Better Health, Brighter Future

Takeda Quarterly Financial Report

For the Year Ended March 31, 2023

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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

	For the fiscal year ended March 31,		Change versus the previous fiscal year		
(JPY millions)	2022	2023	JPY	Actual % Change	CER % Change
Revenue	3,569,006	4,027,478	458,472	12.8 %	(0.8)%
Operating profit	460,844	490,505	29,661	6.4 %	(1.8)%
Profit before tax	302,571	375,090	72,519	24.0 %	13.4 %
Net profit for the year	230,166	317,038	86,872	37.7 %	23.3 %
Basic earnings per share (JPY)	147.14	204.29	57.15	38.8 %	24.3 %

Core Results

Results of Core Operations

	For the fiscal year ended March 31,		Change versus the previous fiscal year		
(JPY billions)	2022	2023	JPY	Actual % Change	CER % Change
Core Revenue	3,420.5	4,027.5	606.9	17.7 %	3.5 %
Core Operating Profit	955.2	1,188.4	233.2	24.4 %	9.1 %
Core EPS (JPY)	425	558	134	31.5 %	13.9 %

Leverage

	As of	
(JPY billions)	March 31, 2022	March 31, 2023
Net debt	(3,233.8)	(3,716.1)
Adjusted EBITDA	1,168.0	1,421.8
Net debt/Adjusted EBITDA ratio	2.8 x	2.6 x

Consolidated Cash Flows

	For the fiscal year ended March 31,		Change versus the previous fiscal year	
(JPY millions)	2022	2023	JPY	%
Cash flows from (used in) operating activities	1,123,105	977,156	(145,949)	(13.0) %
Cash flows from (used in) investing activities	(198,125)	(607,102)	(408,978)	(206.4) %
Cash flows from (used in) financing activities	(1,070,265)	(709,148)	361,116	33.7 %

Free Cash Flow

	For the fiscal year ended March 31,		Change versus the previous fiscal year	
(JPY billions)	2022	2023	JPY	%
Free Cash Flow	943.7	446.2	(497.5)	(52.7) %

Consolidated Financial Position

(JPY millions)	As of March 31, 2022	As of March 31, 2023	Change versus the previous fiscal year-end JPY	Change versus the previous fiscal year-end %
Non-current Assets	10,584,376	11,559,794	975,418	9.2 %
Current Assets	2,593,642	2,397,956	(195,686)	(7.5) %
Total Assets	**13,178,018**	**13,957,750**	**779,732**	**5.9 %**
Non-current Liabilities	5,348,764	5,121,138	(227,626)	(4.3) %
Current Liabilities	2,145,730	2,481,940	336,210	15.7 %
Total Liabilities	**7,494,495**	**7,603,078**	**108,584**	**1.4 %**
Equity	**5,683,523**	**6,354,672**	**671,148**	**11.8 %**
Total liabilities and equity	**13,178,018**	**13,957,750**	**779,732**	**5.9 %**

Forecast and Management Guidance

*Forecast**

(JPY billions)	FY2022 Actual Results	FY2023 Forecast	Change versus the previous year	
Reported:				
Revenue	4,027.5	3,840.0	(187.5)	(4.7)%
Operating profit	490.5	349.0	(141.5)	(28.8)%
Profit before tax	375.1	185.0	(190.1)	(50.7)%
Net profit for the year (attributable to owners of the Company)	317.0	142.0	(175.0)	(55.2)%
EPS (JPY)	204.29	90.75	(113.54)	(55.6)%
Non-IFRS Measures				
Core Operating Profit	1,188.4	1,015.0	(173.4)	(14.6)%
Core EPS (JPY)	558	434	(124)	(22.2)%
Free cash flow	446.2	400.0 - 500.0		
Dividends per share (JPY)	180	188	8	4.4 %

*Refer to *Analysis of Results of Operations, Financial Position, and Cash Flow "Outlook for the Fiscal Year Ending March 31, 2024"* for details.

Management Guidance

Takeda uses change in Core Revenue, Core Operating Profit and Core EPS at Constant Exchange Rate (CER) basis as its Management Guidance.

	FY2023 Management Guidance CER % Change*
Core Revenue	Low-single-digit % decline
Core Operating Profit	Low-10s % decline
Core EPS	Low-20s % decline

*Refer to *Analysis of Results of Operations, Financial Position, and Cash Flow "Core Results, Definition of Core financial measures and Constant Exchange Rate change"* for the definition.

Revenue by Region

		JPY (millions) For the fiscal year ended March 31,							
		Japan	United States	Europe and Canada	Asia (excluding Japan)	Latin America	Russia/CIS	Other	Total
	2021	658,983	1,714,421	739,168	196,964	128,467	62,057	68,945	3,569,006
	2022	512,043	2,103,772	842,668	225,007	160,375	88,431	95,182	4,027,478
Change versus the previous year	JPY	(146,940)	389,352	103,499	28,042	31,908	26,374	26,237	458,472
	%	(22.3)%	22.7 %	14.0 %	14.2 %	24.8 %	42.5 %	38.1 %	12.8 %

"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 fiscal year ended March 31, 2023 were 633.3 billion JPY.

The research and development (R&D) of biopharmaceutical products is a lengthy and expensive process that can span more than 10 years. The process includes multiple studies to evaluate a product's efficacy and safety, followed by submission to regulatory authorities who review the data and decide whether to grant marketing approval. Only a small number of therapeutic candidates pass such rigorous investigation and become available for use in clinical treatment. Once approved, there is ongoing R&D support for marketed products, including life-cycle management, medical affairs, and other investments.

Clinical trials, which must comply with regional and international regulatory guidelines, generally take five to seven years or longer, and require substantial expenditures. In general, clinical trials are performed in accordance with the guidelines set by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. The relevant regional regulatory authorities are the Food and Drug Administration (FDA) for the United States, the European Medicines Agency (EMA) for the EU, the Ministry of Health, Labour and Welfare (MHLW) for Japan and National Medical Products Administration (NMPA) for China.

The three phases of human clinical trials, which may overlap with each other, are as follows:

Phase 1 ("P-1") clinical trials

Conducted using a small group of healthy adult volunteers in order to evaluate safety and absorption, distribution, metabolism and excretion of the drug.

Phase 2 ("P-2") clinical trials

Conducted using a small group of patient volunteers in order to evaluate safety, efficacy, dosage and administration methods. P-2 clinical trials may be divided into two sub-categories, P-2a and P-2b. P-2a are usually pilot studies designed to demonstrate clinical efficacy or biological activity. P-2b studies look to find the optimum dose at which the drug shows biological activity with minimal side-effects.

Phase 3 ("P-3") clinical trials

Conducted using a large number of patient volunteers in order to evaluate safety and efficacy in comparison to other medications already available or placebo.

Of these three phases, Phase 3 requires the largest expenditures and thus the decision to proceed with Phase 3 testing is a critical business decision in the drug development process. For those drug candidates that pass Phase 3 clinical trials, a New Drug Application ("NDA"), Biologics License Application ("BLA") or a Marketing Authorization Application ("MAA") is submitted to the relevant governmental authorities for approval, which if granted permits the subsequent launch of the drug. The preparation of an NDA, BLA or MAA submission involves considerable data collection, verification, analysis and expense. Even after the launch of the product, health authorities require post-marketing surveillance of adverse events, and they may request a post-marketing study to provide additional information regarding the risks and benefits of the product.

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 (Gastrointestinal and inflammation, neuroscience, oncology, and rare genetics and hematology). We are working to harness the potential of cell and gene therapies by investing in new capabilities and next-generation platforms internally and through a network of partnerships. We are embracing data and digital technologies to improve the quality of innovation and accelerate execution.

Takeda's pipeline is positioned to support both the near-term and 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.

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.

Our key in-house R&D facilities include:

- *Greater Boston Area Research and Development Site*: Our Boston R&D site is located in Cambridge, Massachusetts in the United States. It is the center of our global gastrointestinal and inflammation, oncology, and rare genetics and hematology R&D, and also supports R&D in other areas including plasma-derived therapies and vaccines, as well as research in immunomodulation and biologics. The site is home to the Takeda Cell Therapy engine with a state-of-the-art cell therapy manufacturing facility. Furthermore, Takeda signed a 15-year lease for an approximately 600,000 square foot state-of-the-art R&D and office facility under construction in Kendall Square, which Takeda plans to occupy from 2026.
- *Shonan Heath Innovation Park:* Located in Fujisawa and Kamakura in Kanagawa Prefecture in Japan, the Shonan Health Innovation Park ("Shonan iPark") was opened in 2018 when Takeda transformed its Shonan Research Center into the first pharma-led science park in Japan by opening its doors to external parties and is the primary location for Takeda's neuroscience research. To attract more diverse partners and to further the success of the Shonan iPark, Takeda transferred ownership rights of Shonan iPark to a trustee in 2020 and transferred operation of Shonan iPark to a company established by Takeda in 2023. Takeda, as a flagship tenant, is committed to invigorating life science research in Japan.
- *San Diego Research and Development Site*: Our R&D site located in San Diego, California in the United States supports R&D in the gastrointestinal and inflammation and neuroscience areas. The San Diego research center operates as a "biotech-like" site and leverages internal capabilities such as structural biology and biophysics to catalyze research internally and externally.
- *Vienna, Austria Research and Development Site*: Our R&D site, located in Vienna, Austria, supports programs in R&D and in PDT. The research center focuses on biologics programs in R&D and contains manufacturing sites for plasma derived products.

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

R&D pipeline

Gastrointestinal and Inflammation

In Gastrointestinal and Inflammation, Takeda focuses on delivering innovative, life-changing therapeutics for patients with gastrointestinal diseases including those of the liver as well as other immune-mediated inflammatory diseases. Takeda is maximizing the potential of our inflammatory bowel disease (IBD) franchise around ENTYVIO, including development of a subcutaneous formulation and expansion into other indications such as active chronic pouchitis. Takeda is also expanding its position with GATTEX/REVESTIVE, and ALOFISEL which is currently in Phase 3 trial to support further potential geographic expansion in the U.S. Furthermore, Takeda is progressing a pipeline built through in-house discovery, partnerships and business development, exploring opportunities in inflammatory diseases (IBD, celiac disease, psoriasis, psoriatic arthritis, system lupus erythematosus, others), select liver diseases, and motility disorders. Fazirsiran (TAK-999) is an example of an addition through partnership and a potential first-in-class RNAi for alpha-1 antitrypsin-deficiency associated liver disease in late-stage development. TAK-279 is an example of an acquisition through business development of a late-stage, potential best-in-class oral allosteric tyrosine kinase 2 (TYK2) inhibitor with potential to treat inflammatory diseases.

Note: Therapeutic area name is now "Gastrointestinal and Inflammation" (previously called "Gastroenterology (GI)"), expanding the GI identity, to better reflect our pipeline today and our broad ambition in immune-mediated disease.

ENTYVIO / Generic name: vedolizumab

- In February 2023, Takeda announced late-breaking data from the Phase 3 GRAPHITE study presented at the 2023 Tandem Meetings, demonstrating vedolizumab achieved a statistically significant and clinically meaningful improvement in lower gastrointestinal (GI) acute graft-versus-host disease (aGvHD)-free survival by Day 180 after allogeneic hematopoietic stem cell transplantation (allo-HSCT) with no relevant differences in safety profile versus placebo. The Phase 3, randomized, double-blind, placebo-controlled, multicenter GRAPHITE study evaluated the efficacy and safety of vedolizumab as prophylaxis for intestinal aGvHD in patients undergoing allo-HSCT from unrelated donors for the treatment of hematological malignancies. The study met its primary endpoint, with vedolizumab achieving a statistically significant improvement in intestinal aGvHD-free survival versus placebo by Day 180 after allo-HSCT (85.5% of patients in the vedolizumab arm versus 70.9% in the placebo arm [HR=0.45; 95% CI: 0.27, 0.73; $p<0.001$]). No relevant differences in safety profile between the vedolizumab and placebo arms were observed, and no new safety signals were identified. Treatment-related adverse events were reported in 24.8% versus 28.4%, and treatment related serious adverse events in 8.5% versus 6.5% of patients treated with placebo versus vedolizumab, respectively.

- In March 2023, Takeda announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) approved the use of ENTYVIO Pens for subcutaneous (SC) injection 108 mg / Syringes for SC injection 108 mg (ENTYVIO SC) as maintenance therapy for moderate to severe ulcerative colitis patients with inadequate response to conventional treatment. This approval is based on the MLN0002SC-3027 and MLN0002SC-3030 clinical trials, which are international Phase 3 trials to evaluate the efficacy and safety of Entyvio SC as a maintenance therapy. SC delivery may reduce the number of personnel, equipment, facilities and time necessary for preparation of the intravenous formulation, which may minimize errors in administration of the drug. It is also intended to provide ease of handling, convenience, and reduce the time required per administration.
- In March 2023, Takeda announced that *the New England Journal of Medicine* (NEJM) published positive data from the Phase 4 EARNEST study of vedolizumab for the treatment of chronic pouchitis. The published results showed the Phase 4 EARNEST study met its primary efficacy endpoint of clinical and endoscopic remission, as measured by modified Pouchitis Disease Activity Index (mPDAI), at Week 14 in 31% of participants (16 out of 51) receiving vedolizumab versus 10% (5 out of 51) receiving placebo (95% CI: 5 to 38 percentage point [p.p.] difference; p=0.01). This improved outcome compared with placebo was also seen at the equivalent secondary endpoint at Week 34 (35% of vedolizumab patients [18 out of 51] achieved mPDAI remission compared with 18% [9 out of 51] on placebo [95% CI: 0 to 35 p.p. difference]). Serious adverse events occurred in 6% (3 out of 51) and 8% (4 out of 51) of patients in the vedolizumab and placebo groups, respectively. No new safety signals were identified.
- In April 2023, Takeda announced that the U.S. Food and Drug Administration (FDA) accepted for review its Biologics License Application (BLA) resubmission for the investigational subcutaneous (SC) administration of ENTYVIO for maintenance therapy in adults with moderately to severely active ulcerative colitis (UC) after induction therapy with ENTYVIO intravenous (IV). The resubmission is intended to address FDA feedback in a December 2019 Complete Response Letter (CRL). Since receiving the CRL Takeda has worked closely with the FDA to address the Agency's feedback; this resubmission package includes additional data collected to investigate the use of subcutaneous administration of Entyvio. The contents of the letter were unrelated to the IV formulation of Entyvio, the clinical safety and efficacy data, and conclusions from the pivotal VISIBLE 1 trial supporting the Entyvio SC BLA. VISIBLE 1 assessed the safety and efficacy of a SC formulation of Entyvio as maintenance therapy in 216 adult patients with moderately to severely active UC who achieved clinical response at week 6 following two doses of open-label vedolizumab intravenous therapy at weeks 0 and 2. The primary endpoint was clinical remission at week 52, which was defined as a total Mayo score of ≤2 and no subscore >1. Takeda expects a decision from the FDA by the end of 2023.

Development code: TAK-999 / Generic name: fazirsiran

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

Compared with placebo, no dose-dependent or clinically meaningful changes were observed in pulmonary function tests over 1 year with fazirsiran. The companies also provided an outline of a Phase 3 study that was co-developed by Takeda and Arrowhead and is being conducted by Takeda.

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

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

Development code: TAK-279

- In December 2022, Takeda announced that it would acquire all of the capital stock of Nimbus Lakshi, Inc., a wholly owned subsidiary of Nimbus Therapeutics, LLC, that owns or controls the intellectual property rights and other associated assets related to TAK-279 (formerly known at Nimbus as NDI-034858) from Nimbus Therapeutics, LLC. TAK-279 is a highly selective, oral allosteric tyrosine kinase 2 (TYK2) inhibitor being evaluated for the treatment of multiple autoimmune diseases following successful Phase 2b results in psoriasis. In February 2023, Takeda completed the acquisition of Nimbus Lakshmi, Inc. and TAK-279 which has the potential to demonstrate best-in-class efficacy, safety and convenience in psoriasis as well as multiple other immune-mediated diseases, including inflammatory bowel disease, psoriatic arthritis and systemic lupus erythematosus. This acquisition strengthens Takeda's growing late-stage pipeline and potentially expands its portfolio and patient impact across multiple indications, reinforcing Takeda's ability to maintain strong growth globally in the mid- to long-term.
- In March 2023, Takeda announced positive results from a Phase 2b clinical trial of TAK-279 in patients with moderate-to-severe plaque psoriasis. The study met its primary and secondary endpoints, with a statistically significant greater proportion of TAK-279 patients achieving Psoriasis Area and Severity Index (PASI) 75, 90 and 100 in the 5mg, 15mg and 30mg dosing arms compared to placebo at 12 weeks. These data were presented during a late-breaking session at the American Academy of Dermatology (AAD) Annual Meeting. Results showed a significantly greater proportion of patients achieved PASI 75 at doses ≥5mg at 12 Weeks. At the highest dose of TAK-279, 46% of patients achieved PASI 90 and 33% achieved PASI 100 at 12 weeks, indicating a near-total or total clearance of skin lesions. The frequency of adverse events (AEs) was 53-62% in the treatment arms and 44% in the placebo arm. Most events were mild to moderate in severity. Two serious AEs occurred in one patient (15mg) and were considered unrelated. Changes in laboratory parameters were consistent with known effects of allosteric TYK2 inhibition. Based on these Phase 2b results, Takeda will initiate a Phase 3 study of TAK-279 in psoriasis in FY2023. Takeda expects topline results from a Phase 2b study in psoriatic arthritis in FY2023 and will be evaluating TAK-279 in additional immune-mediated diseases including systemic lupus erythematosus (SLE) and inflammatory bowel disease (IBD). Other indications will be explored in the future.

Neuroscience

In Neuroscience, Takeda is focusing its R&D investments on potentially transformative treatments for neurological and neuromuscular diseases of high unmet need and building its pipeline through a combination of in-house expertise and partnerships. By harnessing advances in disease biology understanding, translational tools, and innovative modalities, Takeda is primarily focusing on rare neurology, in particular, on potential investigative therapies for sleep-wake disorders such as narcolepsy and idiopathic hypersomnia with a franchise of orexin-2 receptor agonists (TAK-861, danavorexton (TAK-925), etc.), rare epilepsies with soticlestat (TAK-935) and central nervous system (CNS) and somatic symptoms of Hunter Syndrome with pabinafusp alfa (TAK-141). Additionally, Takeda makes targeted investments to investigate well-defined segments of neuromuscular diseases, neurodegenerative diseases and movement disorders.

Note: Pabinafusp alfa (TAK-141) and TAK-611 will be developed in Neuroscience starting from FY2023 Q1 and may benefit from Neuroscience's CNS expertise.

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.

Development code: TAK-611

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

Oncology

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

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.
- In February 2023, Takeda announced that it submitted an application in Japan seeking approval of a partial change to the manufacturing and marketing authorization for ADCETRIS concerning the indications, dosage and administration of the drug for the treatment of relapsed or refractory CD30-positive cutaneous T-cell lymphoma (CTCL). The application is based on the results of ALCANZA (C25001), a Phase 3 clinical trial conducted outside of Japan evaluating the efficacy and safety of ADCETRIS in patients with relapsed or refractory CD30-positive cutaneous T-cell lymphoma (CTCL), and the results of SGN-35-OU, a Phase 2 investigator-initiated clinical trial in Japan, which evaluated the efficacy and safety of ADCETRIS in Japanese patients.

VECTIBIX / Generic name: panitumumab

- In June 2022, Takeda announced the data from the PARADIGM, a Phase 3 clinical trial of VECTIBIX in chemotherapy- naive Japanese patients with unresectable advanced recurrent colorectal cancer with wild-type RAS gene, was presented at the Plenary Session of the American Society of Clinical Oncology (ASCO) Annual Meeting. PARADIGM is the first prospective trial to evaluate appropriate treatment options for metastatic colorectal cancer patients with wild-type RAS gene and left-side primary tumor (descending colon, sigmoid colon, and rectum). The results of the trial showed that the mFOLFOX6 + VECTIBIX combination provides a statistically significant improvement in overall survival (OS) over the mFOLFOX6 + bevacizumab combination in patients with a left-sided primary tumor or regardless of tumor locations (median OS for left-sided tumors: 37.9 vs. 34.3, HR=0.82 [95.798% CI: 0.68-0.99], p=0.031, overall median OS: 36.2 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. In April 2023, the results of this trial were published in the *Journal of the American Medical Association* (JAMA).

ICLUSIG / Generic name: ponatinib

- In November 2022, Takeda announced that the randomized, Phase 3 PhALLCON trial met its primary endpoint, demonstrating that adult patients with newly-diagnosed Philadelphia chromosome-positive acute lymphoblastic

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

EXKIVITY / Generic name: mobocertinib

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

Rare Genetics and Hematology

In Rare Genetics and Hematology, Takeda focuses on several areas of high unmet medical need. In hereditary angioedema, Takeda aspires to transform the treatment paradigm, including through TAKHZYRO, with continued investment in lifecycle management programs. In rare hematology, Takeda focuses on addressing today's needs in the treatment of bleeding disorders, including through ADVATE and ADYNOVATE/ADYNOVI, as well as on the development of pipeline assets including apadamtase alfa/cinaxadamtase alfa (TAK-755) for the treatment of immune thrombotic thrombocytopenic purpura (iTTP) and congenital thrombotic thrombocytopenic purpura (cTTP). In addition, Takeda aims to redefine the management of post-transplant cytomegalovirus (CMV) infection/disease with LIVTENCITY. While we recently decided to discontinue discovery and pre-clinical activities in adeno-associated virus (AAV) gene therapy, Takeda remains committed to fulfilling our vision to deliver life-transforming medicines to patients with rare diseases.

TAKHZYRO / Generic name: lanadelumab

- In April 2022, Takeda announced that the Phase 3 SPRING study evaluating the safety profile and pharmacokinetics of TAKHZYRO in patients 2 to <12 years of age is complete and has met its primary objectives. The safety profile was consistent with that seen in the clinical program for patients 12 years of age and older; there were no serious adverse events and no dropouts due to adverse events. The study also successfully reached the secondary objective evaluating the clinical activity/outcome of TAKHZYRO in preventing hereditary angioedema (HAE) attacks as well as characterizing the pharmacodynamics of TAKHZYRO in pediatric subjects 2 to <12 years of age.
- In July 2022, Takeda announced late-breaking data from the Phase 3 SPRING study presented at the European Academy of Allergy and Clinical Immunology (EAACI) Hybrid Congress 2022. The primary objective of the open-label, multicenter, Phase 3 (SPRING) study was to evaluate the safety and pharmacokinetics (PK) of TAKHZYRO in patients aged 2 to <12 years with HAE. Clinical outcomes (prevention of HAE attacks) were measured as a secondary objective. In this study, HAE patients received a dose of 150 mg every 4 weeks in patients 2 to <6 years and every 2 weeks in patients aged 6 to <12 years. TAKHZYRO reduced the rate of HAE attacks in children by a mean of 94.8% compared to baseline, from 1.84 attacks per month to 0.08 attacks during treatment. The majority of patients (76.2%) were attack-free during the 52-week treatment period with an average of 99.5% attack-free days. No deaths or serious treatment-emergent adverse events (TEAEs) were reported during the study, and no patients withdrew from the study due to TEAEs. These results are consistent with earlier studies with adult and adolescent patients. These data will be submitted to global regulatory authorities to evaluate a potential label expansion for TAKHZYRO to include the younger patient population.
- In February 2023, Takeda announced that the U.S. Food and Drug Administration (FDA) approved the supplemental Biologics License Application (sBLA) for the expanded use of TAKHZYRO for prophylaxis to prevent attacks of hereditary angioedema (HAE) in pediatric patients 2 to <12 years of age. The application was granted for priority review by the FDA. The sBLA approval was supported by extrapolation of efficacy data from the HELP Study, a Phase 3 trial that included patients 12 to <18 years of age, and additional pharmacokinetic analyses showing similar drug exposures between adults and pediatric patients, as well as safety and pharmacodynamic data from the SPRING Study, an open-label Phase 3 trial in HAE patients 2 to <12 years of age. Prior to this approval, children with HAE 2 to

<6 years of age had no approved prophylaxis treatment, making TAKHZYRO the first prophylaxis treatment for this age group.

LIVTENCITY / Generic name: maribavir

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

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

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

FIRAZYR / Generic name: icatibant

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

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

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

Plasma-Derived Therapies (PDT)

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

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

- In July 2022, Takeda announced that ADVANCE-1, a randomized, placebo-controlled, double-blind Phase 3 clinical trial evaluating HYQVIA for the maintenance treatment of chronic inflammatory demyelinating polyradiculoneuropathy (CIDP), met its primary endpoint. The pivotal ADVANCE-1 clinical trial evaluated the efficacy, safety and tolerability of HYQVIA in 132 adult patients with CIDP who had been on a stable dosing regimen of intravenous immunoglobulin (IVIG) therapy for at least three months prior to infusion. Analysis of the primary endpoint shows that HYQVIA, when administered at the same dose and dosing interval as the patient's previous IVIG, reduced CIDP relapse as compared to placebo [9.7% vs 31.4%, respectively; p-value = 0.0045], as measured by Inflammatory Neuropathy Cause and Treatment (INCAT). The majority of patients in the study received a four-week dosing regimen of HYQVIA. Of the 62 patients treated with HYQVIA, the majority of treatment-related adverse events were reported as mild or moderate. No new safety risks were reported with HYQVIA. The safety profile of HYQVIA in CIDP will be further supported by data from the ongoing ADVANCE-3 clinical trial, the longest extension study of its kind with up to six years of follow-up data on some participants. With full data analyses, Takeda submitted applications for HYQVIA to regulatory authorities in the United States and European Union in fiscal year 2022.
- In April 2023, Takeda announced that the U.S. Food and Drug Administration (FDA) approved a supplemental biologics license application (sBLA) to expand the use of HYQVIA to treat primary immunodeficiency (PI) in children 2-16 years old. The FDA approval of HYQVIA for the treatment of PI in pediatric patients was based on evidence from a pivotal, prospective, open-label, non-controlled Phase 3 clinical trial that included 44 PI patients between the ages of 2 and 16. During the 12-month trial period, HYQVIA was shown to be efficacious with respect to the occurrence of acute serious bacterial infections (aSBIs), a primary endpoint. The mean aSBI rate per year was 0.04 and was statistically significantly lower (with an upper 1-sided 99% confidence interval of 0.21, $p<0.001$) than the predefined success rate of less than one aSBI per subject per year, favoring efficacy of HYQVIA treatment in pediatric subjects with PI diseases. Results from the interim data analysis, where all subjects completed 12 months of participation (one year of observation period) in the study, indicated similar safety profiles to adults.

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

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

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

- In April 2023, Takeda announced that it submitted a New Drug Application (NDA) to the Japanese Ministry of Health, Labour and Welfare (MHLW) for manufacturing and marketing approval of human dry protein C concentrate (TAK-662) for the treatment of venous thromboembolism and purpura fulminans caused by congenital protein C deficiency, as well as for the suppression of thrombi. The application is based primarily on a Phase 1/2 trial in Japanese patients with congenital protein C deficiency and two Phase 2/3 trials (IMAG-098 and 400101) outside of Japan in patients with congenital protein C deficiency. In these trials, TAK-662 demonstrated its efficacy and safety as a treatment for congenital protein C deficiency.

Vaccine

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

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℃, like many other medicines and vaccines, which enables transportation and storage with conventional vaccine supply chain.

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

- In June 2022, Takeda announced that TAK-003 demonstrated continued protection against dengue fever through four and a half years (54 months), with no important safety risks identified, in the pivotal Phase 3 Tetravalent Immunization against Dengue Efficacy Study (TIDES) trial, which was presented at the 8th Northern European Conference on Travel Medicine (NECTM8). Through four and a half years, TAK-003 demonstrated 84.1% vaccine efficacy (VE) (95% CI: 77.8, 88.6) against hospitalized dengue, with 85.9% VE (78.7, 90.7) in seropositive individuals and 79.3% VE (63.5,88.2) in seronegative individuals. TAK-003 also demonstrated overall VE of 61.2% (95% CI: 56.0, 65.8) against virologically-confirmed dengue, with 64.2% VE (58.4, 69.2) in seropositive individuals and 53.5% VE (41.6, 62.9) in seronegative individuals. Observations of VE varied by serotype and remained consistent with previously reported results. TAK-003 was generally well tolerated, and there were no important safety risks identified. No evidence of disease enhancement was observed over the 54-month follow-up exploratory analysis.
- In August 2022, Takeda announced that its dengue vaccine, QDENGA, was approved by the Indonesian National Agency for Drug and Food Control, Badan Pengawas Obat dan Makanan (BPOM), for the prevention of dengue disease caused by any serotype in individuals six years to 45 years of age. QDENGA is the only dengue vaccine approved in Indonesia for use in individuals regardless of previous dengue exposure and without the need for pre-vaccination testing. The approval of QDENGA is based on results through three years after vaccination from the ongoing Phase 3 TIDES trial.
- In October 2022, Takeda announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommended the approval of QDENGA in Europe and in dengue-endemic countries participating in the parallel EU-M4all procedure. In December 2022, Takeda announced that the European Commission (EC) granted marketing authorization for QDENGA for the prevention of dengue disease caused by any serotype in individuals from four years of age in the European Union (EU). EC's approval was supported by results across 19 Phase 1, 2 and 3 trials with more than 28,000 children and adults, including four and a half years of follow-up data from the global, pivotal Phase 3 TIDES trial. Takeda continues to progress regulatory filings in other dengue-endemic countries in Asia and Latin America.
- In November 2022, Takeda announced that the U.S. Food and Drug Administration (FDA) has accepted and granted priority review of the Biologics License Application (BLA) for TAK-003. In the U.S., TAK-003 is being evaluated for the prevention of dengue disease caused by any dengue virus serotype in individuals 4 years through 60 years of age. TAK-003 BLA is supported by safety and efficacy data from the pivotal Phase 3 TIDES trial.
- In March 2023, Takeda announced that QDENGA was approved in Brazil by the National Health Surveillance Agency (ANVISA) for the prevention of dengue caused by any of the four virus serotypes that can be found in individuals from 4 to 60 years of age. QDENGA is the only dengue vaccine approved in Brazil for use in individuals regardless of previous exposure to dengue and without the need for pre-vaccination testing. The approval is based on results across 19 Phase 1, 2 and 3 trials with more than 28,000 children and adults, including four and a half years of follow-up data from the global, pivotal Phase 3 TIDES trial.

Building a sustainable research platform / Enhancing R&D collaboration

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

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

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

Results of Operations (Reported)

Consolidated Financial Results (April 1, 2022 to March 31, 2023)

Billion JPY or percentage

	For the fiscal year ended March 31,		Change versus the previous fiscal year		
	2022	2023		Actual % Change	CER % Change*1
Revenue	3,569.0	4,027.5	458.5	12.8 %	(0.8)%
Cost of sales	(1,106.8)	(1,244.1)	(137.2)	12.4 %	(0.1)%
Selling, general and administrative expenses	(886.4)	(997.3)	(110.9)	12.5 %	(0.9)%
Research and development expenses	(526.1)	(633.3)	(107.2)	20.4 %	3.5 %
Amortization and impairment losses on intangible assets associated with products	(472.9)	(542.4)	(69.5)	14.7 %	(3.2)%
Other operating income	43.1	25.4	(17.7)	(41.0)%	(44.2)%
Other operating expenses	(159.1)	(145.2)	13.8	(8.7)%	(21.1)%
Operating profit	460.8	490.5	29.7	6.4 %	(1.8)%
Finance income and (expenses), net	(142.9)	(106.8)	36.1	(25.3)%	(28.8)%
Share of loss of investments accounted for using the equity method	(15.4)	(8.6)	6.7	(43.8)%	(50.6)%
Profit before tax	302.6	375.1	72.5	24.0 %	13.4 %
Income tax expenses	(72.4)	(58.1)	14.4	(19.8)%	(18.0)%
Net profit for the year	230.2	317.0	86.9	37.7 %	23.3 %

*1 Please refer to Core Results (April 1, 2022 to March 31, 2023), Definition of Core financial measures and Constant Exchange Rate change, for the definition.

Revenue. Revenue for the fiscal year ended March 31, 2023 was 4,027.5 billion JPY, an increase of 458.5 billion JPY, or 12.8% (CER % change: -0.8%), compared to the previous fiscal year. The increase is primarily attributable to favorable foreign exchange rates and growth from business momentum, fully offsetting the decrease of revenue due to the sale of a portfolio of diabetes products in Japan to Teijin Pharma Limited for 133.0 billion JPY, which was recorded as revenue in the 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 628.0 billion JPY, or 21.3%, compared to the previous fiscal year, to 3,572.9 billion JPY. Each of our core therapeutic areas, except Oncology, contributed to positive revenue growth due to favorable foreign exchange rates and growth from business momentum. Generic erosion and intensified competition impacted certain Oncology products in the fiscal year ended March 31, 2023, partially offset by the impacts of favorable foreign exchange rates.

Revenue outside of our core therapeutic areas significantly decreased by 169.6 billion JPY, or 27.2%, compared to the previous fiscal year to 454.6 billion JPY, largely due to the aforementioned non-recurring 133.0 billion JPY selling price of the diabetes portfolio in Japan, which was recorded as revenue in the previous fiscal year.

Revenue by Geographic Region

The following shows revenue by geographic region:

Billion JPY or percentage

Revenue:	For the fiscal year ended March 31, 2022	2023	Change versus the previous fiscal year	Actual % change	CER % change*1
Japan*2	659.0	512.0	(146.9)	(22.3)%	(22.5)%
United States	1,714.4	2,103.8	389.4	22.7 %	2.0 %
Europe and Canada	739.2	842.7	103.5	14.0 %	5.1 %
Asia (excluding Japan)	197.0	225.0	28.0	14.2 %	2.0 %
Latin America	128.5	160.4	31.9	24.8 %	8.0 %
Russia/CIS	62.1	88.4	26.4	42.5 %	9.5 %
Other*3	68.9	95.2	26.2	38.1 %	41.3 %
Total	3,569.0	4,027.5	458.5	12.8 %	(0.8)%

*1 Please refer to Core Results (April 1, 2022 to March 31, 2023), Definition of Core financial measures and Constant Exchange Rate change, for the definition.

*2 The 133.0 billion JPY selling price of the sale of diabetes portfolio in Japan is included in the fiscal year ended March 31, 2022.

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

Revenue by Therapeutic Area

The following shows revenue by therapeutic area:

Billion JPY or percentage

Revenue:	For the fiscal year ended March 31, 2022	2023	Change versus the previous fiscal year	Actual % change	CER % change*1
GI	875.7	1,094.5	218.9	25.0 %	8.7 %
Rare Diseases	611.2	723.4	112.2	18.4 %	4.8 %
Rare Hematology	283.7	304.7	21.0	7.4 %	(5.1)%
Rare Genetics and Other	327.5	418.7	91.2	27.9 %	13.4 %
PDT Immunology	507.0	678.4	171.5	33.8 %	15.3 %
Oncology	468.7	438.7	(30.0)	(6.4)%	(14.4)%
Neuroscience	482.3	637.7	155.4	32.2 %	12.1 %
Other*2	624.2	454.6	(169.6)	(27.2)%	(32.4)%
Total	3,569.0	4,027.5	458.5	12.8 %	(0.8)%

*1 Please refer to Core Results (April 1, 2022 to March 31, 2023), Definition of Core financial measures and Constant Exchange Rate change, for the definition.

*2 The 133.0 billion JPY selling price of the sale of diabetes portfolio in Japan is included in the fiscal year ended March 31, 2022.

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

- *GI.* In Gastroenterology, revenue was 1,094.5 billion JPY, a year-on-year increase of 218.9 billion JPY, or 25.0% (CER % change: 8.7%).

  Sales of ENTYVIO (for ulcerative colitis (“UC”) and Crohn’s disease (“CD”)), Takeda's top-selling product, were 702.7 billion JPY in total, an increase of 181.0 billion JPY, or 34.7%, versus the previous fiscal year. Sales in the U.S. were 491.9 billion JPY, an increase of 142.4 billion JPY, or 40.7%, driven by favorable foreign exchange rates and a continued increase in the first line biologic inflammatory bowel disease (“IBD”) population both in UC and CD. Sales in Europe and Canada were 162.5 billion JPY, an increase of 26.5 billion JPY, or 19.5%, supported by continued launches of the subcutaneous formulation and favorable foreign exchange rates. Sales in the Growth and Emerging Markets were 34.9 billion JPY, an increase of 9.9 billion JPY, or 39.6%, primarily led by growth in Brazil.

  Sales of DEXILANT (for acid reflux disease) were 69.4 billion JPY, an increase of 18.6 billion JPY, or 36.7%, versus the previous fiscal year, due to the increased sales of authorized generics in the U.S. and favorable foreign exchange rates.

  Sales of GATTEX/REVESTIVE (for short bowel syndrome) were 93.1 billion JPY, an increase of 17.3 billion JPY, or 22.9%, versus the previous fiscal year, primarily due to increased market penetration after launch in Japan, pediatric indication demand, and favorable foreign exchange rates.

Sales of TAKECAB/VOCINTI (for acid-related diseases) were 108.7 billion JPY, an increase of 6.3 billion JPY, or 6.2%, versus the previous fiscal year, primarily due to increased sales in China, partially offset by the decrease of sales in Japan due to a negative impact from the market expansion re-pricing applied in April 2022, despite an increase in prescription volume.

Sales of PENTASA (for UC) were 8.4 billion JPY, a decrease of 11.8 billion JPY, or 58.3%, versus the previous fiscal year, due to generic erosion in the U.S. from May 2022.

- *Rare Diseases*. In Rare Diseases, revenue was 723.4 billion JPY, a year-on-year increase of 112.2 billion JPY, or 18.4% (CER % change: 4.8%).

  Revenue of Rare Hematology was 304.7 billion JPY, a year-on-year increase of 21.0 billion JPY, or 7.4% (CER % change: -5.1%).

  Sales of ADYNOVATE/ADYNOVI (for hemophilia A) were 66.6 billion JPY, an increase of 5.8 billion JPY, or 9.6%, and sales of FEIBA (for hemophilia A and B) were 41.3 billion JPY, an increase of 2.1 billion JPY, or 5.4%, versus the previous fiscal year, primarily due to favorable foreign exchange rates largely offset by negative impacts from competition in the U.S.

  Sales of other Rare Hematology products in aggregate increased year-on-year, primarily due to additional indications, newly consolidated products, and favorable foreign exchange rates.

  Revenue of Rare Genetics and Other was 418.7 billion JPY, a year-on-year increase of 91.2 billion JPY, or 27.9% (CER % change: 13.4%).

  Sales of TAKHZYRO (for hereditary angioedema) were 151.8 billion JPY, an increase of 48.6 billion JPY, or 47.0%, versus the previous fiscal year, driven by continued strong demand in the U.S., geographic expansion, and favorable foreign exchange rates.

  Sales of REPLAGAL (for Fabry disease) were 66.7 billion JPY, an increase of 15.0 billion JPY, or 29.1%, versus the previous fiscal year, primarily due to the succession to Takeda of manufacturing and marketing rights in Japan upon expiration of the relevant license agreement in February 2022 and strong demand in the Growth and Emerging Markets.

  Sales of other enzyme replacement therapies ELAPRASE (for Hunter syndrome) and VPRIV (for Gaucher disease) were 85.3 billion JPY, an increase of 12.2 billion JPY, or 16.7%, and 48.4 billion JPY, an increase of 6.0 billion JPY, or 14.1%, respectively, primarily due to favorable foreign exchange rates.

  Sales of LIVTENCITY (for post-transplant cytomegalovirus ("CMV") infection/disease), which was first launched in the U.S. in December 2021, followed by several other countries, were 10.5 billion JPY in the current fiscal year.

- *PDT Immunology*. In Plasma-Derived Therapies ("PDT") Immunology, revenue was 678.4 billion JPY, a year-on-year increase of 171.5 billion JPY, or 33.8% (CER % change: 15.3%).

  Sales of immunoglobulin products in aggregate were 522.2 billion JPY, an increase of 136.3 billion JPY, or 35.3%, versus the previous fiscal year. Sales of each of our three global immunoglobulin brands marked double digit percentage of revenue growth, due to continued strong demand globally and growing supply, especially in the U.S., where the pandemic pressure is now easing, as well as favorable foreign exchange rates. Those include GAMMAGARD LIQUID/KIOVIG (for the treatment of primary immunodeficiency ("PID") and multifocal motor neuropathy ("MMN")), and subcutaneous immunoglobulin therapies (CUVITRU and HYQVIA) which are growing due to their benefit to patients and convenience in administration compared to intravenous therapies.

  Sales of albumin products in aggregate, including HUMAN ALBUMIN and FLEXBUMIN (primarily used for hypovolemia and hypoalbuminemia), were 121.4 billion JPY, an increase of 31.4 billion JPY, or 34.9%, versus the previous fiscal year, driven by strong albumin demand in the U.S. and China and favorable exchange rates.

- *Oncology*. In Oncology, revenue was 438.7 billion JPY, a year-on-year decrease of 30.0 billion JPY, or 6.4% (CER % change: -14.4%), impacted by the rapid generic erosion of VELCADE (for multiple myeloma) sales in the U.S.

  Sales of VELCADE were 27.8 billion JPY, a decrease of 82.3 billion JPY, or 74.8%, versus the previous fiscal year, predominantly due to multiple generic entrants in the U.S. starting in May 2022.

  Sales of ADCETRIS (for malignant lymphomas) were 83.9 billion JPY, an increase of 14.7 billion JPY, or 21.3%, versus the previous fiscal year, led by strong growth in countries such as Argentina, Italy and Japan.

  Sales of ICLUSIG (for leukemia) were 47.2 billion JPY, an increase of 12.3 billion JPY, or 35.4%, versus the previous fiscal year, due to steady growth in the U.S. and favorable foreign exchange rates.

  Sales of ALUNBRIG (for non-small cell lung cancer) were 20.6 billion JPY, an increase of 6.9 billion JPY, or 50.7%, versus the previous fiscal year, benefiting from strong demand in European countries, Growth and Emerging Markets such as China, and Japan.

Sales of ZEJULA (for ovarian cancer) were 12.9 billion JPY, an increase of 4.9 billion JPY, or 61.7%, versus the previous fiscal year, primarily led by increased sales in Japan due to a newly launched tablet formulation in June 2022 in addition to existing capsule formulation.

Sales of LEUPLIN/ENANTONE (for endometriosis, uterine fibroids, premenopausal breast cancer, prostate cancer, etc.), an off-patent product, were 111.3 billion JPY, an increase of 4.9 billion JPY, or 4.6%, versus the previous fiscal year, mainly due to favorable foreign exchange rates.

Sales of NINLARO (for multiple myeloma) were 92.7 billion JPY, an increase of 1.5 billion JPY, or 1.6%, versus the previous fiscal year, aided by favorable foreign exchange rates, which were offset partially by intensified competition and decreased demand mainly in the U.S.

Sales of EXKIVITY (for non-small cell lung cancer), which was first launched in the U.S. in September 2021, followed by several other countries, were 3.7 billion JPY in the current fiscal year.

- *Neuroscience.* In Neuroscience, revenue was 637.7 billion JPY, a year-on-year increase of 155.4 billion JPY, or 32.2% (CER % change: 12.1%).

  Sales of VYVANSE/ELVANSE (for attention deficit hyperactivity disorder ("ADHD")) were 459.3 billion JPY, an increase of 132.2 billion JPY, or 40.4%, versus the previous fiscal year, mainly due to the growth of the adult market including an impact from a shortage of generic versions of the instant release formulation of ADDERALL in the U.S. and favorable foreign exchange rates.

  Sales of TRINTELLIX (for major depressive disorder ("MDD")) were 100.1 billion JPY, an increase of 17.8 billion JPY, or 21.6%, versus the previous fiscal year, due to increasing prescriptions in Japan and favorable foreign exchange rates.

  Sales of ADDERALL XR (for ADHD) were 28.6 billion JPY, an increase of 7.7 billion JPY, or 36.9%, versus the previous fiscal year, mainly due to a shortage of generic versions of the instant release formulation marketed by competitors in the U.S. and favorable foreign exchange rates.

Cost of Sales. Cost of Sales increased by 137.2 billion JPY, or 12.4% (CER % change: -0.1%), to 1,244.1 billion JPY. The increase was predominantly due to the depreciation of the yen in the current fiscal year.

Selling, General and Administrative (SG&A) expenses. SG&A expenses increased by 110.9 billion JPY, or 12.5% (CER % change: -0.9%) compared to the previous fiscal year, to 997.3 billion JPY, mainly due to the impact from the depreciation of the yen in the current fiscal year.

Research and Development (R&D) expenses. R&D expenses increased by 107.2 billion JPY, or 20.4% (CER % change: 3.5%) compared to the previous fiscal year, to 633.3 billion JPY, mainly due to the impact from the depreciation of the yen in the current fiscal year.

Amortization and Impairment Losses on Intangible Assets Associated with Products. Amortization and Impairment Losses on Intangible Assets Associated with Products increased by 69.5 billion JPY, or 14.7% (CER % change: -3.2%) compared to the previous fiscal year, to 542.4 billion JPY, mainly due to the impact from the depreciation of the yen in the current fiscal year.

Other Operating Income. Other Operating Income was 25.4 billion JPY, a decrease of 17.7 billion JPY, or 41.0% (CER % change: -44.2%), compared to the previous fiscal year primarily due to a change in fair value of financial assets and liabilities associated with contingent consideration arrangements recognized and certain settlement proceeds recorded in the previous fiscal year.

Other Operating Expenses. Other Operating Expenses were 145.2 billion JPY, a decrease of 13.8 billion JPY, or 8.7% (CER % change: -21.1%), compared to the previous fiscal year, primarily due to decreases in restructuring expenses attributable to the substantially completed Shire integration in the previous fiscal year and valuation reserve for pre-launch inventory, partially offset by increases in other reserves and provisions including those for certain assets related to option fees Takeda paid as part of collaboration agreements and increase due to the impact from the depreciation of the yen in the current fiscal year.

Operating Profit. As a result of the above factors, Operating Profit increased by 29.7 billion JPY, or 6.4% (CER % change: -1.8%) compared to the previous fiscal year to 490.5 billion JPY.

Net Finance Expenses. Net Finance Expenses were 106.8 billion JPY in the current fiscal year, a decrease of 36.1 billion JPY, or 25.3% (CER % change: 28.8%) compared to Net Finance Expenses of 142.9 billion JPY for the previous fiscal year. This decrease was mainly driven by a positive impact from the remeasurement of warrants to purchase stocks of companies held by Takeda.

Share of Loss of Investments Accounted for Using the Equity Method. Share of Loss of Investments Accounted for Using the Equity Method was 8.6 billion JPY, a decrease of 6.7 billion JPY, or 43.8% (CER % change: -50.6%), compared to the previous fiscal year. The decrease is mainly due to the negative impact from Takeda's share of loss on an investment held by Takeda Ventures, Inc. recorded in the previous fiscal year.

Income Tax Expenses. Income Tax Expenses were 58.1 billion JPY, a decrease of 14.4 billion JPY, or 19.8% (CER % change; -18.0%), compared to the previous fiscal year. This decrease was primarily due to a tax charge of 65.4 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 previous fiscal year as well as increased tax benefits from recognition of deferred tax assets. These decreases were partially offset by the benefits from the US state tax rate change in the previous fiscal year, in addition to higher pretax earnings.

Net Profit for the Year. Net Profit for the Year increased by 86.9 billion JPY, or 37.7% (CER % change: 23.3%), compared to the previous fiscal year to 317.0 billion JPY.

Core Results (April 1, 2022 to March 31, 2023)

Definition of Core financial measures and Constant Exchange Rate change

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

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

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

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

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

	For the fiscal year ended March 31,		Change versus the previous fiscal year		
	2022	2023		Actual % change	CER % change
Core Revenue	3,420.5	4,027.5	606.9	17.7 %	3.5 %
Core Operating Profit	955.2	1,188.4	233.2	24.4 %	9.1 %
Core EPS (yen)	425	558	134	31.5 %	13.9 %

Core Revenue for the fiscal year ended March 31, 2023 was 4,027.5 billion JPY, an increase of 606.9 billion JPY, or 17.7% (CER % change: 3.5%), compared to the previous fiscal year. Core revenue for the previous fiscal year was 3,420.5 billion JPY, which excluded primarily the non-recurring 133.0 billion JPY selling price of the diabetes portfolio in Japan. There were no significant items unrelated to Takeda's core operations excluded from revenue in the current fiscal year, resulting in Core revenue for the current fiscal year being the same as Reported revenue. Business momentum was led by Takeda's Growth and Launch Products* which totaled 1,594.8 billion JPY, a year-on-year increase of 435.8 billion JPY, or 37.6% (CER % change: 18.8%). They now include QDENGA, a dengue vaccine, which was approved in EU and countries including Indonesia and Brazil and launched in several non-endemic countries in the current fiscal year.

* Takeda's Growth and Launch Products in the fiscal year ended March 31, 2023
GI: ENTYVIO, ALOFISEL
Rare Diseases: TAKHZYRO, LIVTENCITY
PDT Immunology: Immunoglobulin products including GAMMAGARD LIQUID/KIOVIG, HYQVIA, and CUVITRU,
Albumin products including HUMAN ALBUMIN and FLEXBUMIN
Oncology: ALUNBRIG, EXKIVITY
Other: SPIKEVAX Intramuscular Injection, NUVAXOVID Intramuscular Injection, QDENGA

Core Operating Profit for the current fiscal year was 1,188.4 billion JPY, an increase of 233.2 billion JPY or 24.4% (CER % change: 9.1%) compared to the previous fiscal year driven by revenue growth in our core therapeutic areas and the depreciation of the yen in the current fiscal year.

Core EPS for the current fiscal year was 558 yen, an increase of 134 yen, or 31.5% (CER % change: 13.9%), compared to the previous fiscal year.

Consolidated Financial Position

Assets. Total Assets as of March 31, 2023 were 13,957.8 billion JPY, reflecting an increase of 779.7 billion JPY compared to the previous fiscal year-end. Intangible Assets increased by 451.1 billion JPY mainly due to the acquisition of Nimbus Lakshmi Inc. and the effect of foreign currency translation partially offset by the decrease due to amortization. Goodwill and Property, Plant and Equipment increased by 383.0 billion JPY and 108.4 billion JPY respectively mainly due to the effect of foreign currency translation. In addition, Inventories increased by 133.3 billion JPY. These increases were partially offset by a decrease in Cash and Cash Equivalents of 316.2 billion JPY.

Liabilities. Total Liabilities as of March 31, 2023 were 7,603.1 billion JPY, reflecting an increase of 108.6 billion JPY compared to the previous fiscal year-end. Trade and Other Payables increased by 132.9 billion JPY and Provisions increased by 68.6 billion JPY. In addition, Bonds and Loans increased by 36.9 billion JPY to 4,382.3 billion JPY* primarily due to the effect of adverse foreign currency translation on USD and EUR denominated debts, as largely offset by the redemption of bonds during the current year. These increases were partially offset by a decrease in Deferred Tax Liabilities of 180.9 billion JPY.

* The carrying amount of Bonds was 3,658.3 billion JPY and Loans was 724.0 billion JPY as of March 31, 2023. Breakdown of Bonds and Loans carrying amount is as follows.

Bonds:

Name of Bond (Face Value if Denominated in Foreign Currency)	Issuance	Maturity	Carrying Amount (Billion JPY)
Unsecured US dollar denominated senior notes (1,301 million USD)	June 2015	June 2025 ~ June 2045	174.2
Unsecured US dollar denominated senior notes (4,000 million USD)	September 2016	September 2023 ~ September 2026	515.3
Unsecured Euro denominated senior notes (3,000 million EUR)	November 2018	November 2026 ~ November 2030	433.6
Unsecured US dollar denominated senior notes (2,250 million USD)	November 2018	November 2023 ~ November 2028	298.8
Hybrid bonds (subordinated bonds)	June 2019	June 2079	498.9
Unsecured US dollar denominated senior notes (7,000 million USD)	July 2020	March 2030 ~ July 2060	928.2
Unsecured Euro denominated senior notes (3,600 million EUR)	July 2020	July 2027 ~ July 2040	519.8
Unsecured JPY denominated senior bonds	October 2021	October 2031	249.4
Commercial Paper	March 2023	June 2023	40.0
Total			3,658.3

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	200.0
Bilateral loans	March 2016 ~ March 2023	April 2024 ~ March 2029	210.0
Other			0.5
Total			724.0

On April 23, 2022, Takeda redeemed 219 million USD of unsecured U.S. dollar-denominated senior notes issued in June 2015 in advance of their original maturity date of June 23, 2022. Following this, on October 27, 2022, Takeda redeemed 1,000 million USD of unsecured U.S. dollar-denominated senior notes issued in November 2018 in advance of their original maturity date of November 26, 2023. Furthermore, on November 21, 2022, Takeda redeemed 750 million EUR of unsecured floating rate senior notes issued in November 2018 on their maturity date. On March 31, 2023, Takeda repaid 75 billion JPY in Bilateral Loans falling due and on the same day entered into new Bilateral Loans of 75 billion JPY maturing on March 30, 2029. Takeda also had short term commercial paper drawings outstanding of 40 billion JPY as at March 31, 2023.

Equity. Total Equity as of March 31, 2023 was 6,354.7 billion JPY, reflecting an increase of 671.1 billion JPY compared to the previous fiscal year-end. This primarily resulted from an increase of 573.9 billion JPY in Other Components of Equity mainly due to a fluctuation in currency translation adjustments reflecting the depreciation of yen. Retained Earnings increased by 61.4 billion JPY primarily attributable to Net Profit for the Year largely offset by the dividends payments of 278.3 billion JPY.

Consolidated Cash Flow

Billion JPY

	For the fiscal year ended March 31,	
	2022	2023
Net cash from (used in) operating activities	1,123.1	977.2
Net cash from (used in) investing activities	(198.1)	(607.1)
Net cash from (used in) financing activities	(1,070.3)	(709.1)
Net increase (decrease) in cash and cash equivalents	(145.3)	(339.1)
Cash and cash equivalents at the beginning of the year	966.2	849.7
Effects of exchange rate changes on cash and cash equivalents	28.8	22.9
Cash and cash equivalents at the end of the year	849.7	533.5

Net cash from operating activities was 977.2 billion JPY for the fiscal year ended March 31, 2023 compared to 1,123.1 billion JPY for the fiscal year ended March 31, 2022. The decrease of 145.9 billion JPY was primarily driven by an unfavorable impact from net of changes in assets and liabilities related to the operating activities, mainly due to a change in trade and other payables and increased income taxes paid. These were partially offset by higher net profit for the year adjusted for non-cash items and other adjustments.

Net cash used in investing activities was 607.1 billion JPY for the fiscal year ended March 31, 2023 compared to 198.1 billion JPY for the fiscal year ended March 31, 2022. The increase of 409.0 billion JPY was mainly due to an increase of 430.2 billion JPY in acquisition of intangible assets primarily resulting from the acquisition of Nimbus Lakshmi Inc.* for the current year, partially offset by a decrease of 49.7 billion JPY in acquisition of business (net of cash and cash equivalents acquired).

* Of the 4.0 billion USD upfront payment, 3.0 billion USD was paid in February 2023 and 0.9 billion USD was paid in April 2023. Remaining 0.1 billion USD is scheduled to be paid in August 2023.

Net cash used in financing activities was 709.1 billion JPY for the fiscal year ended March 31, 2023 compared to 1,070.3 billion JPY for the fiscal year ended March 31, 2022. The decrease of 361.1 billion JPY was mainly due to a decrease in repayments of bonds and long-term loans, net of proceeds from bonds and long-term loans upon refinancing, of 279.1 billion JPY, as well as an increase in commercial paper drawings of 40.0 billion JPY. In addition, there was a decrease in purchase of treasury shares of 50.6 billion JPY resulting from the higher share buybacks conducted in the previous year compared to the current year.

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

Three years have passed since the outbreak of COVID-19. As vaccines and therapies have become broadly available in many countries, governments are relaxing strict measures to prevent the spread of infection, such as travel restrictions. We will continue to adhere to local public health guidance in addition to the internal protocols and monitor any potential impacts of the effects of COVID-19, including new variants, on our business activities, with the intent to protect employees' health and safety, and to ensure our medicines are available to patients who rely on them.

In the fiscal year ended March 31, 2023, Takeda manufactured NUVAXOVID Intramuscular Injection, a novel recombinant protein-based COVID-19 vaccine which was licensed, with manufacturing technologies transferred, from Novavax, at its Hikari facility and distributed it in Japan. Takeda is working with Novavax to develop vaccines against the future variants including the Omicron variant. Takeda will also continue to provide distribution support in bringing an mRNA COVID-19 bivalent vaccine, SPIKEVAX Intramuscular Injection (Omicron targeting bivalent vaccine), to Japan through its partnership with Moderna.

Takeda's Operations in Ukraine and Russia

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

Takeda discontinued activities in Russia that were not essential to maintaining the supply of medicines to patients. This included 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 was 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 provided our humanitarian relief, including monetary and medicine donations to benefit people affected by the conflict in Ukraine, and we will continue to assess ways to provide support to patients across the region.

For the fiscal year ended March 31, 2023, revenue attributable to Russia/CIS represented 2.2% of Takeda’s total consolidated revenue of 4,027.5 billion JPY, as indicated in the Revenue by Geographic Region in Analysis of Results of Operations, Financial Position, and Cash Flow, Business Performance, Results of Operations (Reported). There was no material financial impact on Takeda’s financial results for the current fiscal year 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.

Outlook for the Fiscal Year Ending March 31, 2024

Consolidated reported forecast for the fiscal year ending March 31, 2024 (FY2023) is as below:

Consolidated Reported Forecast for the Fiscal Year Ending March 31, 2024 (FY2023)

Billion JPY or percentage

	FY2022 Actual Results	FY2023 Forecast	Change versus the previous year	
Revenue	4,027.5	3,840.0	(187.5)	(4.7)%
Operating profit	490.5	349.0	(141.5)	(28.8)%
Profit before tax	375.1	185.0	(190.1)	(50.7)%
Net profit for the year (attributable to owners of the Company)	317.0	142.0	(175.0)	(55.2)%
EPS (JPY)	204.29	90.75	(113.54)	(55.6)%
Core Revenue	4,027.5	3,840.0	(187.5)	(4.7)%
Core Operating Profit	1,188.4	1,015.0	(173.4)	(14.6)%
Core EPS (JPY)	558	434	(124)	(22.2)%

[Revenue]

Takeda expects FY2023 revenue to be 3,840.0 billion JPY, a decrease of 187.5 billion JPY or 4.7% from FY2022. While continued momentum of our Growth and Launch Products is expected to largely offset the approximately 330.0 billion JPY anticipated impact from loss of exclusivities (on a CER basis), including VYVANSE (for attention deficit hyperactivity disorder) in the U.S. and AZILVA (for hypertension) in Japan, we also anticipate a lower revenue contribution from COVID-19 vaccines and an unfavorable year-on-year impact from foreign exchange rates.
Takeda does not include any significant non-core items that require adjustment in its revenue forecast; therefore, the Core revenue forecast for FY2023 is the same as the reported revenue forecast.

[Operating Profit]

Operating Profit is expected to decrease by 141.5 billion JPY, or 28.8%, to 349.0 billion JPY, reflecting the impact from loss of exclusivities and lower profit contribution from COVID-19 vaccines. We intend to seek to limit the impact on profit margins through discipline in operating expenses, while still investing in R&D and data and technology to secure long-term competitiveness.
Core Operating Profit, adjusted to exclude items unrelated to Takeda's core operations, is expected to be 1,015.0 billion JPY, a decrease of 173.4 billion JPY, or 14.6%.

[Net profit for the year (attributable to owners of the Company)]

Net profit for the year (attributable to owners of the Company) is expected to be 142.0 billion JPY, a decrease of 175.0 billion JPY, or 55.2%. In addition to the expected decline in Operating Profit of 141.5 billion JPY, net finance expenses are expected to increase by 58.2 billion JPY, mainly due to lower financial income. For these main reasons, Profit Before Tax is expected to decrease by 190.1 billion JPY, or 50.7%, to 185.0 billion JPY. The assumption for the effective tax rate is approximately 23%, which is applied to the Profit Before Tax forecast.
Reported EPS is expected to be 90.75 JPY, a decrease of 113. 54JPY, or 55.6%, and Core EPS is expected to be 434 JPY, a decrease of 124 JPY, or 22.2%.

Major assumptions used in preparing the FY2023 Reported Forecast

Billion JPY or percentage

	FY2022 Actual Results	FY2023 Forecast
FX rates	1 USD = 135 JPY 1 Euro = 141 JPY 1 RUB = 2.1 JPY 1 BRL = 26.3 JPY 1 CNY = 19.7 JPY	1 USD = 131 JPY 1 Euro = 141 JPY 1 RUB = 1.9 JPY 1 BRL = 25.9 JPY 1 CNY = 19.5 JPY
R&D expenses	(633.3)	(643.0)
Amortization of intangible assets associated with products	(485.1)	(480.0)
Impairment of intangible assets associated with products	(57.3)	(50.0)
Other operating income	25.4	14.0
Other operating expenses	(145.2)	(150.0)
Other Core Operating Profit adjustments	(35.6)	—
Finance income and (expenses), net	(106.8)	(165.0)
Free cash flow	446.2	400.0 - 500.0*
Capital expenditures (cash flow base)	(633.7)	(480.0 - 530.0)*
Depreciation and amortization (excluding intangible assets associated with products)	(179.3)	(170.0)
Cash tax rate on adjusted EBITDA (excluding divestitures)	~13%	Mid-to-high teen %

* Reflects approximately 180.0 billion JPY of expenditures related to the acquisition of TAK-279 from Nimbus (1.0 billion USD) and in-licensing of fruquintinib from HUTCHMED (400 million USD). The 1.0 billion USD payment related to the acquisition of TAK-279 represents the portion of the 4.0 billion USD upfront payment paid in April 2023 (0.9 billion USD), and scheduled to be paid in August 2023 (0.1 billion USD).

Management Guidance

Takeda uses change in Core Revenue, Core Operating Profit and Core EPS at Constant Exchange Rate (CER) basis as its Management Guidance.

	FY2023 Management Guidance CER % Change*
Core Revenue	Low-single-digit % decline
Core Operating Profit	Low-10s % decline
Core EPS	Low-20s % decline

* Please refer to Analysis of Results of Operations, Financial Position, and Cash Flow, Results of Operations (Reported), Core Results (April 1, 2022 to March 31, 2023), Definition of Core financial measures and Constant Exchange Rate change, for the definition.

Other assumptions used in preparing the FY2023 Reported Forecast and the Management Guidance

The FY2023 reported forecast and the management guidance assume approximately 330.0 billion JPY revenue loss from loss of exclusivities (on a CER basis), including AZILVA (for hypertension) in Japan in June 2023, and VYVANSE (for attention deficit hyperactivity disorder) in the U.S. in August 2023.

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.

Capital Allocation Policy and Dividends for the Fiscal Year Ended March 31, 2023 and Ending March 31, 2024

(i) Capital Allocation Policy

Guided by our vision to discover and deliver life-transforming treatments, and with a focus on maintaining solid investment grade credit ratings, we will allocate capital to maximize value for patients and shareholders.

Takeda's policy in the allocation of capital is as follows:

- Invest in growth drivers; and
- Shareholder returns.

In respect of "Invest in growth drivers", Takeda makes strategic investments in internal and external opportunities to enhance the pipeline, new product launches, and plasma-derived therapies. With regard to "Shareholder returns", Takeda has adopted a progressive dividend policy of increasing or maintaining the annual dividend per share each year, alongside share buybacks when appropriate.

(ii) Dividend

Takeda is strongly committed to shareholder returns with the dividend as a key component.

[FY2022] 180 yen per share
Year-end dividend per share: 90 yen
Together with the interim dividend of 90 yen per share, the annual dividend will be 180 yen per share.

[FY2023 guidance] 188 yen per share

Consolidated Financial Statements [IFRS]

(1) Consolidated Statements of Profit or Loss

	JPY (millions, except per share data)		USD (millions)(*)
	For the year ended March 31,		For the year ended March 31,
	2022	2023	2023
Revenue	¥ 3,569,006	¥ 4,027,478	$ 30,339
Cost of sales	(1,106,846)	(1,244,072)	(9,372)
Selling, general and administrative expenses	(886,361)	(997,309)	(7,513)
Research and development expenses	(526,087)	(633,325)	(4,771)
Amortization and impairment losses on intangible assets associated with products	(472,915)	(542,443)	(4,086)
Other operating income	43,123	25,424	192
Other operating expenses	(159,075)	(145,247)	(1,094)
Operating profit	460,844	490,505	3,695
Finance income	23,700	62,913	474
Finance expenses	(166,607)	(169,698)	(1,278)
Share of loss of investments accounted for using the equity method	(15,367)	(8,630)	(65)
Profit before tax	302,571	375,090	2,826
Income tax expenses	(72,405)	(58,052)	(437)
Net profit for the year	230,166	317,038	2,388
Attributable to:			
Owners of the Company	230,059	317,017	2,388
Non-controlling interests	107	21	0
Net profit for the year	230,166	317,038	2,388
Earnings per share (JPY)			
Basic earnings per share	147.14	204.29	1.54
Diluted earnings per share	145.87	201.94	1.52

(*) Consolidated statements of profit or loss have been translated solely for the convenience of the reader at an exchange rate of 1USD = 132.75 JPY, the Noon Buying Rate certified by the Federal Reserve Bank of New York on March 31, 2023. 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 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) Consolidated Statements of Comprehensive Income

	JPY (millions)		USD (millions)(*)
	For the year ended March 31,		For the year ended March 31,
	2022	2023	2023
Net profit for the year	¥ 230,166	¥ 317,038	$ 2,388
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	(14,626)	(2,654)	(20)
Remeasurement of defined benefit pension plans	20,783	17,752	134
	6,158	15,098	114
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	583,969	618,773	4,661
Cash flow hedges	2,173	(21,451)	(162)
Hedging cost	2,457	(16,993)	(128)
Share of other comprehensive loss of investments accounted for using the equity method	(497)	(892)	(7)
	588,103	579,437	4,365
Other comprehensive income for the year, net of tax	594,261	594,535	4,479
Total comprehensive income for the year	824,427	911,574	6,867
Attributable to:			
Owners of the Company	824,258	911,529	6,867
Non-controlling interests	168	45	0
Total comprehensive income for the year	824,427	911,574	6,867

(*) Consolidated statements of comprehensive income have been translated solely for the convenience of the reader at an exchange rate of 1USD = 132.75 JPY, the Noon Buying Rate certified by the Federal Reserve Bank of New York on March 31, 2023. 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 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) Consolidated Statements of Financial Position

	JPY (millions)		USD (millions)(*)
	As of March 31, 2022	As of March 31, 2023	As of March 31, 2023
ASSETS			
Non-current assets:			
Property, plant and equipment	¥ 1,582,800	¥ 1,691,229	$ 12,740
Goodwill	4,407,749	4,790,723	36,088
Intangible assets	3,818,544	4,269,657	32,163
Investments accounted for using the equity method	96,579	99,174	747
Other financial assets	233,554	279,683	2,107
Other non-current assets	82,611	63,325	477
Deferred tax assets	362,539	366,003	2,757
Total non-current assets	10,584,376	11,559,794	87,079
Current assets:			
Inventories	853,167	986,457	7,431
Trade and other receivables	696,644	649,429	4,892
Other financial assets	25,305	20,174	152
Income taxes receivable	27,733	32,264	243
Other current assets	141,099	160,868	1,212
Cash and cash equivalents	849,695	533,530	4,019
Assets held for sale	—	15,235	115
Total current assets	2,593,642	2,397,956	18,064
Total assets	13,178,018	13,957,750	105,143
LIABILITIES AND EQUITY			
LIABILITIES			
Non-current liabilities:			
Bonds and loans	4,141,418	4,042,741	30,454
Other financial liabilities	468,943	534,269	4,025
Net defined benefit liabilities	145,847	127,594	961
Income taxes payable	21,634	24,558	185
Provisions	52,199	55,969	422
Other non-current liabilities	67,214	65,389	493
Deferred tax liabilities	451,511	270,620	2,039
Total non-current liabilities	5,348,764	5,121,138	38,577
Current liabilities:			
Bonds and loans	203,993	339,600	2,558
Trade and other payables	516,297	649,233	4,891
Other financial liabilities	196,071	185,537	1,398
Income taxes payable	200,918	232,377	1,750
Provisions	443,502	508,360	3,829
Other current liabilities	584,949	566,689	4,269
Liabilities held for sale	—	144	1
Total current liabilities	2,145,730	2,481,940	18,696
Total liabilities	7,494,495	7,603,078	57,274

	JPY (millions)		USD (millions)(*)
	As of March 31, 2022	As of March 31, 2023	As of March 31, 2023
EQUITY			
Share capital	1,676,263	1,676,345	12,628
Share premium	1,708,873	1,728,830	13,023
Treasury shares	(116,007)	(100,317)	(756)
Retained earnings	1,479,716	1,541,146	11,609
Other components of equity	934,173	1,508,119	11,361
Equity attributable to owners of the Company	5,683,019	6,354,122	47,865
Non-controlling interests	504	549	4
Total equity	5,683,523	6,354,672	47,869
Total liabilities and equity	13,178,018	13,957,750	105,143

(*) consolidated statements of financial position have been translated solely for the convenience of the reader at an exchange rate of 1USD = 132.75 JPY, the Noon Buying Rate certified by the Federal Reserve Bank of New York on March 31, 2023. 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 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) 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 year				230,059		
Other comprehensive income (loss)					583,343	(14,558)
Comprehensive income (loss) for the year	—	—	—	230,059	583,343	(14,558)
Transactions with owners:						
Issuance of new shares	8,118	14,036				
Acquisition of treasury shares			(79,447)			
Disposal of treasury shares		(0)	1			
Dividends				(284,246)		
Changes in ownership				(2,143)		
Transfers from other components of equity				26,141		(5,357)
Share-based compensation		43,374				
Exercise of share-based awards		(36,960)	22,992			
Total transactions with owners	8,118	20,450	(56,454)	(260,249)	—	(5,357)
As of March 31, 2022	1,676,263	1,708,873	(116,007)	1,479,716	984,141	22,068

	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 year				—	230,059	107	230,166
Other comprehensive income (loss)	2,173	2,457	20,783	594,200	594,200	61	594,261
Comprehensive income (loss) for the year	2,173	2,457	20,783	594,200	824,258	168	824,427
Transactions with owners:							
Issuance of new shares				—	22,154		22,154
Acquisition of treasury shares				—	(79,447)		(79,447)
Disposal of treasury shares				—	1		1
Dividends				—	(284,246)		(284,246)
Changes in ownership				—	(2,143)	(3,804)	(5,948)
Transfers from other components of equity			(20,783)	(26,141)	—		—
Share-based compensation				—	43,374		43,374
Exercise of share-based awards				—	(13,968)		(13,968)
Total transactions with owners	—	—	(20,783)	(26,141)	(314,276)	(3,804)	(318,080)
As of March 31, 2022	(65,901)	(6,135)	—	934,173	5,683,019	504	5,683,523

	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, 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 year				317,017		
Other comprehensive income (loss)					617,866	(2,663)
Comprehensive income (loss) for the year	—	—	—	317,017	617,866	(2,663)
Transactions with owners:						
Issuance of new shares	82	82				
Acquisition of treasury shares		(5)	(27,060)			
Disposal of treasury shares		0	0			
Dividends				(278,313)		
Transfers from other components of equity				24,687		(6,935)
Share-based compensation		62,670				
Exercise of share-based awards		(42,791)	42,749			
Total transactions with owners	82	19,956	15,689	(253,626)	—	(6,935)
As of March 31, 2023	1,676,345	1,728,830	(100,317)	1,541,146	1,606,128	12,470

	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, 2022	(65,901)	(6,135)	—	934,173	5,683,019	504	5,683,523
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 year				—	317,017	21	317,038
Other comprehensive income (loss)	(21,451)	(16,993)	17,752	594,512	594,512	24	594,535
Comprehensive income (loss) for the year	(21,451)	(16,993)	17,752	594,512	911,529	45	911,574
Transactions with owners:							
Issuance of new shares				—	164		164
Acquisition of treasury shares				—	(27,065)		(27,065)
Disposal of treasury shares				—	1		1
Dividends				—	(278,313)		(278,313)
Transfers from other components of equity			(17,752)	(24,687)	—		—
Share-based compensation				—	62,670		62,670
Exercise of share-based awards				—	(42)		(42)
Total transactions with owners	—	—	(17,752)	(24,687)	(242,586)	—	(242,586)
As of March 31, 2023	(87,352)	(23,127)	—	1,508,119	6,354,122	549	6,354,672

(5) Consolidated Statements of Cash Flows

	JPY (millions)		USD (millions)(*)
	For the year ended March 31,		For the year ended March 31,
	2022	2023	2023
Cash flows from operating activities:			
Net profit for the year	¥ 230,166	¥ 317,038	$ 2,388
Depreciation and amortization	583,151	664,400	5,005
Impairment losses	54,515	64,394	485
Equity-settled share-based compensation	43,374	60,672	457
Loss on sales and disposal of property, plant and equipment	655	10	0
Gain on divestment of business and subsidiaries	(7,829)	(6,807)	(51)
Change in fair value of financial assets and liabilities associated with contingent consideration arrangements, net	(11,195)	3,991	30
Finance (income) and expenses, net	142,907	106,785	804
Share of loss of investments accounted for using the equity method	15,367	8,630	65
Income tax expenses	72,405	58,052	437
Changes in assets and liabilities:			
Decrease in trade and other receivables	127,294	75,127	566
Increase in inventories	(46,148)	(79,155)	(596)
Increase (decrease) in trade and other payables	125,157	(84,804)	(639)
Increase (decrease) in provisions	(58,090)	31,899	240
Increase (decrease) in other financial liabilities	(49,608)	31,669	239
Other, net	41,409	(88,778)	(669)
Cash generated from operations	1,263,528	1,163,122	8,762
Income taxes paid	(147,724)	(198,439)	(1,495)
Tax refunds and interest on tax refunds received	7,301	12,473	94
Net cash from operating activities	1,123,105	977,156	7,361
Cash flows from investing activities:			
Interest received	2,919	5,054	38
Dividends received	3,401	3,562	27
Acquisition of property, plant and equipment	(123,252)	(140,657)	(1,060)
Proceeds from sales of property, plant and equipment	1,815	962	7
Acquisition of intangible assets	(62,785)	(493,032)	(3,714)
Acquisition of investments	(8,341)	(10,151)	(76)
Proceeds from sales and redemption of investments	16,921	22,254	168
Acquisition of businesses, net of cash and cash equivalents acquired	(49,672)	—	—
Proceeds from sales of business, net of cash and cash equivalents divested	28,196	7,958	60
Other, net	(7,328)	(3,052)	(23)
Net cash used in investing activities	(198,125)	(607,102)	(4,573)

	JPY (millions)		USD (millions)(*)
	For the year ended March 31,		For the year ended March 31,
	2022	2023	2023
Cash flows from financing activities:			
Net increase (decrease) in short-term loans and commercial papers	(2)	40,000	301
Proceeds from issuance of bonds and long-term loans	249,334	75,000	565
Repayments of bonds and long-term loans	(810,115)	(356,670)	(2,687)
Acquisition of treasury shares	(77,531)	(26,929)	(203)
Interest paid	(108,207)	(108,555)	(818)
Dividends paid	(283,665)	(279,416)	(2,105)
Repayments of lease liabilities	(39,694)	(43,401)	(327)
Other, net	(385)	(9,178)	(69)
Net cash used in financing activities	(1,070,265)	(709,148)	(5,342)
Net decrease in cash and cash equivalents	(145,285)	(339,094)	(2,554)
Cash and cash equivalents at the beginning of the year	966,222	849,695	6,401
Effects of exchange rate changes on cash and cash equivalents	28,758	22,929	173
Cash and cash equivalents at the end of the year	849,695	533,530	4,019

(*) Consolidated statements of cash flows have been translated solely for the convenience of the reader at an exchange rate of 1USD = 132.75 JPY, the Noon Buying Rate certified by the Federal Reserve Bank of New York on March 31, 2023. 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 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)

On April 26, 2023, Takeda entered into new Syndicated Loans of 100 billion JPY with various banks maturing on April 26, 2030. The new Syndicated Loans have an effective interest rate of 0.68%. The proceeds from these Syndicated Loans were used to repay 100 billion JPY in existing Syndicated Loans falling due on the same day.

Supplementary Information

1. Pipeline

– Clinical Development Activities

- The following table lists the pipeline assets that we are clinically developing as of May 11, 2023 (the date of our annual earnings release), unless otherwise specifically noted. 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, unless otherwise specified.
- 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.’

Gastrointestinal and Inflammation 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 α4β7 integrin (injection)	Biologic and other	Subcutaneous formulation for ulcerative colitis	Japan U.S.	Approved (Mar 2023) Filed (Apr 2023)*
			Subcutaneous formulation for Crohn's disease	Japan U.S.	Filed (Oct 2022) 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 *Helicobacter pylori* eradication)	China	Filed (Aug 2022)
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-999[1] <fazirsiran>	GalNAc based RNA interference (RNAi) (injection)	Peptide/ Oligo-nucleotide	Alpha-1 antitrypsin-deficiency associated liver disease	U.S. EU	P-III P-III
TAK-625[2] <maralixibat>	IBAT inhibitor (oral)	Small molecule	Alagille Syndrome	Japan	P-III
			Progressive Familial Intrahepatic Cholestasis	Japan	P-III
TAK-227/ZED1227[3]	Transglutaminase 2 inhibitor (oral)	Small molecule	Celiac disease	-	P-II (b)

TAK-279	TYK2 inhibitor (oral)	Small molecule	Psoriasis	-	P-II (b)
			Psoriatic Arthritis	-	P-II (b)
TAK-062 <zamaglutenase>	Glutenase (oral)	Biologic and other	Celiac disease	-	P-II
TAK-101[4]	Tolerizing Immune Modifying nanoParticle (TIMP) (injection)	Biologic and other	Celiac disease	-	P-II
TAK-951	Peptide agonist (subcutaneous infusion)	Peptide/ Oligo-nucleotide	Nausea and vomiting	-	P-II
TAK-105	Peptide agonist (subcutaneous infusion)	Peptide/ Oligo-nucleotide	Nausea and vomiting	-	P-I
TAK-647	Anti MAdCAM-1 antibody (injection)	Biologic and other	Nonalcoholic Steatohepatitis (NASH)	-	P-I[5]

1. Partnership with Arrowhead Pharmaceuticals, Inc.
2. Partnership with Mirum Pharmaceuticals.
3. Partnership with Zedira and Dr. Falk Pharma.
4. Acquired development and commercialization license for TAK-101 from COUR Pharmaceuticals. Previously known as TIMP-GLIA.
5. Study actively recruiting

* Event occurred after the end of the Q4 reporting period: Update after April 1, 2023

Additions since FY2022 Q3: TAK-279 for Psoriasis (P-II (b)) and Psoriatic Arthritis (P-II (b))
TAK-647 for Nonalcoholic Steatohepatitis (NASH) (P-I)
Removals since FY2022 Q3: TAK-954 for Post-operative gastrointestinal dysfunction (P-II (b), discontinued)
TAK-018/EB80184 for Crohn's disease (post-operative and ileal-dominant) (P-II (a), discontinued)

Neuroscience Pipeline

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Country/ Region	Stage
TAK-935 <soticlestat>	CH24H inhibitor (oral)	Small molecule	Dravet syndrome	Global	P-III
			Lennox-Gastaut syndrome	Global	P-III
TAK-141/JR-141[1] <pabinafusp alfa>	Fusion protein of an antibody against the human transferrin receptor and iduronate-2-sulfatase [recombinant] (injection)	Biologic	Hunter syndrome (CNS and somatic symptoms)	EU	P-III
TAK-861	Orexin 2R agonist (oral)	Small molecule	Narcolepsy type 1	-	P-II (b)
			Narcolepsy type 2	-	P-II (b)
TAK-071	M1 positive allosteric modulator (M1PAM) (oral)	Small molecule	Parkinson's disease	-	P-II
TAK-041/NBI-846[2]	GPR139 agonist (oral)	Small molecule	Anhedonia in major depressive disorder (MDD)	-	P-II
TAK-653/NBI-845[2]	AMPA receptor potentiator (oral)	Small molecule	Inadequate response to treatment in major depressive disorder (MDD)	-	P-II
TAK-341/MEDI1341[3]	Alpha-synuclein antibody (injection)	Biologic and other	Multiple systems atrophy (MSA)	-	P-II
TAK-611	Human arylsulfatase A for intrathecal administration [recombinant] (injection)	Biologic and other	Metachromatic leukodystrophy	-	P-II
TAK-594/DNL593[4]	Brain-penetrant progranulin fusion protein (injection)	Biologic and other	Frontotemporal dementia	-	P-II
TAK-925 <danavorexton>	Orexin 2R agonist (injection)	Small molecule	Postanesthesia Recovery, narcolepsy	-	P-I
TAK-920/DNL919[4]	Brain-penetrant TREM2 agonist monoclonal antibody (injection)	Biologic and other	Alzheimer's disease	-	P-I

1. Partnership with JCR Pharma. JCR leads development.
2. Partnership with Neurocrine Biosciences. Neurocrine leads development.
3. Partnership with AstraZeneca. P-I Parkinson's disease study is completed.
4. Partnership with Denali Therapeutics. Denali leads P-I development.

Additions since FY2022 Q3: None
Removals since FY2022 Q3: None

Oncology Pipeline

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Country/ Region	Stage
TAK-788 <mobocertinib> *EXKIVITY* (U.S., China)	EGFR/HER2 exon 20 inhibitor (oral)	Small molecule	Previously treated Non-Small Cell Lung Cancer with EGFR exon 20 insertion[1]	China EU[2] Japan	Approved (Jan 2023) Filing withdrawn (Jul 2022) P-III
			Treatment Naïve Non-Small Cell Lung Cancer with EGFR exon 20 insertion	Global	P-III
TAK-113[3] <fruquintinib>	VEGFR inhibitor (oral)	Small molecule	Metastatic Colorectal Cancer (mCRC)	U.S. EU Japan	Filed (March 2023) P-III P-III
SGN-35[4] <brentuximab vedotin> *ADCETRIS* (EU, Japan, China)	CD30 monoclonal antibody-drug conjugate (injection)	Biologic and other	Relapsed or refractory cutaneous T-cell lymphoma	Japan	Filed (Feb 2023)
			First line Hodgkin's lymphoma – Stage III	EU	Filed (Mar 2023)
MLN9708 <ixazomib> *NINLARO* (Global)	Proteasome inhibitor (oral)	Small molecule	Maintenance therapy in patients with newly diagnosed Multiple Myeloma following autologous stem cell transplant (TOURMALINE-MM3)	U.S. EU	P-III P-III
<cabozantinib>[5] *CABOMETYX* (Japan)	Multi-targeted kinase inhibitor (oral)	Small molecule	Metastatic Castration-Resistant Prostate Cancer in combination with atezolizumab[6]	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-385 <relugolix>	LH-RH antagonist (oral)	Small molecule	Prostate cancer	Japan China	P-III 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 IFNα (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-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. The U.S. FDA review was 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), South Korea (Jul 2022), and Brazil (Mar 2023).
2. Following discussions with the EMA, Takeda decided to withdraw the marketing authorization application (MAA).
3. Partnership with HUTCHMED
4. Partnership with Seagen, Inc.
5. Partnership with Exelixis, Inc.
6. Partnership with Chugai Pharmaceutical. Takeda operates P-III development
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 FY2022 Q3: TAK-113 for Metastatic Colorectal Cancer (mCRC) (U.S. [Filed], EU and Japan [P-III])
SGN-35 for Relapsed or refractory cutaneous T-cell lymphoma (Japan, Filed)
SGN-35 for First line Hodgkin's lymphoma – Stage III (EU, Filed)

Removals since FY2022 Q3: MLN9708 for Maintenance therapy in patients with newly diagnosed Multiple Myeloma not treated with stem cell transplant (TOURMALINE-MM4) (U.S., EU, China, discontinued)
Niraparib for Breast cancer (Japan, P-III, discontinued enrollment)

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-620[1] <maribavir> *LIVTENCITY* (U.S., EU)	Benzimidazole riboside inhibitor (oral)	Small molecule	Post-transplant cytomegalovirus (CMV) infection/disease resistant/refractory to (val) ganciclovir, cidofovir or foscarnet	EU China	Approved (Nov 2022) Filed (Dec 2022)
			Treatment of CMV Infection/disease Post Transplantation (Including HSCT)	Japan	P-III
TAK-743 <lanadelumab> *TAKHZYRO* (Global)	Plasma kallikrein inhibitor (injection)	Biologic and other	Pediatric Hereditary Angioedema	U.S. EU	Approved (Feb 2023) Filed (Dec 2022)
TAK-672[2] *OBIZUR* (U.S., EU)	Porcine Coagulation Factor VIII [recombinant] (injection)	Biologic and other	Acquired hemophilia A (AHA)	China Japan	Filed (Jun 2022) P-II/III
TAK-577 *VONVENDI* (U.S., Japan) *VEYVONDI* (EU)	von Willebrand factor [recombinant] (injection)	Biologic and other	Adult on-demand and surgery treatment of von Willebrand disease	China	Filed (Jan 2023)
			Adult prophylactic treatment of von Willebrand disease	EU China	Filed (Mar 2023) P-III
			Pediatric on-demand and surgery treatment of von Willebrand disease	Global	P-III
TAK-660 *ADYNOVATE* (U.S., Japan) *ADYNOVI* (EU)	Antihemophilic factor [recombinant], PEGylated (injection)	Biologic and other	Pediatric Hemophilia A	EU	P-III
TAK-755[3] <apadamtase alfa/ cinaxadamtase alfa>	Replacement of the deficientADAMTS13 enzyme (injection)	Biologic and other	Congenital Thrombotic Thrombocytopenic Purpura	Global	P-III
			Immune Thrombotic Thrombocytopenic Purpura	U.S. EU	P-II P-II
			Sickle cell disease	U.S.	P-I
TAK-079[4] <mezagitamab>	Anti-CD38 monoclonal antibody (injection)	Biologic and other	Myasthenia gravis	-	P-II
			Immune thrombocytopenic purpura	-	P-II
			Systemic lupus erythematosus	-	P-I/II
			Immunoglobulin A nephropathy	-	P-I

1. Partnership with GlaxoSmithKline
2. Partnership with Ipsen
3. Partnership with KM Biologics.
4. Relapsed/refractory Multiple Myeloma will continue until trial completion.

Additions since FY2022 Q3: None
Removals since FY2022 Q3: TAK-620 for HSCT Recipients with First CMV Infection (U.S., EU, P-III, discontinued)
TAK-743 for Bradykinin-Mediated Angioedema (Global, P-III, 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> *HYQVIA* (U.S., EU)	Immunoglobulin (IgG) + recombinant hyaluronidase replacement therapy (subcutaneous infusion)	Biologic and other	Pediatric indication for primary immunodeficiency	U.S.	Approved (Apr 2023)*
			Chronic inflammatory demyelinating polyradiculoneuropathy	U.S. EU	Filed (Feb 2023) Filed (Mar 2023)
			Chronic inflammatory demyelinating polyradiculoneuropathy and Multifocal Motor Neuropathy	Japan	P-III
			Primary Immunodeficiencies	Japan	P-III
TAK-662 *CEPROTIN* (U.S., EU)	Protein C concentrate [human] (injection)	Biologic and other	Long-term prophylaxis treatment of severe congenital protein C deficiency	EU	Approved (Dec 2022)
			Severe congenital protein C deficiency	Japan	Filed (Apr 2023)*
TAK-664 <IG Infusion 20% (Human)> *CUVITRU* (U.S., EU)	Immunoglobulin 20% [human] (subcutaneous infusion)	Biologic and other	Primary Immunodeficiencies and Secondary Immunodeficiencies	Japan	Filed (Oct 2022)
TAK-880 <10% IVIG (Low IgA)>	Immunoglobulin (10%) [human] (injection) (Low IgA)	Biologic and other	Primary Immunodeficiencies and Multifocal Motor Neuropathy	U.S. EU	Filed (Jan 2023) Filing in preparation[2]
TAK-330 *PROTHROMPLEX TOTAL* (EU)	Four-factor prothrombin complex concentrate [human] (injection)	Biologic and other	Coagulation Disorder, Direct Oral Anticoagulants (DOAC) reversal in surgical situations	U.S.	P-III
TAK-961 <5% IVIG> *GLOVENIN-I* （Japan）	Immunoglobulin (5%) [human] (injection)	Biologic and other	Autoimmune Encephalitis (AE)	Japan	P-III
TAK-881 <Facilitated 20% SCIG>	Immunoglobulin (20%) [human] + recombinant hyaluronidase replacement therapy (injection)	Biologic and other	Immunodeficiencies	U.S. E.U.	P-I/II

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

* Event occurred after the end of the Q4 reporting period: Update after April 1, 2023

Additions since FY2022 Q3: TAK-662 for Long-term prophylaxis treatment of severe congenital protein C deficiency (EU, Approved)
TAK-961 for Autoimmune Encephalitis (Japan, P-III)
Removals since FY2022 Q3: 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] *NUVAXOVID* *Intramuscular Injection* (Japan)	SARS-CoV-2 vaccine (injection)	Biologic and other	Active immunization for the prevention of COVID-19 (primary and booster)	Japan	Approved (Apr 2022)
			Active immunization for the prevention of COVID-19 (heterologous booster)	Japan	P-III
TAK-003[2] *QDENGA* (EU)	Tetravalent dengue vaccine (injection)	Biologic and other	For the prevention of dengue fever of any severity, due to any serotype, in individuals aged 4 and older	EU U.S.	Approved (Dec 2022)[3] Filed (Nov 2022)
			For the prevention of dengue fever of any severity, due to any serotype, in individuals aged 4 and older (booster extension)	-	P-III
TAK-426[4]	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. QDENGA (TAK-003) was approved in Indonesia (Aug 2022) and Brazil (Mar 2023).
3. Takeda participated in the European Medicines Agency's (EMA) parallel assessment of a medicinal product for use in EU, and through the EU-M4all procedure for countries outside of the EU. In October 2022, the Committee for Medicinal Products for Human Use (CHMP) of the EMA recommended the approval of TAK-003 in Europe and in dengue-endemic countries participating in the parallel EU-M4all procedure.
4. Partnership with The Biomedical Advanced Research and Development Authority (BARDA) of the U.S. Government

Additions since FY2022 Q3: None
Removals since FY2022 Q3: 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-620 <maribavir>	Post-transplant cytomegalovirus (CMV) infection/disease resistant/refractory to (val) ganciclovir, cidofovir or foscarnet	EU	Approved (Nov 2022)
TAK-003	For the prevention of dengue fever of any severity, due to any serotype, in individuals aged 4 and older	EU	Approved (Dec 2022)
TAK-662	Long-term prophylaxis treatment of severe congenital protein C deficiency	EU	Approved (Dec 2022)
TAK-788 <mobocertinib>	Previously treated Non-Small Cell Lung Cancer with EGFR exon 20 insertion	China	Approved (Jan 2023)
TAK-743 <lanadelumab>	Pediatric Hereditary Angioedema	U.S.	Approved (Feb 2023)
MLN0002 <vedolizumab>	Subcutaneous formulation for ulcerative colitis	Japan	Approved (Mar 2023)
TAK-771 <IG Infusion 10% (Human) w/ Recombinant Human Hyaluronidase>	Pediatric indication for primary immunodeficiency	U.S.	Approved (Apr 2023)*
TAK-672	Acquired hemophilia A (AHA)	China	Filed (Jun 2022)
TAK-438 <vonoprazan>	Acid related diseases (adjunct to *Helicobacter pylori* eradication)	China	Filed (Aug 2022)
TAK-664	Primary Immunodeficiencies and Secondary Immunodeficiencies	Japan	Filed (Oct 2022)
MLN0002 <vedolizumab>	Subcutaneous formulation for Crohn's disease	Japan	Filed (Oct 2022)
TAK-003	For the prevention of dengue fever of any severity, due to any serotype, in individuals aged 4 and older	U.S.	Filed (Nov 2022)
TAK-620 <maribavir>	Post-transplant cytomegalovirus (CMV) infection/disease resistant/refractory to (val) ganciclovir, cidofovir or foscarnet	China	Filed (Dec 2022)
TAK-743 <lanadelumab>	Pediatric Hereditary Angioedema	EU	Filed (Dec 2022)

TAK-577	Adult on-demand and surgery treatment of von Willebrand disease	China	Filed (Jan 2023)
TAK-880	Primary Immunodeficiencies and Multifocal Motor Neuropathy	U.S.	Filed (Jan 2023)
TAK-771 <IG Infusion 10% (Human) w/ Recombinant Human Hyaluronidase>	Chronic inflammatory demyelinating polyradiculoneuropathy	U.S.	Filed (Feb 2023)
SGN-35 <brentuximab vedotin>	Relapsed or refractory cutaneous T-cell lymphoma	Japan	Filed (Feb 2023)
TAK-771 <IG Infusion 10% (Human) w/ Recombinant Human Hyaluronidase>	Chronic inflammatory demyelinating polyradiculoneuropathy	EU	Filed (Mar 2023)
SGN-35 <brentuximab vedotin>	First line Hodgkin's lymphoma – Stage III	EU	Filed (Mar 2023)
TAK-113 <fruquintinib>	Metastatic Colorectal Cancer (mCRC)	U.S.	Filed (Mar 2023)
TAK-577	Adult prophylactic treatment of von Willebrand disease	EU	Filed (Mar 2023)
MLN0002 <vedolizumab>	Subcutaneous formulation for ulcerative colitis	U.S.	Filed (Apr 2023)*
TAK-662	Severe congenital protein C deficiency	Japan	Filed (Apr 2023)*
TAK-999 <fazirsiran>	Alpha-1 antitrypsin-deficiency associated liver disease	U.S. EU	P-III
<niraparib>	Breast cancer	Japan	P-III
TAK-620 <maribavir>	Treatment of CMV Infection/disease Post Transplantation (Including HSCT)	Japan	P-III
TAK-755 <apadamtase alfa/ cinaxadamtase alfa>	Congenital Thrombotic Thrombocytopenic Purpura	Japan China	P-III
TAK-330	Coagulation Disorder, Direct Oral Anticoagulants (DOAC) reversal in surgical situations	U.S.	P-III
TAK-625 <maralixibat>	Alagille Syndrome	Japan	P-III
TAK-625 <maralixibat>	Progressive Familial Intrahepatic Cholestasis	Japan	P-III
TAK-279	Psoriasis	-	P-II (b)
TAK-279	Psoriatic Arthritis	-	P-II (b)

TAK-861	Narcolepsy type 1	-	P-II (b)
TAK-861	Narcolepsy type 2	-	P-II (b)
TAK-573 <modakafusp alfa>	Relapsed/refractory Multiple Myeloma	-	P-II
TAK-007	Relapsed/refractory B cell malignancies	-	P-II
TAK-341/MEDI1341	Multiple system atrophy (MSA)	-	P-II
TAK-062 <zamaglutenase>	Celiac disease	-	P-II
TAK-594/DNL593	Frontotemporal dementia	-	P-II
TAK-500	Solid tumors	-	P-I
TAK-280	B7-H3 expressing solid tumors	-	P-I
TAK-920/DNL919	Alzheimer's disease	-	P-I
TAK-079 <mezagitamab>	Immunoglobulin A nephropathy	-	P-I
TAK-647	Nonalcoholic Steatohepatitis (NASH)	-	P-I**

* Event occurred after the end of the Q4 reporting period: Update after April 1, 2023

** Study actively recruiting

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 to discontinue pursuit of 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.
TAK-834	Hypoparathyroidism (P-I study in Japan completed)	Japan development was discontinued along with the discontinuation of manufacturing NATPAR/NATPARA globally.
TAK-510	Nausea and vomiting (P-I)	Phase 1 data did not support further development.
<cabozantinib>	2L metastatic Non-Small Cell Lung Cancer in combination with atezolizumab (Japan, P-III)	Phase 3 CONTACT-01 study did not meet its primary endpoint. The result did not support further development in this indication.
TAK-954	Post-operative gastrointestinal dysfunction (P-II(b))	Phase 2 (b) study did not meet its endpoints. Takeda and Theravance Biopharma mutually agreed to discontinue further development of this program and the parties' collaboration agreement.
TAK-018/EB8018 <sibofimloc>	Crohn's disease (post-operative and ileal-dominant) (P-II(a))	Phase 2 (a) study did not meet its endpoints.
MLN9708 <ixazomib>	Maintenance therapy in patients with newly diagnosed Multiple Myeloma not treated with stem cell transplant (TOURMALINE-MM4) (U.S., EU, China, P-III)	While there are ongoing discussions with regulatory bodies around world, given the final analysis of the trial, Takeda will not pursue this indication in the US, EU (NINLARO has been approved in the maintenance setting in Japan, South Korea, Thailand, Taiwan, and Brazil).
TAK-620 <maribavir>	HSCT Recipients with First CMV Infection (U.S., EU, P-III)	After reviewing the study data with regulatory bodies, Takeda decided not to pursue this indication further.
TAK-743 <lanadelumab>	Bradykinin-Mediated Angioedema (Global, P-III)	The Phase 3 study in angioedema patients with normal C1 inhibitor did not meet its primary endpoint. There were no new safety signals and TAKHZYRO's indication for prophylaxis to prevent attacks of Hereditary Angioedema (HAE) remains unchanged.
<niraparib>	Breast cancer (Japan, P-III)	Following GSK's permanent discontinuation of enrolment in the ZEST global Phase 3 study due to eligibility challenges impacting the ability to fully enroll targeted patients, Takeda discontinued enrollment in this study in Japan.

Note: Takeda decided to discontinue discovery and pre-clinical efforts in adeno-associated virus (AAV) gene therapy.

IV. Research & Development collaborations/partnering

– The following tables describe research & development collaborations/partnering and externalization projects entered into by Takeda, but do not represent a comprehensive list of all Takeda R&D collaborations. All of the "subject" descriptions listed below are as of the date of execution of the relevant agreement unless otherwise noted.

– ‡ shows collaborations/partnering and ♦ shows externalization project, which have been executed since April 1, 2022.

Gastrointestinal and Inflammation

Partner	Country of incorporation	Subject
Arrowhead Pharmaceuticals	U.S.	Collaboration and licensing agreement to develop fazirsiran (TAK-999; ARO-AAT), an 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.
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.
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.
Mirum Pharmaceuticals	U.S.	Exclusive licensing agreement for the development and commercialization of maralixibat (TAK-625) in Japan for Alagille syndrome (ALGS), progressive familial intrahepatic cholestasis (PFIC), and biliary atresia (BA).
Sosei Heptares	U.K.	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.
UCSD/Fortis Advisors	U.S.	Technology license for the development of oral budesonide formulation (TAK-721) for treatment of eosinophilic esophagitis.
Zedira/Dr. Falk Pharma‡	Germany	Collaboration and license agreement to develop and commercialize a potential first-in-class therapy TAK-227/ZED1227, a tissue transglutaminase 2 (TG2) inhibitor, designed to prevent the immune response to gluten in celiac disease. Takeda has exclusive rights in the US and other territories outside of Europe, Canada, Australia and China.

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	U.K.	Agreement for the joint development and commercialization of MEDI1341/TAK-341, an alpha-synuclein antibody currently in development as a potential treatment for Multiple system atrophy (MSA) and Parkinson's disease.
BioMarin	U.S.	Agreement for the in-license of enabling technology for the exogenous replacement of Arylsulfatase A enzyme with intrathecal (IT) administration directly into the central nervous system for the long-term treatment of patients with metachromatic leukodystrophy (MLD), a rapidly-progressive and ultimately fatal neuro-degenerative rare disease (TAK-611).
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.
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.
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/NBI-846, TAK-653/NBI-845 and TAK-831/NBI-844 (luvadaxistat). 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. In June 2021, Takeda decided not to cost share further TAK-831/NBI-844 (luvadaxistat) development; Takeda maintains its right to receive milestones and royalties regarding TAK-831/NBI-844 (luvadaxistat).
PeptiDream	Japan	Collaborative research and exclusive license agreement to create peptide-drug conjugates (PDCs) for neuromuscular and neurodegenerative diseases.
Wave Life Sciences	Singapore	Multi-program option agreement to co-develop and co-commercialize antisense oligonucleotides for a range of neurological diseases.

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).
HUTCHMED‡	China	Exclusive licensing agreement with HUTCHMED (China) Limited and its subsidiary HUTCHMED Limited for the further development and commercialization of fruquintinib (TAK-113) in all indications, including metastatic colorectal cancer, outside of mainland China, Hong Kong and Macau.
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 (MDACC)	U.S.	Exclusive license and research agreement to utilize MDACC's platform and expertise, and to leverage Takeda's development, manufacturing and commercialization capabilities to bring patients cord blood-derived chimeric antigen receptor-directed natural killer (CAR-NK) cell therapies 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 (Comparative In Vivo Oncology) 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.
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.
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.
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	Collaboration and license agreement for the development of therapeutic uses of rADAMTS13 (TAK-755), including but not limited to 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.
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.

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.
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 (hsIgG) candidate.
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. In February 2023, MHLW cancelled the order of the remaining doses not yet supplied. Takeda is working with Novavax to develop vaccines against the future variants including the Omicron variant.
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 Intermuscular 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 assumed 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 neuroscience, oncology and gastroenterology 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 investment.
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 (Vδ1) gamma delta (γδ). Both acquisitions were closed in April 2022.
NuBiyota	Canada	Collaboration and License Agreement for the development and commercialization of Microbial Ecosystem Therapeutic (MET) products for gastroenterology indications.
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.
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. Following a review of its pipeline, Takeda informed Finch of its decision to terminate the collaboration with Finch, effective November 17, 2022, in accordance with the terms of the agreement, resulting in the return to Finch of worldwide rights to develop and commercialize TAK-524 and any other microbiome product candidates for inflammatory bowel disease.
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.
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.
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.
StrideBio	U.S.	Collaboration and license agreement to develop *in vivo* adeno-associated viruses (AAV) based therapies for Friedreich's Ataxia (FA) and two additional undisclosed targets.
Theravance Biopharma	U.S.	Global license, development and commercialization agreement for TAK-954, a selective 5-HT4 receptor agonist for motility disorders.
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.
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.
Skyhawk Therapeutics	U.S.	Collaboration and licensing agreement to develop and commercialize RNA modulation therapies targeting neurodegenerative diseases.

■ 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] FY21Q4 YTD	Reported [*1] FY22Q4 YTD	YOY		Core CER Change [*1*5] YOY
Total revenue	3,569.0	4,027.5	458.5	12.8 %	3.5 %
Japan [*2]	659.0	512.0	(146.9)	(22.3)%	(1.5)%
% of revenue	18.5%	12.7%	(5.8)pt		
United States	1,714.4	2,103.8	389.4	22.7 %	2.0 %
% of revenue	48.0%	52.2%	4.2pt		
Europe and Canada	739.2	842.7	103.5	14.0 %	5.1 %
% of revenue	20.7%	20.9%	0.2pt		
Growth and Emerging Markets [*3]	456.4	569.0	112.6	24.7 %	12.5 %
% of revenue	12.8%	14.1%	1.3pt		
Asia (excluding Japan)	197.0	225.0	28.0	14.2 %	2.0 %
% of revenue	5.5%	5.6%	0.1pt		
Latin America	128.5	160.4	31.9	24.8 %	14.8 %
% of revenue	3.6%	4.0%	0.4pt		
Russia/CIS	62.1	88.4	26.4	42.5 %	9.5 %
% of revenue	1.7%	2.2%	0.5pt		
Other [*4]	68.9	95.2	26.2	38.1 %	41.3 %
% of revenue	1.9%	2.4%	0.4pt		
Of which royalty / service income [*2]	273.3	105.2	(168.1)	(61.5)%	(21.9)%

*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 FY21Q4YTD.

*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 *Analysis of Results of Operations, Financial Position, and Cash Flow "Core Results, Definition of Core financial measures and Constant Exchange Rate change"* for the definition.

Quarterly

	Reported [*1]											
	FY21				FY22							
(Bn JPY)	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%	1,002.3	18.6%	1,096.6	21.7%	956.2	9.5 %
Japan [*2]	259.0	131.9	139.4	128.7	140.5	(45.7)%	120.8	(8.4)%	128.5	(7.8)%	122.2	(5.1)%
% of revenue	27.3%	15.6%	15.5%	14.7%	14.5%		12.1%		11.7%		12.8%	
United States	412.2	426.2	458.6	417.4	501.1	21.6%	531.5	24.7%	589.2	28.5%	482.0	15.5 %
% of revenue	43.4%	50.4%	50.9%	47.8%	51.5%		53.0 %		53.7 %		50.4 %	
Europe and Canada	178.7	175.2	187.0	198.2	205.6	15.0%	203.4	16.1%	223.4	19.5%	210.3	6.1 %
% of revenue	18.8%	20.7%	20.7%	22.7%	21.1%		20.3 %		20.4 %		22.0 %	
Growth and Emerging Markets [*3]	99.7	111.5	116.3	129.0	125.3	25.7%	146.6	31.5%	155.4	33.6%	141.7	9.9 %
% of revenue	10.5%	13.2%	12.9%	14.8%	12.9%		14.6 %		14.2 %		14.8 %	
Asia (excluding Japan)	40.3	49.4	50.1	57.2	46.1	14.4%	59.6	20.7%	63.3	26.5%	56.0	(2.1)%
% of revenue	4.2%	5.8%	5.6%	6.5%	4.7%		5.9 %		5.8 %		5.9 %	
Latin America	30.1	31.3	32.2	34.9	40.3	34.0%	43.0	37.2%	38.2	18.6%	38.9	11.5 %
% of revenue	3.2%	3.7%	3.6%	4.0%	4.1%		4.3 %		3.5 %		4.1 %	
Russia/CIS	12.3	12.8	18.5	18.5	17.4	40.8%	20.5	60.4%	28.9	56.2%	21.7	17.6 %
% of revenue	1.3%	1.5%	2.1%	2.1%	1.8%		2.0 %		2.6 %		2.3 %	
Other [*4]	17.0	18.0	15.5	18.4	21.6	26.8%	23.6	30.7%	25.0	61.1%	25.0	36.2 %
% of revenue	1.8%	2.1%	1.7%	2.1%	2.2%		2.4 %		2.3 %		2.6 %	
Of which royalty / service income [*2]	157.7	25.4	27.4	62.7	33.6	(78.7%)	26.8	5.3%	28.0	2.3%	16.8	(73.2)%

*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													
	FY21Q4 YTD	FY22Q4 YTD	YOY	US	YOY	Japan	YOY	EUCAN	YOY	GEM*5	YOY	Ex-US	YOY
GI	**875.7**	**1,094.5**	**25.0 %**	**634.9**	**30.1 %**	**113.8**	**5.2 %**	**231.8**	**19.2 %**	**92.7**	**37.6 %**	**21.3**	**20.3 %**
ENTYVIO	521.8	702.7	34.7 %	491.9	40.7 %	13.5	19.3 %	162.5	19.5 %	34.9	39.6 %		
TAKECAB/VOCINTI *1	102.4	108.7	6.2 %	—	(100.0) %	93.5	(1.1) %	—	-	15.2	96.5 %		
GATTEX/REVESTIVE	75.8	93.1	22.9 %	68.5	12.2 %	5.8	267.7 %	13.6	23.4 %	5.2	148.7 %		
DEXILANT	50.8	69.4	36.7 %	38.9	37.2 %	—	-	13.3	27.9 %	17.2	42.9 %		
PANTOLOC/CONTROLOC*2	40.3	45.5	13.0 %	2.6	20.0 %	—	-	30.5	15.6 %	12.4	6.0 %		
LIALDA/MEZAVANT *3	26.5	23.7	(10.3) %	2.5	(72.0) %							21.3	20.3 %
PENTASA	20.2	8.4	(58.3) %	8.4	(58.3) %								
RESOLOR/MOTEGRITY	13.0	18.2	39.7 %	15.6	58.0 %	—	-	2.6	(17.3) %	—	-		
ALOFISEL	1.8	2.7	47.9 %	—	-	0.1	-	2.4	52.7 %	0.2	(22.9) %		
Others	23.2	22.1	(4.9) %	6.6	(17.3) %	0.8	21.5 %	7.0	16.0 %	7.7	(10.3) %		
Rare Diseases	**611.2**	**723.4**	**18.4 %**	**332.4**	**23.3 %**	**36.2**	**16.0 %**	**197.3**	**6.1 %**	**157.6**	**26.5 %**		
Rare Hematology	**283.7**	**304.7**	**7.4 %**	**129.3**	**7.8 %**	**22.9**	**(7.5)%**	**65.8**	**(2.0)%**	**86.7**	**20.7 %**		
ADVATE	118.5	118.2	(0.3) %	59.0	7.1 %	4.1	(28.3) %	21.5	(15.8) %	33.5	4.4 %		
ADYNOVATE/ADYNOVI	60.7	66.6	9.6 %	28.9	10.6 %	14.2	(3.9) %	16.8	16.5 %	6.6	23.3 %		
FEIBA *4	39.2	41.3	5.4 %	12.2	(3.5) %	0.7	8.3 %	8.8	(10.5) %	19.6	21.9 %		
RECOMBINATE	12.3	12.8	3.8 %	11.9	4.0 %	—	-	0.8	(1.6) %	0.1	20.0 %		
HEMOFIL/IMMUNATE/IMMUNINE*4	17.7	19.6	10.5 %	3.1	(8.5) %	—	-	3.6	(14.1) %	12.8	27.3 %		
Other PDT Products *4	3.9	4.4	13.2 %	(0.0)	-	0.1	-	4.0	12.5 %	0.4	3.2 %		
Others	31.4	41.9	33.7 %	14.2	25.5 %	3.9	6.1 %	10.3	17.4 %	13.6	77.3 %		
Rare Genetics and Other	**327.5**	**418.7**	**27.9 %**	**203.1**	**35.8 %**	**13.2**	**106.8 %**	**131.5**	**10.7 %**	**70.9**	**34.3 %**		
TAKHZYRO	103.2	151.8	47.0 %	112.1	41.7 %	1.3	-	30.9	46.9 %	7.5	141.8 %		
ELAPRASE	73.1	85.3	16.7 %	25.7	26.6 %	0.3	(68.1) %	30.1	10.2 %	29.1	19.1 %		
REPLAGAL	51.7	66.7	29.1 %	—	-	8.8	282.6 %	38.1	8.7 %	19.8	37.9 %		
VPRIV	42.4	48.4	14.1 %	20.3	16.2 %	1.1	(14.8) %	16.0	3.0 %	10.9	35.8 %		
FIRAZYR	26.7	24.6	(7.7) %	14.9	10.5 %	1.6	(6.3) %	5.0	(46.1) %	3.1	38.5 %		
CINRYZE *4	19.3	18.4	(4.7) %	13.6	1.2 %	—	-	4.3	(18.0) %	0.4	(22.7) %		
LIVTENCITY	1.3	10.5	692.4 %	9.9	644.8 %	—	-	0.6	-	0.0	2,981.4 %		
Others	9.7	13.0	33.6 %	6.5	49.1 %	—	-	6.5	21.7 %	0.0	(51.5) %		

*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												
	FY21Q4 YTD	FY22Q4 YTD	YOY	US	YOY	Japan	YOY	EUCAN	YOY	GEM*5	YOY	Ex-US	YOY
PDT Immunology	**507.0**	**678.4**	**33.8 %**	**441.2**	**33.7 %**							**237.3**	**34.0 %**
immunoglobulin *1	385.9	522.2	35.3 %	391.1	35.7 %							131.1	34.4 %
albumin *1	90.0	121.4	34.9 %	23.2	33.2 %							98.3	35.3 %
Others *1	31.1	34.8	12.0 %	26.9	11.2 %							7.9	15.0 %
Oncology	**468.7**	**438.7**	**(6.4)%**	**158.8**	**(28.5)%**	**91.4**	**8.4 %**	**88.4**	**11.8 %**	**91.4**	**23.1 %**	**8.8**	**(2.6)%**
VELCADE *2	110.0	27.8	(74.8) %	25.9	(75.7) %							1.8	(46.0) %
LEUPLIN/ENANTONE	106.5	111.3	4.6 %	22.3	(6.7) %	25.4	(7.0) %	34.7	8.0 %	28.8	25.2 %		
NINLARO	91.2	92.7	1.6 %	57.0	6.1 %	6.6	8.6 %	11.5	(15.2) %	17.6	(1.2) %		
ADCETRIS	69.2	83.9	21.3 %			12.7	10.0 %	34.5	22.2 %	36.8	24.8 %		
ICLUSIG *2	34.9	47.2	35.4 %	40.2	37.8 %							7.0	23.3 %
VECTIBIX	24.7	25.8	4.5 %			25.8	4.5 %						
ALUNBRIG	13.6	20.6	50.7 %	8.0	18.1 %	1.8	70.1 %	6.2	60.9 %	4.6	130.5 %		
ZEJULA	8.0	12.9	61.7 %			10.6	58.8 %			2.3	76.5 %		
CABOMETYX	6.4	7.9	24.3 %			7.9	24.3 %						
EXKIVITY	1.0	3.7	288.1 %	3.2	231.1 %	—	-	0.0	-	0.5	7,858.2 %		
Others	3.3	4.9	48.1 %	2.1	150.9 %	0.6	4.1 %	1.4	16.0 %	0.7	15.2 %		
Neuroscience	**482.3**	**637.7**	**32.2 %**	**502.6**	**35.3 %**	**30.8**	**(11.5)%**	**86.3**	**31.4 %**	**17.9**	**76.3 %**		
VYVANSE/ELVANSE	327.1	459.3	40.4 %	372.2	38.6 %	0.5	(6.2) %	69.7	43.0 %	16.9	82.0 %		
TRINTELLIX	82.3	100.1	21.6 %	91.9	19.5 %	8.2	50.8 %			—	-		
INTUNIV	18.9	16.4	(13.6) %	0.5	291.4 %	6.0	(16.6) %	8.9	(17.7) %	0.9	18.8 %		
ADDERALL XR	20.9	28.6	36.9 %	26.2	38.8 %	—	-	2.4	19.6 %	—	-		
ROZEREM	11.7	8.7	(25.7) %	0.1	-	8.4	(28.5) %	0.0	(2.0) %	0.1	8.7 %		
Others	21.4	24.7	15.3 %	11.6	57.5 %	7.8	(21.7) %	5.3	29.6 %	—	(100.0) %		
Others *3	**624.2**	**454.6**	**(27.2)%**										
AZILVA *4	76.3	72.9	(4.5) %	—	-	72.9	(4.5) %	—	-	—	-		
LOTRIGA	32.7	16.7	(48.8) %			16.7	(48.8) %						
FOSRENOL *2	13.6	13.5	(0.6) %	1.3	(19.2) %							12.2	2.0 %
ACTOVEGIN	13.4	15.8	17.6 %	—	-	—	-	0.8	5.1 %	15.0	18.3 %		

*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 FY21Q4YTD.

*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

- Quarterly
- Q1

(Bn JPY)	Reported												
	FY21 Q1	FY22 Q1	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 %		
RECOMBINATE	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

■ Q1

(Bn JPY)	Reported											
	FY21 Q1	FY22 Q1	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 FY21Q1.

*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

■ Q2

(Bn JPY)	Reported													
	FY21 Q2	FY22 Q2	YOY	US	YOY	Japan	YOY	EUCAN	YOY	GEM*5	YOY	Ex-US	YOY
GI	**218.6**	**276.0**	**26.3 %**	**161.9**	**31.4 %**	**27.8**	**5.5 %**	**56.2**	**17.2 %**	**24.6**	**43.1 %**	**5.5**	**40.3 %**
ENTYVIO	130.5	178.3	36.6 %	125.9	43.8 %	3.4	17.9 %	39.9	17.8 %	9.1	47.5 %		
TAKECAB/VOCINTI *1	24.8	27.1	8.9 %	—	-	22.7	(1.6) %	—	-	4.3	150.6 %		
GATTEX/REVESTIVE	18.7	26.5	41.7 %	20.2	31.6 %	1.4	875.0 %	3.2	19.6 %	1.7	207.3 %		
DEXILANT	14.9	15.7	5.0 %	8.1	(7.1) %	—	-	3.4	31.7 %	4.1	14.8 %		
PANTOLOC/CONTROLOC*2	9.4	10.9	15.4 %	0.6	47.8 %	—	-	7.1	16.3 %	3.1	8.6 %		
LIALDA/MEZAVANT *3	5.3	5.6	4.9 %	0.1	(95.4) %							5.5	40.3 %
PENTASA	5.2	2.1	(58.8) %	2.1	(58.8) %								
RESOLOR/MOTEGRITY	3.2	3.8	20.9 %	3.2	32.7 %	—	-	0.7	(14.8) %	—	-		
ALOFISEL	0.4	0.5	25.9 %	—	-	0.0	-	0.5	39.3 %	0.0	(51.2) %		
Others	6.1	5.5	(9.5) %	1.7	(20.1) %	0.2	3.0 %	1.5	(7.7) %	2.1	(1.2) %		
Rare Diseases	**144.6**	**180.6**	**24.9 %**	**84.0**	**35.2 %**	**8.8**	**32.6 %**	**48.0**	**3.1 %**	**39.9**	**36.0 %**		
Rare Hematology	**69.4**	**76.6**	**10.4 %**	**31.9**	**13.5 %**	**5.6**	**(6.3)%**	**16.3**	**(4.6)%**	**22.8**	**25.1 %**		
ADVATE	30.6	30.3	(1.2) %	13.9	4.4 %	1.0	(30.7) %	5.6	(20.7) %	9.7	10.9 %		
ADYNOVATE/ADYNOVI	14.6	16.9	15.7 %	7.7	17.6 %	3.5	(2.4) %	3.9	25.0 %	1.8	32.7 %		
FEIBA *4	8.8	10.8	22.7 %	3.6	60.2 %	0.2	19.4 %	2.6	(8.8) %	4.4	24.4 %		
RECOMBINATE	2.6	3.0	13.2 %	2.8	15.9 %	—	-	0.2	(9.2) %	0.0	(58.6) %		
HEMOFIL/IMMUNATE/IMMUNINE*4	5.1	5.3	3.3 %	0.7	(15.2) %	—	-	0.9	(31.6) %	3.7	23.5 %		
Other PDT Products *4	1.1	1.0	(7.4) %	(0.0)	-	0.0	-	0.9	2.1 %	0.1	(62.3) %		
Others	6.6	9.5	43.0 %	3.3	16.8 %	0.9	11.3 %	2.2	31.5 %	3.1	132.0 %		
Rare Genetics and Other	**75.2**	**104.0**	**38.3 %**	**52.1**	**53.1 %**	**3.1**	**410.1 %**	**31.7**	**7.5 %**	**17.1**	**53.9 %**		
TAKHZYRO	22.1	38.8	75.8 %	29.1	75.4 %	0.2	-	7.2	44.0 %	2.2	406.6 %		
ELAPRASE	16.2	20.2	24.7 %	6.3	28.9 %	0.2	-	7.6	13.3 %	6.1	31.0 %		
REPLAGAL	11.9	16.7	40.6 %	—	-	2.1	-	9.1	3.6 %	5.5	76.3 %		
VPRIV	10.5	11.5	8.9 %	4.9	18.0 %	0.3	(17.2) %	3.9	(3.1) %	2.4	17.6 %		
FIRAZYR	7.5	6.6	(11.5) %	4.2	1.5 %	0.4	0.7 %	1.3	(44.9) %	0.8	20.6 %		
CINRYZE *4	4.6	4.9	6.0 %	3.8	20.8 %	—	-	1.1	(19.2) %	0.1	(62.3) %		
LIVTENCITY	—	2.0	-	2.0	-	—	-	0.0	-	0.0	-		
Others	2.4	3.3	36.6 %	1.8	60.6 %	—	-	1.5	16.8 %	0.0	(78.1) %		

*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

■ Q2

(Bn JPY)	Reported												
	FY21 Q2	FY22 Q2	YOY	US	YOY	Japan	YOY	EUCAN	YOY	GEM*4	YOY	Ex-US	YOY
PDT Immunology	**130.8**	**172.1**	**31.6 %**	**115.0**	**32.5 %**							**57.1**	**29.8 %**
immunoglobulin *1	99.7	133.2	33.6 %	102.2	33.6 %							31.1	33.6 %
albumin *1	24.0	29.8	24.1 %	5.6	18.8 %							24.2	25.4 %
Others *1	7.1	9.1	27.6 %	7.3	28.0 %							1.9	26.1 %
Oncology	**112.3**	**107.8**	**(4.0)%**	**37.0**	**(27.6)%**	**22.3**	**2.4 %**	**21.0**	**9.9 %**	**25.5**	**40.2 %**	**2.1**	**(7.2)%**
VELCADE *2	25.0	4.3	(82.6) %	3.9	(83.7) %							0.4	(53.4) %
LEUPLIN/ENANTONE	27.6	25.7	(7.1) %	4.9	(29.9) %	5.6	(25.4) %	7.6	6.0 %	7.5	27.2 %		
NINLARO	21.4	25.1	17.0 %	14.7	22.4 %	1.6	9.4 %	3.3	(3.6) %	5.4	20.8 %		
ADCETRIS	16.9	21.8	28.6 %			3.1	8.7 %	8.3	14.5 %	10.4	51.9 %		
ICLUSIG *2	7.5	12.0	59.6 %	10.3	67.4 %							1.6	23.8 %
VECTIBIX	6.6	6.6	(0.2) %			6.6	(0.2) %						
ALUNBRIG	3.1	5.2	65.3 %	1.9	33.9 %	0.4	40.3 %	1.4	55.9 %	1.4	181.3 %		
ZEJULA	1.8	3.3	86.0 %			2.7	85.8 %			0.6	87.3 %		
CABOMETYX	1.5	1.9	34.0 %			1.9	34.0 %						
EXKIVITY	0.2	0.7	212.2 %	0.7	206.1 %	—	-	0.0	-	0.0	-		
Others	0.7	1.3	85.9 %	0.5	258.7 %	0.2	-	0.4	2.7 %	0.2	12.9 %		
Neuroscience	**120.3**	**159.9**	**32.9 %**	**125.1**	**32.2 %**	**10.0**	**17.7 %**	**20.2**	**35.5 %**	**4.6**	**98.8 %**		
VYVANSE/ELVANSE	80.1	111.3	39.0 %	90.4	35.5 %	0.0	(96.7) %	16.5	49.4 %	4.4	107.2 %		
TRINTELLIX	22.2	28.4	27.9 %	26.4	26.4 %	2.0	51.0 %			—	-		
INTUNIV	4.2	5.3	26.5 %	0.1	261.1 %	2.9	109.8 %	2.0	(21.3) %	0.2	27.8 %		
ADDERALL XR	5.7	6.3	11.8 %	5.8	12.4 %	—	-	0.5	5.0 %	—	-		
ROZEREM	3.1	3.2	3.5 %	0.0	(42.2) %	3.1	5.0 %	0.0	114.1 %	0.0	(21.2) %		
Others	5.1	5.4	6.2 %	2.3	33.5 %	1.9	(24.8) %	1.1	48.0 %	—	-		
Others	**118.2**	**105.9**	**(10.4)%**										
AZILVA *3	17.7	17.6	(0.4) %	—	-	17.6	(0.4) %	—	-	—	-		
LOTRIGA	8.2	2.1	(74.6) %			2.1	(74.6) %						
FOSRENOL *2	3.6	3.3	(8.6) %	0.3	(66.5) %							3.1	6.4 %
ACTOVEGIN	3.5	4.4	27.7 %	—	-	—	-	0.3	35.1 %	4.1	27.2 %		

*1 PDT products

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

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

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

■ Q3

(Bn JPY)	Reported													
	FY21 Q3	FY22 Q3	YOY	US	YOY	Japan	YOY	EUCAN	YOY	GEM*5	YOY	Ex-US	YOY
GI	**236.6**	**311.1**	**31.5 %**	**186.0**	**40.0 %**	**31.1**	**(0.4)%**	**63.1**	**23.9 %**	**25.4**	**56.3 %**	**5.5**	**2.3 %**
ENTYVIO	139.5	201.3	44.3 %	144.5	52.6 %	3.6	15.5 %	43.6	22.4 %	9.6	58.4 %		
TAKECAB/VOCINTI *1	29.3	29.8	2.0 %	—	-	25.5	(6.5) %	—	-	4.3	122.7 %		
GATTEX/REVESTIVE	19.8	29.8	50.4 %	22.1	39.4 %	1.7	180.8 %	4.0	38.4 %	2.0	311.0 %		
DEXILANT	14.4	17.1	18.6 %	8.6	1.3 %	—	-	3.8	34.6 %	4.7	51.5 %		
PANTOLOC/CONTROLOC*2	10.2	11.6	13.4 %	—	(100.0) %	—	-	8.5	22.8 %	3.1	14.9 %		
LIALDA/MEZAVANT *3	7.3	6.3	(13.3) %	0.9	(55.4) %							5.5	2.3 %
PENTASA	5.7	2.6	(54.7) %	2.6	(54.7) %								
RESOLOR/MOTEGRITY	3.7	5.6	50.8 %	5.0	64.9 %	—	-	0.6	(10.3) %	—	-		
ALOFISEL	0.6	0.8	53.1 %	—	-	0.0	-	0.8	56.9 %	0.1	(21.8) %		
Others	6.1	6.1	0.5 %	2.3	(4.7) %	0.2	33.2 %	1.8	22.1 %	1.8	(12.0) %		
Rare Diseases	**162.8**	**191.4**	**17.5 %**	**89.7**	**26.0 %**	**10.1**	**(3.1)%**	**50.1**	**4.5 %**	**41.5**	**24.7 %**		
Rare Hematology	**70.0**	**76.9**	**9.9 %**	**31.3**	**5.0 %**	**6.4**	**(9.2)%**	**16.9**	**(2.4)%**	**22.3**	**41.2 %**		
ADVATE	28.0	29.7	6.1 %	14.6	3.8 %	1.2	(20.2) %	4.9	(19.2) %	9.0	42.1 %		
ADYNOVATE/ADYNOVI	15.9	15.5	(2.8) %	5.5	(13.2) %	3.9	(6.9) %	4.4	13.5 %	1.6	11.2 %		
FEIBA *4	8.8	11.3	28.3 %	3.3	17.6 %	0.1	(40.8) %	2.8	45.1 %	5.1	31.1 %		
RECOMBINATE	3.3	3.5	6.2 %	3.2	6.3 %	—	-	0.2	13.8 %	0.0	(75.3) %		
HEMOFIL/IMMUNATE/IMMUNINE*4	5.2	4.2	(18.5) %	0.9	(6.4) %	—	-	1.0	(20.1) %	2.3	(21.8) %		
Other PDT Products *4	1.1	1.2	10.6 %	(0.0)	100.0 %	0.0	-	1.1	8.1 %	0.1	15.7 %		
Others	7.7	11.5	49.3 %	3.7	46.4 %	1.2	0.4 %	2.5	(16.7) %	4.2	299.8 %		
Rare Genetics and Other	**92.8**	**114.4**	**23.3 %**	**58.4**	**41.1 %**	**3.7**	**10.0 %**	**33.2**	**8.4 %**	**19.2**	**9.7 %**		
TAKHZYRO	30.9	44.1	42.6 %	33.5	38.4 %	0.4	-	7.9	33.6 %	2.2	189.6 %		
ELAPRASE	22.9	22.6	(1.4) %	6.7	27.2 %	0.1	(82.0) %	7.3	6.2 %	8.5	(16.1) %		
REPLAGAL	13.6	16.3	19.2 %	—	-	2.3	59.5 %	9.8	13.2 %	4.2	17.5 %		
VPRIV	11.2	13.0	16.2 %	5.3	17.7 %	0.4	(17.4) %	4.1	7.6 %	3.2	33.6 %		
FIRAZYR	7.1	6.4	(9.6) %	3.8	21.8 %	0.5	(38.7) %	1.2	(51.2) %	0.9	38.3 %		
CINRYZE *4	4.5	5.3	17.1 %	4.0	28.7 %	—	-	1.0	(23.7) %	0.2	628.5 %		
LIVTENCITY	0.2	3.1	1,525.0 %	3.0	1,456.3 %	—	-	0.1	-	0.0	-		
Others	2.4	3.8	56.3 %	2.1	116.4 %	—	-	1.7	16.6 %	0.0	(77.5) %		

*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

■ Q3

(Bn JPY)	Reported													
	FY21 Q3	FY22 Q3	YOY	US	YOY	Japan	YOY	EUCAN	YOY	GEM*4	YOY	Ex-US	YOY
PDT Immunology	**125.2**	**188.4**	**50.5 %**	**124.9**	**52.7 %**							**63.6**	**46.3 %**
immunoglobulin *1	97.0	145.4	49.9 %	111.6	55.2 %							33.8	34.9 %
albumin *1	19.7	33.7	70.9 %	6.1	78.2 %							27.6	69.3 %
Others *1	8.5	9.3	9.3 %	7.1	11.0 %							2.1	4.0 %
Oncology	**125.4**	**119.7**	**(4.6)%**	**42.8**	**(28.6)%**	**24.8**	**1.8 %**	**23.1**	**19.0 %**	**26.7**	**41.2 %**	**2.2**	**(17.7)%**
VELCADE *2	29.3	3.9	(86.7)%	3.2	(88.6)%							0.7	(34.3)%
LEUPLIN/ENANTONE	28.4	31.5	11.2 %	8.4	32.2 %	7.1	(13.4)%	8.5	9.3 %	7.6	24.9 %		
NINLARO	24.9	27.1	8.7 %	16.7	7.3 %	1.7	1.5 %	3.4	(3.0)%	5.3	26.8 %		
ADCETRIS	17.6	24.1	36.4 %			3.4	9.4 %	9.2	34.6 %	11.5	48.9 %		
ICLUSIG *2	8.8	12.3	39.5 %	10.8	49.7 %							1.5	(6.9)%
VECTIBIX	6.6	6.8	3.5 %			6.8	3.5 %						
ALUNBRIG	3.9	6.1	55.7 %	2.3	13.7 %	0.4	37.2 %	1.7	64.4 %	1.7	212.3 %		
ZEJULA	2.4	3.5	44.7 %			2.9	41.7 %			0.6	62.6 %		
CABOMETYX	1.8	2.1	19.8 %			2.1	19.8 %						
EXKIVITY	0.2	0.8	289.2 %	0.8	284.2 %	—	-	0.0	-	0.0	245.8 %		
Others	1.4	1.4	3.1 %	0.6	79.9 %	0.3	(56.0)%	0.4	11.7 %	0.2	61.5 %		
Neuroscience	**128.9**	**174.8**	**35.6 %**	**135.1**	**35.8 %**	**9.5**	**2.1 %**	**23.7**	**34.3 %**	**6.6**	**163.3 %**		
VYVANSE/ELVANSE	85.7	124.2	44.9 %	98.3	39.7 %	0.4	8,453.2 %	19.3	47.2 %	6.2	173.4 %		
TRINTELLIX	23.0	29.9	30.1 %	27.6	29.1 %	2.3	43.4 %			—	-		
INTUNIV	5.0	6.2	22.4 %	0.1	21.5 %	3.3	95.6 %	2.3	(22.1)%	0.4	64.0 %		
ADDERALL XR	6.3	6.5	3.5 %	6.0	3.9 %	—	-	0.6	(0.1)%	—	-		
ROZEREM	3.1	1.3	(58.3)%	(0.0)	90.3 %	1.3	(60.3)%	(0.0)	-	0.0	81.1 %		
Others	5.7	6.7	16.6 %	3.1	52.4 %	2.1	(23.1)%	1.5	56.2 %	—	-		
Others	**122.3**	**111.1**	**(9.2)%**										
AZILVA *3	19.7	19.4	(1.5)%	—	-	19.4	(1.5)%	—	-	—	-		
LOTRIGA	8.7	2.8	(67.6)%			2.8	(67.6)%						
FOSRENOL *2	3.2	3.4	6.0 %	0.2	-							3.2	0.7 %
ACTOVEGIN	4.3	4.0	(8.9)%	—	-	—	-	0.2	23.1 %	3.7	(10.3)%		

*1 PDT products

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

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

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

■

■ Q4

(Bn JPY)	Reported													
	FY21 Q4	FY22 Q4	YOY	US	YOY	Japan	YOY	EUCAN	YOY	GEM*5	YOY	Ex-US	YOY
GI	**210.0**	**237.0**	**12.9 %**	**128.7**	**12.5 %**	**26.2**	**4.9 %**	**56.7**	**17.0 %**	**20.5**	**14.3 %**	**5.0**	**18.1 %**
ENTYVIO	126.4	154.9	22.5 %	103.6	24.0 %	3.2	15.7 %	40.1	18.7 %	8.1	26.1 %		
TAKECAB/VOCINTI *1	24.0	24.2	0.6 %	—	(100.0) %	21.2	0.1 %	—	-	2.9	8.9 %		
GATTEX/REVESTIVE	19.1	14.9	(22.3) %	9.3	(36.3) %	1.6	90.4 %	3.3	17.2 %	0.6	(20.7) %		
DEXILANT	10.6	14.3	34.2 %	7.4	42.8 %	—	-	3.0	10.9 %	3.9	40.9 %		
PANTOLOC/CONTROLOC*2	10.2	11.7	15.0 %	1.0	134.5 %	—	-	7.5	11.6 %	3.2	5.8 %		
LIALDA/MEZAVANT *3	7.4	6.1	(17.7) %	1.2	(64.2) %							5.0	18.1 %
PENTASA	4.4	1.1	(74.8) %	1.1	(74.8) %								
RESOLOR/MOTEGRITY	2.9	4.8	66.1 %	4.2	91.8 %	—	-	0.6	(16.5) %	—	-		
ALOFISEL	0.5	0.7	51.2 %	—	-	0.1	-	0.7	53.6 %	0.0	(51.3) %		
Others	4.4	4.3	(0.9) %	0.9	35.0 %	0.2	(13.2) %	1.6	17.0 %	1.7	(22.2) %		
Rare Diseases	**148.3**	**169.8**	**14.5 %**	**76.2**	**17.0 %**	**7.6**	**29.6 %**	**48.1**	**9.8 %**	**38.0**	**13.2 %**		
Rare Hematology	**72.1**	**72.1**	**(0.0)%**	**30.6**	**5.9 %**	**4.9**	**(6.9)%**	**15.5**	**5.3 %**	**21.1**	**(9.2)%**		
ADVATE	29.2	26.1	(10.6) %	13.8	9.4 %	0.8	(27.2) %	4.8	(10.1) %	6.7	(33.9) %		
ADYNOVATE/ADYNOVI	14.9	16.7	12.4 %	7.6	17.9 %	3.1	(4.1) %	4.4	14.9 %	1.6	19.5 %		
FEIBA *4	10.2	8.7	(14.8) %	2.5	(33.7) %	0.1	58.7 %	1.3	(30.1) %	4.8	5.4 %		
RECOMBINATE	2.7	3.1	14.1 %	2.8	12.0 %	—	-	0.2	11.4 %	0.1	323.9 %		
HEMOFIL/IMMUNATE/IMMUNINE*4	4.2	4.7	12.9 %	0.6	(20.8) %	—	-	0.8	9.9 %	3.4	22.8 %		
Other PDT Products *4	0.9	1.1	23.2 %	—	(100.0) %	0.0	-	1.0	22.9 %	0.1	(5.1) %		
Others	10.1	11.7	15.8 %	3.3	16.7 %	0.8	0.2 %	3.0	51.2 %	4.6	2.3 %		
Rare Genetics and Other	**76.2**	**97.8**	**28.3 %**	**45.6**	**25.9 %**	**2.7**	**365.9 %**	**32.6**	**12.0 %**	**16.9**	**63.9 %**		
TAKHZYRO	24.8	34.9	40.7 %	24.7	34.3 %	0.4	-	8.4	62.6 %	1.4	10.3 %		
ELAPRASE	15.4	20.3	31.9 %	6.3	22.2 %	(0.2)	(2,646.6) %	7.4	6.7 %	6.8	108.4 %		
REPLAGAL	12.1	16.2	33.2 %	—	-	2.0	2,060.4 %	9.2	5.6 %	5.0	49.7 %		
VPRIV	10.2	12.0	17.6 %	5.1	15.1 %	0.2	(11.7) %	3.9	1.5 %	2.8	63.9 %		
FIRAZYR	5.2	4.8	(7.7) %	2.9	4.9 %	0.3	20.7 %	0.8	(51.8) %	0.8	64.8 %		
CINRYZE *4	4.6	3.6	(22.2) %	2.7	(12.8) %	—	-	0.8	(34.5) %	0.0	(79.4) %		
LIVTENCITY	1.1	3.2	180.9 %	2.7	138.8 %	—	-	0.5	-	0.0	1,554.8 %		
Others	2.6	2.7	3.0 %	1.2	(3.7) %	—	-	1.5	8.7 %	0.0	(23.0) %		

*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

■ Q4

(Bn JPY)	Reported											
	FY21 Q4	FY22 Q4	YOY	US	YOY	Japan	YOY	EUCAN	YOY	GEM*4	YOY	Ex-US	YOY
PDT Immunology	**143.7**	**176.0**	**22.5 %**	**106.0**	**16.5 %**							**70.0**	**32.8 %**
immunoglobulin *1	107.6	131.7	22.5 %	93.9	16.0 %							37.9	42.0 %
albumin *1	28.5	35.9	25.9 %	5.6	41.6 %							30.3	23.4 %
Others *1	7.6	8.4	10.0 %	6.5	6.5 %							1.8	24.0 %
Oncology	**109.6**	**93.8**	**(14.5)%**	**30.7**	**(39.3)%**	**20.8**	**20.7 %**	**20.2**	**5.2 %**	**19.5**	**(4.7)%**	**2.5**	**21.7 %**
VELCADE *2	25.6	3.0	(88.2) %	2.8	(88.6) %							0.2	(73.0) %
LEUPLIN/ENANTONE	24.2	26.1	7.8 %	4.2	(27.9) %	6.1	50.2 %	8.5	13.0 %	7.3	7.1 %		
NINLARO	20.5	16.8	(18.1) %	10.8	0.5 %	1.4	3.4 %	1.3	(61.1) %	3.3	(36.1) %		
ADCETRIS	17.4	18.2	4.3 %			2.9	4.6 %	8.4	17.8 %	6.9	(8.7) %		
ICLUSIG *2	8.2	11.7	42.9 %	9.3	38.0 %							2.4	65.8 %
VECTIBIX	5.3	5.7	7.0 %			5.7	7.0 %						
ALUNBRIG	3.5	4.8	36.3 %	1.9	16.6 %	0.5	92.4 %	1.7	51.7 %	0.8	38.2 %		
ZEJULA	2.2	3.1	38.2 %			2.4	32.1 %			0.6	67.6 %		
CABOMETYX	1.6	1.7	10.4 %			1.7	10.4 %						
EXKIVITY	0.5	1.5	186.6 %	1.0	85.3 %	—	-	0.0	-	0.5	11,340.8 %		
Others	0.6	1.2	110.2 %	0.7	215.5 %	—	-	0.4	45.0 %	0.2	42.2 %		
Neuroscience	**119.7**	**160.6**	**34.2 %**	**134.1**	**48.6 %**	**1.7**	**(82.6)%**	**22.0**	**27.3 %**	**2.8**	**10.0 %**		
VYVANSE/ELVANSE	82.1	123.8	50.9 %	103.6	56.0 %	(0.2)	-	17.8	36.0 %	2.7	14.0 %		
TRINTELLIX	19.3	20.4	5.7 %	18.4	2.5 %	2.0	47.6 %			—	-		
INTUNIV	6.4	(0.3)	-	0.0	24.0 %	(2.5)	-	2.1	(16.2) %	0.1	(35.1) %		
ADDERALL XR	4.9	9.5	93.1 %	8.8	97.6 %	—	-	0.8	53.2 %	—	-		
ROZEREM	2.2	0.9	(61.8) %	0.0	-	0.8	(68.1) %	—	(100.0) %	0.0	(47.2) %		
Others	4.7	6.3	32.1 %	3.3	83.4 %	1.6	(8.2) %	1.3	12.3 %	—	-		
Others	**142.0**	**118.9**	**(16.3)%**										
AZILVA *3	16.2	16.3	0.4 %	—	-	16.3	0.4 %	—	-	—	-		
LOTRIGA	7.9	3.4	(57.1) %			3.4	(57.1) %						
FOSRENOL *2	3.4	2.6	(23.3) %	0.3	(31.4) %							2.4	(22.3) %
ACTOVEGIN	2.4	4.2	76.3 %	—	-	—	-	0.2	65.6 %	4.0	76.9 %		

*1 PDT products

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

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

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

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Product Sales Analysis (Reported & Core CER Change)

(Bn JPY)	FY21 Reported				FY22 Reported & Core CER Change[*4]													
					YOY			YOY				YOY				YOY			
	Q1	Q2	Q3	Q4	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 %**	**276.0**	**26.3 %**	**8.2 %**	**11.7 %**	**311.1**	**31.5 %**	**9.8 %**	**11.1 %**	**237.0**	**12.9 %**	**1.0 %**	**8.7 %**
ENTYVIO	125.4	130.5	139.5	126.4	168.3	34.2 %	19.4 %	178.3	36.6 %	15.0 %	17.1 %	201.3	44.3 %	17.9 %	17.4 %	154.9	22.5 %	8.1 %	15.2 %
TAKECAB/VOCINTI [*1]	24.3	24.8	29.3	24.0	27.6	13.9 %	11.8 %	27.1	8.9 %	6.2 %	9.0 %	29.8	2.0 %	(0.3)%	5.5 %	24.2	0.6 %	(0.4)%	4.1 %
GATTEX/REVESTIVE	18.1	18.7	19.8	19.1	21.9	20.9 %	7.0 %	26.5	41.7 %	17.6 %	12.4 %	29.8	50.4 %	21.9 %	15.7 %	14.9	(22.3)%	(30.7)%	4.0 %
DEXILANT	10.8	14.9	14.4	10.6	22.3	107.0 %	76.5 %	15.7	5.0 %	(13.3)%	24.4 %	17.1	18.6 %	(3.8)%	14.3 %	14.3	34.2 %	16.6 %	14.8 %
PANTOLOC/CONTROLOC[*2]	10.4	9.4	10.2	10.2	11.3	8.5 %	2.1 %	10.9	15.4 %	5.7 %	3.8 %	11.6	13.4 %	0.1 %	2.6 %	11.7	15.0 %	3.8 %	2.9 %
LIALDA/MEZAVANT	6.4	5.3	7.3	7.4	5.7	(10.9)%	(18.2)%	5.6	4.9 %	(7.6)%	(13.4)%	6.3	(13.3)%	(27.0)%	(18.7)%	6.1	(17.7)%	(26.2)%	(20.8)%
PENTASA	4.8	5.2	5.7	4.4	2.6	(47.2)%	(54.1)%	2.1	(58.8)%	(67.0)%	(60.8)%	2.6	(54.7)%	(63.7)%	(61.8)%	1.1	(74.8)%	(78.0)%	(65.4)%
RESOLOR/MOTEGRITY	3.2	3.2	3.7	2.9	3.9	21.8 %	7.3 %	3.8	20.9 %	0.6 %	4.0 %	5.6	50.8 %	21.0 %	10.2 %	4.8	66.1 %	44.7 %	17.9 %
ALOFISEL	0.4	0.4	0.6	0.5	0.6	59.3 %	50.0 %	0.5	25.9 %	16.9 %	33.0 %	0.8	53.1 %	37.3 %	34.7 %	0.7	51.2 %	37.8 %	35.6 %
Others	6.7	6.1	6.1	4.4	6.1	(8.5)%	(15.9)%	5.5	(9.5)%	(20.1)%	(17.9)%	6.1	0.5 %	(14.1)%	(16.7)%	4.3	(0.9)%	(9.6)%	(15.3)%
Rare Diseases	**155.5**	**144.6**	**162.8**	**148.3**	**181.6**	**16.8 %**	**7.3 %**	**180.6**	**24.9 %**	**9.3 %**	**8.3 %**	**191.4**	**17.5 %**	**(0.9)%**	**5.0 %**	**169.8**	**14.5 %**	**4.0 %**	**4.8 %**
Rare Hematology	**72.2**	**69.4**	**70.0**	**72.1**	**79.1**	**9.6 %**	**0.7 %**	**76.6**	**10.4 %**	**(3.7)%**	**(1.5)%**	**76.9**	**9.9 %**	**(7.4)%**	**(3.4)%**	**72.1**	**(0.0)%**	**(10.0)%**	**(5.1)%**
ADVATE	30.7	30.6	28.0	29.2	32.1	4.7 %	(4.7)%	30.3	(1.2)%	(14.2)%	(9.4)%	29.7	6.1 %	(11.6)%	(10.1)%	26.1	(10.6)%	(19.3)%	(12.4)%
ADYNOVATE/ADYNOVI	15.4	14.6	15.9	14.9	17.5	13.9 %	4.8 %	16.9	15.7 %	3.1 %	4.0 %	15.5	(2.8)%	(13.8)%	(2.2)%	16.7	12.4 %	2.4 %	(1.0)%
FEIBA [*3]	11.4	8.8	8.8	10.2	10.5	(7.6)%	(12.3)%	10.8	22.7 %	7.8 %	(3.6)%	11.3	28.3 %	10.0 %	0.5 %	8.7	(14.8)%	(21.6)%	(5.2)%
RECOMBINATE	3.7	2.6	3.3	2.7	3.2	(12.7)%	(24.1)%	3.0	13.2 %	(7.7)%	(17.3)%	3.5	6.2 %	(15.4)%	(16.7)%	3.1	14.1 %	(0.5)%	(13.1)%
HEMOFIL/IMMUNATE/ IMMUNINE[*3]	3.3	5.1	5.2	4.2	5.4	63.9 %	53.9 %	5.3	3.3 %	(5.4)%	17.9 %	4.2	(18.5)%	(32.0)%	(1.1)%	4.7	12.9 %	5.1 %	0.3 %
Other PDT Products [*3]	0.9	1.1	1.1	0.9	1.1	31.8 %	25.1 %	1.0	(7.4)%	(15.4)%	2.6 %	1.2	10.6 %	(2.4)%	0.8 %	1.1	23.2 %	13.2 %	3.6 %
Others	6.9	6.6	7.7	10.1	9.2	33.3 %	21.3 %	9.5	43.0 %	19.4 %	20.4 %	11.5	49.3 %	20.6 %	20.5 %	11.7	15.8 %	(0.7)%	13.7 %
Rare Genetics and Other	**83.3**	**75.2**	**92.8**	**76.2**	**102.5**	**23.1 %**	**13.1 %**	**104.0**	**38.3 %**	**21.3 %**	**17.0 %**	**114.4**	**23.3 %**	**4.0 %**	**12.2 %**	**97.8**	**28.3 %**	**17.3 %**	**13.4 %**
TAKHZYRO	25.5	22.1	30.9	24.8	34.0	33.7 %	18.7 %	38.8	75.8 %	46.1 %	31.4 %	44.1	42.6 %	15.5 %	25.1 %	34.9	40.7 %	24.4 %	25.0 %
ELAPRASE	18.6	16.2	22.9	15.4	22.2	19.3 %	12.0 %	20.2	24.7 %	14.4 %	13.1 %	22.6	(1.4)%	(16.4)%	1.4 %	20.3	31.9 %	20.9 %	5.5 %
REPLAGAL	14.1	11.9	13.6	12.1	17.6	25.3 %	21.5 %	16.7	40.6 %	34.6 %	27.5 %	16.3	19.2 %	12.0 %	22.2 %	16.2	33.2 %	30.9 %	24.2 %
VPRIV	10.5	10.5	11.2	10.2	11.9	13.5 %	4.3 %	11.5	8.9 %	(3.7)%	0.3 %	13.0	16.2 %	0.2 %	0.3 %	12.0	17.6 %	9.7 %	2.5 %
FIRAZYR	6.9	7.5	7.1	5.2	6.8	(1.7)%	(11.5)%	6.6	(11.5)%	(24.5)%	(18.3)%	6.4	(9.6)%	(24.3)%	(20.3)%	4.8	(7.7)%	(15.6)%	(19.4)%
CINRYZE [*3]	5.6	4.6	4.5	4.6	4.7	(16.7)%	(24.8)%	4.9	6.0 %	(10.1)%	(18.2)%	5.3	17.1 %	(4.4)%	(14.0)%	3.6	(22.2)%	(31.7)%	(18.2)%
LIVTENCITY	—	—	0.2	1.1	2.2	-	-	2.0	-	-	-	3.1	1,525.0 %	1,180.5 %	3,053.2 %	3.2	180.9 %	145.3 %	561.7 %
Others	2.2	2.4	2.4	2.6	3.2	42.0 %	30.4 %	3.3	36.6 %	18.5 %	24.2 %	3.8	56.3 %	30.8 %	26.5 %	2.7	3.0 %	(8.2)%	17.0 %

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

*2 Generic name: pantoprazole

*3 PDT products

*4 Refer to *Analysis of Results of Operations, Financial Position, and Cash Flow "Core Results, Definition of Core financial measures and Constant Exchange Rate change"* for the definition.

(Bn JPY)	FY21 Reported				FY22 Reported & Core CER Change[*4]													
					YOY			YOY				YOY				YOY			
	Q1	Q2	Q3	Q4	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 %**	**172.1**	**31.6 %**	**11.1 %**	**14.2 %**	**188.4**	**50.5 %**	**24.1 %**	**17.6 %**	**176.0**	**22.5 %**	**9.5 %**	**15.3 %**
immunoglobulin [*1]	81.6	99.7	97.0	107.6	111.8	37.0 %	22.1 %	133.2	33.6 %	12.7 %	16.9 %	145.4	49.9 %	22.5 %	18.9 %	131.7	22.5 %	8.6 %	16.0 %
albumin [*1]	17.8	24.0	19.7	28.5	22.0	23.8 %	10.5 %	29.8	24.1 %	5.9 %	7.8 %	33.7	70.9 %	47.1 %	20.5 %	35.9	25.9 %	16.0 %	19.0 %
Others [*1]	7.8	7.1	8.5	7.6	8.0	2.8 %	(8.3)%	9.1	27.6 %	6.6 %	(1.2)%	9.3	9.3 %	(10.6)%	(4.6)%	8.4	10.0 %	(2.8)%	(4.2)%
Oncology	**121.4**	**112.3**	**125.4**	**109.6**	**117.5**	**(3.2)%**	**(10.1)%**	**107.8**	**(4.0)%**	**(13.1)%**	**(11.5)%**	**119.7**	**(4.6)%**	**(14.5)%**	**(12.6)%**	**93.8**	**(14.5)%**	**(20.2)%**	**(14.4)%**
VELCADE	30.1	25.0	29.3	25.6	16.5	(45.3)%	(52.2)%	4.3	(82.6)%	(85.9)%	(67.5)%	3.9	(86.7)%	(89.6)%	(75.1)%	3.0	(88.2)%	(89.8)%	(78.6)%
LEUPLIN/ENANTONE	26.2	27.6	28.4	24.2	28.0	6.8 %	2.8 %	25.7	(7.1)%	(12.5)%	(5.1)%	31.5	11.2 %	5.5 %	(1.4)%	26.1	7.8 %	3.3 %	(0.3)%
NINLARO	24.4	21.4	24.9	20.5	23.7	(2.6)%	(12.8)%	25.1	17.0 %	(0.8)%	(7.2)%	27.1	8.7 %	(9.3)%	(8.0)%	16.8	(18.1)%	(26.8)%	(12.2)%
ADCETRIS	17.2	16.9	17.6	17.4	20.0	15.9 %	10.5 %	21.8	28.6 %	20.5 %	15.5 %	24.1	36.4 %	23.7 %	18.3 %	18.2	4.3 %	(0.6)%	13.5 %
ICLUSIG	10.4	7.5	8.8	8.2	11.3	8.6 %	(4.1)%	12.0	59.6 %	34.5 %	12.1 %	12.3	39.5 %	15.1 %	13.1 %	11.7	42.9 %	25.0 %	15.9 %
VECTIBIX	6.2	6.6	6.6	5.3	6.7	8.4 %	8.4 %	6.6	(0.2)%	(0.2)%	4.0 %	6.8	3.5 %	3.5 %	3.8 %	5.7	7.0 %	7.0 %	4.5 %
ALUNBRIG	3.1	3.1	3.9	3.5	4.5	45.9 %	34.7 %	5.2	65.3 %	46.8 %	40.8 %	6.1	55.7 %	35.1 %	38.6 %	4.8	36.3 %	25.3 %	35.2 %
ZEJULA	1.6	1.8	2.4	2.2	3.0	94.0 %	92.2 %	3.3	86.0 %	83.5 %	87.5 %	3.5	44.7 %	42.8 %	68.8 %	3.1	38.2 %	35.9 %	59.6 %
CABOMETYX	1.6	1.5	1.8	1.6	2.1	34.3 %	34.3 %	1.9	34.0 %	34.0 %	34.2 %	2.1	19.8 %	19.8 %	28.8 %	1.7	10.4 %	10.4 %	24.3 %
EXKIVITY	—	0.2	0.2	0.5	0.7	-	-	0.7	212.2 %	153.6 %	409.6 %	0.8	289.2 %	206.4 %	314.4 %	1.5	186.6 %	154.5 %	228.4 %
Others	0.6	0.7	1.4	0.6	1.0	47.7 %	44.0 %	1.3	85.9 %	77.8 %	61.3 %	1.4	3.1 %	(3.3)%	28.3 %	1.2	110.2 %	98.0 %	40.8 %
Neuroscience	**113.4**	**120.3**	**128.9**	**119.7**	**142.4**	**25.6 %**	**10.7 %**	**159.9**	**32.9 %**	**10.4 %**	**10.6 %**	**174.8**	**35.6 %**	**9.6 %**	**10.2 %**	**160.6**	**34.2 %**	**17.9 %**	**12.1 %**
VYVANSE/ELVANSE	79.2	80.1	85.7	82.1	100.0	26.2 %	10.3 %	111.3	39.0 %	14.2 %	12.3 %	124.2	44.9 %	15.9 %	13.5 %	123.8	50.9 %	32.2 %	18.2 %
TRINTELLIX	17.9	22.2	23.0	19.3	21.4	20.0 %	5.2 %	28.4	27.9 %	4.9 %	5.1 %	29.9	30.1 %	4.4 %	4.8 %	20.4	5.7 %	(6.7)%	2.1 %
INTUNIV	3.3	4.2	5.0	6.4	5.1	57.3 %	49.1 %	5.3	26.5 %	16.6 %	30.7 %	6.2	22.4 %	9.4 %	22.1 %	(0.3)	-	-	(20.1)%
ADDERALL XR	3.9	5.7	6.3	4.9	6.2	56.4 %	33.9 %	6.3	11.8 %	(9.9)%	8.0 %	6.5	3.5 %	(17.0)%	(1.9)%	9.5	93.1 %	65.3 %	14.0 %
ROZEREM	3.2	3.1	3.1	2.2	3.3	2.9 %	2.5 %	3.2	3.5 %	3.1 %	2.8 %	1.3	(58.3)%	(58.5)%	(17.5)%	0.9	(61.8)%	(62.1)%	(26.0)%
Others	5.9	5.1	5.7	4.7	6.4	8.4 %	1.0 %	5.4	6.2 %	(3.6)%	(1.1)%	6.7	16.6 %	2.5 %	0.1 %	6.3	32.1 %	20.6 %	4.6 %
Others [*2]	**241.6**	**118.2**	**122.3**	**142.0**	**118.7**	**(50.9)%**	**4.8 %**	**105.9**	**(10.4)%**	**(16.8)%**	**(6.5)%**	**111.1**	**(9.2)%**	**(18.9)%**	**(10.8)%**	**118.9**	**(16.3)%**	**(12.4)%**	**(11.2)%**
AZILVA [*3]	22.6	17.7	19.7	16.2	19.6	(13.6)%	(13.6)%	17.6	(0.4)%	(0.4)%	(7.8)%	19.4	(1.5)%	(1.5)%	(5.8)%	16.3	0.4 %	0.4 %	(4.5)%
LOTRIGA	7.8	8.2	8.7	7.9	8.4	7.5 %	7.5 %	2.1	(74.6)%	(74.6)%	(34.6)%	2.8	(67.6)%	(67.6)%	(46.2)%	3.4	(57.1)%	(57.1)%	(48.8)%
FOSRENOL	3.4	3.6	3.2	3.4	4.2	24.9 %	16.3 %	3.3	(8.6)%	(17.0)%	(1.0)%	3.4	6.0 %	(6.2)%	(2.6)%	2.6	(23.3)%	(31.0)%	(9.8)%
ACTOVEGIN	3.2	3.5	4.3	2.4	3.2	(1.1)%	(16.6)%	4.4	27.7 %	(9.3)%	(12.8)%	4.0	(8.9)%	(33.5)%	(20.9)%	4.2	76.3 %	39.6 %	(10.2)%

*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.

*4 Refer to *Analysis of Results of Operations, Financial Position, and Cash Flow "Core Results, Definition of Core financial measures and Constant Exchange Rate change"* for the definition.

Product Forecasts

(Bn JPY)	FY22 Reported Annual	FY23 Reported Forecasts Annual	FY23 Reported Forecasts YOY		FY23 Core Forecasts at CER*4 YOY
GI	**1,094.5**		**High-single-digit growth**		**Low-10s % growth**
ENTYVIO	702.7	788.0	85.3	12 %	15 %
TAKECAB/VOCINTI *1	108.7	132.0	23.3	21 %	22 %
GATTEX/REVESTIVE	93.1	106.0	12.9	14 %	16 %
DEXILANT	69.4	36.0	(33.4)	(48)%	(46)%
PANTOLOC/CONTROLOC*2	45.5	43.0	(2.5)	(6)%	(4)%
LIALDA/MEZAVANT	23.7	26.0	2.3	9 %	13 %
RESOLOR/MOTEGRITY	18.2	19.0	0.8	5 %	11 %
ALOFISEL	2.7	4.0	1.3	47 %	65 %
Others	30.5			(20)% to (25)%	(20)% to (25)%
Rare Diseases	**723.4**				
Rare Hematology	**304.7**			**High-single-digit decline**	**Mid-single-digit decline**
ADVATE	118.2	172.0	(12.7)	(7)%	(6)%
ADYNOVATE/ADYNOVI	66.6				
FEIBA *3	41.3	37.0	(4.3)	(10)%	(8)%
RECOMBINATE	12.8	10.0	(2.8)	(22)%	(15)%
VONVENDI	12.2	15.0	2.8	23 %	28 %
HEMOFIL/IMMUNATE/ IMMUNINE*3	19.6	17.0	(2.6)	(13)%	(14)%
Other PDT Products *3	4.4	4.0	(0.4)	(10)%	(4)%
Others	29.7			(15)% to (20)%	(10)% to (15)%
Rare Genetics and Other	**418.7**			**Mid-single-digit growth**	**High-single-digit growth**
TAKHZYRO	151.8	158.0	6.2	4 %	7 %
ELAPRASE	85.3	84.0	(1.3)	(2)%	0 %
REPLAGAL	66.7	76.0	9.3	14 %	13 %
VPRIV	48.4	51.0	2.6	5 %	7 %
FIRAZYR	24.6	20.0	(4.6)	(19)%	(18)%
CINRYZE *3	18.4	16.0	(2.4)	(13)%	(9)%
LIVTENCITY	10.5			120% to 150%	120% to 150%
Others	13.0			(5%) to (10)%	0% to (5)%

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

*2 Generic name: pantoprazole

*3 PDT products

*4 Refer to *Analysis of Results of Operations, Financial Position, and Cash Flow "Core Results, Definition of Core financial measures and Constant Exchange Rate change"* for the definition.

Average FX rates for FY22: 1 USD = 135 JPY, 1 Euro = 141 JPY, 1 RUB = 2.1 JPY, 1 BRL = 26.3 JPY, 1 CNY = 19.7 JPY

Assumption of FX rates for FY23 Reported Forecasts : 1 USD = 131 JPY, 1 Euro = 141 JPY, 1 RUB = 1.9 JPY, 1 BRL = 25.9 JPY, 1 CNY = 19.5 JPY

(Bn JPY)	FY22 Reported Annual	FY23 Reported Forecasts Annual	YOY		FY23 Core Forecasts at CER[*4] YOY
PDT Immunology	**678.4**			**10% to 20%**	**10% to 20%**
immunoglobulin *1	522.2			10% to 20%	10% to 20%
albumin *1	121.4			5% to 15%	5% to 15%
Others *1 *3	34.8			5% to 15%	5% to 15%
Oncology	**438.7**			**Low-single-digit growth**	**Low-single-digit growth**
LEUPLIN/ENANTONE	111.3	109.0	(2.3)	(2)%	(2)%
NINLARO	92.7	91.0	(1.7)	(2)%	0 %
ADCETRIS	83.9	94.0	10.1	12 %	12 %
ICLUSIG	47.2	48.0	0.8	2 %	4 %
VELCADE	27.8	6.0	(21.8)	(78)%	(76)%
VECTIBIX	25.8	26.0	0.2	1 %	1 %
ALUNBRIG	20.6	29.0	8.4	41 %	43 %
ZEJULA	12.9	14.0	1.1	8 %	11 %
CABOMETYX	7.9	10.0	2.1	27 %	27 %
EXKIVITY	3.7			70% to 100%	70% to 100%
Others	4.9			>30%	>30%
Neuroscience	**637.7**			**High-20s % decline**	**Mid-20s % decline**
VYVANSE/ELVANSE	459.3	283.0	(176.3)	(38)%	(38)%
TRINTELLIX	100.1	108.0	7.9	8 %	11 %
ADDERALL XR	28.6	17.0	(11.6)	(41)%	(37)%
INTUNIV	16.4	34.0	17.6	108 %	111 %
Others	33.4			>(30)%	>(30)%
Others	**454.6**			**>(30)%**	**>(30)%**
AZILVA [*2]	72.9	30.0	(42.9)	(59)%	(59)%
FOSRENOL	13.5	10.0	(3.5)	(26)%	(22)%

*1 PDT products

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

*3 Others in PDT Immunology include GLASSIA and ARALAST.

*4 Refer to Analysis of Results of Operations, Financial Position, and Cash Flow "Core Results, Definition of Core financial measures and Constant Exchange Rate change" for the definition.

Average FX rates for FY22: 1 USD = 135 JPY, 1 Euro = 141 JPY, 1 RUB = 2.1 JPY, 1 BRL = 26.3 JPY, 1 CNY = 19.7 JPY

Assumption of FX rates for FY23 Reported Forecasts : 1 USD = 131 JPY, 1 Euro = 141 JPY, 1 RUB = 1.9 JPY, 1 BRL = 25.9 JPY, 1 CNY = 19.5 JPY

FINANCIAL APPENDIX

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 income and expenses (excluding depreciation and amortization), finance income and expenses (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 period. 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 Reported Results with Actual and CER % Change

(Billion JPY)	FY2021	FY2022		vs. PY	
				ACTUAL % CHANGE	CER % CHANGE*1
Revenue	3,569.0	4,027.5	458.5	12.8%	(0.8)%
Cost of sales	(1,106.8)	(1,244.1)	(137.2)	(12.4)%	0.1%
Gross profit	2,462.2	2,783.4	321.2	13.0%	(1.1)%
Margin	*69.0 %*	*69.1 %*		*0.1 pp*	*(0.2) pp*
SG&A expenses	(886.4)	(997.3)	(110.9)	(12.5)%	0.9%
R&D expenses	(526.1)	(633.3)	(107.2)	(20.4)%	(3.5)%
Amortization of intangible assets associated with products	(418.8)	(485.1)	(66.3)	(15.8)%	2.0%
Impairment losses on intangible assets associated with products	(54.1)	(57.3)	(3.2)	(5.9)%	12.7%
Other operating income	43.1	25.4	(17.7)	(41.0)%	(44.2)%
Other operating expenses	(159.1)	(145.2)	13.8	8.7%	21.1%
Operating profit	460.8	490.5	29.7	6.4%	(1.8)%
Margin	*12.9 %*	*12.2 %*		*(0.7) pp*	*(0.1) pp*
Finance income	23.7	62.9	39.2	165.5%	144.6%
Finance expenses	(166.6)	(169.7)	(3.1)	(1.9)%	4.2%
Share of profit (loss) of investments accounted for using the equity method	(15.4)	(8.6)	6.7	43.8%	50.6%
Profit before tax	302.6	375.1	72.5	24.0%	13.4%
Income tax expenses	(72.4)	(58.1)	14.4	19.8%	18.0%
Net profit for the year	230.2	317.0	86.9	37.7%	23.3%
Non-controlling interests	(0.1)	(0.0)	0.1	80.1%	83.9%
Net profit attributable to owners of the Company	230.1	317.0	87.0	37.8%	23.4%
Basic EPS (yen)	147.14	204.29	57.15	38.8%	24.3%

*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 Q4 (Jan-Mar) Reported Results with Actual and CER % Change

(Billion JPY)	FY2021 Q4 (Jan-Mar)	FY2022 Q4 (Jan-Mar)	vs. PY		
				ACTUAL % CHANGE	CER % CHANGE*1
Revenue	873.3	956.2	82.9	9.5%	(1.2)%
Cost of sales	(308.4)	(309.8)	(1.4)	(0.5)%	8.9%
Gross profit	564.9	646.4	81.5	14.4%	3.1%
Margin	*64.7 %*	*67.6 %*		*2.9 pp*	*2.8 pp*
SG&A expenses	(223.4)	(254.8)	(31.4)	(14.0)%	(3.1)%
R&D expenses	(143.6)	(160.9)	(17.3)	(12.1)%	0.3%
Amortization of intangible assets associated with products	(109.7)	(114.5)	(4.8)	(4.3)%	8.7%
Impairment losses on intangible assets associated with products	(39.5)	(18.7)	20.8	52.7%	58.7%
Other operating income	8.9	8.7	(0.1)	(1.2)%	(4.8)%
Other operating expenses	(59.0)	(17.6)	41.4	70.2%	71.4%
Operating profit	(1.6)	88.6	90.2	—	—
Margin	*(0.2)%*	*9.3 %*		*9.4 pp*	*9.9 pp*
Finance income	20.0	14.0	(6.0)	(30.0)%	(28.9)%
Finance expenses	(62.3)	(49.2)	13.2	21.1%	24.4%
Share of profit (loss) of investments accounted for using the equity method	(10.1)	(5.5)	4.6	45.6%	46.7%
Profit before tax	(54.0)	47.9	102.0	—	—
Income tax expenses	42.7	(16.8)	(59.5)	—	—
Net profit for the period	(11.4)	31.1	42.5	—	—
Non-controlling interests	0.0	(0.0)	(0.0)	—	—
Net profit attributable to owners of the Company	(11.4)	31.1	42.5	—	—
Basic EPS (yen)	(7.31)	20.03	27.34	—	—

*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 Core Results with Actual and CER % Change

(Billion JPY)	FY2021	FY2022		vs. PY	
				ACTUAL % CHANGE	CER % CHANGE*1
Revenue	3,420.5	4,027.5	606.9	17.7%	3.5%
Cost of sales	(1,060.6)	(1,208.4)	(147.8)	(13.9)%	(1.4)%
Gross profit	2,359.9	2,819.1	459.2	19.5%	4.5%
Margin	*69.0 %*	*70.0 %*		*1.0 pp*	*0.6 pp*
SG&A expenses	(880.2)	(997.3)	(117.1)	(13.3)%	0.2%
R&D expenses	(524.5)	(633.4)	(108.9)	(20.8)%	(3.8)%
Operating profit	955.2	1,188.4	233.2	24.4%	9.1%
Margin	*27.9 %*	*29.5 %*		*1.6 pp*	*1.5 pp*
Finance income	2.6	16.9	14.3	554.3%	486.3%
Finance expenses	(124.4)	(143.5)	(19.0)	(15.3)%	(4.7)%
Share of profit (loss) of investments accounted for using the equity method	3.7	0.2	(3.5)	(95.1)%	(85.8)%
Profit before tax	837.0	1,062.0	224.9	26.9%	10.9%
Income tax expenses	(173.2)	(195.6)	(22.4)	(12.9)%	(2.4)%
Net profit for the year	663.8	866.4	202.6	30.5%	13.1%
Non-controlling interests	(0.1)	(0.0)	0.1	80.1%	83.9%
Net profit attributable to owners of the Company	663.7	866.4	202.6	30.5%	13.1%
Basic EPS (yen)	425	558	134	31.5%	13.9%

*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 Q4 (Jan-Mar) Core Results with Actual and CER % Change

(Billion JPY)	FY2021 Q4 (Jan-Mar)	FY2022 Q4 (Jan-Mar)		vs. PY	
				ACTUAL % CHANGE	CER % CHANGE*1
Revenue	857.9	956.2	98.3	11.5%	0.6%
Cost of sales	(295.9)	(306.7)	(10.8)	(3.7)%	6.0%
Gross profit	561.9	649.4	87.5	15.6%	4.1%
Margin	*65.5 %*	*67.9 %*		*2.4 pp*	*2.3 pp*
SG&A expenses	(221.1)	(254.4)	(33.3)	(15.1)%	(4.0)%
R&D expenses	(143.6)	(161.3)	(17.7)	(12.3)%	0.1%
Operating profit	197.3	233.7	36.5	18.5%	7.2%
Margin	*23.0 %*	*24.4 %*		*1.4 pp*	*1.5 pp*
Finance income	22.9	13.3	(9.5)	(41.7)%	(38.1)%
Finance expenses	(55.7)	(34.9)	20.8	37.4%	49.2%
Share of profit (loss) of investments accounted for using the equity method	(0.1)	(2.3)	(2.2)	(3,763.0)%	(3,466.8)%
Profit before tax	164.4	209.9	45.5	27.7%	18.7%
Income tax expenses	(22.1)	(50.6)	(28.5)	(129.2)%	(122.5)%
Net profit for the period	142.3	159.2	17.0	11.9%	2.6%
Non-controlling interests	0.0	(0.0)	(0.0)	—	—
Net profit attributable to owners of the Company	142.3	159.2	16.9	11.9%	2.6%
Basic EPS (yen)	92	102	11	11.9%	2.5%

*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 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	4,027.5					4,027.5
Cost of sales	(1,244.1)				35.7	(1,208.4)
Gross profit	2,783.4				35.7	2,819.1
SG&A expenses	(997.3)				(0.0)	(997.3)
R&D expenses	(633.3)				(0.0)	(633.4)
Amortization of intangible assets associated with products	(485.1)	485.1				—
Impairment losses on intangible assets associated with products	(57.3)		57.3			—
Other operating income	25.4			(25.4)		—
Other operating expenses	(145.2)			145.2		—
Operating profit	490.5	485.1	57.3	119.8	35.6	1,188.4
Margin	12.2 %					29.5%
Finance income and (expenses), net	(106.8)				(19.8)	(126.6)
Share of profit (loss) of investments accounted for using the equity method	(8.6)				8.8	0.2
Profit before tax	375.1	485.1	57.3	119.8	24.6	1,062.0
Tax expenses	(58.1)	(103.5)	(12.5)	(25.5)	3.9	(195.6)
Non-controlling interests	(0.0)					(0.0)
Net profit attributable to owners of the Company	317.0	381.6	44.9	94.4	28.5	866.4
EPS (yen)	204					558
Number of shares (millions)	1,552					1,552

FY2022 Q4 (Jan-Mar) 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	956.2					956.2
Cost of sales	(309.8)				3.0	(306.7)
Gross profit	646.4				3.0	649.4
SG&A expenses	(254.8)				0.4	(254.4)
R&D expenses	(160.9)				(0.3)	(161.3)
Amortization of intangible assets associated with products	(114.5)	114.5				—
Impairment losses on intangible assets associated with products	(18.7)		18.7			—
Other operating income	8.7			(8.7)		—
Other operating expenses	(17.6)			17.6		—
Operating profit	88.6	114.5	18.7	8.9	3.1	233.7
Margin	9.3 %					24.4%
Finance income and (expenses), net	(35.2)				13.6	(21.5)
Share of profit (loss) of investments accounted for using the equity method	(5.5)				3.2	(2.3)
Profit before tax	47.9	114.5	18.7	8.9	19.9	209.9
Tax expenses	(16.8)	(24.1)	(4.3)	(1.4)	(4.1)	(50.6)
Non-controlling interests	(0.0)					(0.0)
Net profit attributable to owners of the Company	31.1	90.4	14.5	7.5	15.8	159.2
EPS (yen)	20					102
Number of shares (millions)	1,555					1,555

FY2021 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	TEVA JV related accounting adjustments	Others	
Revenue	3,569.0				(133.0)		(0.8)	(14.6)	3,420.5
Cost of sales	(1,106.8)				0.6			45.6	(1,060.6)
Gross profit	2,462.2				(132.4)		(0.8)	31.0	2,359.9
SG&A expenses	(886.4)				1.0			5.1	(880.2)
R&D expenses	(526.1)							1.6	(524.5)
Amortization of intangible assets associated with products	(418.8)	418.8							—
Impairment losses on intangible assets associated with products	(54.1)		54.1						—
Other operating income	43.1			(41.7)			(1.4)		—
Other operating expenses	(159.1)			159.1					—
Operating profit	460.8	418.8	54.1	117.4	(131.4)		(2.2)	37.7	955.2
Margin	12.9 %								27.9%
Finance income and (expenses), net	(142.9)							21.0	(121.9)
Share of profit (loss) of investments accounted for using the equity method	(15.4)						7.3	11.8	3.7
Profit before tax	302.6	418.8	54.1	117.4	(131.4)		5.1	70.5	837.0
Tax expenses	(72.4)	(89.7)	(15.2)	(26.1)	40.2	65.4	(1.6)	(73.8)	(173.2)
Non-controlling interests	(0.1)								(0.1)
Net profit attributable to owners of the Company	230.1	329.1	38.9	91.2	(91.2)	65.4	3.5	(3.2)	663.7
EPS (yen)	147								425
Number of shares (millions)	1,564								1,564

*1 Tax charges of 65.4 billion JPY arising from the 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, net of 0.5 billion JPY of associated tax benefit.

FY2021 Q4 (Jan-Mar) 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	TEVA JV related accounting adjustments	Others	
Revenue	873.3						(0.8)	(14.6)	857.9
Cost of sales	(308.4)							12.5	(295.9)
Gross profit	564.9						(0.8)	(2.1)	561.9
SG&A expenses	(223.4)							2.3	(221.1)
R&D expenses	(143.6)							0.0	(143.6)
Amortization of intangible assets associated with products	(109.7)	109.7							—
Impairment losses on intangible assets associated with products	(39.5)		39.5						—
Other operating income	8.9			(8.5)			(0.3)		—
Other operating expenses	(59.0)			59.0					—
Operating profit	(1.6)	109.7	39.5	50.5			(1.1)	0.2	197.3
Margin	(0.2)%								23.0%
Finance income and (expenses), net	(42.3)							9.5	(32.8)
Share of profit (loss) of investments accounted for using the equity method	(10.1)						0.7	9.4	(0.1)
Profit before tax	(54.0)	109.7	39.5	50.5			(0.5)	19.1	164.4
Tax expenses	42.7	(20.8)	(11.6)	(8.6)		0.8	0.1	(24.6)	(22.1)
Non-controlling interests	0.0								0.0
Net profit attributable to owners of the Company	(11.4)	88.9	28.0	41.9		0.8	(0.3)	(5.6)	142.3
EPS (yen)	(7)								92
Number of shares (millions)	1,554								1,554

*1 Interest on tax charges arising from the 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)	FY2021	FY2022	Change versus the previous year	
Net profit	230.2	317.0	86.9	37.7%
Depreciation, amortization and impairment loss	637.7	728.8	91.1	
Decrease (increase) in trade working capital	206.3	(88.8)	(295.1)	
Income taxes paid	(147.7)	(198.4)	(50.7)	
Tax refunds and interest on tax refunds received	7.3	12.5	5.2	
Other	189.4	206.1	16.7	
Net cash from operating activities	1,123.1	977.2	(145.9)	(13.0)%
Adjustment for cash temporarily held by Takeda on behalf of third parties*1	(32.0)	81.7	113.7	
Acquisition of PP&E	(123.3)	(140.7)	(17.4)	
Proceeds from sales of PP&E	1.8	1.0	(0.9)	
Acquisition of intangible assets	(62.8)	(493.0)	(430.2)	
Acquisition of investments	(8.3)	(10.2)	(1.8)	
Proceeds from sales and redemption of investments	16.9	22.3	5.3	
Proceeds from sales of business, net of cash and cash equivalents divested	28.2	8.0	(20.2)	
Free Cash Flow	943.7	446.2	(497.5)	(52.7)%
Upfront payment related to the acquisition of TAK-279*2	—	391.1	391.1	
Free Cash Flow excluding upfront payment related to the acquisition of TAK-279	943.7	837.3	(106.3)	(11.3)%

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

*2 This represents the portion of the 4.0 billion USD upfront payment related to the acquisition of TAK-279 paid in February 2023 (such portion totaling 3.0 billion USD), converted to JPY using the Japanese yen – U.S. dollar exchange rate of 130.38 applied to this transaction in the consolidated statements of cash flows. This payment is mainly included in the net cash used in investing activities as Acquisition of intangible assets in the consolidated statements of cash flow.

FY2022 Net Debt to Adjusted EBITDA

NET DEBT/ADJUSTED EBITDA RATIO

(Billion JPY)	FY2022
Cash and cash equivalents *1	407.7
Book value debt on consolidated statements of financial position	(4,382.3)
Hybrid bond 50% equity credit	250.0
FX adjustment *2	8.5
Gross debt *3	(4,123.9)
Net cash (debt)	**(3,716.1)**
Upfront payment related to the acquisition of TAK-279 *4	400.4
Net cash (debt) excluding upfront payment related to the acquisition of TAK-279	**(3,315.7)**
Net debt/Adjusted EBITDA ratio	**2.6 x**
Net debt/Adjusted EBITDA ratio excluding upfront payment related to the acquisition of TAK-279	**2.3 x**
Adjusted EBITDA	**1,421.8**

NET INCREASE (DECREASE) IN CASH

(Billion JPY)	FY2021	FY2022	Change versus the previous year	
Net cash from operating activities	1,123.1	977.2	(145.9)	(13.0)%
Acquisition of PP&E	(123.3)	(140.7)		
Proceeds from sales of PP&E	1.8	1.0		
Acquisition of intangible assets	(62.8)	(493.0)		
Acquisition of investments	(8.3)	(10.2)		
Proceeds from sales and redemption of investments	16.9	22.3		
Acquisition of business, net of cash and cash equivalents acquired	(49.7)	—		
Proceeds from sales of business, net of cash and cash equivalents divested	28.2	8.0		
Net decrease in short-term loans and commercial papers	(0.0)	40.0		
Proceeds from long-term loans	—	75.0		
Repayment of long-term loans	(414.1)	(75.2)		
Proceeds from issuance of bonds	249.3	—		
Repayment of bonds	(396.0)	(281.5)		
Purchase of treasury shares	(77.5)	(26.9)		
Interest paid	(108.2)	(108.6)		
Dividends paid	(283.7)	(279.4)		
Others	(41.1)	(47.0)		
Net increase (decrease) in cash	(145.3)	(339.1)	(193.8)	(133.4)%

*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. 250.0 billion JPY reduction in debt due to 500.0 billion JPY 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.

*4 This represents the portion of the 4.0 billion USD upfront payment related to the acquisition of TAK-279 paid in February 2023 (such portion totaling 3.0 billion USD), converted to JPY using the Japanese yen – U.S. dollar exchange rate of 133.48, which is applicable to translation of foreign currency denominated cash as of March 31, 2023.

FY2021 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. 250.0 billion JPY reduction in debt due to 500.0 billion JPY 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 and FY2021 Net Profit to Adjusted EBITDA Bridge

(Billion JPY)	FY2021	FY2022	Change versus the previous year	
Net profit	230.2	317.0	86.9	37.7%
Income tax expenses	72.4	58.1		
Depreciation and amortization	583.2	664.4		
Interest expense, net	117.8	111.5		
EBITDA	1,003.6	1,151.0	147.4	14.7%
Impairment losses	54.5	64.4		
Other operating expense (income), net, excluding depreciation and amortization and other miscellaneous expenses (non-cash item)	106.3	109.0		
Finance expense (income), net, excluding interest income and expense, net	25.1	(4.7)		
Share of loss on investments accounted for under the equity method	15.4	8.6		
Other adjustments:	(30.2)	93.5		
Non-core expense related to COVID-19	10.4	9.9		
Sales of Japan diabetes portfolio and other non-core product divestitures	(144.8)	—		
Impact on profit related to fair value step up of inventory in Shire acquisition	31.9	24.9		
Other costs*1	72.4	58.7		
EBITDA from divested products*2	(6.6)	—		
Adjusted EBITDA	1,168.0	1,421.8	253.8	21.7%

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

*2 Represents adjustments for EBITDA from divested products which are removed as part of Adjusted EBITDA

CAPEX, Depreciation and Amortization and Impairment Losses

(Billion JPY)	FY2021	FY2022	vs. PY		FY2023 Forecast
Capital expenditures*1	186.0	633.7	447.7	240.6%	480.0 - 530.0*3
Tangible assets	123.3	140.7	17.4	14.1%	
Intangible assets	62.8	493.0	430.2	685.3%	
Depreciation and amortization	583.2	664.4	81.2	13.9%	650.0
Depreciation of tangible assets*2 (A)	135.8	153.7	18.0	13.2%	
Amortization of intangible assets (B)	447.4	510.7	63.3	14.1%	
Of which Amortization associated with products (C)	418.8	485.1	66.3	15.8%	480.0
Of which Amortization excluding intangible assets associated with products (D)	28.6	25.6	(3.0)	(10.5)%	
Depreciation and amortization (excluding intangible assets associated with products) (A)+(D)	164.4	179.3	14.9	9.1%	170.0
Impairment losses	54.5	64.4	9.9	18.1%	
Impairment losses associated with products	54.1	57.3	3.2	5.9%	50.0
Amortization and impairment losses on intangible assets associated with products	472.9	542.4	69.5	14.7%	530.0

*1 Cash flow base

*2 Including depreciation of investment properties

*3 FY2023 Forecast reflects approximately 180.0 billion JPY of expenditures related to the acquisition of TAK-279 from Nimbus (1.0 billion USD) and in-licensing of fruquintinib from HUTCHMED (400 million USD). The 1.0 billion USD payment related to the acquisition of TAK-279 represents the portion of the 4.0 billion USD upfront payment paid in April 2023 (0.9 billion USD), and scheduled to be paid in August 2023 (0.1 billion USD).

FY2022 Results vs. Forecast (Oct. 2022)

	(BN JPY)	FY2022 Forecast (October 27, 2022)	FY2022 Actual	vs. Forecast		Variances
REPORTED	Revenue	3,930.0	4,027.5	97.5	2.5 %	Business momentum and FX benefit
	R&D expenses	(620.0)	(633.3)	(13.3)	(2.1)%	Mainly due to FX
	Amortization of intangible assets associated with products	(480.0)	(485.1)	(5.1)	(1.1)%	Mainly due to FX
	Impairment losses on intangible assets associated with products	(50.0)	(57.3)	(7.3)	(14.7)%	FX impact, plus termination of early-stage partnered programs (e.g. TAK-018, TAK-954)
	Other operating income	13.0	25.4	12.4	95.6 %	FY2022 Actual includes liability release related to SHP647 and accelerated realization of deferred income
	Other operating expenses	(100.0)	(145.2)	(45.2)	(45.2)%	FY2022 Actual includes restructuring costs and higher than anticipated pre-launch inventory
	Operating profit	530.0	490.5	(39.5)	(7.5)%	
	Finance income (expenses), net	(105.0)	(106.8)	(1.8)	(1.7)%	
	Profit before tax	426.0	375.1	(50.9)	(12.0)%	FY2022 Actual includes (8.6) BN JPY equity method loss, mainly due to JV impairment
	Net profit attributable to owners of the Company	307.0	317.0	10.0	3.3 %	Lower than anticipated tax rate due to recognition of previously unrecognized tax losses
	Basic EPS (yen)	198	204	6	3.3 %	
	Core Revenue[*1]	3,930.0	4,027.5	97.5	2.5 %	Business momentum and FX benefit
	Core Operating Profit[*1]	1,180.0	1,188.4	8.4	0.7 %	Business momentum and FX benefit
	Core EPS (yen)	525	558	33	6.4 %	Lower than anticipated tax rate due to recognition of previously unrecognized tax losses
	Free cash flow	650.0 to 750.0	446.2			FY2022 Actual includes the 3.0 billion USD portion of the 4.0 billion USD upfront payment related to the acquisition of TAK-279 paid in February 2023.
	CAPEX (cash flow base)	(260.0) to (310.0)	(633.7)			
	Depreciation and amortization (excl. intangible assets associated with products)	(160.0)	(179.3)	(19.3)	(12.1)%	Mainly due to FX
	Cash tax rate on adjusted EBITDA (excl. divestitures)	mid-teen %	~13%			
	USD/JPY (yen)	132	135	2	1.9 %	
	EUR/JPY (yen)	138	141	2	1.7 %	

*1 Please refer to A-1 Definition of Core Financial Measures, Constant Exchange Rate change, and Free Cash Flow, for the definition and A-7 FY2022 Reconciliation from Reported to Core, for reconciliation.

FY2023 Detailed Forecast

	(BN JPY)	FY2022 Actual	FY2023 Forecast (May 11, 2023)	vs. PY		Variances
REPORTED	Revenue	4,027.5	3,840.0	(187.5)	(4.7)%	Growth & Launch Products momentum largely offsetting LOE impact (e.g. VYVANSE, AZILVA), with additional headwinds from lower coronavirus vaccines revenue and FX
	R&D expenses	(633.3)	(643.0)	(9.7)	(1.5)%	Increase would be (4.0%) vs. PY on a CER basis
	Amortization of intangible assets associated with products	(485.1)	(480.0)	5.1	1.1 %	
	Impairment losses on intangible assets associated with products	(57.3)	(50.0)	7.3	12.8 %	
	Other operating income	25.4	14.0	(11.4)	(44.9)%	Fewer one-time gains anticipated in FY2023
	Other operating expenses	(145.2)	(150.0)	(4.8)	(3.3)%	Includes expectations for higher restructuring costs and additional pre-launch inventory
	Operating profit	490.5	349.0	(141.5)	(28.8)%	
	Finance income (expenses), net	(106.8)	(165.0)	(58.2)	(54.5)%	Lower financial income due to one-time revaluation gains booked in FY2022
	Profit before tax	375.1	185.0	(190.1)	(50.7)%	
	Net profit attributable to owners of the Company	317.0	142.0	(175.0)	(55.2)%	
	Basic EPS (yen)	204	91	(114)	(55.6)%	
	Core Revenue*1	4,027.5	3,840.0	(187.5)	(4.7)%	Growth & Launch Products momentum largely offsetting LOE impact (e.g. VYVANSE, AZILVA), with additional headwinds from lower coronavirus vaccines revenue and FX
	Core Operating Profit*1	1,188.4	1,015.0	(173.4)	(14.6)%	
	Core EPS (yen)	558	434	(124)	(22.2)%	Normalization of core tax rate following tax benefit in FY2022
	Free cash flow	446.2	400.0 to 500.0			FY2023 Forecast reflects approximately 180.0 BN JPY of expenditures related to the acquisition of TAK-279 from Nimbus (1.0 BN USD) and in-licensing of fruquintinib from HUTCHMED (400 MM USD).
	CAPEX (cash flow base)	(633.7)	(480.0) to (530.0)			
	Depreciation and amortization (excl. intangible assets associated with products)	(179.3)	(170.0)	9.3	5.2 %	
	Cash tax rate on adjusted EBITDA (excl. divestitures)	~13%	Mid-to-high teen %			
	USD/JPY (yen)	135	131	(4)	(2.9)%	
	EUR/JPY (yen)	141	141	0	0.3 %	

*1 Please refer to A-1 Definition of Core Financial Measures, Constant Exchange Rate change, and Free Cash Flow, for the definition and A-18 FY2023 Reconciliation from Reported Operating Profit to Core Operating Profit Forecast, for reconciliation.

FY2023 Reconciliation from Reported Operating Profit to Core Operating Profit Forecast

(Billion JPY)	REPORTED	REPORTED TO CORE ADJUSTMENTS			CORE
		Amortization of intangible assets	Impairment of intangible assets	Other operating income (expenses)	
Revenue	3,840.0				3,840.0
Cost of sales					
Gross Profit					
SG&A and R&D expenses					
Amortization of intangible assets associated with products	(480.0)	480.0			—
Impairment losses on intangible assets associated with products	(50.0)		50.0		—
Other operating income	14.0			(14.0)	—
Other operating expenses	(150.0)			150.0	—
Operating profit	349.0	480.0	50.0	136.0	1,015.0

FX Rates and FY2023 Currency Sensitivity

Average Exchange Rates vs. JPY				Impact of depreciation of yen from April 2023 to March 2024 (100 million JPY)				
	FY2021 Actual (Apr-Mar)	FY2022 Actual (Apr-Mar)	FY2023 Assumption (Apr-Mar)		Revenue (IFRS)	Operating Profit (IFRS)	Net Profit (IFRS)	Core Operating Profit (non-IFRS)
USD	112	135	131	1% depreciation	195.9	17.0	6.7	61.5
				1 yen depreciation	149.6	13.0	5.1	47.0
EUR	131	141	141	1% depreciation	53.5	(39.1)	(31.6)	(30.1)
				1 yen depreciation	37.9	(27.8)	(22.4)	(21.3)
RUB	1.5	2.1	1.9	1% depreciation	5.6	3.2	2.5	3.8
CNY	17.5	19.7	19.5		18.8	11.1	8.5	11.1
BRL	20.9	26.3	25.9		10.0	6.3	4.9	6.4

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