of the previous fiscal year. This increase was mainly driven by the expansion of new prescriptions in the Japanese market due to TAKECAB's efficacy in reflux esophagitis and the prevention of recurrence of gastric and duodenal ulcers during low-dose aspirin administration, despite a negative impact associated with the market expansion re-pricing applied in April 2022 in Japan. Sales of GATTEX/REVESTIVE (for short bowel syndrome) were 21.9 billion JPY, an increase of 3.8 billion JPY, or 20.9%, primarily due to increased market penetration and new country launches including Japan in August 2021.
- *Rare Diseases*. In Rare Diseases, revenue was 181.6 billion JPY, a year-on-year increase of 26.2 billion JPY, or 16.8% (CER % change: 7.3%).

Revenue in Rare Hematology increased by 6.9 billion JPY, or 9.6% (CER % change: 0.7%), to 79.1 billion JPY. Sales of ADVATE (for hemophilia A) increased by 1.4 billion JPY, or 4.7%, to 32.1 billion JPY, and sales of ADYNOVATE/ADYNOVI (for hemophilia A) increased by 2.1 billion JPY, or 13.9%, to 17.5 billion JPY, both helped by favorable foreign exchange rates. FEIBA (for hemophilia A and B) sales decreased by 0.9 billion JPY, or 7.6%, to 10.5 billion JPY, negatively impacted by competition in the U.S.

Revenue in Rare Genetics and Other was 102.5 billion JPY, a year-on-year increase of 19.2 billion JPY, or 23.1% (CER % change: 13.1%). Sales of TAKHZYRO (for hereditary angioedema) were 34.0 billion JPY, an increase of 8.6 billion JPY, or 33.7%, versus the same period of the previous fiscal year primarily due to expansion of the prophylactic market, continued geographic expansion and strong patient uptake. Sales of REPLAGAL (for Fabry disease) increased by 3.6 billion JPY, or 25.3%, to 17.6 billion JPY, primarily due to the succession of manufacturing and marketing rights in Japan upon expiration of the license agreement in February 2022. Sales of other enzyme replacement therapies ELAPRASE (for Hunter syndrome) and VPRIV (for Gaucher disease) increased by 3.6 billion JPY and 1.4 billion JPY, respectively, primarily due to Growth and Emerging Markets. Sales of LIVTENCITY (for post-transplant cytomegalovirus (“CMV”) infection/disease), which was launched in the U.S. in December 2021, were 2.2 billion JPY in the current period.

- *PDT Immunology.* In Plasma-Derived Therapies (“PDT”) Immunology, revenue increased by 34.7 billion JPY, or 32.3% (CER % change: 18.0%) compared to the same period of the previous fiscal year, to 141.9 billion JPY. Aggregate sales of immunoglobulin products were 111.8 billion JPY, an increase of 30.2 billion JPY, or 37.0%, compared to the same period of the previous fiscal year. In particular, sales of GAMMAGARD LIQUID (for the treatment of primary immunodeficiency (“PID”) and multifocal motor neuropathy (“MMN”)) increased due to continued strong demand globally, especially in the U.S. where the pandemic pressure is now easing, and enabled by growing supply. In addition, CUVITRU and HYQVIA, which are SCIG (subcutaneous immunoglobulin) therapies, marked double digit percentage of revenue growth. Aggregate sales of albumin products including HUMAN ALBUMIN and FLEXBUMIN (primarily used for hypovolemia and hypoalbuminemia) were 22.0 billion JPY, an increase of 4.2 billion JPY, or 23.8%, versus the same period of the previous fiscal year driven by strong HUMAN ALBUMIN demand in Growth and Emerging Markets.
- *Oncology.* In Oncology, revenue was 117.5 billion JPY, a year-on-year decrease of 3.9 billion JPY, or 3.2% (CER % change: -10.1%), impacted by the start of rapid generic erosion of VELCADE (for multiple myeloma) sales in the U.S. Sales of VELCADE decreased by 13.6 billion JPY, or 45.3% versus the same period of the previous fiscal year to 16.5 billion JPY predominantly due to multiple generic entrants in the U.S. starting in May 2022. Sales of NINLARO (for multiple myeloma) were 23.7 billion JPY, a decrease of 0.6 billion JPY, or 2.6%, versus the same period of the previous fiscal year. Sales of NINLARO in the U.S. decreased by 0.6 billion JPY, or 4.0%, due to competition and decreased demand. Decreased sales of VELCADE and NINLARO were partially offset by increases in sales of other Oncology products such as ADCETRIS (for malignant lymphomas) with sales increase of 2.7 billion JPY, or 15.9%, versus the same period of the previous fiscal year to 20.0 billion JPY, led by strong growth in countries such as Italy and Japan. Sales of LEUPLIN/ENANTONE (for endometriosis, uterine fibroids, premenopausal breast cancer, prostatic cancer, etc.), an off-patented product, increased by 1.8 billion JPY, or 6.8%, versus the same period of the previous fiscal year to 28.0 billion JPY mainly driven by increased sales in China with improved supply, which was partially offset by a decrease in Japan due to generic erosion and competition. Sales of ALUNBRIG (for non-small cell lung cancer) were 4.5 billion JPY, an increase of 1.4 billion JPY, or 45.9%, benefitting from strong demand in Japan and Europe. Sales of ZEJULA (for ovarian cancer) increased by 1.5 billion JPY, or 94.0%, to 3.0 billion JPY, predominantly in Japan. Sales of EXKIVITY (for non-small cell lung cancer), which launched in the U.S. in September 2021, was 0.7 billion JPY in the current period.
- *Neuroscience.* In Neuroscience, revenue was 142.4 billion JPY, a year-on-year increase of 29.0 billion JPY, or 25.6% (CER % change: 10.7%). Sales of VYVANSE/ELVANSE (for attention deficit hyperactivity disorder (“ADHD”)) were 100.0 billion JPY, an increase of 20.8 billion JPY, or 26.2%, versus the same period of the previous fiscal year mainly driven by the growth of the adult market in the U.S. Sales of TRINTELLIX (for major depressive disorder (“MDD”)) were 21.4 billion JPY, an increase of 3.6 billion JPY, or 20.0%, versus the same period of the previous fiscal year, primarily due to increasing prescriptions in the U.S. and in Japan. Sales of ADDERALL XR (for ADHD) increased by 2.2 billion JPY, or 56.4%, versus the same period of the previous fiscal year, to 6.2 billion JPY due to the sales increase mainly in the U.S. Sales of INTUNIV (for ADHD) also increased by 1.9 billion JPY, or 57.3%, versus the same period of the previous fiscal year, to 5.1 billion JPY driven by the sales increase in Japan.

Cost of Sales. Cost of Sales increased by 51.6 billion JPY, or 21.4% (CER % change: 11.3%), to 292.9 billion JPY. The increase was primarily due to the depreciation of the yen and a sales increase in our core therapeutic areas as compared to the same period of the previous fiscal year. The Cost of Sales Ratio increased by 4.7 pp compared to the same period of the previous fiscal year to 30.1%. The main reason for the increase in the Cost of Sales Ratio was the effect of the sale of a portfolio of diabetes products in Japan with the selling price of 133.0 billion JPY being recorded in revenue in the same period of the previous fiscal year.

Selling, General and Administrative (SG&A) expenses. SG&A expenses increased by 11.6 billion JPY, or 5.3% (CER % change: -4.4%) compared to the same period of the previous fiscal year, to 231.5 billion JPY, due to the impact from the depreciation of the yen in the current period.

Research and Development (R&D) expenses. R&D expenses increased by 21.1 billion JPY, or 17.2% (CER % change: 4.4%) compared to the same period of the previous fiscal year, to 143.6 billion JPY, mainly due to the impact from the depreciation of the yen in the current period.

Amortization and Impairment Losses on Intangible Assets Associated with Products. Amortization and Impairment Losses on Intangible Assets Associated with Products increased by 28.5 billion JPY, or 27.7% (CER % change: 12.5%) compared to the same period of the previous fiscal year, to 131.3 billion JPY, mainly due to the impact from the depreciation of the yen in the current period and impairment charges related to certain assets recorded in the current period.

Other Operating Income. Other Operating Income was 5.5 billion JPY, a decrease of 5.6 billion JPY, or 50.7% (CER % change: -52.5%), compared to the same period of the previous fiscal year primarily due to certain settlement proceeds received in the same period of the previous fiscal year.

Other Operating Expenses. Other Operating Expenses were 28.2 billion JPY, an increase of 2.4 billion JPY, or 9.4% (CER % change: -6.2%), compared to the same period of the previous fiscal year, primarily due to an increase of 6.6 billion JPY valuation reserve for pre-launch inventories, which was partially offset by a decrease in restructuring expenses attributable to the decrease in Shire integration costs.

Operating Profit. As a result of the above factors, Operating Profit decreased by 98.0 billion JPY, or 39.4% (CER % change: -42.2%) compared to the same period of the previous fiscal year to 150.5 billion JPY.

Net Finance Income. Net Finance Income was 5.5 billion JPY in the current period, an increase of 30.7 billion JPY compared to Net Finance Expenses of 25.2 billion JPY for the same period of the previous fiscal year. Included in the current period are a gain on prior equity method investments related to the acquisition of GammaDelta Therapeutics and Adaptate Biotherapeutics in April 2022 as well as a derivative gain on the warrant to purchase stocks of a company that went public in May 2022 recorded in the current period.

Share of Loss of Investments Accounted for Using the Equity Method. Share of Loss of Investments Accounted for Using the Equity Method was 0.5 billion JPY, an increase of 0.1 billion JPY, or 39.3% (CER % change: -2.0%), compared to the same period of the previous fiscal year.

Income Tax Expenses. Income Tax Expenses were 50.5 billion JPY, a decrease of 34.8 billion JPY, or 40.8% (CER % change: -41.7%), compared to the same period of the previous year. This decrease 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 in the same period of the previous year as well as lower pretax earnings. These decreases were partially offset by the tax benefits from internal entity restructuring transactions in the same period of the previous year and tax charges from write-down of deferred tax assets in the current period.

Net Profit for the Period. Net Profit for the Period decreased by 32.7 billion JPY, or 23.7% (CER % change: -28.7%), compared to the same period of the previous fiscal year to 105.0 billion JPY.

Core Results (April 1 to June 30, 2022)

Definition of Core financial measures and Constant Exchange Rate change

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

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

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

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

Results of Core Operations

	Billion JPY or percentage				
	FY2021 Q1	FY2022 Q1	Change versus the same period of the previous fiscal year		
				Actual % change	CER % change
Core Revenue	816.6	972.5	155.9	19.1 %	8.3 %
Core Operating Profit	248.9	319.1	70.1	28.2 %	17.0 %
Core EPS (yen)	113	145	32	28.5 %	15.8 %

Core Revenue for the three-month period ended June 30, 2022 was 972.5 billion JPY, an increase of 155.9 billion JPY, or 19.1% (CER % change: 8.3%), compared to the same period of the previous fiscal year. Core revenue for the three-month period ended June 30, 2021, was 816.6 billion JPY, which excluded the non-recurring 133.0 billion JPY selling price of the diabetes portfolio in Japan. There was no significant item unrelated to Takeda's core operations excluded from revenue in the current period, therefore, Core revenue was the same as Reported revenue at 972.5 billion JPY. Business momentum was led by Takeda's Growth and Launch Products* which totaled 363.6 billion JPY, a year-on-year increase of 104.5 billion JPY, or 40.3% (CER % change: 25.8%).

* Takeda's Growth and Launch Products

GI: ENTYVIO, ALOFISEL

Rare Diseases: TAKHZYRO, LIVTENCITY

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

Albumin products including HUMAN ALBUMIN and FLEXBUMIN

Oncology: ALUNBRIG, EXKIVITY

Other: SPIKEVAX Intramuscular Injection, NUVAXOVID Intramuscular Injection

Core Operating Profit for the current period was 319.1 billion JPY, an increase of 70.1 billion JPY or 28.2% (CER % change: 17.0%) compared to the same period of the previous fiscal year driven by revenue growth in our core therapeutic areas and the depreciation of the yen in the current period.

Core EPS for the current period was 145 yen, an increase of 32 yen, or 28.5% (CER % change: 15.8%), compared to the same period of the previous fiscal year.

Consolidated Financial Position

Assets. Total Assets as of June 30, 2022 were 14,065.4 billion JPY, reflecting an increase of 887.4 billion JPY compared to the previous fiscal year-end. Goodwill, Intangible Assets, and Property, Plant and Equipment increased by 405.9 billion JPY, 326.5 billion JPY, and 122.6 billion JPY respectively mainly due to the effect of foreign currency translation. The increases including the impact on these assets were partially offset by a decrease of 203.7 billion JPY in Cash and Cash Equivalents.

Liabilities. Total Liabilities as of June 30, 2022 were 7,748.0 billion JPY, reflecting an increase of 253.5 billion JPY compared to the previous fiscal year-end. Bonds and Loans increased by 256.8 billion JPY to 4,602.3 billion JPY* primarily due to the effect of foreign currency translation and Income Taxes Payable increased by 53.4 billion JPY. These increases were partially offset by a decrease in Trade and Other Payables of 91.9 billion JPY.

* The carrying amount of Bonds was 3,873.3 billion JPY and Loans was 728.9 billion JPY as of June 30, 2022. Breakdown of Bonds and Loans carrying amount is as follows.

Bonds:

Name of Bond (Face Value if Denominated in Foreign Currency)	Issuance	Maturity	Carrying Amount (Billion JPY)
Unsecured US dollar denominated senior notes (1,301 million USD)	June 2015	June 2025 ~ June 2045	177.6
Unsecured US dollar denominated senior notes (4,000 million USD)	September 2016	September 2023 ~ September 2026	521.1
Unsecured Euro denominated senior notes (3,750 million EUR)	November 2018	November 2022 ~ November 2030	530.6
Unsecured US dollar denominated senior notes (3,250 million USD)	November 2018	November 2023 ~ November 2028	440.8
Hybrid bonds (subordinated bonds)	June 2019	June 2079	498.3
Unsecured US dollar denominated senior notes (7,000 million USD)	July 2020	March 2030 ~ July 2060	947.1
Unsecured Euro denominated senior notes (3,600 million EUR)	July 2020	July 2027 ~ July 2040	508.4
Unsecured JPY denominated senior bonds	October 2021	October 2031	249.4
Total			3,873.3

Loans:

Name of Loan (Face Value if Denominated in Foreign Currency)	Execution	Maturity	Carrying Amount (Billion JPY)
Syndicated loans	April 2016	April 2023 ~ April 2026	200.0
Syndicated loans	April 2017	April 2027	113.5
Syndicated loans (1,500 million USD)	April 2017	April 2027	204.1
Bilateral loans	March 2016 ~ April 2017	March 2023 ~ March 2026	210.0
Other			1.4
Total			728.9

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

Equity. Total Equity as of June 30, 2022 was 6,317.4 billion JPY, an increase of 633.9 billion JPY compared to the previous fiscal year-end. This was primarily resulted from an increase of 668.5 billion JPY in Other Components of Equity mainly due to fluctuation in currency translation adjustments reflecting the depreciation of yen. This increase was partially offset by a decrease in Retained Earnings of 20.0 billion JPY and an increase in Treasury Shares of 13.2 billion JPY mainly due to the share buybacks conducted in the current period. The decrease in Retained Earnings was primarily attributable to the dividends payments of 138.2 billion JPY partially offset by Net Profit for the Period.

Consolidated Cash Flow

	Billion JPY	
	FY2021 Q1	FY2022 Q1
Net cash from (used in) operating activities	166.9	84.2
Net cash from (used in) investing activities	(70.4)	(94.7)
Net cash from (used in) financing activities	(411.0)	(215.7)
Net increase (decrease) in cash and cash equivalents	(314.6)	(226.2)
Cash and cash equivalents at the beginning of the year	966.2	849.7
Effects of exchange rate changes on cash and cash equivalents	3.3	22.5
Cash and cash equivalents at the end of the period	654.9	646.0

Net cash from operating activities was 84.2 billion JPY for the current period compared to 166.9 billion JPY for the same period of the previous year. The decrease of 82.6 billion JPY was primarily driven by lower net profit for the period adjusted for non-cash items and other adjustments, which includes income and expenses related to the financing activities, as well as a decrease in trade and other payables and a decrease in other financial liabilities. These unfavorable impacts were partially offset by an increase in provisions.

Net cash used in investing activities was 94.7 billion JPY for the current period compared to 70.4 billion JPY for the same period of the previous year. This increase of 24.3 billion JPY was mainly due to an increase of 43.8 billion JPY in acquisition of intangible assets and an increase of 12.3 billion JPY in acquisition of property, plant and equipment, partially offset by a decrease of 27.5 billion JPY in acquisition of business (net of cash and cash equivalents acquired).

Net cash used in financing activities was 215.7 billion JPY for the current period compared to 411.0 billion JPY for the same period of the previous year. The decrease of 195.3 billion JPY was mainly due to a decrease in repayments of bonds and long-term loans of 216.1 billion JPY, partially offset by an increase in purchase of treasury shares of 24.4 billion JPY resulting from the share buybacks conducted in the current period.

Outlook for the Fiscal Year Ending March 31, 2023

The full year consolidated reported forecast for the fiscal year ending March 31, 2023 (FY2022) has not been changed from the forecast announced at the FY2021 financial results announcement on May 11, 2022.

Full Year Reported Forecast for the Fiscal Year Ending March 31, 2023 (FY2022)

	Billion JPY or percentage			
	FY2021	FY2022	Change over the previous year	
Revenue	3,569.0	3,690.0	121.0	3.4 %
Operating profit	460.8	520.0	59.2	12.8 %
Profit before tax	302.6	411.0	108.4	35.8 %
Net profit for the year (attributable to owners of the Company)	230.1	292.0	61.9	26.9 %
EPS (JPY)	147.14	188.13	40.99	27.9 %
Core Revenue	3,420.5	3,690.0	269.5	7.9 %
Core Operating Profit	955.2	1,100.0	144.8	15.2 %
Core EPS (JPY)	425	484	60	14.0 %

Major assumptions used in preparing the FY2022 Revised Reported Forecast

	Billion JPY or percentage	
	FY2021	FY2022
FX rates	1 USD = 112 JPY	1 USD = 119 JPY
	1 Euro = 131 JPY	1 Euro = 133 JPY
	1 RUB = 1.5 JPY	1 RUB = 1.3 JPY
	1 BRL = 20.9 JPY	1 BRL = 24.0 JPY
	1 CNY = 17.4 JPY	1 CNY = 18.8 JPY
R&D expenses	(526.1)	(570.0)
Amortization of intangible assets associated with products	(418.8)	(438.0)
Of which Shire acquisition related	(339.7)	(358.0)
Impairment of intangible assets associated with products	(54.1)	(50.0)
Other operating income	43.1	12.0
Other operating expenses	(159.1)	(73.0)
Japan diabetes portfolio divestiture gain	131.4	—
Other Core Operating Profit adjustments	(36.9)	(31.0)
Of which Shire acquisition related to unwind of inventories step-up	(31.9)	(22.0)
Finance income and (expenses), net	(142.9)	(107.0)
Free cash flow	943.7	600.0 - 700.0
Capital expenditures (cash flow base)	(186.0)	(260.0 - 310.0)
Depreciation and amortization (excluding intangible assets associated with products)	(161.0)	(150.0)
Cash tax rate on adjusted EBITDA (excluding divestitures)	~12%	Mid-teen %

Management Guidance

Beginning with FY2022, Takeda uses growth in its Core financial measures on a Constant Exchange Rate basis (“Core Growth at CER”) to provide its Management Guidance. The full year management guidance for the fiscal year ending March 31, 2023 (FY2022) has not been changed from the management guidance announced at the FY2021 financial results announcement on May 11, 2022.

	FY2022 Management Guidance Core Growth at CER*
Core Revenue Growth	Low-single-digit growth
Core Operating Profit Growth	High-single-digit growth
Core EPS Growth	High-single-digit growth

*1 Refer to "[Financial Appendix](#)" for the definition and reconciliations of core financial measures and CER (Constant Exchange Rate).

Other assumptions used in preparing the FY2022 Reported Forecast and the Management Guidance

- Based on currently available information, Takeda expects that its financial results for FY2022 will not be materially affected by COVID-19 or the crisis in Ukraine and Russia and, accordingly, Takeda's FY2022 reported forecast and the management guidance reflect this expectation.
- The FY2022 reported forecast and the management guidance include approximately 50.0 billion JPY revenue contribution from COVID-19 vaccines.

Forward looking statements

All forecasts in this document are based on information currently available to management, and do not represent a promise or guarantee to achieve these forecasts. Various uncertain factors could cause actual results to differ, such as changes in the business environment and fluctuations in foreign exchange rates. Should any significant event occur which requires the forecast to be revised, the Company will disclose it in a timely manner.

Other

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

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

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

Takeda's Operations in Ukraine and Russia

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

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

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

In the three-month period ended June 30, 2022, revenue attributable to Russia/CIS represented 1.8% of Takeda's total consolidated revenue of 972.5 billion JPY, as indicated in the Revenue by Region in [Results of Operations \(Reported\)](#). There was no material financial impact on Takeda's financial results for the current period resulting from the crisis in these countries. However, depending on the future status of the crisis, our results of operations and financial conditions could be adversely affected.

Condensed Interim Consolidated Financial Statements [IFRS]

(1) Condensed Interim Consolidated Statements of Profit or Loss

	JPY (millions, except per share data)		USD (millions) ^(*)
	Three-month Period Ended June 30,		Three-month Period Ended June 30,
	2021	2022	2022
Revenue	¥ 949,603	¥ 972,465	\$ 7,167
Cost of sales	(241,264)	(292,882)	(2,158)
Selling, general and administrative expenses	(219,843)	(231,480)	(1,706)
Research and development expenses	(122,480)	(143,607)	(1,058)
Amortization and impairment losses on intangible assets associated with products	(102,824)	(131,277)	(967)
Other operating income	11,118	5,479	40
Other operating expenses	(25,758)	(28,182)	(208)
Operating profit	248,552	150,515	1,109
Finance income	45,851	60,925	449
Finance expenses	(71,068)	(55,469)	(409)
Share of loss of investments accounted for using the equity method	(357)	(497)	(4)
Profit before tax	222,978	155,473	1,146
Income tax expenses	(85,252)	(50,452)	(372)
Net profit for the period	137,726	105,021	774
Attributable to:			
Owners of the Company	137,684	105,014	774
Non-controlling interests	43	7	0
Net profit for the period	137,726	105,021	774
Earnings per share (JPY)			
Basic earnings per share	87.96	67.94	0.50
Diluted earnings per share	87.45	67.56	0.50

(*) Condensed interim consolidated statements of profit or loss have been translated solely for the convenience of the reader at an exchange rate of 1USD = 135.69 JPY, the Noon Buying Rate certified by the Federal Reserve Bank of New York on June 30, 2022. The rate and methodologies used for the convenience translations differ from the currency exchange rates and translation methodologies under IFRS used for the preparation of the condensed interim consolidated financial statements. The translation should not be construed as a representation that the Japanese yen amounts could be converted into U.S. dollars at the above or any other rate.

(2) Condensed Interim Consolidated Statements of Comprehensive Income

	JPY (millions)		USD (millions) ^(*)
	Three-month Period Ended June 30,		Three-month Period Ended June 30,
	2021	2022	2022
Net profit for the period	¥ 137,726	¥ 105,021	\$ 774
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	15,877	(180)	(1)
Remeasurement of defined benefit pension plans	(57)	10,533	78
	15,819	10,354	76
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	28,280	722,771	5,327
Cash flow hedges	12,948	(25,473)	(188)
Hedging cost	2,230	(27,415)	(202)
Share of other comprehensive income (loss) of investments accounted for using the equity method	2	(641)	(5)
	43,460	669,242	4,932
Other comprehensive income for the period, net of tax	59,279	679,596	5,008
Total comprehensive income for the period	197,005	784,617	5,782
Attributable to:			
Owners of the Company	196,956	784,571	5,782
Non-controlling interests	49	46	0
Total comprehensive income for the period	197,005	784,617	5,782

(*) Condensed interim consolidated statements of comprehensive income have been translated solely for the convenience of the reader at an exchange rate of 1USD = 135.69 JPY, the Noon Buying Rate certified by the Federal Reserve Bank of New York on June 30, 2022. The rate and methodologies used for the convenience translations differ from the currency exchange rates and translation methodologies under IFRS used for the preparation of the condensed interim consolidated financial statements. The translation should not be construed as a representation that the Japanese yen amounts could be converted into U.S. dollars at the above or any other rate.

(3) Condensed Interim Consolidated Statements of Financial Position

	JPY (millions)		USD (millions) ^(*)
	As of March 31, 2022	As of June 30, 2022	As of June 30, 2022
ASSETS			
Non-current assets:			
Property, plant and equipment	¥ 1,582,800	¥ 1,705,367	\$ 12,568
Goodwill	4,407,749	4,813,610	35,475
Intangible assets	3,818,544	4,145,090	30,548
Investments accounted for using the equity method	96,579	97,091	716
Other financial assets	233,554	284,516	2,097
Other non-current assets	82,611	84,677	624
Deferred tax assets	362,539	385,559	2,841
Total non-current assets	10,584,376	11,515,911	84,869
Current assets:			
Inventories	853,167	927,511	6,836
Trade and other receivables	696,644	762,126	5,617
Other financial assets	25,305	18,543	137
Income taxes receivable	27,733	31,966	236
Other current assets	141,099	163,377	1,204
Cash and cash equivalents	849,695	645,991	4,761
Total current assets	2,593,642	2,549,515	18,789
Total assets	13,178,018	14,065,426	103,659
LIABILITIES AND EQUITY			
LIABILITIES			
Non-current liabilities:			
Bonds and loans	4,141,418	4,320,357	31,840
Other financial liabilities	468,943	508,863	3,750
Net defined benefit liabilities	145,847	139,273	1,026
Income taxes payable	21,634	26,566	196
Provisions	52,199	56,418	416
Other non-current liabilities	67,214	72,819	537
Deferred tax liabilities	451,511	456,806	3,367
Total non-current liabilities	5,348,764	5,581,101	41,131
Current liabilities:			
Bonds and loans	203,993	281,897	2,078
Trade and other payables	516,297	424,358	3,127
Other financial liabilities	196,071	139,648	1,029
Income taxes payable	200,918	249,433	1,838
Provisions	443,502	464,929	3,426
Other current liabilities	584,949	606,677	4,471
Total current liabilities	2,145,730	2,166,942	15,970
Total liabilities	7,494,495	7,748,043	57,101

	JPY (millions)		USD (millions) ^(*)
	As of March 31, 2022	As of June 30, 2022	As of June 30, 2022
<u>EQUITY</u>			
Share capital	1,676,263	1,676,277	12,354
Share premium	1,708,873	1,707,336	12,583
Treasury shares	(116,007)	(129,184)	(952)
Retained earnings	1,479,716	1,459,764	10,758
Other components of equity	934,173	1,602,638	11,811
Equity attributable to owners of the company	5,683,019	6,316,832	46,553
Non-controlling interests	504	551	4
Total equity	5,683,523	6,317,383	46,557
Total liabilities and equity	13,178,018	14,065,426	103,659

(*) Condensed interim consolidated statements of financial position have been translated solely for the convenience of the reader at an exchange rate of 1USD = 135.69 JPY, the Noon Buying Rate certified by the Federal Reserve Bank of New York on June 30, 2022. The rate and methodologies used for the convenience translations differ from the currency exchange rates and translation methodologies under IFRS used for the preparation of the condensed interim consolidated financial statements. The translation should not be construed as a representation that the Japanese yen amounts could be converted into U.S. dollars at the above or any other rate.

(4) Condensed Interim Consolidated Statements of Changes in Equity

	JPY (millions)					
	Equity attributable to owners of the company				Other components of 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
As of April 1, 2021	1,668,145	1,688,424	(59,552)	1,509,906	400,798	41,983
Net profit for the period				137,684		
Other comprehensive income (loss)					28,208	15,944
Comprehensive income (loss) for the period	—	—	—	137,684	28,208	15,944
Transactions with owners:						
Issuance of new shares	980	6,898				
Acquisition of treasury shares			(4,464)			
Disposal of treasury shares		(0)	0			
Dividends				(141,859)		
Changes in ownership				(2,143)		
Transfers from other components of equity				224		(281)
Share-based compensation		8,547				
Exercise of share-based awards		(21,365)	21,671			
Total transactions with owners	980	(5,919)	17,208	(143,779)	—	(281)
As of June 30, 2021	1,669,125	1,682,504	(42,344)	1,503,811	429,006	57,646

	Equity attributable to owners of the company						
	Equity attributable to owners of the company				Other components of equity		
	Cash flow hedges	Hedging cost	Remeasurements of defined benefit pension plans	Total other components of equity	Total equity attributable to owners of the Company	Non-controlling interests	Total equity
As of April 1, 2021	(68,075)	(8,592)	—	366,114	5,173,037	4,140	5,177,177
Net profit for the period				—	137,684	43	137,726
Other comprehensive income (loss)	12,948	2,230	(57)	59,272	59,272	7	59,279
Comprehensive income (loss) for the period	12,948	2,230	(57)	59,272	196,956	49	197,005
Transactions with owners:							
Issuance of new shares				—	7,878		7,878
Acquisition of treasury shares				—	(4,464)		(4,464)
Disposal of treasury shares				—	0		0
Dividends				—	(141,859)		(141,859)
Changes in ownership				—	(2,143)	(3,804)	(5,948)
Transfers from other components of equity			57	(224)	—		—
Share-based compensation				—	8,547		8,547
Exercise of share-based awards				—	307		307
Total transactions with owners	—	—	57	(224)	(131,734)	(3,804)	(135,539)
As of June 30, 2021	(55,126)	(6,362)	—	425,163	5,238,258	385	5,238,643

JPY (millions)						
Equity attributable to owners of the company						
	Share capital	Share premium	Treasury shares	Retained earnings	Other components of equity	
					Exchange differences on translation of foreign operations	Changes in fair value of financial assets measured at fair value through other comprehensive income
As of April 1, 2022	1,676,263	1,708,873	(116,007)	1,479,716	984,141	22,068
Effect of hyperinflation				(1,960)	4,121	
Restated opening balance	1,676,263	1,708,873	(116,007)	1,477,756	988,263	22,068
Net profit for the period				105,014		
Other comprehensive income (loss)					722,137	(225)
Comprehensive income (loss) for the period				105,014	722,137	(225)
Transactions with owners:						
Issuance of new shares	14	14				
Acquisition of treasury shares		(5)	(27,045)			
Dividends				(138,218)		
Transfers from other components of equity				15,213		(4,679)
Share-based compensation		12,292				
Exercise of share-based awards		(13,838)	13,867			
Total transactions with owners	14	(1,537)	(13,177)	(123,005)		(4,679)
As of June 30, 2022	1,676,277	1,707,336	(129,184)	1,459,764	1,710,399	17,163

Equity attributable to owners of the company							
Other components of equity							
	Cash flow hedges	Hedging cost	Remeasurements of defined benefit pension plans	Total other components of equity	Total equity attributable to owners of the Company	Non-controlling interests	Total equity
Effect of hyperinflation				4,121	2,161		2,161
Restated opening balance	(65,901)	(6,135)	—	938,294	5,685,180	504	5,685,684
Net profit for the period				—	105,014	7	105,021
Other comprehensive income (loss)	(25,473)	(27,415)	10,533	679,557	679,557	39	679,596
Comprehensive income (loss) for the period	(25,473)	(27,415)	10,533	679,557	784,571	46	784,617
Transactions with owners:							
Issuance of new shares				—	29		29
Acquisition of treasury shares				—	(27,050)		(27,050)
Dividends				—	(138,218)		(138,218)
Transfers from other components of equity			(10,533)	(15,213)	—		—
Share-based compensation				—	12,292		12,292
Exercise of share-based awards				—	30		30
Total transactions with owners	—	—	(10,533)	(15,213)	(152,918)	—	(152,918)
As of June 30, 2022	(91,375)	(33,549)	—	1,602,638	6,316,832	551	6,317,383

(5) Condensed Interim Consolidated Statements of Cash Flows

	JPY (millions)		USD (millions)(*)
	Three-month Period Ended June 30,		Three-month Period Ended June 30,
	2021	2022	2022
Cash flows from operating activities:			
Net profit for the period	¥ 137,726	¥ 105,021	\$ 774
Depreciation and amortization	142,948	158,283	1,167
Impairment losses	53	14,238	105
Equity-settled share-based compensation	8,547	12,292	91
Loss on sales and disposal of property, plant and equipment	94	7	0
Gain on divestment of business and subsidiaries	(365)	(320)	(2)
Change in fair value of financial assets and liabilities associated with contingent consideration arrangements, net	(934)	136	1
Finance (income) and expenses, net	25,216	(5,456)	(40)
Share of loss of investments accounted for using the equity method	357	497	4
Income tax expenses	85,252	50,452	372
Changes in assets and liabilities:			
Increase in trade and other receivables	(41,835)	(17,970)	(132)
Increase in inventories	(21,009)	(9,118)	(67)
Decrease in trade and other payables	(24,854)	(97,123)	(716)
Decrease in provisions	(65,217)	(20,106)	(148)
Decrease in other financial liabilities	(7,985)	(44,152)	(325)
Other, net	(35,236)	(41,583)	(306)
Cash generated from operations	202,760	105,097	775
Income taxes paid	(35,902)	(24,945)	(184)
Tax refunds and interest on tax refunds received	—	4,090	30
Net cash from operating activities	166,858	84,241	621
Cash flows from investing activities:			
Interest received	349	470	3
Dividends received	139	138	1
Acquisition of property, plant and equipment	(29,838)	(42,125)	(310)
Proceeds from sales of property, plant and equipment	79	34	0
Acquisition of intangible assets	(12,454)	(56,251)	(415)
Acquisition of investments	(3,251)	(2,933)	(22)
Proceeds from sales and redemption of investments	483	6,178	46
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	(543)	(224)	(2)
Net cash used in investing activities	(70,445)	(94,714)	(698)

	JPY (millions)		USD (millions)(*)
	Three-month Period Ended June 30,		Three-month Period Ended June 30,
	2021	2022	2022
Cash flows from financing activities:			
Net increase in short-term loans and commercial papers	1	—	—
Repayments of bonds and long-term loans	(242,919)	(26,804)	(198)
Acquisition of treasury shares	(2,542)	(26,929)	(198)
Interest paid	(23,218)	(22,770)	(168)
Dividends paid	(132,032)	(128,873)	(950)
Repayments of lease liabilities	(10,328)	(10,325)	(76)
Other, net	—	(17)	(0)
Net cash used in financing activities	(411,038)	(215,717)	(1,590)
Net decrease in cash and cash equivalents	(314,625)	(226,190)	(1,667)
Cash and cash equivalents at the beginning of the year	966,222	849,695	6,262
Effects of exchange rate changes on cash and cash equivalents	3,324	22,485	166
Cash and cash equivalents at the end of the period	654,920	645,991	4,761

(*) Condensed interim consolidated statements of cash flows have been translated solely for the convenience of the reader at an exchange rate of 1USD = 135.69 JPY, the Noon Buying Rate certified by the Federal Reserve Bank of New York on June 30, 2022. The rate and methodologies used for the convenience translations differ from the currency exchange rates and translation methodologies under IFRS used for the preparation of the condensed interim consolidated financial statements. The translation should not be construed as a representation that the Japanese yen amounts could be converted into U.S. dollars at the above or any other rate.

(6) Other Information

(Significant Subsequent Events)

Not applicable.

Supplementary Information

1. Pipeline	28
• I. Clinical Development Activities	28
• II. Recent Progress in stage	35
• III. Discontinued projects	35
• IV. Main Research & Development collaborations	36
2. Supplementary Revenue Information	42
• Revenue by region	42
◦ Year to date	42
◦ Quarterly	43
• Product Sales Analysis	44
◦ Year to date	44
• Product Sales Analysis (Reported & Core Growth)	46
• Product Forecast	48

1. Pipeline

I. Clinical Development Activities

- The following table lists the pipeline assets that we are clinically developing as of July 28, 2022. The assets in our pipeline are in various stages of development, and the contents of the pipeline may change as therapeutic candidates currently under development drop out and new therapeutic candidates are introduced. Whether the therapeutic candidates listed below are ever successfully released as products depends on various factors, including the results of pre-clinical and clinical trials, market conditions for various drugs and regulatory approvals.
- This table primarily shows the indications for which we are actively pursuing regulatory approval and those regulatory approvals granted during fiscal year 2022. We are also conducting additional studies of certain assets to examine their potential for use in further indications and in additional formulations.
- The listings in this table are limited to the U.S., EU and Japan and China, but we are also actively conducting development activities in other regions, including in Emerging Markets. Country/region column denotes where a pivotal clinical study is ongoing or a filing has been made with our specific intention to pursue approval in any of the U.S., EU, Japan or China. 'Global' refers to U.S., EU, Japan and China.
- Brand name and country/region indicate the brand name and country in which the specific asset has already been approved for any indication in any of the U.S., EU, Japan or China and Takeda has commercialization rights for such asset.
- Stage-ups are recognized in the table upon achievement of First Subject In.
- Modality of our pipeline assets in the following table is classified into either of the following categories: 'small molecule', 'peptide/oligonucleotide', 'cell and gene therapy' or 'biologic and other.'

Oncology Pipeline

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Country/ Region	Stage
MLN9708 <ixazomib> NINLARO (Global)	Proteasome inhibitor (oral)	Small molecule	Maintenance therapy in patients with newly diagnosed Multiple Myeloma not treated with stem cell transplant	U.S. EU China	P-III P-III P-III
			Maintenance therapy in patients with newly diagnosed Multiple Myeloma following autologous stem cell transplant	U.S. EU	P-III P-III
<cabozantinib> ¹ CABOMETYX (Japan)	Multi-targeted kinase inhibitor (oral)	Small molecule	2L metastatic Non-Small Cell Lung Cancer in combination with atezolizumab ²	Japan	P-III
			Metastatic Castration-Resistant Prostate Cancer in combination with atezolizumab ³	Japan	P-III
<ponatinib> ICLUSIG (U.S.)	BCR-ABL inhibitor (oral)	Small molecule	Front line Philadelphia chromosome-positive Acute Lymphoblastic Leukemia	U.S.	P-III
			Pediatric indication for Philadelphia chromosome-positive Acute Lymphoblastic Leukemia	-	P-I
TAK-788 <mobocertinib> EXKIVITY (U.S.)	EGFR/HER2 exon 20 inhibitor (oral)	Small molecule	Treatment Naïve Non-Small Cell Lung Cancer with EGFR exon 20 insertion	Global	P-III
			Previously treated Non-Small Cell Lung Cancer with EGFR exon 20 insertion ⁴	China EU ⁵ Japan	Filed (Jul 2021) Filing withdrawn (Jul 2022) P-III
TAK-385 <relugolix>	LH-RH antagonist (oral)	Small molecule	Prostate cancer	Japan China	P-III P-III

[Table of Contents](#)

<niraparib> ⁶ ZEJULA (Japan)	PARP 1/2 inhibitor (oral)	Small molecule	Breast cancer	Japan	P-III
TAK-981 <subasumstat>	SUMO inhibitor (injection)	Small molecule	Multiple cancers	-	P-II
TAK-573 ⁷ <modakafusp alfa>	Anti-CD38-targeted IgG4 genetically fused with an attenuated IFN α (injection)	Biologic and other	Relapsed/refractory Multiple Myeloma	-	P-II
			Solid tumors	-	P-I
TAK-007 ⁸	CD19 CAR-NK (injection)	Cell and gene therapy	Relapsed/refractory B cell malignancies	-	P-I/II
TAK-102 ⁹	GPC3 CAR-T (injection)	Cell and gene therapy	Solid tumors	-	P-I
TAK-103 ⁹	Mesothelin CAR-T (injection)	Cell and gene therapy	Solid tumors	-	P-I
TAK-676	STING agonist (injection)	Small molecule	Solid tumors	-	P-I
TAK-500	STING agonist antibody drug conjugate (injection)	Biologic and other	Solid tumors	-	P-I
TAK-940 ¹⁰	CD19 1XX CAR-T (injection)	Cell and gene therapy	Relapsed/refractory B cell malignancies	-	P-I
TAK-186 ¹¹	T Cell Engager (Injection)	Biologic and other	EGFR expressing solid tumors	-	P-I
TAK-280 ¹¹	T Cell Engager (Injection)	Biologic and other	B7-H3 expressing solid tumors	-	P-I

1. Partnership with Exelixis, Inc.
2. Partnership with Chugai Pharmaceutical. Chugai operates Phase 3 development
3. Partnership with Chugai Pharmaceutical. Takeda operates Phase 3 development
4. The U.S. FDA review is being conducted under Project Orbis, an initiative of the FDA Oncology Center of Excellence (OCE), which provides a framework for concurrent submission and review of oncology products among international partners. Currently, approval was granted in the U.K. (May 2022), the Switzerland (Jun 2022), Australia (Jul 2022) and South Korea (Jul 2022).
5. Following discussions with the EMA, Takeda decided to withdraw the marketing authorization application (MAA).
6. Partnership with GSK
7. Partnership with Teva Pharmaceutical Industries Ltd.
8. Partnership with The University of Texas MD Anderson Cancer Center
9. Partnership with Noile-Immune Biotech, Inc.
10. Partnership with Memorial Sloan Kettering Cancer Center
11. Acquired via acquisition of Maverick Therapeutics, Inc.

Additions since FY2021 Q4: Niraparib breast cancer (Japan, P-III)

TAK-280 B7-H3 expressing solid tumors (P-I)

Removals since FY2021 Q4: Brigatinib H2H vs Alectinib (U.S., EU, P-III, discontinued)

TAK-605 for solid tumors (P-I, TAK-605 collaboration ended)

Rare Genetics and Hematology Pipeline

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Country/ Region	Stage
TAK-743 <lanadelumab> <i>TAKHZYRO</i> (Global)	Plasma kallikrein inhibitor (injection)	Biologic and other	Pediatric Hereditary Angioedema	Global	P-III
			Bradykinin-Mediated Angioedema	Global	P-III
TAK-577 <i>VONVENDI</i> (U.S., Japan) <i>VEYVONDI</i> (EU)	von Willebrand factor [recombinant] (injection)	Biologic and other	Adult prophylactic treatment of von Willebrand disease	EU China	P-III P-III
			Pediatric on-demand and surgery treatment of von Willebrand disease	Global	P-III
TAK-620 ¹ <maribavir> <i>LIVTENCITY</i> (U.S.)	Benzimidazole riboside inhibitor (oral)	Small molecule	Post-transplant cytomegalovirus (CMV) infection/ disease resistant/refractory to (val) ganciclovir, cidofovir or foscarnet	EU	Filed (Jun 2021)
			HSCT Recipients with First CMV Infection	U.S. EU	P-III P-III
			Treatment of CMV Infection/disease Post Transplantation (Including HSCT)	Japan	P-III
TAK-660 <i>ADYNOVATE</i> (U.S., Japan) <i>ADYNOVI</i> (EU)	Antihemophilic factor [recombinant], PEGylated (injection)	Biologic and other	Pediatric Hemophilia A	EU	P-III
TAK-755 ²	Replacement of the deficient-ADAMTS13 enzyme (injection)	Biologic and other	Congenital Thrombotic Thrombocytopenic Purpura	U.S. EU	P-III P-III
			Immune Thrombotic Thrombocytopenic Purpura	U.S. EU	P-II P-II
			Sickle cell disease	U.S.	P-I
TAK-672 ³ <i>OBIZUR</i> (US, EU)	Porcine Coagulation Factor VIII (Recombinant) (injection)	Biologic and other	Acquired hemophilia A (AHA)	China Japan	Filed (Jun 2022) P-II/III
TAK-141/JR-141 ⁴ <pabinafusp alfa>	Recombinant fusion protein of an antibody against the human transferrin receptor and iduronate-2-sulfatase (injection)	Biologic	Hunter syndrome (CNS and somatic symptoms)	EU	P-III
TAK-611	Recombinant human arylsulfatase A for intrathecal administration (injection)	Biologic and other	Metachromatic leukodystrophy	-	P-II

Table of Contents

TAK-079 ⁵ <mezagitamab>	Anti-CD38 monoclonal antibody (injection)	Biologic and other	Myasthenia gravis	-	P-II
			Immune thrombocytopenic purpura	-	P-II
			Systemic lupus erythematosus	-	P-I/II
TAK-834 NATPARA (U.S.) NATPAR (EU)	Parathyroid hormone (injection)	Biologic and other	Hypoparathyroidism	Japan	P-I ⁶

- Partnership with GlaxoSmithKline
- Partnership with KM Biologics for co-exclusive license for commercialization in Japan only
- Partnership with Ipsen
- Geographically-focused collaboration and license agreement with JCR Pharma. Takeda will exclusively commercialize TAK-141/JR-141 outside of the United States, including Canada, Europe, and other regions (excluding Japan and certain other Asia-Pacific countries). Takeda receives an option under a separate option agreement, which allows Takeda to acquire an exclusive license to commercialize TAK-141/JR-141 in the U.S. upon completion of the Phase 3 program.
- Relapsed/refractory Multiple Myeloma will continue until trial completion.
- P-I study in Japan completed; P-III study under review.

Additions since FY2021 Q4: TAK-672 for acquired hemophilia A (AHA) (Filed in China)

TAK-620 for Treatment of CMV Infection/disease Post Transplantation (Including HSCT) (Japan, P-III)

Removals since FY2021 Q4: None

Neuroscience Pipeline

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Country/ Region	Stage
TAK-935 <soficlistat>	CH24H inhibitor (oral)	Small molecule	Dravet syndrome	Global	P-III
			Lennox-Gastaut syndrome	Global	P-III
TAK-071	M1 positive allosteric modulator (M1PAM) (oral)	Small molecule	Parkinson's disease	-	P-II
TAK-041 ¹	GPR139 agonist (oral)	Small molecule	Anhedonia in major depressive disorder (MDD)	-	P-II
TAK-653 ¹	AMPA receptor potentiator (oral)	Small molecule	Inadequate response to treatment in major depressive disorder (MDD)	-	P-II
TAK-594/DNL593 ²	Brain-penetrant progranulin fusion protein (injection)	Biologic and other	Frontotemporal dementia	-	P-I/II
TAK-341/MEDI1341 ³	Alpha-synuclein antibody (injection)	Biologic and other	Parkinson's disease	-	P-I
TAK-861	Orexin 2R agonist (oral)	Small molecule	Sleep disorders, other disorders	-	P-I
TAK-925	Orexin 2R agonist (injection)	Small molecule	Post-anesthesia recovery, narcolepsy	-	P-I

Table of Contents

1. Partnership with Neurocrine Biosciences. Neurocrine leads development
2. Partnership with Denali Therapeutics. Denali leads Phase 1 development
3. Partnership with AstraZeneca. AstraZeneca leads Phase 1 development

Additions since FY2021 Q4: None

Removals since FY2021 Q4: TAK-994 for Narcolepsy (P-II, discontinued)

GI Pipeline

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Country/ Region	Stage
MLN0002 <vedolizumab> ENTYVIO (Global)	Humanized monoclonal antibody against $\alpha 4\beta 7$ integrin (injection)	Biologic and other	Subcutaneous formulation for ulcerative colitis	U.S. Japan	Complete Response Letter (CRL) received (Dec 2019) ⁵ Filed (Aug 2019)
			Subcutaneous formulation for Crohn's disease	U.S. Japan	P-III P-III
			Graft-versus-Host Disease prophylaxis in patients undergoing allogeneic hematopoietic stem cell transplantation	EU Japan	P-III P-III
			Pediatrics Study (ulcerative colitis, Crohn's disease)	Global	P-III
TAK-438 <vonoprazan> TAKECAB (Japan) VOCINTI (China)	Potassium-competitive acid blocker (oral)	Small molecule	Acid related diseases (adjunct to <i>Helicobacter pylori</i> eradication)	China	P-III
Cx601 <darvadstrocel> ALOFISEL (EU, Japan)	A suspension of allogeneic expanded adipose- derived stem cells (injection)	Biologic and other	Refractory complex perianal fistulas in patients with Crohn's disease	U.S.	P-III
			Pediatric indication for refractory complex perianal fistulas in patients with Crohn's disease	EU Japan	P-III P-III
TAK-954 ¹	5-HT ₄ - hydroxytryptamine receptor agonist (injection)	Small molecule	Post-operative gastrointestinal dysfunction	-	P-II (b)
TAK-999 ² <fazirsiran>	GalNAc based RNA interference (RNAi) (injection)	Peptide/ Oligo- nucleotide	Alpha-1 antitrypsin-deficiency associated liver disease	U.S. EU	P-II (b) P-II (b)
TAK-101 ³	Tolerizing Immune Modifying nanoParticle (TIMP) (injection)	Biologic and other	Celiac disease	-	P-II (a)
TAK-018/EB8018 ⁴ <sibofimloc>	FimH antagonist (oral)	Small molecule	Crohn's disease (post-operative and ileal-dominant)	-	P-II (a)
TAK-951	Peptide agonist (sub-cutaneous)	Peptide/ Oligo- nucleotide	Nausea and vomiting	-	P-II
TAK-510	Peptide agonist (sub-cutaneous)	Peptide/ Oligo- nucleotide	Nausea and vomiting	-	P-I

[Table of Contents](#)

TAK-105	Peptide agonist (sub-cutaneous)	Peptide/ Oligo-nucleotide	Nausea and vomiting	-	P-I
TAK-062	Glutenase (oral)	Biologic and other	Celiac disease	-	P-I

1. Partnership with Theravance Biopharma, Inc.
2. Partnership with Arrowhead Pharmaceuticals, Inc.
3. Acquired development and commercialization license for TAK-101 from COUR Pharmaceuticals. Previously known as TIMP-GLIA.
4. Partnership with Enterome Bioscience SA
5. In active discussions with the FDA. Timelines under review; target resubmission filing anticipated in FY2023.

Additions since FY2021 Q4: None

Removals since FY2021 Q4: TAK-039 for Clostridium difficile infections (P-I, discontinued)

Plasma-Derived Therapies Pipeline

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Country/ Region	Stage
TAK-771 ¹ <IG Infusion 10% (Human) w/ Recombinant Human Hyaluronidase> <i>HYQVIA</i> (U.S., EU)	Immunoglobulin (IgG) + recombinant hyaluronidase replacement therapy (injection)	Biologic and other	Pediatric indication for primary immunodeficiency	U.S.	Filed (Jul 2022)*
			Chronic inflammatory demyelinating polyradiculoneuropathy	U.S. EU	P-III P-III
			Chronic inflammatory demyelinating polyradiculoneuropathy and Multifocal Motor Neuropathy	Japan	P-III
			Primary Immunodeficiencies	Japan	P-III
TAK-664 <i>CUVITRU</i> (U.S., EU)	Immunoglobulin 20% [human] (subcutaneous)	Biologic and other	Primary immunodeficiencies	Japan	P-III
TAK-880 <10% IVIG (Low IgA)>	Immunoglobulin (10%) [human] (injection) (Low IgA)	Biologic and other	Primary Immunodeficiencies and Multifocal Motor Neuropathy	U.S. EU	Filing in preparation ²
TAK-662 <i>CEPROTIN</i> (U.S., EU)	Protein C concentrate [human] (injection)	Biologic and other	Severe congenital protein C deficiency	Japan	P-I/II
TAK-881 <Facilitated 20% SCIG>	Immunoglobulin (20%) [human] + recombinant hyaluronidase replacement therapy (injection)	Biologic and other	Immunodeficiencies	-	P-I/II

1. Partnership with Halozyme
2. Non-interventional study to collect data is in progress

* Event occurred after the end of the Q1 reporting period: Update after July 1, 2022

Additions since FY2021 Q4: None

Removals since FY2021 Q4: None

Vaccines Pipeline

Development code Brand name (country/region)	Type of vaccine (administration route)	Modality	Indications / additional formulations	Country/ Region	Stage
TAK-019/ NVX-CoV2373 ¹ <i>Nuvaxovid</i> <i>Intramuscular Injection</i> (Japan)	SARS-CoV-2 vaccine (injection)	Biologic and other	Active immunization for the prevention of COVID-19 (primary and booster)	Japan	Approved (Apr 2022)
TAK-003	Tetravalent dengue vaccine (injection)	Biologic and other	For the prevention of dengue fever of any severity, due to any serotype, in individuals aged 4 up to 60 years of age	EU and EU- M4all -	Filed (Mar 2021) ³ P-III
TAK-426 ²	Zika vaccine (injection)	Biologic and other	Active immunization for the prevention of disease caused by Zika virus	-	P-I

1. Partnership with Novavax, Inc.

2. Partnership with The Biomedical Advanced Research and Development Authority (BARDA) of the U.S. Government

3. In addition to filing in the EU and through the EU-M4all (previously Article 58) procedure for countries outside of the EU, filings began in dengue endemic countries in Latin America and Asia that are not participating in the EU-M4all procedure.

Additions since FY2021 Q4: None

Removals since FY2021 Q4: None

II. Recent Progress in stage [Progress in stage since April 1st, 2022]

Development code <generic name>	Indications / additional formulations	Country/Region	Progress in stage
TAK-019/ NVX-CoV2373	Active immunization for the prevention of COVID-19 (primary and booster)	Japan	Approved (Apr 2022)
SGN-35 <brentuximab vedotin>	1L CD30-positive Hodgkin lymphoma (pediatric indication)	Japan	Approved (May 2022)
TAK-672	Acquired hemophilia A (AHA)	China	Filed (Jun 2022)
TAK-771 <IG Infusion 10% (Human) w/ Recombinant Human Hyaluronidase>	Pediatric indication for primary immunodeficiency	U.S.	Filed (Jul 2022)*
<niraparib>	Breast cancer	Japan	P-III
TAK-620 <maribavir>	Treatment of CMV Infection/disease Post Transplantation (Including HSCT)	Japan	P-III
TAK-573 <modakafusp alfa>	Relapsed/refractory Multiple Myeloma	-	P-II
TAK-500	Solid tumors	-	P-I
TAK-280	B7-H3 expressing solid tumors	-	P-I

* Event occurred after the end of the Q1 reporting period: Update after July 1, 2022

III. Discontinued projects [Update since April 1st, 2022]

Development code <generic name>	Indications (Region/Country, Stage)	Reason
<brigatinib>	2L ALK-positive Non-Small Cell Lung Cancer (head-to-head with alectinib) (U.S., EU, P-III)	The study met futility boundary for the primary endpoint.
TAK-994	Narcolepsy (P-II)	TAK-994 was on clinical hold, we have made data driven decision to stop further development and pivot to TAK-861 and other molecules in orexin portfolio like TAK-925.
TAK-039	Clostridium difficile infection (P-I)	Takeda made the strategic decision not to continue pursuing TAK-039 in order to further optimize the portfolio.
TAK-605	Solid tumors (P-I)	Takeda has decided to terminate its collaboration with Turnstone Biologics to develop the armored oncolytic virus TAK-605 for strategic reasons and has returned global rights to the asset back to Turnstone. The two companies' discovery efforts to identify additional novel product candidates based on the vaccinia virus platform are ongoing.

IV. Main Research & Development collaborations/partnering

- This table primarily shows the main research & development collaborations/partnering and externalization projects. This list is not a” comprehensive list of all Takeda R&D collaborations.
- † shows collaborations/partnering and ♦ shows externalization project, which have been executed since April 1, 2022.

Oncology

Partner	Country of incorporation	Subject
Adimab	U.S.	Agreement for the discovery, development and commercialization of three mAbs and three CD3 Bi-Specific antibodies for oncology indications.
Crescendo Biologics	U.K	Collaboration and licensing agreement for the discovery, development and commercialization of Humabody®-based therapeutics for cancer indications.
Egle Therapeutics	France	Identify novel tumor-specific regulatory T cell targets and develop unique anti-suppressor-based immunotherapies.
Exelixis, Inc.	U.S.	Exclusive licensing agreement to commercialize and develop novel cancer therapy cabozantinib and all potential future cabozantinib indications in Japan, including advanced renal cell carcinoma and hepatocellular carcinoma.
GlaxoSmithKline	U.K.	Exclusive licensing agreement to develop and commercialize novel cancer therapy niraparib for the treatment of all tumor types in Japan, and all tumor types excluding prostate cancer in South Korea and Taiwan.
Heidelberg Pharma	Germany	Antibody-Drug-Conjugate (ADC) research collaboration on 2 targets and licensing agreement (α -amanitin payload and proprietary linker).
KSQ Therapeutics	U.S.	Strategic collaboration to research, develop and commercialize novel immune-based therapies for cancer using KSQ’s CRISPRomics® technology.
MD Anderson Cancer Center	U.S.	Exclusive license and research agreement to develop cord blood-derived chimeric antigen receptor-directed natural killer (CAR NK) cell therapies, ‘armored’ with IL-15, for the treatment of B cell malignancies and other cancers.
Memorial Sloan Kettering Cancer Center	U.S.	Strategic research collaboration and license to develop novel chimeric antigen receptor T cell (CAR-T) products for the treatment of multiple myeloma, acute myeloid leukemia and additional solid tumor indications. The collaboration is co-led by Michel Sadelain, who is currently head of the Center for Cell Engineering at Memorial Sloan Kettering
National Cancer Center of Japan	Japan	Partnership agreement to develop basic research to clinical development by promoting exchanges among researchers, physicians, and others engaged in anti-cancer drug discovery and cancer biology research.
Noile-Immune Biotech	Japan	Collaboration agreement for the development of next generation CAR-T cell therapy, developed by Professor Koji Tamada at Yamaguchi University. Takeda has exclusive options to obtain licensing rights for the development and commercialization of Noile-Immune Biotech’s pipeline and products resulting from this partnership. Due to the success of the collaboration, Takeda licensed NIB-102 and NIB-103.
Presage Biosciences	U.S.	Research collaboration and license for multiple programs using Presage’s proprietary platform CIVO to evaluate patients’ unique responses to microdoses of cancer drugs.
Seagen	U.S.	Agreement for the joint development of ADCETRIS, an ADC technology which targets CD30 for the treatment of HL. Approved in 67 countries with ongoing clinical trials for additional indications.
Teva	Israel	Agreement for worldwide License to TEV-48573 (TAK-573) (modakafusp alfa, Anti-CD38-Attenukine™) and multi-target discovery collaboration accessing Teva’s Attenukine™ platform.
Turnstone Biologics	U.S.	Collaboration to conduct collaborative discovery efforts to identify additional novel product candidates based on a Turnstone’s vaccinia virus platform. Takeda has decided to terminate its collaboration to develop the armored oncolytic virus TAK-605 for strategic reasons and has returned global rights to the asset back to Turnstone (FY2022).

Rare Genetics and Hematology

Partner	Country of incorporation	Subject
Asklepios Biopharmaceuticals	U.S.	Agreement for multiple research and development collaborations using FVIII Gene Therapy for the treatment of Hemophilia A and B.
BioMarin	U.S.	Agreement for the in-license of enabling technology for the exogenous replacement of iduronate-2-sulfatase with Idursulfase-IT in patients via direct delivery to the CNS for the long-term treatment of Hunter Syndrome in patients with cognitive impairment in order to slow progression of cognitive impairment (TAK-609).
Carmine Therapeutics	Singapore	Research collaboration agreement to discover, develop and commercialize transformative non-viral gene therapies for two rare disease targets using Carmine's REGENT(TM) technology, based on red blood cell extracellular vesicles.
Code Bio	U.S.	Collaboration and license agreement for Takeda and Code Bio to design and develop a targeted gene therapy leveraging Code Bio's 3DNA platform for a liver-directed rare disease program, plus conduct additional studies for central nervous system-directed rare disease programs. Takeda has the right to exercise options for an exclusive license for four programs.
Codexis, Inc.	U.S.	Strategic collaboration and license for the research and development of novel gene therapies for certain disease indications, including the treatment of lysosomal storage disorders and blood factor deficiencies.
Ensoma	U.S.	Research collaboration and license provides Takeda with an exclusive worldwide license to Ensoma's Engenious™ vectors for up to five rare disease indication.
Evox Therapeutics	U.K.	Collaboration for developing novel protein replacement and mRNA therapies and targeted delivery using Evox's proprietary exosome technology. Partnership for up to five rare disease targets with Takeda assuming responsibility for its clinical development.
Evozyne	U.S.	Research collaboration and license agreement with Takeda to research and develop proteins that could be incorporated into next-generation gene therapies for up to four rare disease targets.
GlaxoSmithKline	U.K.	In-license agreement between GSK and University of Michigan for TAK-620 (maribavir) in the treatment of human cytomegalovirus.
JCR Pharmaceuticals	Japan	Exclusive collaboration and license agreement to commercialize TAK-141 (JR-141, pabinafusp alfa), applied with J-Brain Cargo®, JCR's proprietary blood-brain barrier (BBB) penetration technology, for the treatment of Hunter syndrome (MPS II). Takeda will exclusively commercialize TAK-141 outside of the United States, including Canada, Europe, and other regions (excluding Japan and certain other Asia-Pacific countries). Takeda receives an option under a separate option agreement, which allows Takeda to acquire an exclusive license to commercialize TAK-141 in the U.S. upon completion of the Phase 3 program. In March 2022, Takeda and JCR has entered into new exclusive license and collaboration agreement to develop gene therapies that apply J-Brain Cargo® BBB penetration technology for lysosomal storage disorders (LSDs); Takeda has the option to nominate additional rare disease and other disease indications.
Immusoft	U.S.	Research collaboration and license option agreement to discover, develop and commercialize cell therapies in rare inherited metabolic disorders with central nervous system (CNS) manifestations and complications using Immusoft's Immune System Programming (ISP™) technology platform.
IPSEN	France	Purchase agreement for the development of Obizur for the treatment of Acquired Hemophilia A including for patients with Congenital Hemophilia A with inhibitors indication in elective or emergency surgery.
KM Biologics	Japan	Agreement for the development collaboration of TAK-755 to overcome the ADAMTS13 deficiency in TTP.
Poseida Therapeutics	U.S.	Research collaboration and exclusive license agreement to utilize Poseida's piggyBac, Cas-CLOVER, biodegradable DNA and RNA nanoparticle delivery technology and other proprietary genetic engineering platforms for up to eight gene therapies. The collaboration will focus on developing non-viral in vivo gene therapy programs, including Poseida's Hemophilia A program.
Selecta Biosciences	U.S.	Research collaboration and license agreement to develop targeted, next-generation gene therapies for two indications within the field of lysosomal storage disorders using Selecta's ImmTOR platform.
Xenetic Biosciences	U.S.	Exclusive R&D license agreement for PolyXen delivery technology for hemophilia factors VII, VIII, IX, X.

Neuroscience

Partner	Country of incorporation	Subject
Anima Biotech	U.S.	Strategic collaboration to discover and develop mRNA translation modulators for genetically-defined neurological diseases.
AstraZeneca	UK	Agreement for the joint development and commercialization of MEDI1341, an alpha-synuclein antibody currently in development as a potential treatment for Parkinson’s disease.
BridGene Biosciences	U.S.	Research collaboration to discover small molecule drugs for “undruggable” targets using BridGene’s chemoproteomics platform.
CNDAP (Cure Network Dolby Acceleration Partners)	U.S.	Research collaboration to develop small molecules targeting tau, a protein involved in Alzheimer’s disease and other major brain disorders.
Denali Therapeutics	U.S.	Strategic option and collaboration agreement to develop and commercialize up to three specified therapeutic product candidates for neurodegenerative diseases, incorporating Denali’s transport vehicle (TV) platform for increased exposure of biotherapeutic products in the brain; options exercised on DNL593/TAK-594 and DNL919/TAK-920 in Q3 FY2021.
Lundbeck	Denmark	Collaboration agreement to develop and commercialize vortioxetine.
Luxna Biotech	Japan	Exclusive worldwide license agreement for the use of Luxna’s breakthrough xeno nucleic acid technology for multiple undisclosed target genes in the area of neurological diseases.
Neurocrine Biosciences	U.S.	Collaboration to develop and commercialize 7 compounds in Takeda’s early-to-mid stage neuroscience pipeline, including TAK-041, TAK-653 and TAK-831. Takeda will be entitled to certain development milestones, commercial milestones and royalties on net sales and will, at certain development events, be able opt in or out of a 50:50 profit share on all clinical programs on an asset-by-asset basis.
PeptiDream	Japan	Collaborative research and exclusive license agreement to create peptide-drug conjugates (PDCs) for neuromuscular and neurodegenerative diseases.
Skyhawk Therapeutics	U.S.	Collaboration and licensing agreement to develop and commercialize RNA modulation therapies targeting neurodegenerative diseases.
StrideBio	U.S.	Collaboration and license agreement to develop <i>in vivo</i> adeno-associated viruses (AAV) based therapies for Friedreich’s Ataxia (FA) and two additional undisclosed targets.
Wave Life Sciences	Singapore	Multi-program option agreement to co-develop and co-commercialize antisense oligonucleotides for a range of neurological diseases.

Gastroenterology

Partner	Country of incorporation	Subject
Ambys Medicines	U.S.	Collaboration agreement for the application of novel modalities, including cell and gene therapy and gain-of-function drug therapy, to meet the urgent need for treatments that restore liver function and prevent the progression to liver failure across multiple liver diseases. Under the terms of the agreement, Takeda has an option to ex-U.S. commercialization rights for the first 4 products that reach an investigational new drug application.
Arcturus	U.S.	Collaboration agreement to develop RNA-based therapeutics for the treatment of non-alcoholic steatohepatitis and other gastrointestinal related disorders using Arcturus’ wholly-owned LUNAR™ lipid-mediated delivery systems and UNA Oligomer chemistry.
Arrowhead Pharmaceuticals	U.S.	Collaboration and licensing agreement to develop fazirsiran (TAK-999; ARO-AAT), a Phase 2 investigational RNA interference (RNAi) therapy in development to treat alpha-1 antitrypsin-associated liver disease (AATLD). ARO-AAT is a potential first-in-class therapy designed to reduce the production of mutant alpha-1 antitrypsin protein, the cause of AATLD progression.
Beacon Discovery	U.S.	Collaboration agreement for the G-protein coupled receptor drug discovery and development program to identify drug candidates for a range of gastrointestinal disorders. The agreement grants Takeda worldwide rights to develop, manufacture and commercialize products resulting from the collaboration.
Cerevance	U.S.	Multi-year research alliance to identify novel target proteins expressed in the central nervous system and to develop new therapies against them for certain GI disorders. Goal of the collaboration is to select, confirm and validate targets from gene expression data sets generated by Cerevance’s NETSseq technology.
COUR Pharmaceuticals	U.S.	Takeda has acquired an exclusive global license to develop and commercialize the investigational medicine TIMP-GLIA (TAK-101), an immune modifying nanoparticle containing gliadin proteins.

Engitix	U.K.	Collaboration and licensing agreement to utilize Engitix’s unique extracellular matrix discovery platform to identify and develop novel therapeutics for liver fibrosis and fibrostenotic inflammatory bowel disease, including Crohn’s disease and ulcerative colitis.
Enterome	France	Collaboration agreement to research and develop microbiome targets thought to play crucial roles in gastrointestinal disorders, including inflammatory bowel diseases (e.g. ulcerative colitis). The agreement includes a global license and co-development of EB8018/TAK-018 in Crohn’s disease.
Finch Therapeutics	U.S.	Global agreement to develop TAK-524, a live biotherapeutic product composed of cultured bacterial strains linked to favorable clinical outcomes in studies of microbiota transplantations in inflammatory bowel disease. Under the terms of the agreement, Takeda has the exclusive worldwide rights to develop and commercialize TAK-524 and rights to follow-on products in inflammatory bowel diseases. Following a contract amendment in Aug 2021, Takeda assumed sole responsibility for development of TAK-524, prior to the start of clinical development.
Genevant Sciences Corporation	U.S.	Collaboration and License Agreements to leverage Genevant’s hepatic stellate cell-partitioning LNP platform to deliver Takeda-designed RNAi oligonucleotides intended to halt or reverse the progression of liver fibrosis, and to deliver Takeda-designed non-viral gene therapies for the treatment of specified rare liver diseases.
NuBiyota	Canada	Collaboration and License Agreement for the development and commercialization of Microbial Ecosystem Therapeutic (MET) products for gastroenterology indications.
Mirum Pharmaceuticals	U.S.	Exclusive licensing agreement for the development and commercialization of maralixibat in Japan for Alagille syndrome (ALGS), progressive familial intrahepatic cholestasis (PFIC), and biliary atresia (BA).
Sosei Heptares	UK	Collaboration and License agreement to leverage Sosei Heptares’s StaR® technology and structural biology expertise with GPCRs to enable structure based drug discovery to advance novel therapeutics for gastroenterology diseases.
Theravance Biopharma	U.S.	Global license, development and commercialization agreement for TAK-954, a selective 5-HT4 receptor agonist for motility disorders.
UCSD/Fortis Advisors	U.S.	Technology license for the development of oral budesonide formulation (TAK-721) for treatment of eosinophilic esophagitis.

Plasma Derived Therapies

Partner	Country of incorporation	Subject
Halozyme	U.S.	Agreement for the in-license of Halozyme’s proprietary ENHANZE™ platform technology to increase dispersion and absorption of HyQvia. Ongoing development work for a U.S. pediatric indication to treat primary immunodeficiencies and a Phase 3 indication in Chronic Inflammatory Demyelinating Polyradiculoneuropathy.
Kamada	Israel	In-license agreement to develop and commercialize IV Alpha-1 proteinase inhibitor (Glassia); Exclusive supply and distribution of Glassia in the U.S., Canada, Australia and New Zealand; work on post market commitments ongoing.
Johnson & Johnson/Momenta Pharmaceuticals	U.S.	In-licensing agreement with Momenta Pharmaceuticals, Inc. which was acquired by Johnson & Johnson for an investigational hypersialylated immunoglobulin (hslgG) candidate.
ProThera Biologics	U.S.	Global licensing agreement to develop a novel plasma-derived Inter-alpha Inhibitor Proteins (IAIP) therapy for the treatment of acute inflammatory conditions.
PreviPharma	EU	Research collaboration and option agreement to develop new targeted proteins

Vaccines

Partner	Country of incorporation	Subject
U.S. Government - The Biomedical Advanced Research and Development Authority (BARDA)	U.S.	Partnership to develop TAK-426, a Zika vaccine candidate, for the U.S. with the option to use data generated for filing also in affected regions around the world.
Novavax	U.S.	Partnership for the development, manufacturing and commercialization of Nuvaxovid Intramuscular Injection, Novavax' COVID-19 vaccine in Japan, which is being funded by the Government of Japan's Ministry of Health, Labour and Welfare (MHLW) and Agency for Medical Research and Development (AMED). Takeda finalized an agreement with the MHLW to supply 150 million doses of Nuvaxovid, the supply of which will be dependent on many factors, including need.
Moderna	U.S.	Three-way agreement with Moderna and the Government of Japan's Ministry of Health Labour & Welfare (MHLW) to import and distribute Moderna's COVID-19 vaccine, known as Spikevax Intramuscular Injection in Japan. The MHLW granted special approval for the primary series in May 2021 and regulatory approval for a 50 µg booster dose in December 2021. Takeda started importation of 93 million doses (50 µg booster dose) to Japan in 2022, in addition to the 50 million doses (100 µg) delivered in 2021. As of August 2022, Moderna will assume responsibility for all Spikevax™ activities, including import, local regulatory, development, quality assurance and commercialization. Takeda will continue to provide distribution support under the current national vaccination campaign for Moderna COVID-19 vaccines for a transitional period. Both companies will be responsible for ensuring proper implementation of operations associated with this transfer.

Other / Multiple Therapeutic Area

Partner	Country of incorporation	Subject
Bridge Medicines	U.S.	Partnership with Tri-Institutional Therapeutics Discovery Institute, Bay City Capital and Deerfield Management in the establishment of Bridge Medicines. Bridge Medicines will give financial, operational and managerial support to move projects seamlessly from a validating, proof-of-concept study to an in-human clinical trial.
Center for iPS Cell Research Application, Kyoto University (CiRA)	Japan	Collaboration agreement for clinical applications of iPS cells in Takeda strategic areas including applications in neurosciences, oncology and GI as well as discovery efforts in additional areas of compelling iPSC translational science.
Charles River Laboratories	U.S.	Collaboration on multiple integrated programs across Takeda's core therapeutic areas using Charles River Laboratories' end-to-end drug discovery and safety assessment platform to progress these programs towards candidate status.
Evotec SE	Germany	Research alliance to support Takeda's growing number of research stage gene therapy discovery programs. Evotec and Takeda have also entered into a multi-RNA target alliance to discover and develop RNA targeting small molecule therapeutics for targets that are difficult to address via more conventional approaches.
Massachusetts Institute of Technology	U.S.	MIT-Takeda Program to fuel the development and application of artificial intelligence (AI) capabilities to benefit human health and drug development. Centered within the Abdul Latif Jameel Clinic for Machine Learning in Health (J-Clinic), the new program will leverage the combined expertise of both organizations, and is supported by Takeda's three-year investment (with the potential for a two-year extension).
Portal Instruments	U.S.	Agreement for the development and commercialization of Portal's jet injector drug delivery device for potential use with Takeda's investigational or approved biologic medicines.
Schrödinger	U.S.	Agreement for the multi-target research collaboration combining Schrödinger's in silico platform-driven drug discovery capabilities with Takeda's deep therapeutic area knowledge and expertise in structural biology.
Stanford University	U.S.	Collaboration agreement with Stanford University to form the Stanford Alliance for Innovative Medicines to more effectively develop innovative treatments and therapies.
Tri-Institutional Therapeutics Discovery Institute (Tri-I TDI)	U.S.	Agreement for the collaboration of academic institutions and industry to more effectively develop innovative treatments and therapies.
Twist Bioscience	U.S.	Agreement and license for Takeda to access Twist's "Library of Libraries," a panel of synthetic antibody phage display libraries derived only from sequences that exist in the human body. Together, the companies will work to discover, validate and optimize new antibody candidates.

Completed Partnerships [Update since April 1st, 2022]

Partner	Country of incorporation	Subject
GammaDelta Therapeutics	U.K.	Collaboration agreement to discover and develop new immunotherapies in oncology using GammaDelta Therapeutics' novel T cell platform based on the unique properties of gamma delta T cells derived from human tissues. Takeda exercised its option to acquire GammaDelta Therapeutics in October 2021. Separately, in January 2022, Takeda exercised its option to acquire Adaptate Biotherapeutics, a UK based spin-out company from GammaDelta Therapeutics focused on developing antibody-based therapeutics for the modulation of variable delta 1 (V δ 1) gamma delta ($\gamma\delta$). Both acquisitions were closed in April 2022.

■ Clinical study protocol summaries

Clinical study protocol summaries are disclosed on the English-language web-site (<https://clinicaltrials.takeda.com/>) and clinical study protocol information in the Japanese-language is disclosed on the Japanese-language web-site (<https://www.takeda.com/what-we-do/research-and-development/takeda-clinical-trial-transparency/>).

We anticipate that this disclosure will assure transparency of information on Takeda's clinical trials for the benefit of healthcare professionals, their patients and other stakeholders, which we believe will contribute to the appropriate use of Takeda's products worldwide.

2. Supplementary Revenue Information

Revenue by region

Year to date

(Bn JPY)	Reported *1				Core CER Change *1*5
	FY21Q1 YTD	FY22Q1 YTD	YOY		YOY
Total revenue	949.6	972.5	22.9	2.4 %	8.3 %
Japan *2	259.0	140.5	(118.4)	(45.7)%	11.3 %
% of revenue	27.3%	14.5%	(12.8)pt		
United States	412.2	501.1	88.8	21.6 %	5.4 %
% of revenue	43.4%	51.5%	8.1pt		
Europe and Canada	178.7	205.6	26.8	15.0 %	9.3 %
% of revenue	18.8%	21.1%	2.3pt		
Growth and Emerging Markets *3	99.7	125.3	25.6	25.7 %	15.1 %
% of revenue	10.5%	12.9%	2.4pt		
Asia (excluding Japan)	40.3	46.1	5.8	14.4 %	2.9 %
% of revenue	4.2%	4.7%	0.5pt		
Latin America	30.1	40.3	10.2	34.0 %	16.7 %
% of revenue	3.2%	4.1%	1.0pt		
Russia/CIS	12.3	17.4	5.0	40.8 %	24.7 %
% of revenue	1.3%	1.8%	0.5pt		
Other *4	17.0	21.6	4.6	26.8 %	34.2 %
% of revenue	1.8%	2.2%	0.4pt		
Of which royalty / service income *2	157.7	33.6	(124.1)	(78.7)%	30.9 %

*1 Revenue amount is classified into countries or regions based on the customer location.

*2 The 133.0 billion JPY selling price of the sale of diabetes portfolio in Japan is included in FY21Q1YTD.

*3 GEM: Growth and Emerging Markets, which include Asia (excluding Japan), Latin America, Russia/CIS, Middle East, Oceania and Africa.

*4 Other region includes Middle East, Oceania and Africa.

*5 Refer to "[Financial Appendix](#)" for the definition and reconciliations of core financial measures and CER (Constant Exchange Rate).

Quarterly

(Bn JPY)	Reported *1											
	FY21				FY22							
	Q1	Q2	Q3	Q4	Q1	YOY	Q2	YOY	Q3	YOY	Q4	YOY
Total revenue	949.6	844.8	901.3	873.3	972.5	2.4%						
Japan *2	259.0	131.9	139.4	128.7	140.5	(45.7%)						
% of revenue	27.3%	15.6%	15.5%	14.7%	14.5%							
United States	412.2	426.2	458.6	417.4	501.1	21.6%						
% of revenue	43.4%	50.4%	50.9%	47.8%	51.5%							
Europe and Canada	178.7	175.2	187.0	198.2	205.6	15.0%						
% of revenue	18.8%	20.7%	20.7%	22.7%	21.1%							
Growth and Emerging Markets *3	99.7	111.5	116.3	129.0	125.3	25.7%						
% of revenue	10.5%	13.2%	12.9%	14.8%	12.9%							
Asia (excluding Japan)	40.3	49.4	50.1	57.2	46.1	14.4%						
% of revenue	4.2%	5.8%	5.6%	6.5%	4.7%							
Latin America	30.1	31.3	32.2	34.9	40.3	34.0%						
% of revenue	3.2%	3.7%	3.6%	4.0%	4.1%							
Russia/CIS	12.3	12.8	18.5	18.5	17.4	40.8%						
% of revenue	1.3%	1.5%	2.1%	2.1%	1.8%							
Other *4	17.0	18.0	15.5	18.4	21.6	26.8%						
% of revenue	1.8%	2.1%	1.7%	2.1%	2.2%							
Of which royalty / service income *2	157.7	25.4	27.4	62.7	33.6	(78.7%)						

*1 Revenue amount is classified into countries or regions based on the customer location.

*2 The 133.0 billion JPY selling price of the sale of diabetes portfolio in Japan is included in FY21Q1.

*3 GEM: Growth and Emerging Markets, which include Asia (excluding Japan), Latin America, Russia/CIS, Middle East, Oceania and Africa.

*4 Other region includes Middle East, Oceania and Africa.

Product Sales Analysis (vs PY Reported Actual) (Sales amount includes royalty income and service income)

- Year to date

(Bn JPY)	Reported												
	FY21Q1 YTD	FY22Q1 YTD	YOY	US	YOY	Japan	YOY	EUCAN	YOY	GEM*5	YOY	Ex-US	YOY
GI	210.5	270.4	28.4 %	158.4	34.7 %	28.7	12.1 %	55.7	18.3 %	22.2	38.8 %	5.4	26.6 %
ENTYVIO	125.4	168.3	34.2 %	117.9	40.9 %	3.3	29.4 %	38.9	18.8 %	8.2	27.7 %		
TAKECAB/VOCINTI *1	24.3	27.6	13.9 %	—	-	24.0	4.9 %	—	-	3.6	164.1 %		
GATTEX/REVESTIVE	18.1	21.9	20.9 %	16.9	11.1 %	1.1	-	3.2	17.6 %	0.8	232.4 %		
DEXILANT	10.8	22.3	107.0 %	14.9	147.3 %	—	-	3.0	35.5 %	4.4	74.5 %		
PANTOLOC/CONTROLOC*2	10.4	11.3	8.5 %	0.9	37.7 %	—	-	7.4	11.4 %	3.0	(3.8)%		
LIALDA/MEZAVANT *3	6.4	5.7	(10.9)%	0.4	(83.6)%							5.4	26.6 %
PENTASA	4.8	2.6	(47.2)%	2.6	(47.2)%								
RESOLOR/MOTEGRITY	3.2	3.9	21.8 %	3.2	42.1 %	—	-	0.7	(25.1)%	—	-		
ALOFISEL	0.4	0.6	59.3 %	—	-	0.0	-	0.5	58.6 %	0.1	40.5 %		
Others	6.7	6.1	(8.5)%	1.7	(38.8)%	0.3	73.7 %	2.0	34.1 %	2.1	(6.4)%		
Rare Diseases	155.5	181.6	16.8 %	82.6	16.0 %	9.7	17.1 %	51.0	7.5 %	38.3	34.5 %		
Rare Hematology	72.2	79.1	9.6 %	35.6	7.0 %	6.0	(7.0)%	17.1	(5.0)%	20.5	40.9 %		
ADVATE	30.7	32.1	4.7 %	16.7	10.8 %	1.0	(34.7)%	6.2	(12.1)%	8.1	17.7 %		
ADYNOVATE/ADYNOVI	15.4	17.5	13.9 %	8.2	19.4 %	3.6	(1.9)%	4.1	13.9 %	1.6	31.0 %		
FEIBA *4	11.4	10.5	(7.6)%	2.9	(26.5)%	0.3	19.8 %	2.1	(34.2)%	5.3	29.2 %		
RECOMBIMATE	3.7	3.2	(12.7)%	3.1	(12.0)%	—	-	0.2	(22.7)%	0.0	(23.5)%		
HEMOFIL/IMMUNATE/IMMUNINE*4	3.3	5.4	63.9 %	0.9	5.9 %	—	-	1.0	(1.6)%	3.5	148.1 %		
Other PDT Products *4	0.9	1.1	31.8 %	—	(100.0)%	—	-	1.0	18.3 %	0.2	441.4 %		
Others	6.9	9.2	33.3 %	3.9	24.4 %	1.0	14.1 %	2.5	22.6 %	1.8	115.2 %		
Rare Genetics and Other	83.3	102.5	23.1 %	47.0	23.9 %	3.7	100.0 %	34.0	15.1 %	17.8	27.7 %		
TAKHZYRO	25.5	34.0	33.7 %	24.8	24.6 %	0.3	-	7.4	49.3 %	1.6	153.3 %		
ELAPRASE	18.6	22.2	19.3 %	6.4	28.4 %	0.3	(39.5)%	7.7	15.0 %	7.8	20.7 %		
REPLAGAL	14.1	17.6	25.3 %	—	-	2.4	207.5 %	10.0	12.6 %	5.2	18.2 %		
VPRIV	10.5	11.9	13.5 %	5.0	13.9 %	0.3	(11.4)%	4.1	6.3 %	2.4	32.4 %		
FIRAZYR	6.9	6.8	(1.7)%	4.0	15.6 %	0.5	43.6 %	1.6	(38.5)%	0.7	35.8 %		
CINRYZE *4	5.6	4.7	(16.7)%	3.2	(23.5)%	—	-	1.4	4.4 %	0.1	(19.9)%		
LIVTENCITY	—	2.2	-	2.2	-	—	-	0.0	-	—	-		
Others	2.2	3.2	42.0 %	1.4	35.6 %	—	-	1.7	49.2 %	0.0	(25.8)%		

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

*2 generic name: pantoprazole

*3 License-out product : Regional breakdown is not available due to contract.

*4 PDT products

*5 GEM: Growth and Emerging Markets, which include Asia (excluding Japan), Latin America, Russia/CIS, Middle East, Oceania and Africa

(Bn JPY)	Reported												
	FY21Q1 YTD	FY22Q1 YTD	YOY	US	YOY	Japan	YOY	EUCAN	YOY	GEM*5	YOY	Ex-US	YOY
PDT Immunology	107.2	141.9	32.3 %	95.3	35.6 %							46.6	26.2 %
immunoglobulin *1	81.6	111.8	37.0 %	83.5	41.4 %							28.4	25.6 %
albumin *1	17.8	22.0	23.8 %	5.8	10.4 %							16.2	29.5 %
Others *1	7.8	8.0	2.8 %	6.0	0.2 %							2.0	11.1 %
Oncology	121.4	117.5	(3.2)%	48.2	(20.2)%	23.6	12.3 %	24.0	13.1 %	19.7	18.1 %	2.0	(3.1)%
VELCADE *2	30.1	16.5	(45.3)%	15.9	(45.7)%							0.5	(29.8)%
LEUPLIN/ENANTONE	26.2	28.0	6.8 %	4.9	1.3 %	6.6	(12.3)%	10.1	4.5 %	6.4	52.1 %		
NINLARO	24.4	23.7	(2.6)%	14.8	(4.0)%	1.8	20.7 %	3.6	3.4 %	3.6	(10.8)%		
ADCETRIS	17.2	20.0	15.9 %			3.3	17.3 %	8.5	22.7 %	8.1	9.0 %		
ICLUSIG *2	10.4	11.3	8.6 %	9.8	8.0 %							1.5	12.8 %
VECTIBIX	6.2	6.7	8.4 %			6.7	8.4 %						
ALUNBRIG	3.1	4.5	45.9 %	1.9	11.8 %	0.5	133.9 %	1.4	74.7 %	0.7	86.0 %		
ZEJULA	1.6	3.0	94.0 %			2.5	94.1 %			0.6	93.7 %		
CABOMETYX	1.6	2.1	34.3 %			2.1	34.3 %						
EXKIVITY	—	0.7	-	0.7	-	—	-	—	-	0.0	-		
Others	0.6	1.0	47.7 %	0.3	105.0 %	0.2	-	0.3	12.8 %	0.2	(21.6)%		
Neuroscience	113.4	142.4	25.6 %	108.4	24.2 %	9.7	29.3 %	20.4	28.9 %	3.9	39.5 %		
VYVANSE/ELVANSE	79.2	100.0	26.2 %	80.0	22.8 %	0.2	13,929.4 %	16.1	40.2 %	3.6	41.9 %		
TRINTELLIX	17.9	21.4	20.0 %	19.5	16.9 %	1.9	64.6 %			—	-		
INTUNIV	3.3	5.1	57.3 %	0.2	-	2.2	522.6 %	2.4	(10.9)%	0.2	12.8 %		
ADDERALL XR	3.9	6.2	56.4 %	5.6	60.5 %	—	-	0.6	24.6 %	—	-		
ROZEREM	3.2	3.3	2.9 %	0.0	(53.1)%	3.2	4.5 %	0.0	-	0.0	29.2 %		
Others	5.9	6.4	8.4 %	2.9	60.3 %	2.2	(25.7)%	1.3	13.1 %	—	(100.0)%		
Others *3	241.6	118.7	(50.9)%										
AZILVA *4	22.6	19.6	(13.6)%	—	-	19.6	(13.6)%	—	-	—	-		
LOTRIGA	7.8	8.4	7.5 %			8.4	7.5 %						
FOSRENOL *2	3.4	4.2	24.9 %	0.7	23.9 %							3.5	25.2 %
ACTOVEGIN	3.2	3.2	(1.1)%	—	-	—	-	0.0	(77.6)%	3.1	4.3 %		

*1 PDT products

*2 License-out product : Regional breakdown is not available due to contract.

*3 The 133.0 billion JPY selling price of the sale of diabetes portfolio in Japan is included in FY21Q1YTD.

*4 The figures include the amounts of fixed dose combinations.

*5 GEM: Growth and Emerging Markets, which include Asia (excluding Japan), Latin America, Russia/CIS, Middle East, Oceania and Africa

Product Sales Analysis (Reported & Core CER Change)

(Bn JPY)	FY21 Reported				FY22 Reported & Core CER Change															
	Q1	Q2	Q3	Q4	YOY			YOY				YOY				YOY				
					Q1	Reported (QTD)	Core@CER (QTD)	Q2	Reported (QTD)	Core@CER (QTD)	Core@CER (YTD)	Q3	Reported (QTD)	Core@CER (QTD)	Core@CER (YTD)	Q4	Reported (QTD)	Core@CER (QTD)	Core@CER (YTD)	
GI	210.5	218.6	236.6	210.0	270.4	28.4 %	15.4 %													
ENTYVIO	125.4	130.5	139.5	126.4	168.3	34.2 %	19.4 %													
TAKECAB/VOCINTI *1	24.3	24.8	29.3	24.0	27.6	13.9 %	11.8 %													
GATTEX/REVESTIVE	18.1	18.7	19.8	19.1	21.9	20.9 %	7.0 %													
DEXILANT	10.8	14.9	14.4	10.6	22.3	107.0 %	76.5 %													
PANTOLOC/CONTROLOC*2	10.4	9.4	10.2	10.2	11.3	8.5 %	2.1 %													
LIALDA/MEZAVANT	6.4	5.3	7.3	7.4	5.7	(10.9)%	(18.2)%													
PENTASA	4.8	5.2	5.7	4.4	2.6	(47.2)%	(54.1)%													
RESOLOR/MOTTEGRITY	3.2	3.2	3.7	2.9	3.9	21.8 %	7.3 %													
ALOFISEL	0.4	0.4	0.6	0.5	0.6	59.3 %	50.0 %													
Others	6.7	6.1	6.1	4.4	6.1	(8.5)%	(15.9)%													
Rare Diseases	155.5	144.6	162.8	148.3	181.6	16.8 %	7.3 %													
Rare Hematology	72.2	69.4	70.0	72.1	79.1	9.6 %	0.7 %													
ADVATE	30.7	30.6	28.0	29.2	32.1	4.7 %	(4.7)%													
ADYNOVATE/ADYNOVI	15.4	14.6	15.9	14.9	17.5	13.9 %	4.8 %													
FEIBA *3	11.4	8.8	8.8	10.2	10.5	(7.6)%	(12.3)%													
RECOMBINATE	3.7	2.6	3.3	2.7	3.2	(12.7)%	(24.1)%													
HEMOFIL/IMMUNATE/ IMMUNINE*3	3.3	5.1	5.2	4.2	5.4	63.9 %	53.9 %													
Other PDT Products *3	0.9	1.1	1.1	0.9	1.1	31.8 %	25.1 %													
Others	6.9	6.6	7.7	10.1	9.2	33.3 %	21.3 %													
Rare Genetics and Other	83.3	75.2	92.8	76.2	102.5	23.1 %	13.1 %													
TAKHZYRO	25.5	22.1	30.9	24.8	34.0	33.7 %	18.7 %													
ELAPRASE	18.6	16.2	22.9	15.4	22.2	19.3 %	12.0 %													
REPLAGAL	14.1	11.9	13.6	12.1	17.6	25.3 %	21.5 %													
VPRIV	10.5	10.5	11.2	10.2	11.9	13.5 %	4.3 %													
FIRAZYR	6.9	7.5	7.1	5.2	6.8	(1.7)%	(11.5)%													
CINRYZE *3	5.6	4.6	4.5	4.6	4.7	(16.7)%	(24.8)%													
LIVTENCITY	—	—	0.2	1.1	2.2	-	-													
Others	2.2	2.4	2.4	2.6	3.2	42.0 %	30.4 %													

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

*2 Generic name: pantoprazole

*3 PDT products

Refer to "[Financial Appendix](#)" for the definition and reconciliations of core financial measures and CER (Constant Exchange Rate).

[Table of Contents](#)

(Bn JPY)	FY21 Reported				FY22 Reported & Core CER Change														
	Q1	Q2	Q3	Q4	YOY			YOY				YOY				YOY			
					Q1	Reported (QTD)	Core@CER (QTD)	Q2	Reported (QTD)	Core@CER (QTD)	Core@CER (YTD)	Q3	Reported (QTD)	Core@CER (QTD)	Core@CER (YTD)	Q4	Reported (QTD)	Core@CER (QTD)	Core@CER (YTD)
PDT Immunology	107.2	130.8	125.2	143.7	141.9	32.3 %	18.0 %												
immunoglobulin *1	81.6	99.7	97.0	107.6	111.8	37.0 %	22.1 %												
albumin *1	17.8	24.0	19.7	28.5	22.0	23.8 %	10.5 %												
Others *1	7.8	7.1	8.5	7.6	8.0	2.8 %	(8.3)%												
Oncology	121.4	112.3	125.4	109.6	117.5	(3.2)%	(10.1)%												
VELCADE	30.1	25.0	29.3	25.6	16.5	(45.3)%	(52.2)%												
LEUPLIN/ENANTONE	26.2	27.6	28.4	24.2	28.0	6.8 %	2.8 %												
NINLARO	24.4	21.4	24.9	20.5	23.7	(2.6)%	(12.8)%												
ADCETRIS	17.2	16.9	17.6	17.4	20.0	15.9 %	10.5 %												
ICLUSIG	10.4	7.5	8.8	8.2	11.3	8.6 %	(4.1)%												
VECTIBIX	6.2	6.6	6.6	5.3	6.7	8.4 %	8.4 %												
ALUNBRIG	3.1	3.1	3.9	3.5	4.5	45.9 %	34.7 %												
ZEJULA	1.6	1.8	2.4	2.2	3.0	94.0 %	92.2 %												
CABOMETYX	1.6	1.5	1.8	1.6	2.1	34.3 %	34.3 %												
EXKIVITY	—	0.2	0.2	0.5	0.7	-	-												
Others	0.6	0.7	1.4	0.6	1.0	47.7 %	44.0 %												
Neuroscience	113.4	120.3	128.9	119.7	142.4	25.6 %	10.7 %												
VYVANSE/ELVANSE	79.2	80.1	85.7	82.1	100.0	26.2 %	10.3 %												
TRINTELLIX	17.9	22.2	23.0	19.3	21.4	20.0 %	5.2 %												
INTUNIV	3.3	4.2	5.0	6.4	5.1	57.3 %	49.1 %												
ADDERALL XR	3.9	5.7	6.3	4.9	6.2	56.4 %	33.9 %												
ROZEREM	3.2	3.1	3.1	2.2	3.3	2.9 %	2.5 %												
Others	5.9	5.1	5.7	4.7	6.4	8.4 %	1.0 %												
Others *2	241.6	118.2	122.3	142.0	118.7	(50.9)%	4.8 %												
AZILVA *3	22.6	17.7	19.7	16.2	19.6	(13.6)%	(13.6)%												
LOTRIGA	7.8	8.2	8.7	7.9	8.4	7.5 %	7.5 %												
FOSRENOL	3.4	3.6	3.2	3.4	4.2	24.9 %	16.3 %												
ACTOVEGIN	3.2	3.5	4.3	2.4	3.2	(1.1)%	(16.6)%												

*1 PDT products

*2 The 133.0 billion JPY selling price of the sale of diabetes portfolio in Japan is included in FY21Q1 Reported.

*3 The figures include the amounts of fixed dose combinations.

Refer to "[Financial Appendix](#)" for the definition and reconciliations of core financial measures and CER (Constant Exchange Rate).

Product Forecasts

(Bn JPY)	FY21 Reported	FY22 Reported Forecasts			FY22 Core CER Forecasts
	Annual	Annual	YOY		
GI	875.7	Mid-teen growth			Low-teen growth
ENTYVIO	521.8	659.0	137.2	26 %	20 %
TAKECAB/VOCINTI *1	102.4	112.0	9.6	9 %	9 %
GATTEX/REVESTIVE	75.8	91.0	15.2	20 %	15 %
DEXILANT	50.8	40.0	(10.8)	(21)%	(26)%
PANTOLOC/CONTROLOC*2	40.3	40.0	(0.3)	(1)%	(3)%
LIALDA/MEZAVANT	26.5	23.0	(3.5)	(13)%	(15)%
PENTASA	20.2	17.0	(3.2)	(16)%	(21)%
RESOLOR/MOTEGRITY	13.0	14.0	1.0	8 %	4 %
ALOFISEL	1.8	4.0	2.2	117 %	102 %
Others	23.2			-25% to -20%	-30% to -25%
Rare Diseases	611.2				
Rare Hematology	283.7	Low-single-digit growth			Low-single-digit decrease
ADVATE	118.5	173.0	(6.2)	(3)%	(8)%
ADYNOVATE/ADYNOVI	60.7				
FEIBA *3	39.2	38.0	(1.2)	(3)%	(7)%
RECOMBINATE	12.3	13.0	0.7	6 %	4 %
HEMOFIL/IMMUNATE/IMMUNINE*3	17.7	19.0	1.3	7 %	4 %
Other PDT Products *3	3.9	4.0	0.1	2 %	4 %
Others	31.4			+25% to +30%	+20% to +25%
Rare Genetics and Other	327.5	Low-teen growth			High-single-digit growth
TAKHZYRO	103.2	125.0	21.8	21 %	15 %
ELAPRASE	73.1	77.0	3.9	5 %	4 %
REPLAGAL	51.7	68.0	16.3	31 %	30 %
VPRIV	42.4	46.0	3.6	8 %	6 %
FIRAZYR	26.7	21.0	(5.7)	(21)%	(25)%
CINRYZE *3	19.3	13.0	(6.3)	(33)%	(37)%
LIVTENCITY	1.3			+>200%	+>200%
Others	9.7			-20% to -10%	-30% to -20%

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

*2 Generic name: pantoprazole

*3 PDT products

Average FX rates for FY21: 1 USD = 112 JPY, 1 Euro = 131 JPY, 1 RUB = 1.5 JPY, 1 BRL = 20.9 JPY, 1 CNY = 17.4 JPY

Assumption of FX rates for FY22 Reported Forecasts : 1 USD = 119 JPY, 1 Euro = 133 JPY, 1 RUB = 1.3 JPY, 1 BRL = 24.0 JPY, 1 CNY = 18.8 JPY

Refer to "[Financial Appendix](#)" for the definition and reconciliations of core financial measures and CER (Constant Exchange Rate).

(Bn JPY)	FY21 Reported	FY22 Reported Forecasts			FY22 Core CER Forecasts
	Annual	Annual	YOY		
PDT Immunology	507.0	+20% to +30%			+10% to +20%
immunoglobulin *1	385.9	+20% to +30%			+10% to +20%
albumin *1	90.0	+20% to +30%			+10% to +20%
Others *1	31.1	0% to +10%			0% to +10%
Oncology	468.7	Low-single-digit decrease			Mid-single-digit decrease
VELCADE	110.0	47.0	(63.0)	(57)%	(61)%
LEUPLIN/ENANTONE	106.5	106.0	(0.5)	(0)%	(3)%
NINLARO	91.2	103.0	11.8	13 %	8 %
ADCETRIS	69.2	75.0	5.8	8 %	7 %
ICLUSIG	34.9	41.0	6.1	18 %	10 %
VECTIBIX	24.7	24.0	(0.7)	(3)%	(3)%
ALUNBRIG	13.6	26.0	12.4	91 %	85 %
ZEJULA	8.0	12.0	4.0	50 %	50 %
CABOMETYX	6.4	8.0	1.6	26 %	26 %
EXKIVITY	1.0	+>300%			+>300%
Others	3.3	+>30%			+>30%
Neuroscience	482.3	High-single-digit growth			Low-single-digit growth
VYVANSE/ELVANSE	327.1	372.0	44.9	14 %	7 %
TRINTELLIX	82.3	95.0	12.7	15 %	9 %
INTUNIV	18.9	19.0	0.1	0 %	(4)%
ADDERALL XR	20.9	9.0	(11.9)	(57)%	(59)%
ROZEREM	11.7	8.0	(3.7)	(31)%	(30)%
Others	21.4	-10% to -5%			-10% to -5%
Others	624.1	->30%			-20% to -10%
AZILVA *2	76.3	73.0	(3.3)	(4)%	(4)%
LOTRIGA	32.7	13.0	(19.7)	(60)%	(60)%
FOSRENOL	13.6	11.0	(2.6)	(19)%	(20)%
ACTOVEGIN	13.4	12.0	(1.4)	(11)%	(3)%

*1 PDT products

*2 The figures include the amounts of fixed dose combinations.

Average FX rates for FY21: 1 USD = 112 JPY, 1 Euro = 131 JPY, 1 RUB = 1.5 JPY, 1 BRL = 20.9 JPY, 1 CNY = 17.4 JPY

Assumption of FX rates for FY22 Reported Forecasts : 1 USD = 119 JPY, 1 Euro = 133 JPY, 1 RUB = 1.3 JPY, 1 BRL = 24.0 JPY, 1 CNY = 18.8 JPY

Refer to "[Financial Appendix](#)" for the definition and reconciliations of core financial measures and CER (Constant Exchange Rate).



FINANCIAL APPENDIX

Definition of Non-IFRS Measures

Definition of Core Financial Measures, Constant Exchange Rate change, and Free Cash Flow [A-1](#)

Definition of EBITDA/Adjusted EBITDA and Net Debt [A-2](#)

Reconciliations and Other Financial Information

FY2022 Q1 Reported Results with Actual and CER % Change [A-3](#)

FY2022 Q1 Core Results with Actual and CER % Change [A-4](#)

FY2022 Q1 Reconciliation from Reported to Core [A-5](#)

FY2021 Q1 Reconciliation from Reported to Core [A-6](#)

Free Cash Flow [A-7](#)

FY2022 Q1 Net Debt to Adjusted EBITDA [A-8](#)

FY2021 Q4 Net Debt to Adjusted EBITDA [A-9](#)

FY2022 Q1 and FY2021 Q1 Net Profit to Adjusted EBITDA Bridge [A-10](#)

FY2022 Q1 Net Profit to Adjusted EBITDA LTM Bridge [A-11](#)

FY2022 Full Year FX Rates Assumptions and Currency Sensitivity [A-12](#)

CAPEX, depreciation and amortization and impairment losses [A-13](#)

FY2022 Full Year Detailed Forecast [A-14](#)

FY2022 Full Year Core Operating Profit Adjustment Items & Cash Flow Forecast [A-15](#)

FY2022 Full Year Reconciliation from Reported Operating Profit to Core Operating Profit [A-16](#)

Important Notice

Important Notice [A-17](#)



Definition of Core Financial Measures, Constant Exchange Rate change, and Free Cash Flow

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

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

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

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

We present **Free Cash Flow** because we believe that this measure is useful to investors as similar measures of liquidity are frequently used by securities analysts, investors and other interested parties in the evaluation of companies in our industry. Free Cash Flow is also used by our management to evaluate our liquidity and our cash flows, particularly as they relate to our ability to meet our liquidity requirements and to support our capital allocation policies. We also believe that Free Cash Flow is helpful to investors in understanding how our strategic divestitures of non-core businesses and of portions of our investment portfolio contribute to the cash flows and liquidity available to us.

We define Free Cash Flow as cash flows from operating activities, subtracting acquisition of property, plant and equipment ("PP&E"), intangible assets and investments as well as removing any other cash that is not available to Takeda's immediate or general business use, and adding proceeds from sales of PP&E, as well as from sales of investments and businesses, net of cash and cash equivalents divested.

The usefulness of Free Cash Flow to investors has significant limitations including, but not limited to, (i) it may not be comparable to similarly titled measures used by other companies, including those in our industry, (ii) it does not reflect the effect of our current and future contractual and other commitments requiring the use or allocation of capital and (iii) the addition of proceeds from sales and redemption of investments and the proceeds from sales of business, net of cash and cash equivalents divested do not reflect cash received from our core ongoing operations. Free Cash Flow should not be considered in isolation and is not, and should not be viewed as, a substitute for cash flows from operating activities or any other measure of liquidity presented in accordance with IFRS. The most directly comparable measure under IFRS for Free Cash Flow is net cash from operating activities.



Definition of EBITDA/Adjusted EBITDA and Net Debt

We present **EBITDA and Adjusted EBITDA** because we believe that these measures are useful to investors as they are frequently used by securities analysts, investors and other interested parties in the evaluation of companies in our industry. We further believe that Adjusted EBITDA is helpful to investors in identifying trends in its business that could otherwise be obscured by certain items unrelated to ongoing operations because they are highly variable, difficult to predict, may substantially impact our results of operations and may limit the ability to evaluate our performance from one period to another on a consistent basis.

EBITDA and Adjusted EBITDA should not be considered in isolation or construed as alternatives to operating income, net profit for the year or any other measure of performance presented in accordance with IFRS. These non-IFRS measures may not be comparable to similarly-titled measures presented by other companies.

The usefulness of EBITDA and Adjusted EBITDA to investors has limitations including, but not limited to, (i) they may not be comparable to similarly titled measures used by other companies, including those in our industry, (ii) they exclude financial information and events, such as the effects of an acquisition or amortization of intangible assets, that some may consider important in evaluating our performance, value or prospects for the future, (iii) they exclude items or types of items that may continue to occur from period to period in the future and (iv) they may not exclude all items which investors may consider to be unrelated to our long-term operations. These non-IFRS measures are not, and should not be viewed as, substitutes for IFRS reported net income (loss). We encourage investors to review our historical financial statements in their entirety and caution investors to IFRS measures as the primary means of evaluating our performance, value and prospects for the future, and EBITDA and Adjusted EBITDA as supplemental measures.

We define EBITDA as consolidated net profit before income tax expenses, depreciation and amortization and net interest expense. We define Adjusted EBITDA as EBITDA further adjusted to exclude impairment losses, other operating expenses and income (excluding depreciation and amortization), finance expenses and income (excluding net interest expense), our share of loss from investments accounted for under the equity method and other items that management believes are unrelated to our core operations such as purchase accounting effects and transaction related costs.

The most closely comparable measure presented in accordance with IFRS is net profit for the year. Please refer to Net Profit to Adjusted EBITDA Bridge for a reconciliation to the respective most closely comparable measures presented in accordance with IFRS.

We present **Net Debt** because we believe that it is useful to investors in that our management uses it to monitor and evaluate our indebtedness, net of cash and cash equivalents, and, in conjunction with Adjusted EBITDA, to monitor our leverage. We also believe that similar measures of indebtedness are frequently used by securities analysts, investors and other interested parties in the evaluation of companies in our industry.

We define Net Debt first by calculating the sum of the current and non-current portions of bonds and loans as shown on our consolidated statement of financial position, which is then adjusted to reflect (i) the use of prior 12-month average exchange rates for non-JPY debt outstanding at the beginning of the period and the use of relevant spot rates for new non-JPY debt incurred and existing non-JPY debt redeemed during the reporting period, which reflects the methodology our management uses to monitor our leverage, and (ii) a 50% equity credit applied to our aggregate principal amount of 500.0 billion hybrid (subordinated) bonds issued in June 2019 by S&P Global Rating Japan in recognition of the equity-like features of those bonds pursuant to such agency's ratings methodology. From this figure, we deduct cash and cash equivalents, excluding cash that is temporarily held by Takeda on behalf of third parties related to vaccine operations and the trade receivables sales program, to calculate Net Debt.

The usefulness of Net Debt to investors has significant limitations including, but not limited to, (i) it may not be comparable to similarly titled measures used by other companies, including those in our industry, (ii) it does not reflect the amounts of interest payments to be paid on our indebtedness, (iii) it does not reflect any restrictions on our ability to prepay or redeem any of our indebtedness, (iv) it does not reflect any fees, costs or other expenses that we may incur in converting cash equivalents to cash, in converting cash from one currency into another or in moving cash within our consolidated group, (v) it applies to gross debt an adjustment for average foreign exchange rates which, although consistent with our financing agreements, does not reflect the actual rates at which we would be able to convert one currency into another and (vi) it reflects an equity credit due to the fact that the amounts of our subordinated bonds, although we believe it to be reasonable, do not affect the status of those instruments as indebtedness. Net Debt should not be considered in isolation and are not, and should not be viewed as, a substitute for bonds and loans or any other measure of indebtedness presented in accordance with IFRS.

The most directly comparable measures under IFRS for Net Debt is bonds and loans. Please refer to Net Debt to Adjusted EBITDA for a reconciliation to this measure.



FY2022 Q1 Reported Results with Actual and CER % Change

(Billion JPY)	FY2021Q1	FY2022Q1		vs. PY	
				ACTUAL % CHANGE	CER % CHANGE ^{*1}
Revenue	949.6	972.5	22.9	2.4%	(6.8)%
Cost of sales	(241.3)	(292.9)	(51.6)	(21.4)%	(11.3)%
Gross profit	708.3	679.6	(28.8)	(4.1)%	(13.0)%
<i>Margin</i>	<i>74.6 %</i>	<i>69.9 %</i>		<i>(4.7) pp</i>	<i>(5.0) pp</i>
SG&A expenses	(219.8)	(231.5)	(11.6)	(5.3)%	4.4%
R&D expenses	(122.5)	(143.6)	(21.1)	(17.2)%	(4.4)%
Amortization of intangible assets associated with products	(102.8)	(117.0)	(14.2)	(13.8)%	(0.6)%
Impairment losses on intangible assets associated with products	—	(14.2)	(14.2)	—	—
Other operating income	11.1	5.5	(5.6)	(50.7)%	(52.5)%
Other operating expenses	(25.8)	(28.2)	(2.4)	(9.4)%	6.2%
Operating profit	248.6	150.5	(98.0)	(39.4)%	(42.2)%
<i>Margin</i>	<i>26.2 %</i>	<i>15.5 %</i>		<i>(10.7) pp</i>	<i>(9.9) pp</i>
Finance income	45.9	60.9	15.1	32.9%	29.8%
Finance expenses	(71.1)	(55.5)	15.6	21.9%	22.8%
Share of profit (loss) of investments accounted for using the equity method	(0.4)	(0.5)	(0.1)	(39.3)%	2.0%
Profit before tax	223.0	155.5	(67.5)	(30.3)%	(33.7)%
Income tax expenses	(85.3)	(50.5)	34.8	40.8%	41.7%
Net profit for the period	137.7	105.0	(32.7)	(23.7)%	(28.7)%
Non-controlling interests	(0.0)	(0.0)	0.0	82.9%	86.4%
Net profit attributable to owners of the Company	137.7	105.0	(32.7)	(23.7)%	(28.7)%
Basic EPS (yen)	87.96	67.94	(20.02)	(22.8)%	(27.8)%

*1 Please refer to A-1 Definition of Core Financial Measures, Constant Exchange Rate change, and Free Cash Flow, for the definition.

Note: % change versus prior year is presented as positive when favorable to profits, and negative when unfavorable to profits.



FY2022 Q1 Core Results with Actual and CER % Change

(Billion JPY)	FY2021 Q1	FY2022 Q1		vs. PY	
				ACTUAL % CHANGE	CER % CHANGE ^{*1}
Revenue	816.6	972.5	155.9	19.1%	8.3%
Cost of sales	(227.9)	(278.2)	(50.4)	(22.1)%	(12.1)%
Gross profit	588.7	694.3	105.5	17.9%	6.9%
<i>Margin</i>	72.1 %	71.4 %		(0.7) pp	(1.0) pp
SG&A expenses	(218.0)	(231.7)	(13.7)	(6.3)%	3.5%
R&D expenses	(121.8)	(143.5)	(21.7)	(17.8)%	(4.9)%
Operating profit	248.9	319.1	70.1	28.2%	17.0%
<i>Margin</i>	30.5 %	32.8 %		2.3 pp	2.4 pp
Finance income	36.3	23.7	(12.6)	(34.8)%	(34.8)%
Finance expenses	(64.0)	(50.8)	13.2	20.6%	20.7%
Share of profit (loss) of investments accounted for using the equity method	2.0	1.0	(1.0)	(50.8)%	(48.5)%
Profit before tax	223.2	292.9	69.7	31.2%	18.8%
Income tax expenses	(46.6)	(68.7)	(22.2)	(47.6)%	(36.0)%
Net profit for the period	176.6	224.2	47.5	26.9%	14.3%
Non-controlling interests	(0.0)	(0.0)	0.0	82.9%	86.4%
Net profit attributable to owners of the Company	176.6	224.1	47.6	26.9%	14.3%
Basic EPS (yen)	113	145	32	28.5%	15.8%

*1 Please refer to A-1 Definition of Core Financial Measures, Constant Exchange Rate change, and Free Cash Flow, for the definition.

Note: % change versus prior year is presented as positive when favorable to profits, and negative when unfavorable to profits.



FY2022 Q1 Reconciliation from Reported to Core

(Billion JPY)	REPORTED	REPORTED TO CORE ADJUSTMENTS				CORE
		Amortization of intangible assets	Impairment of intangible assets	Other operating income/expenses	Others	
Revenue	972.5					972.5
Cost of sales	(292.9)				14.7	(278.2)
Gross profit	679.6				14.7	694.3
SG&A expenses	(231.5)				(0.2)	(231.7)
R&D expenses	(143.6)				0.1	(143.5)
Amortization of intangible assets associated with products	(117.0)	117.0				—
Impairment losses on intangible assets associated with products	(14.2)		14.2			—
Other operating income	5.5			(5.5)		—
Other operating expenses	(28.2)			28.2		—
Operating profit	150.5	117.0	14.2	22.7	14.6	319.1
<i>Margin</i>	15.5 %					32.8%
Finance income and (expenses), net	5.5				(32.6)	(27.1)
Share of profit (loss) of investments accounted for using the equity method	(0.5)				1.5	1.0
Profit before tax	155.5	117.0	14.2	22.7	(16.6)	292.9
Tax expenses	(50.5)	(25.1)	(3.1)	(3.9)	13.8	(68.7)
Non-controlling interests	(0.0)					(0.0)
Net profit attributable to owners of the Company	105.0	92.0	11.1	18.8	(2.7)	224.1
EPS (yen)	68					145
Number of shares (millions)	1,546					1,546



FY2021 Q1 Reconciliation from Reported to Core

(Billion JPY)	REPORTED	REPORTED TO CORE ADJUSTMENTS						CORE
		Amortization of intangible assets	Impairment of intangible assets	Other operating income/expenses	Sale of Japan diabetes portfolio	Irish Tax Assessment *1	Others	
Revenue	949.6		—		(133.0)			816.6
Cost of sales	(241.3)				0.6		12.8	(227.9)
Gross profit	708.3		—		(132.4)		12.8	588.7
SG&A expenses	(219.8)				1.0		0.9	(218.0)
R&D expenses	(122.5)						0.7	(121.8)
Amortization of intangible assets associated with products	(102.8)	102.8						—
Impairment losses on intangible assets associated with products	—							—
Other operating income	11.1			(10.8)			(0.4)	—
Other operating expenses	(25.8)			25.1			0.7	—
Operating profit	248.6	102.8	—	14.3	(131.4)		14.7	248.9
<i>Margin</i>	26.2 %							30.5%
Finance income and (expenses), net	(25.2)						(2.5)	(27.7)
Share of profit (loss) of investments accounted for using the equity method	(0.4)						2.3	2.0
Profit before tax	223.0	102.8	—	14.3	(131.4)		14.5	223.2
Tax expenses	(85.3)	(22.9)		(4.8)	40.2	62.7	(36.5)	(46.6)
Non-controlling interests	(0.0)						0.0	(0.0)
Net profit attributable to owners of the Company	137.7	79.9	—	9.5	(91.2)	62.7	(22.0)	176.6
EPS (yen)	88							113
Number of shares (millions)	1,565							1,565

*1 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.



Free Cash Flow

(Billion JPY)			Change versus the previous year	
	FY2021 Q1	FY2022 Q1		
Net profit	137.7	105.0	(32.7)	(23.7)%
Depreciation, amortization and impairment loss	143.0	172.5	29.5	
Decrease (increase) in trade working capital	(87.7)	(124.2)	(36.5)	
Income taxes paid	(35.9)	(24.9)	11.0	
Tax refunds and interest on tax refunds received	—	4.1	4.1	
Other	9.7	(48.2)	(58.0)	
Net cash from operating activities	166.9	84.2	(82.6)	(49.5)%
Adjustment for cash temporarily held by Takeda on behalf of third parties ^{*1}	5.9	53.5	47.6	
Acquisition of PP&E	(29.8)	(42.1)	(12.3)	
Proceeds from sales of PP&E	0.1	0.0	(0.0)	
Acquisition of intangible assets	(12.5)	(56.3)	(43.8)	
Acquisition of investments	(3.3)	(2.9)	0.3	
Proceeds from sales and redemption of investments	0.5	6.2	5.7	
Proceeds from sales of business, net of cash and cash equivalents divested	2.1	—	(2.1)	
Free Cash Flow	129.9	42.6	(87.3)	(67.2)%

*1 Adjustment refers to cash temporarily held by Takeda on behalf of third parties related to vaccine operations and the trade receivables sales program.

FY2022 Q1 Net Debt to Adjusted EBITDA

NET DEBT/ADJUSTED EBITDA RATIO

(Billion JPY)	FY2022 Q1
Cash and cash equivalents ^{*1}	492.0
Book value debt on consolidated statements of financial position	(4,602.3)
Hybrid bond 50% equity credit	250.0
FX adjustment ^{*2}	414.1
Gross debt ^{*3}	(3,938.2)
Net cash (debt)	(3,446.2)
Net debt/Adjusted EBITDA ratio	2.8 x
Adjusted EBITDA	1,244.3

NET INCREASE (DECREASE) IN CASH

(Billion JPY)	FY2021 Q1	FY2022 Q1	Change versus the previous year	
Net cash from operating activities	166.9	84.2	(82.6)	(49.5)%
Acquisition of PP&E	(29.8)	(42.1)		
Proceeds from sales of PP&E	0.1	0.0		
Acquisition of intangible assets	(12.5)	(56.3)		
Acquisition of investments	(3.3)	(2.9)		
Proceeds from sales and redemption of investments	0.5	6.2		
Acquisition of business, net of cash and cash equivalents acquired	(27.5)	—		
Proceeds from sales of business, net of cash and cash equivalents divested	2.1	—		
Net increase (decrease) in short-term loans and commercial papers	0.0	—		
Repayment of long-term loans	(220.1)	—		
Proceeds from issuance of bonds	—	—		
Repayment of bonds	(22.8)	(26.8)		
Purchase of treasury shares	(2.5)	(26.9)		
Interest paid	(23.2)	(22.8)		
Dividends paid	(132.0)	(128.9)		
Others	(10.4)	(10.0)		
Net increase (decrease) in cash	(314.6)	(226.2)	88.4	(28.1)%

*1 Includes short-term investments which mature or become due within one year from the reporting date and excludes cash temporarily held by Takeda on behalf of third parties related to vaccine operations and the trade receivables sales program.

*2 FX adjustment refers to change from month-end rate to average rate used for non-JPY debt calculation outstanding at the beginning of the period to match with adjusted EBITDA (which is calculated based on average rates). New non-JPY debt incurred and existing non-JPY debt redeemed during the reporting period are translated to JPY at relevant spot rates as of the relevant date.

*3 Bonds and loans of current and non-current liabilities. 250Bn yen reduction in debt due to 500Bn yen hybrid bond issuance in June 2019, given that the hybrid bond qualifies for 50% equity credit for leverage purposes. Includes non-cash adjustments related to debt amortization and FX impact.

FY2021 Q4 Net Debt to Adjusted EBITDA

NET DEBT/ADJUSTED EBITDA RATIO

(Billion JPY)	FY2021
Cash and cash equivalents ^{*1}	642.2
Book value debt on consolidated statements of financial position	(4,345.4)
Hybrid bond 50% equity credit	250.0
FX adjustment ^{*2}	219.4
Gross debt ^{*3}	(3,876.0)
Net cash (debt)	(3,233.8)
Net debt/Adjusted EBITDA ratio	2.8 x
Adjusted EBITDA	1,168.0

NET INCREASE (DECREASE) IN CASH

(Billion JPY)	FY2020	FY2021	vs. PY	
Net cash from operating activities	1,010.9	1,123.1	112.2	11.1 %
Acquisition of PP&E	(111.2)	(123.3)		
Proceeds from sales of PP&E	46.5	1.8		
Acquisition of intangible assets	(125.3)	(62.8)		
Acquisition of investments	(12.6)	(8.3)		
Proceeds from sales and redemption of investments	74.6	16.9		
Acquisition of business, net of cash and cash equivalents acquired	—	(49.7)		
Proceeds from sales of business, net of cash and cash equivalents divested	530.4	28.2		
Net increase (decrease) in short-term loans and commercial papers	(149.0)	(0.0)		
Repayment of long-term loans	(792.5)	(414.1)		
Proceeds from issuance of bonds	1,179.5	249.3		
Repayment of bonds	(859.2)	(396.0)		
Purchase of treasury shares	(2.1)	(77.5)		
Interest paid	(107.3)	(108.2)		
Dividends paid	(283.4)	(283.7)		
Others	(83.1)	(41.1)		
Net increase (decrease) in cash	316.1	(145.3)	(461.4)	-

*1 Includes short-term investments which mature or become due within one year from the reporting date and excludes cash temporarily held by Takeda on behalf of third parties related to vaccine operations and the trade receivables sales program.

*2 FX adjustment refers to change from month-end rate to average rate used for non-JPY debt calculation outstanding at the beginning of the period to match with adjusted EBITDA (which is calculated based on average rates). New non-JPY debt incurred and existing non-JPY debt redeemed during the reporting period are translated to JPY at relevant spot rates as of the relevant date.

*3 Bonds and loans of current and non-current liabilities. 250Bn yen reduction in debt due to 500Bn yen hybrid bond issuance in June 2019, given that the hybrid bond qualifies for 50% equity credit for leverage purposes. Includes non-cash adjustments related to debt amortization and FX impact.



FY2022 Q1 and FY2021 Q1 Net Debt to Adjusted EBITDA Bridge

(Billion JPY)	FY2021 Q1	FY2022 Q1	Change versus the previous year	
Net profit	137.7	105.0	(32.7)	(23.7)%
Income tax expenses	85.3	50.5		
Depreciation and amortization	142.9	158.3		
Interest expense, net	29.9	28.5		
EBITDA	395.9	342.3	(53.6)	(13.5)%
Impairment losses	0.1	14.2		
Other operating expense (income), net, excluding depreciation and amortization and other miscellaneous expenses (non-cash item)	12.6	21.5		
Finance expense (income), net, excluding interest income and expense, net	(4.7)	(34.0)		
Share of loss on investments accounted for under the equity method	0.4	0.5		
Other adjustments:	(108.6)	26.7		
Non-core expense related to COVID-19	3.4	2.7		
Sales of Japan diabetes portfolio and other non-core product divestitures	(131.4)	—		
Impact on profit related to fair value step up of inventory in Shire acquisition	10.8	12.4		
Other costs ^{*1}	8.7	11.6		
Adjusted EBITDA	295.6	371.2	75.6	25.6 %

*1 Includes adjustments for non-cash equity-based compensation expense and other one time non-cash expense.



FY2022 Q1 Net Debt to Adjusted EBITDA LTM Bridge

(Billion JPY)	FY2021 Full Year (Apr-Mar)	FY2021 Q1 (Apr - Jun)	FY2022 Q1 (Apr - Jun)	FY2022 Q1 LTM ^{*1} (Jul-Jun)
Net profit	230.2	137.7	105.0	197.5
Income tax expenses	72.4	85.3	50.5	37.6
Depreciation and amortization	583.2	142.9	158.3	598.5
Interest expense, net	117.8	29.9	28.5	116.4
EBITDA	1,003.6	395.9	342.3	950.0
Impairment losses	54.5	0.1	14.2	68.7
Other operating expense (income), net, excluding depreciation and amortization and other miscellaneous expenses (non-cash item)	106.3	12.6	21.5	115.2
Finance expense (income), net, excluding interest income and expense, net	25.1	(4.7)	(34.0)	(4.2)
Share of loss on investments accounted for under the equity method	15.4	0.4	0.5	15.5
Other adjustments:	(30.2)	(108.6)	26.7	105.0
Non-core expense related to COVID-19	10.4	3.4	2.7	9.7
Sale of Japan diabetes portfolio	(144.8)	(131.4)	—	(13.4)
Impact on profit related to fair value step up of inventory in Shire acquisition	31.9	10.8	12.4	33.5
Other costs ^{*2}	72.4	8.7	11.6	75.2
Adjusted EBITDA	1,174.5	295.6	371.2	1,250.2
EBITDA from divested products ^{*3}	(6.6)			(5.9)
Adjusted EBITDA (LTM)	1,168.0			1,244.3

*1 LTM represents Last Twelve Months (July 2021 - June 2022). Calculated by subtracting FY2021 Q1 from FY2021 Full Year and adding FY2022 Q1.

*2 Includes adjustments for non-cash equity-based compensation expense and other one time non-cash expense.

*3 Represents adjustments for EBITDA from divested products which are removed as part of LTM Adjusted EBITDA.

FX Rates and FY2022 Currency Sensitivity

Average Exchange Rates vs. JPY			Impact of depreciation of yen from April 2022 to March 2023 on FY2022 forecast (100 million JPY)					
	FY2021 Actual (Apr-Jun)	FY2022 Actual (Apr-Jun)	FY2022 Assumption (Apr-Mar)		Revenue (IFRS)	Operating Profit (IFRS)	Net Profit (IFRS)	Core Operating Profit (non-IFRS)
USD	110	127	119	1% depreciation	192.2	34.7	29.8	75.1
				1 yen depreciation	161.7	29.2	25.1	63.2
EUR	132	137	133	1% depreciation	49.6	(31.6)	(33.5)	(21.8)
				1 yen depreciation	37.4	(23.8)	(25.3)	(16.5)
RUB	1.5	1.8	1.3		4.0	2.1	2.1	2.5
CNY	17.0	19.4	18.8	1% depreciation	15.6	8.6	8.6	8.6
BRL	20.2	26.3	24.0		8.8	5.5	5.5	5.6



CAPEX, Depreciation and Amortization and Impairment Losses

(Billion JPY)	FY2021	FY2021 Q1	FY2022 Q1	vs. PY		FY2022 Forecast
Capital expenditures*	186.0	42.3	98.4	56.1	132.6 %	260.0 to 310.0
Tangible assets	123.3	29.8	42.1	12.3	41.2 %	
Intangible assets	62.8	12.5	56.3	43.8	351.7 %	
* Cash flow base						
Depreciation and amortization	579.8	142.0	157.5	15.4	10.9 %	588.0
Depreciation of tangible assets* (A)	132.4	32.4	34.7	2.3	7.0 %	
Amortization of intangible assets (B)	447.4	109.6	122.8	13.2	12.0 %	
Of which Amortization associated with products (C)	418.8	102.8	117.0	14.2	13.8 %	438.0
Of which Amortization excluding intangible assets associated with products (D)	28.6	6.8	5.8	(1.1)	(15.5)%	
* Excluding depreciation from investment properties						
Depreciation and amortization (excluding intangible assets associated with products) (A)+(D)	161.0	39.2	40.4	1.2	3.1 %	150.0
Impairment losses	54.5	0.1	14.2	14.2	— %	
Impairment losses associated with products	54.1	—	14.2	14.2	— %	50.0
Amortization and impairment losses on intangible assets associated with products	472.9	102.8	131.3	28.5	27.7 %	488.0



FY2022 Detailed Forecast

(Billion JPY)	FY2021 Actual	FY2022 Forecast	vs. PY		Variances
Revenue	3,569.0	3,690.0	121.0	3.4 %	Core business growth & Fx tailwind offsetting the decrease from FY2021 booking of 133.0B in reported revenue from sale of Japan diabetes business
Cost of sales	(1,106.8)	N/D ^{*1}			
R&D expenses	(526.1)	(570.0)	(43.9)	(8.3)%	Fx: Majority of R&D spend is in USD. R&D expenses are expected to grow slower than revenue on CER basis
Amortization of intangible assets associated with products	(418.8)	(438.0)	(19.2)	(4.6)%	Fx: Amortization is primarily of USD- and EUR-denominated assets
Impairment losses on intangible assets associated with products	(54.1)	(50.0)	4.1	7.6 %	
Other operating income	43.1	12.0	(31.1)	(72.2)%	Lower divestiture income & other one-offs
Other operating expenses	(159.1)	(73.0)	86.1	54.1 %	Lower restructuring costs, lower pre-launch inventory & other expenses
Operating profit	460.8	520.0	59.2	12.8 %	
Finance income and (expenses), net	(142.9)	(107.0)	35.9	25.1 %	Lower interest expenses, and fewer one-offs
Profit before tax	302.6	411.0	108.4	35.8 %	
Net profit attributable to owners of the Company	230.1	292.0	61.9	26.9 %	
Basic EPS (yen)	147.14	188.13	40.99	27.9 %	
Core Revenue ^{*2}	3,420.5	3,690.0	269.5	7.9 %	Core business growth & Fx tailwind
Core Operating Profit ^{*2}	955.2	1,100.0	144.8	15.2 %	
Core EPS (yen)	425	484	60	14.0 %	
USD/JPY (yen)	112	119	7		
EUR/JPY (yen)	131	133	2		

*1. Not Disclosed.

*2. Please refer to A-1 Definition of Core Financial Measures, Constant Exchange Rate change, and Free Cash Flow, for the definition and A-16 FY2022 Full Year Reconciliation from Reported Operating Profit to Core Operating Profit, for reconciliation.

FY2022 Core Operating Profit Adjustment Items & Cash Flow Forecast



CORE OPERATING PROFIT ADJUSTMENT ITEMS

(Billion JPY)	FY2022 Q1	FY2022 Forecast
Amortization of intangible assets associated with products	117.0	438.0
<i>Of which Shire-acquisition related</i>	94.7	358.0
Impairment losses on intangible assets associated with products	14.2	50.0
Other operating income	(5.5)	(12.0)
Other operating expenses	28.2	73.0
Other Core Operating Profit adjustments	14.6	31.0
<i>Of which Shire-acquisition related to unwind of inventories step-up</i>	12.4	22.0
Total core operating profit adjustments	168.5	580.0

CASH FLOW GUIDANCE

(Billion JPY)	FY2022 Q1	FY2022 Forecast
Free cash flow	42.6	600.0 to 700.0
CAPEX (cash flow base)	(98.4)	(260.0) to (310.0)
Depreciation and amortization (excluding intangible assets associated with products)	(40.4)	(150.0)
Cash tax rate on adjusted EBITDA (excluding divestitures)	N/A	mid-teen %



FY2022 Reconciliation from Reported Operating Profit to Core Operating Profit

(Billion JPY)	REPORTED	REPORTED TO CORE ADJUSTMENTS				CORE
		Amortization of intangible assets	Impairment of intangible assets	Other operating income (expenses)	Others	
Revenue	3,690.0					3,690.0
Cost of sales					24.0	
Gross Profit					24.0	
SG&A and R&D expenses					7.0	
Amortization of intangible assets associated with products	(438.0)	438.0				—
Impairment losses on intangible assets associated with products	(50.0)		50.0			—
Other operating income	12.0			(12.0)		—
Other operating expenses	(73.0)			73.0		—
Operating profit	520.0	438.0	50.0	61.0	31.0	1,100.0

Important Notice

For the purposes of this notice, “report” means this document, any oral presentation, any question and answer session and any written or oral material discussed or distributed by Takeda Pharmaceutical Company Limited (“Takeda”) regarding this report. This report (including any oral briefing and any question-and-answer in connection with it) is not intended to, and does not constitute, represent or form part of any offer, invitation or solicitation of any offer to purchase, otherwise acquire, subscribe for, exchange, sell or otherwise dispose of, any securities or the solicitation of any vote or approval in any jurisdiction. No shares or other securities are being offered to the public by means of this report. No offering of securities shall be made in the United States except pursuant to registration under the U.S. Securities Act of 1933, as amended, or an exemption therefrom. This report is being given (together with any further information which may be provided to the recipient) on the condition that it is for use by the recipient for information purposes only (and not for the evaluation of any investment, acquisition, disposal or any other transaction). Any failure to comply with these restrictions may constitute a violation of applicable securities laws.

The companies in which Takeda directly and indirectly owns investments are separate entities. In this report, “Takeda” is sometimes used for convenience where references are made to Takeda and its subsidiaries in general. Likewise, the words “we”, “us” and “our” are also used to refer to subsidiaries in general or to those who work for them. These expressions are also used where no useful purpose is served by identifying the particular company or companies.

The product names appearing in this document are trademarks or registered trademarks owned by Takeda, or their respective owners.

Forward-Looking Statements

This report and any materials distributed in connection with this report may contain forward-looking statements, beliefs or opinions regarding Takeda’s future business, future position and results of operations, including estimates, forecasts, targets and plans for Takeda. Without limitation, forward-looking statements often include words such as “targets”, “plans”, “believes”, “hopes”, “continues”, “expects”, “aims”, “intends”, “ensures”, “will”, “may”, “should”, “would”, “could”, “anticipates”, “estimates”, “projects” or similar expressions or the negative thereof. These forward-looking statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those expressed or implied by the forward-looking statements: the economic circumstances surrounding Takeda’s global business, including general economic conditions in Japan and the United States; competitive pressures and developments; changes to applicable laws and regulations, including global health care reforms; challenges inherent in new product development, including uncertainty of clinical success and decisions of regulatory authorities and the timing thereof; uncertainty of commercial success for new and existing products; manufacturing difficulties or delays; fluctuations in interest and currency exchange rates; claims or concerns regarding the safety or efficacy of marketed products or product candidates; the impact of health crises, like the novel coronavirus pandemic, on Takeda and its customers and suppliers, including foreign governments in countries in which Takeda operates, or on other facets of its business; the timing and impact of post-merger integration efforts with acquired companies; the ability to divest assets that are not core to Takeda’s operations and the timing of any such divestment(s); the extent to which our internal energy conservation measures and future advancements in renewable energy or low carbon energy technology will enable us to reduce our greenhouse gas emissions; and other factors identified in Takeda’s most recent Annual Report on Form 20-F and Takeda’s other reports filed with the U.S. Securities and Exchange Commission, available on Takeda’s website at: <https://www.takeda.com/investors/sec-filings/> or at www.sec.gov. Takeda does not undertake to update any of the forward-looking statements contained in this report or any other forward-looking statements it may make, except as required by law or stock exchange rule. Past performance is not an indicator of future results and the results or statements of Takeda in this report may not be indicative of, and are not an estimate, forecast, guarantee or projection of Takeda’s future results.

Financial Information and Certain Non-IFRS Financial Measures

Takeda's financial statements are prepared in accordance with International Financial Reporting Standards ("IFRS").

This report and materials distributed in connection with this report include certain financial measures not presented in accordance with IFRS, such as Core Revenue, Core Operating Profit, Core Net Profit, Core EPS, Constant Exchange Rate ("CER") change, Net Debt, EBITDA, Adjusted EBITDA and Free Cash Flow. Takeda's management evaluates results and makes operating and investment decisions using both IFRS and non-IFRS measures included in this presentation. These non-IFRS measures exclude certain income, cost and cash flow items which are included in, or are calculated differently from, the most closely comparable measures presented in accordance with IFRS. By including these non-IFRS measures, management intends to provide investors with additional information to further analyze Takeda's performance and core results, including when controlling for the effect of fluctuations in exchange rates. Takeda's non-IFRS measures are not prepared in accordance with IFRS and such non-IFRS measures should be considered a supplement to, and not a substitute for, measures prepared in accordance with IFRS (which we sometimes refer to as "reported" measures). Investors are encouraged to review the definitions and reconciliations of non-IFRS financial measures to their most directly comparable IFRS measures.

Medical information

This report contains information about products that may not be available in all countries, or may be available under different trademarks, for different indications, in different dosages, or in different strengths. Nothing contained herein should be considered a solicitation, promotion or advertisement for any prescription drugs including the ones under development.