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Takeda Quarterly Financial Report

For the Quarter Ended December 31, 2022

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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

(JPY millions)	Nine-month period ended December 31,		Change versus the same period of the previous fiscal year		
	2021	2022	JPY	Actual % Change	CER % Change
Revenue	2,695,717	3,071,322	375,606	13.9 %	(0.7)%
Operating profit	462,463	401,943	(60,520)	(13.1)%	(20.3)%
Profit before tax	356,618	327,175	(29,443)	(8.3)%	(16.5)%
Net profit for the period	241,541	285,903	44,362	18.4 %	4.8 %
Basic earnings per share (yen)	154.09	184.32	30.23	19.6 %	5.9 %

Core Results

Results of Core Operations

(JPY billions)	Nine-month period ended December 31,		Change versus the same period of the previous fiscal year		
	2021	2022	JPY	Actual % change	CER % change
Core Revenue	2,562.7	3,071.3	508.6	19.8 %	4.5 %
Core Operating Profit	757.9	954.7	196.7	26.0 %	9.7 %
Core EPS (yen)	333	456	123	37.0 %	17.1 %

Leverage

(JPY billions)	As of	
	March 31, 2022	December 31, 2022
Net debt	(3,233.8)	(3,415.7)
Adjusted EBITDA	1,168.0	1,381.2
Net debt/Adjusted EBITDA ratio	2.8 x	2.5 x

Consolidated Cash Flows

(JPY millions)	Nine-month period ended December 31,		Change versus the same period of the previous fiscal year	
	2021	2022	JPY	%
Cash flows from (used in) operating activities	747,521	683,463	(64,058)	(8.6) %
Cash flows from (used in) investing activities	(172,487)	(168,610)	3,877	2.2 %
Cash flows from (used in) financing activities	(826,465)	(702,548)	123,917	15.0 %

Free Cash Flow

(JPY billions)	Nine-month period ended December 31,		Change versus the same period of the previous fiscal year	
	2021	2022	JPY	%
Free Cash Flow	671.3	585.2	(86.1)	(12.8) %

Consolidated Financial Position

(JPY millions)	As of		Change versus the previous fiscal year-end	
	March 31, 2022	December 31, 2022	JPY	%
Non-current Assets	10,584,376	10,908,758	324,383	3.1 %
Current Assets	2,593,642	2,595,946	2,304	0.1 %
Total Assets	13,178,018	13,504,705	326,687	2.5 %
Non-current Liabilities	5,348,764	5,091,397	(257,367)	(4.8) %
Current Liabilities	2,145,730	2,236,809	91,079	4.2 %
Total Liabilities	7,494,495	7,328,206	(166,288)	(2.2) %
Equity	5,683,523	6,176,498	492,975	8.7 %
Total liabilities and equity	13,178,018	13,504,705	326,687	2.5 %

Forecast and Management Guidance

Forecast*

(JPY billions)	FY2021 Actual Results	FY2022 Latest Forecast (October 27, 2022)	vs. FY2021 Actual Results	
Reported:				
Revenue	3,569.0	3,930.0	361.0	10.1 %
Operating profit	460.8	530.0	69.2	15.0 %
Profit before tax	302.6	426.0	123.4	40.8 %
Net profit for the year (attributable to owners of the Company)	230.1	307.0	76.9	33.4 %
EPS (JPY)	147.14	197.83	50.69	34.4 %
Non-IFRS Measures				
Core Operating Profit	955.2	1,180.0	224.8	23.5 %
Core EPS (JPY)	425	525	100	23.6 %
Free cash flow	943.7	650.0 - 750.0		
Dividends per share (Yen)	180	180	—	—

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

Management Guidance

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

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

*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)							
		Period Ended December 31, 2022							
		Japan	United States	Europe and Canada	Asia (excluding Japan)	Latin America	Russia/CIS	Other	Total
	2021	530,245	1,297,020	540,978	139,770	93,545	43,582	50,577	2,695,717
	2022	389,843	1,621,772	632,403	169,024	121,425	66,700	70,156	3,071,322
Change versus the previous year	JPY	(140,402)	324,752	91,425	29,254	27,880	23,118	19,579	375,606
	%	(26.5)%	25.0 %	16.9 %	20.9 %	29.8 %	53.0 %	38.7 %	13.9 %

"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 nine-month period ended December 31, 2022 were 472.4 billion JPY.

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

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

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

R&D pipeline

Oncology

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

ADCETRIS / Generic name: brentuximab vedotin

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

VECTIBIX / Generic name: panitumumab

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

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

ICLUSIG / Generic name: ponatinib

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

EXKIVITY / Generic name: mobocertinib

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

Rare Genetics & Hematology

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

TAKHZYRO / Generic name: lanadelumab

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

treatment-emergent adverse events (TEAEs) were reported during the study, and no patients withdrew from the study due to TEAEs. These results are consistent with earlier studies with adult and adolescent patients. These data will be submitted to global regulatory authorities to evaluate a potential label expansion for TAKHZYRO to include the younger patient population.

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

LIVTENCITY / Generic name: maribavir

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

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

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

FIRAZYR / Generic name: icatibant

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

Development code: TAK-611

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

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

In December 2022, Takeda announced that it has received Orphan Drug Designation from the Japanese Ministry of Health, Labour and Welfare (MHLW) for TAK-755 for the expected indication of thrombotic thrombocytopenic purpura (TTP). As the first recombinant ADAMTS13 (rADAMTS13) drug targeting TTP, TAK-755 is developed globally for the treatment of congenital TTP (cTTP) and acquired (immune) TTP (iTTP).

In January 2023, Takeda announced that the totality of evidence from a pre-planned interim analysis of a pivotal Phase 3 study supports the efficacy and safety of TAK-755 as enzyme replacement therapy for cTTP. The study evaluated TAK-755 compared to plasma-based therapies, which are the current standard of care (SoC), in a randomized cross-over study. The interim results showed that TAK-755 reduced the incidence of thrombocytopenia events by 60% (95% Confidence Interval, 30%-70%), an important marker of disease activity in cTTP, as compared to SoC. The proportion of subjects experiencing adverse events determined to be related to the treatment was substantially lower among subjects during treatment with TAK-755 (8.9%) compared to that while receiving SoC therapy (47.7%). Based on these data from the Phase 3 interim analysis, Takeda aims to seek marketing authorization for TAK-755 as the first rADAMTS13 replacement therapy for cTTP, a disorder with considerable unmet patient need.

Neuroscience

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

Development code: TAK-994

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

Gastroenterology (GI)

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

Development code: TAK-999 / Generic name: fazirsiran

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

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

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

Plasma-Derived Therapies (PDT)

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

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

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

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

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

Vaccines

In Vaccines, Takeda is applying innovation to tackle some of the world's most challenging infectious diseases such as dengue (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°C, like many other medicines and vaccines, which enables transportation and storage with conventional vaccine supply chain.

QDENG A / 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, QDENG A, 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. QDENG A 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 QDENG A 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 QDENG A 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 QDENG A 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.

Building a sustainable research platform / Enhancing R&D collaboration

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

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

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

Results of Operations (Reported)

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

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

*1 Please refer to [Core Results](#), *Definition of Core financial measures and Constant Exchange Rate change*, for the definition.

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

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

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

Revenue by Geographic Region

The following shows revenue by geographic region:

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

*1 Please refer to [Core Results](#), *Definition of Core financial measures and Constant Exchange Rate change*, for the definition.

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

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

Revenue by Therapeutic Area

The following shows revenue by therapeutic area:

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

*1 Please refer to [Core Results](#), *Definition of Core financial measures and Constant Exchange Rate change*, for the definition.

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

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

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

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

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

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

Cost of Sales. Cost of Sales increased by 135.8 billion JPY, or 17.0% (CER % change: 3.4%), to 934.3 billion JPY. The increase was primarily due to the depreciation of the yen and a sales increase in our core therapeutic areas as compared to the

same period of the previous fiscal year. The Cost of Sales Ratio increased by 0.8 pp compared to the same period of the previous fiscal year to 30.4%. The main reason for the increase in the Cost of Sales Ratio was the effect of the sale of a portfolio of diabetes products in Japan with the selling price of 133.0 billion JPY being recorded in revenue in the same period of the previous fiscal year.

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

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

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

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

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

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

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

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

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

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

Core Results (April 1 to December 31, 2022)

Definition of Core financial measures and Constant Exchange Rate change

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

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

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

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

Results of Core Operations

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

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

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

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

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

Consolidated Financial Position

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

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

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

Bonds:

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

Loans:

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

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

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

Consolidated Cash Flows

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

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

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

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

Outlook for the Fiscal Year Ending March 31, 2023

Based on Takeda's financial results through the nine-month period ended December 31, 2022, and taking into account the anticipated financial outlook for the remaining three-month period of the fiscal year ending March 31, 2023 (FY2022), the full year consolidated reported forecast for FY2022 has not been revised from the latest forecast announced on October 27, 2022.

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

	Billion JPY or percentage			
	FY2021 Actual Results	FY2022 Latest Forecast (October 27, 2022)	vs. FY2021 Actual Results	
Revenue	3,569.0	3,930.0	361.0	10.1 %
Operating profit	460.8	530.0	69.2	15.0 %
Profit before tax	302.6	426.0	123.4	40.8 %
Net profit for the year (attributable to owners of the Company)	230.1	307.0	76.9	33.4 %
EPS (JPY)	147.14	197.83	50.69	34.4 %
Core Revenue	3,420.5	3,930.0	509.5	14.9 %
Core Operating Profit	955.2	1,180.0	224.8	23.5 %
Core EPS (JPY)	425	525	100	23.6 %

Major assumptions used in preparing the FY2022 Reported Forecast

	Billion JPY or percentage	
	FY2021 Actual Results	FY2022 Latest Forecast (October 27, 2022)
FX rates	1 USD = 112 JPY 1 Euro = 131 JPY 1 RUB = 1.5 JPY 1 BRL = 20.9 JPY 1 CNY = 17.4 JPY	1 USD = 132 JPY 1 Euro = 138 JPY 1 RUB = 2.1 JPY 1 BRL = 26.4 JPY 1 CNY = 19.8 JPY
R&D expenses	(526.1)	(620.0)
Amortization of intangible assets associated with products	(418.8)	(480.0)
Of which Shire acquisition related	(339.7)	(390.0)
Impairment of intangible assets associated with products	(54.1)	(50.0)
Other operating income	43.1	13.0
Other operating expenses	(159.1)	(100.0)
Japan diabetes portfolio divestiture gain	131.4	—
Other Core Operating Profit adjustments	(36.9)	(33.0)
Of which Shire acquisition related to unwind of inventories step-up	(31.9)	(25.0)
Finance income and (expenses), net	(142.9)	(105.0)
Free cash flow	943.7	650.0 - 750.0
Capital expenditures (cash flow base)	(186.0)	(260.0 - 310.0)
Depreciation and amortization (excluding intangible assets associated with products)	(161.0)	(160.0)
Cash tax rate on adjusted EBITDA (excluding divestitures)	~12%	Mid-teen %

Management Guidance

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

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

* Please refer to *Core Results, Definition of Core financial measures and Constant Exchange Rate change*, for the definition.

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

- Based on currently available information, Takeda expects that its financial results for FY2022 will not be materially affected by COVID-19 or the crisis in Ukraine and Russia and, accordingly, Takeda's FY2022 reported forecast and the management guidance reflect this expectation.
- The FY2022 reported forecast and the management guidance include approximately 50.0 billion JPY revenue contribution from COVID-19 vaccines.
- Free cash flow and capital expenditures assumptions do not include the impact of acquisitions that have been announced but not completed yet, including the upfront cash payment for the acquisition of NDI-034858 from Nimbus Therapeutics, LLC, for 4 billion USD, as the exact timing of cash payment is dependent upon deal close.

Forward looking statements

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

Other

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

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

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

Takeda's Operations in Ukraine and Russia

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

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

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

In the nine-month period ended December 31, 2022, revenue attributable to Russia/CIS represented 2.2% of Takeda's total consolidated revenue of 3,071.3 billion, as indicated in the Revenue by Region in [Results of Operations \(Reported\)](#). There was no material financial impact on Takeda's financial results for the current period resulting from the crisis in these countries. However, depending on the future status of the crisis, our results of operations and financial conditions could be adversely affected.

Condensed Interim Consolidated Financial Statements [IFRS]

(1) Condensed Interim Consolidated Statements of Profit or Loss

	JPY (millions, except per share data)		USD (millions) ^(*)
	Nine-month Period Ended December 31,		Nine-month Period Ended December 31,
	2021	2022	2022
Revenue	¥ 2,695,717	¥ 3,071,322	\$ 23,301
Cost of sales	(798,466)	(934,300)	(7,088)
Selling, general and administrative expenses	(662,932)	(742,513)	(5,633)
Research and development expenses	(382,459)	(472,381)	(3,584)
Amortization and impairment losses on intangible assets associated with products	(323,632)	(409,219)	(3,105)
Other operating income	34,269	16,676	127
Other operating expenses	(100,034)	(127,643)	(968)
Operating profit	462,463	401,943	3,049
Finance income	42,949	55,130	418
Finance expenses	(143,539)	(126,765)	(962)
Share of loss of investments accounted for using the equity method	(5,255)	(3,133)	(24)
Profit before tax	356,618	327,175	2,482
Income tax expenses	(115,077)	(41,273)	(313)
Net profit for the period	241,541	285,903	2,169
Attributable to:			
Owners of the Company	241,417	285,883	2,169
Non-controlling interests	124	19	0
Net profit for the period	241,541	285,903	2,169
Earnings per share (JPY)			
Basic earnings per share	154.09	184.32	1.40
Diluted earnings per share	153.03	182.65	1.39

(*) Condensed interim consolidated statements of profit or loss have been translated solely for the convenience of the reader at an exchange rate of 1USD = 131.81 JPY, the Noon Buying Rate certified by the Federal Reserve Bank of New York on December 30, 2022. The rate and methodologies used for the convenience translations differ from the currency exchange rates and translation methodologies under IFRS used for the preparation of the condensed interim consolidated financial statements. The translation should not be construed as a representation that the Japanese yen amounts could be converted into U.S. dollars at the above or any other rate.

(2) Condensed Interim Consolidated Statements of Comprehensive Income

	JPY (millions)		USD (millions) ^(*)
	Nine-month Period Ended December 31,		Nine-month Period Ended December 31,
	2021	2022	2022
Net profit for the period	¥ 241,541	¥ 285,903	\$ 2,169
Other comprehensive income (loss)			
Items that will not be reclassified to profit or loss:			
Changes in fair value of financial assets measured at fair value through other comprehensive income	(5,951)	730	6
Remeasurement of defined benefit pension plans	(2,912)	12,977	98
	(8,862)	13,707	104
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	206,582	481,206	3,651
Cash flow hedges	13,958	(17,584)	(133)
Hedging cost	5,969	(12,107)	(92)
Share of other comprehensive loss of investments accounted for using the equity method	(145)	(915)	(7)
	226,365	450,599	3,419
Other comprehensive income for the period, net of tax	217,503	464,306	3,523
Total comprehensive income for the period	459,044	750,209	5,692
Attributable to:			
Owners of the Company	458,887	750,193	5,691
Non-controlling interests	157	16	0
Total comprehensive income for the period	459,044	750,209	5,692

(*) Condensed interim consolidated statements of comprehensive income have been translated solely for the convenience of the reader at an exchange rate of 1USD = 131.81 JPY, the Noon Buying Rate certified by the Federal Reserve Bank of New York on December 30, 2022. The rate and methodologies used for the convenience translations differ from the currency exchange rates and translation methodologies under IFRS used for the preparation of the condensed interim consolidated financial statements. The translation should not be construed as a representation that the Japanese yen amounts could be converted into U.S. dollars at the above or any other rate.

(3) Condensed Interim Consolidated Statements of Financial Position

	JPY (millions)		USD (millions) ^(*)
	As of March 31, 2022	As of December 31, 2022	As of December 31, 2022
ASSETS			
Non-current assets:			
Property, plant and equipment	¥ 1,582,800	¥ 1,656,416	\$ 12,567
Goodwill	4,407,749	4,690,949	35,589
Intangible assets	3,818,544	3,765,757	28,570
Investments accounted for using the equity method	96,579	94,426	716
Other financial assets	233,554	275,043	2,087
Other non-current assets	82,611	66,774	507
Deferred tax assets	362,539	359,393	2,727
Total non-current assets	10,584,376	10,908,758	82,761
Current assets:			
Inventories	853,167	927,286	7,035
Trade and other receivables	696,644	707,318	5,366
Other financial assets	25,305	41,467	315
Income taxes receivable	27,733	72,554	550
Other current assets	141,099	154,824	1,175
Cash and cash equivalents	849,695	685,141	5,198
Assets held for sale	—	7,356	56
Total current assets	2,593,642	2,595,946	19,695
Total assets	13,178,018	13,504,705	102,456
LIABILITIES AND EQUITY			
LIABILITIES			
Non-current liabilities:			
Bonds and loans	4,141,418	3,914,884	29,701
Other financial liabilities	468,943	503,542	3,820
Net defined benefit liabilities	145,847	132,809	1,008
Income taxes payable	21,634	25,152	191
Provisions	52,199	59,628	452
Other non-current liabilities	67,214	66,701	506
Deferred tax liabilities	451,511	388,681	2,949
Total non-current liabilities	5,348,764	5,091,397	38,627
Current liabilities:			
Bonds and loans	203,993	372,019	2,822
Trade and other payables	516,297	381,109	2,891
Other financial liabilities	196,071	180,575	1,370
Income taxes payable	200,918	188,779	1,432
Provisions	443,502	473,194	3,590
Other current liabilities	584,949	639,959	4,855
Liabilities held for sale	—	1,173	9
Total current liabilities	2,145,730	2,236,809	16,970
Total liabilities	7,494,495	7,328,206	55,597

	JPY (millions)		USD (millions) ^(*)
	As of March 31, 2022	As of December 31, 2022	As of December 31, 2022
EQUITY			
Share capital	1,676,263	1,676,334	12,718
Share premium	1,708,873	1,712,036	12,989
Treasury shares	(116,007)	(100,314)	(761)
Retained earnings	1,479,716	1,507,720	11,439
Other components of equity	934,173	1,380,202	10,471
Equity attributable to owners of the company	5,683,019	6,175,978	46,855
Non-controlling interests	504	520	4
Total equity	5,683,523	6,176,498	46,859
Total liabilities and equity	13,178,018	13,504,705	102,456

(*) Condensed interim consolidated statements of financial position have been translated solely for the convenience of the reader at an exchange rate of 1USD = 131.81 JPY, the Noon Buying Rate certified by the Federal Reserve Bank of New York on December 30, 2022. The rate and methodologies used for the convenience translations differ from the currency exchange rates and translation methodologies under IFRS used for the preparation of the condensed interim consolidated financial statements. The translation should not be construed as a representation that the Japanese yen amounts could be converted into U.S. dollars at the above or any other rate.

(4) Condensed Interim Consolidated Statements of Changes in Equity

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

	JPY (millions)					
	Equity attributable to owners of the company				Other components of equity	
	Share capital	Share premium	Treasury shares	Retained earnings	Exchange differences on translation of foreign operations	Changes in fair value of financial assets measured at fair value through other comprehensive income
As of April 1, 2021	1,668,145	1,688,424	(59,552)	1,509,906	400,798	41,983
Net profit for the period				241,417		
Other comprehensive income (loss)					206,337	(5,883)
Comprehensive income (loss) for the period	—	—	—	241,417	206,337	(5,883)
Transactions with owners:						
Issuance of new shares	8,118	14,036				
Acquisition of treasury shares			(54,451)			
Disposal of treasury shares		(0)	1			
Dividends				(284,246)		
Changes in ownership				(2,143)		
Transfers from other components of equity				1,992		(4,904)
Share-based compensation		32,057				
Exercise of share-based awards		(36,955)	22,989			
Total transactions with owners	8,118	9,138	(31,461)	(284,397)	—	(4,904)
As of December 31, 2021	1,676,263	1,697,562	(91,013)	1,466,926	607,135	31,196

	Equity attributable to owners of the company							
	Other components of equity				Total other components of equity	Total equity attributable to owners of the Company	Non-controlling interests	Total equity
	Cash flow hedges	Hedging cost	Remeasurements of defined benefit pension plans					
As of April 1, 2021	(68,075)	(8,592)	—	366,114	5,173,037	4,140	5,177,177	
Net profit for the period				—	241,417	124	241,541	
Other comprehensive income (loss)	13,958	5,969	(2,912)	217,470	217,470	33	217,503	
Comprehensive income (loss) for the period	13,958	5,969	(2,912)	217,470	458,887	157	459,044	
Transactions with owners:								
Issuance of new shares				—	22,154		22,154	
Acquisition of treasury shares				—	(54,451)		(54,451)	
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			2,912	(1,992)	—		—	
Share-based compensation				—	32,057		32,057	
Exercise of share-based awards				—	(13,966)		(13,966)	
Total transactions with owners	—	—	2,912	(1,992)	(300,594)	(3,804)	(304,399)	
As of December 31, 2021	(54,116)	(2,623)	—	581,592	5,331,330	493	5,331,822	

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

	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 period				285,883		
Other comprehensive income (loss)					480,326	698
Comprehensive income (loss) for the period	—	—	—	285,883	480,326	698
Transactions with owners:						
Issuance of new shares	71	71				
Acquisition of treasury shares		(5)	(27,056)			
Disposal of treasury shares		0	1			
Dividends				(278,321)		
Transfers from other components of equity				22,402		(9,424)
Share-based compensation		45,823				
Exercise of share-based awards		(42,727)	42,749			
Total transactions with owners	71	3,162	15,693	(255,919)	—	(9,424)
As of December 31, 2022	1,676,334	1,712,036	(100,314)	1,507,720	1,468,588	13,341

	Equity attributable to owners of the company						
	Other components of equity				Total equity attributable to owners of the Company	Non-controlling interests	Total equity
	Cash flow hedges	Hedging cost	Remeasurements of defined benefit pension plans	Total other components of 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 period				—	285,883	19	285,903
Other comprehensive income (loss)	(17,584)	(12,107)	12,977	464,310	464,310	(4)	464,306
Comprehensive income (loss) for the period	(17,584)	(12,107)	12,977	464,310	750,193	16	750,209
Transactions with owners:							
Issuance of new shares				—	142		142
Acquisition of treasury shares				—	(27,062)		(27,062)
Disposal of treasury shares				—	1		1
Dividends				—	(278,321)		(278,321)
Transfers from other components of equity			(12,977)	(22,402)	—		—
Share-based compensation				—	45,823		45,823
Exercise of share-based awards				—	22		22
Total transactions with owners	—	—	(12,977)	(22,402)	(259,395)	—	(259,395)
As of December 31, 2022	(83,486)	(18,242)	—	1,380,202	6,175,978	520	6,176,498

(5) Condensed Interim Consolidated Statements of Cash Flows

	JPY (millions)		USD (millions)(*)
	Nine-month Period Ended December 31,		Nine-month Period Ended December 31,
	2021	2022	2022
Cash flows from operating activities:			
Net profit for the period	¥ 241,541	¥ 285,903	\$ 2,169
Depreciation and amortization	430,877	502,990	3,816
Impairment losses	14,666	41,969	318
Equity-settled share-based compensation	32,057	45,823	348
Loss (gain) on sales and disposal of property, plant and equipment	258	(161)	(1)
Gain on divestment of business and subsidiaries	(1,095)	(959)	(7)
Change in fair value of financial assets and liabilities associated with contingent consideration arrangements, net	(9,683)	4,323	33
Finance (income) and expenses, net	100,589	71,635	543
Share of loss of investments accounted for using the equity method	5,255	3,133	24
Income tax expenses	115,077	41,273	313
Changes in assets and liabilities:			
Decrease in trade and other receivables	82,243	6,856	52
Increase in inventories	(39,268)	(34,240)	(260)
Decrease in trade and other payables	(1,797)	(144,971)	(1,100)
Increase (decrease) in provisions	(70,098)	11,605	88
Decrease in other financial liabilities	(51,158)	(7,906)	(60)
Other, net	(858)	21,258	161
Cash generated from operations	848,607	848,529	6,438
Income taxes paid	(107,224)	(173,363)	(1,315)
Tax refunds and interest on tax refunds received	6,138	8,297	63
Net cash from operating activities	747,521	683,463	5,185
Cash flows from investing activities:			
Interest received	2,468	2,792	21
Dividends received	2,598	3,234	25
Acquisition of property, plant and equipment	(87,673)	(104,888)	(796)
Proceeds from sales of property, plant and equipment	412	80	1
Acquisition of intangible assets	(46,541)	(84,721)	(643)
Acquisition of investments	(7,600)	(5,441)	(41)
Proceeds from sales and redemption of investments	16,065	20,553	156
Acquisition of businesses, net of cash and cash equivalents acquired	(49,672)	—	—
Proceeds from sales of business, net of cash and cash equivalents divested	2,138	—	—
Other, net	(4,683)	(219)	(2)
Net cash used in investing activities	(172,487)	(168,610)	(1,279)

	JPY (millions)		USD (millions)(*)
	Nine-month Period Ended December 31,		Nine-month Period Ended December 31,
	2021	2022	2022
Cash flows from financing activities:			
Net decrease in short-term loans and commercial papers	(2)	—	—
Proceeds from issuance of bonds and long-term loans	249,334	—	—
Repayments of bonds and long-term loans	(635,047)	(281,585)	(2,136)
Acquisition of treasury shares	(52,538)	(26,929)	(204)
Interest paid	(84,917)	(86,563)	(657)
Dividends paid	(273,024)	(268,997)	(2,041)
Repayments of lease liabilities	(29,904)	(32,510)	(247)
Other, net	(366)	(5,964)	(45)
Net cash used in financing activities	(826,465)	(702,548)	(5,330)
Net decrease in cash and cash equivalents	(251,430)	(187,695)	(1,424)
Cash and cash equivalents at the beginning of the year	966,222	849,695	6,446
Effects of exchange rate changes on cash and cash equivalents	9,549	23,141	176
Cash and cash equivalents at the end of the period	724,341	685,141	5,198

(*) Condensed interim consolidated statements of cash flows have been translated solely for the convenience of the reader at an exchange rate of 1USD = 131.81 JPY, the Noon Buying Rate certified by the Federal Reserve Bank of New York on December 30, 2022. The rate and methodologies used for the convenience translations differ from the currency exchange rates and translation methodologies under IFRS used for the preparation of the condensed interim consolidated financial statements. The translation should not be construed as a representation that the Japanese yen amounts could be converted into U.S. dollars at the above or any other rate.

(6) Other Information

(Significant Subsequent Events)

Not applicable.

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1. Pipeline

I. Clinical Development Activities

- The following table lists the pipeline assets that we are clinically developing as of February 2, 2023. The assets in our pipeline are in various stages of development, and the contents of the pipeline may change as therapeutic candidates currently under development drop out and new therapeutic candidates are introduced. Whether the therapeutic candidates listed below are ever successfully released as products depends on various factors, including the results of pre-clinical and clinical trials, market conditions for various drugs and regulatory approvals.
- This table primarily shows the indications for which we are actively pursuing regulatory approval and those regulatory approvals granted during fiscal year 2022. We are also conducting additional studies of certain assets to examine their potential for use in further indications and in additional formulations.
- The listings in this table are limited to the U.S., EU and Japan and China, but we are also actively conducting development activities in other regions, including in Emerging Markets. Country/region column denotes where a pivotal clinical study is ongoing or a filing has been made with our specific intention to pursue approval in any of the U.S., EU, Japan or China. 'Global' refers to U.S., EU, Japan and China.
- Brand name and country/region indicate the brand name and country in which the specific asset has already been approved for any indication in any of the U.S., EU, Japan or China and Takeda has commercialization rights for such asset.
- Stage-ups are recognized in the table upon achievement of First Subject In.
- Modality of our pipeline assets in the following table is classified into either of the following categories: 'small molecule', 'peptide/oligonucleotide', 'cell and gene therapy' or 'biologic and other.'

Oncology Pipeline

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Country/ Region	Stage
TAK-788 <mobocertinib> <i>EXKIVITY</i> (U.S.)	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
MLN9708 <ixazomib> <i>NINLARO</i> (Global)	Proteasome inhibitor (oral)	Small molecule	Maintenance therapy in patients with newly diagnosed Multiple Myeloma not treated with stem cell transplant (TOURMALINE-MM4)	U.S. EU China	P-III P-III P-III
			Maintenance therapy in patients with newly diagnosed Multiple Myeloma following autologous stem cell transplant (TOURMALINE-MM3)	U.S. EU	P-III P-III
<cabozantinib> ³ <i>CABOMETYX</i> (Japan)	Multi-targeted kinase inhibitor (oral)	Small molecule	Metastatic Castration-Resistant Prostate Cancer in combination with atezolizumab ⁴	Japan	P-III
<ponatinib> <i>ICLUSIG</i> (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
<niraparib> ⁵ <i>ZEJULA</i> (Japan)	PARP 1/2 inhibitor (oral)	Small molecule	Breast cancer	Japan	P-III
TAK-981 <subasumstat>	SUMO inhibitor (injection)	Small molecule	Multiple cancers	-	P-II

TAK-573 ⁶ <modakafusp alfa>	Anti-CD38-targeted IgG4 genetically fused with an attenuated IFN α (injection)	Biologic and other	Relapsed/refractory Multiple Myeloma	-	P-II
			Solid tumors	-	P-I
TAK-007 ⁷	CD19 CAR-NK (injection)	Cell and gene therapy	Relapsed/refractory B cell malignancies	-	P-II
TAK-102 ⁸	GPC3 CAR-T (injection)	Cell and gene therapy	Solid tumors	-	P-I
TAK-103 ⁸	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 ⁹	CD19 1XX CAR-T (injection)	Cell and gene therapy	Relapsed/refractory B cell malignancies	-	P-I
TAK-186 ¹⁰	T Cell Engager (Injection)	Biologic and other	EGFR expressing solid tumors	-	P-I
TAK-280 ¹⁰	T Cell Engager (Injection)	Biologic and other	B7-H3 expressing solid tumors	-	P-I

1. The U.S. FDA review is being conducted under Project Orbis, an initiative of the FDA Oncology Center of Excellence (OCE), which provides a framework for concurrent submission and review of oncology products among international partners. Currently, approval was granted in the U.K. (May 2022), the Switzerland (Jun 2022), Australia (Jul 2022) and South Korea (Jul 2022).

2. Following discussions with the EMA, Takeda decided to withdraw the marketing authorization application (MAA).

3. Partnership with Exelixis, Inc.

4. Partnership with Chugai Pharmaceutical. Takeda operates P-III development

5. Partnership with GSK

6. Partnership with Teva Pharmaceutical Industries Ltd.

7. Partnership with The University of Texas MD Anderson Cancer Center

8. Partnership with Noile-Immune Biotech, Inc.

9. Partnership with Memorial Sloan Kettering Cancer Center

10. Acquired via acquisition of Maverick Therapeutics, Inc.

* Event occurred after the end of the Q3 reporting period: Update after January 1, 2023

Additions since FY2022 Q2: None

Removals since FY2022 Q2: Cabozantinib for Non-Small Cell Lung Cancer (Japan, P-III, discontinued)

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> <i>LIVTENCITY</i> (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)
			HSCT Recipients with First CMV Infection	U.S. EU	P-III P-III
			Treatment of CMV Infection/disease Post Transplantation (Including HSCT)	Japan	P-III
TAK-672 ² <i>OBIZUR</i> (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-743 <lanadelumab> <i>TAKHZYRO</i> (Global)	Plasma kallikrein inhibitor (injection)	Biologic and other	Pediatric Hereditary Angioedema	U.S. EU	Filed (Oct 2022) Filed (Dec 2022)
			Bradykinin-Mediated Angioedema	Global	P-III
TAK-577 <i>VONVENDI</i> (U.S., Japan) <i>VEYVONDI</i> (EU)	von Willebrand factor [recombinant] (injection)	Biologic and other	Adult on-demand and surgery treatment of von Willebrand disease	China	Filed (Jan 2023)*
			Adult prophylactic treatment of von Willebrand disease	EU China	P-III P-III
			Pediatric on-demand and surgery treatment of von Willebrand disease	Global	P-III
TAK-660 <i>ADYNOVATE</i> (U.S., Japan) <i>ADYNOVI</i> (EU)	Antihemophilic factor [recombinant], PEGylated (injection)	Biologic and other	Pediatric Hemophilia A	EU	P-III
TAK-755 ³ <apadamtase alfa/ cinaxadamtase alfa>	Replacement of the deficient-ADAMTS13 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-141/JR-141 ⁴ <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-611	Human arylsulfatase A for intrathecal administration [recombinant] (injection)	Biologic and other	Metachromatic leukodystrophy	-	P-II

TAK-079 ⁵ <mezagitamab>	Anti-CD38 monoclonal antibody (injection)	Biologic and other	Myasthenia gravis	-	P-II
			Immune thrombocytopenic purpura	-	P-II
			Systemic lupus erythematosus	-	P-I/II
			Immunoglobulin A nephropathy	-	P-I

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

* Event occurred after the end of the Q3 reporting period: Update after January 1, 2023

Additions since FY2022 Q2: TAK-577 for Adult on-demand and surgery treatment of von Willebrand disease (China, Filed, Jan 2023)
TAK-079 for immunoglobulin A nephropathy (P-I)

Removals since FY2022 Q2: None

Neuroscience Pipeline

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Country/ Region	Stage
TAK-935 <oticlestat>	CH24H inhibitor (oral)	Small molecule	Dravet syndrome	Global	P-III
			Lennox-Gastaut syndrome	Global	P-III
TAK-071	M1 positive allosteric modulator (M1PAM) (oral)	Small molecule	Parkinson's disease	-	P-II
TAK-041/NBI-846 ¹	GPR139 agonist (oral)	Small molecule	Anhedonia in major depressive disorder (MDD)	-	P-II
TAK-653/NBI-845 ¹	AMPA receptor potentiator (oral)	Small molecule	Inadequate response to treatment in major depressive disorder (MDD)	-	P-II
TAK-341/MEDI1341 ²	Alpha-synuclein antibody (injection)	Biologic and other	Multiple systems atrophy (MSA)	-	P-II
TAK-594/DNL593 ³	Brain-penetrant progranulin fusion protein (injection)	Biologic and other	Frontotemporal dementia	-	P-I/II
TAK-861	Orexin 2R agonist (oral)	Small molecule	Sleep disorders, other disorders	-	P-I
TAK-925	Orexin 2R agonist (injection)	Small molecule	Post-anesthesia recovery, narcolepsy	-	P-I
TAK-920/DNL919 ³	Brain-penetrant TREM2 agonist monoclonal antibody (injection)	Biologic and other	Alzheimer's disease	-	P-I

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

Additions since FY2022 Q2: None

Removals since FY2022 Q2: None

Gastroenterology (GI) Pipeline

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Country/ Region	Stage
MLN0002 <vedolizumab> ENTYVIO (Global)	Humanized monoclonal antibody against $\alpha 4\beta 7$ integrin (injection)	Biologic and other	Subcutaneous formulation for ulcerative colitis	U.S. Japan	Complete Response Letter (CRL) received (Dec 2019) ⁶ Filed (Aug 2019)
			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 <i>Helicobacter pylori</i> 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-227/ZED1227 ¹	Transglutaminase 2 inhibitor (oral)	Small molecule	Celiac disease	-	P-II (b)
TAK-954 ²	5-HT ₄ - hydroxytryptamine receptor agonist (injection)	Small molecule	Post-operative gastrointestinal dysfunction	-	P-II (b)
TAK-999 ³ <fazirsiran>	GalNAc based RNA interference (RNAi) (injection)	Peptide/ Oligo-nucleotide	Alpha-1 antitrypsin-deficiency associated liver disease	U.S. EU	P-II (b) P-II (b)
TAK-018/EB8018 ⁴ <sibofimloc>	FimH antagonist (oral)	Small molecule	Crohn's disease (post-operative and ileal-dominant)	-	P-II (a)
TAK-062 <zamaglutinase>	Glutenase (oral)	Biologic and other	Celiac disease	-	P-II
TAK-101 ⁵	Tolerizing Immune Modifying nanoParticle (TIMP) (injection)	Biologic and other	Celiac disease	-	P-II
TAK-951	Peptide agonist (sub-cutaneous)	Peptide/ Oligo-nucleotide	Nausea and vomiting	-	P-II
TAK-105	Peptide agonist (sub-cutaneous)	Peptide/ Oligo-nucleotide	Nausea and vomiting	-	P-I

1. Partnership with Zedira and Dr. Falk Pharma. Takeda has an exclusive license to develop and commercialize TAK-227/ZED1227 in the US and other territories outside of Europe, Canada, Australia, and China.

2. Partnership with Theravance Biopharma, Inc.

3. Partnership with Arrowhead Pharmaceuticals, Inc.

4. Partnership with Enterome Bioscience SA

5. Acquired development and commercialization license for TAK-101 from COUR Pharmaceuticals. Previously known as TIMP-GLIA.

6. In active discussions with the FDA. Timelines under review; target resubmission filing anticipated in FY2023.

Additions since FY2022 Q2: None

Removals since FY2022 Q2: TAK-510 for Nausea and vomiting (P-I, discontinued)

Plasma-Derived Therapies Pipeline

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

1. Partnership with Halozyme

2. Non-interventional study to collect data is in progress

* Event occurred after the end of the Q3 reporting period: Update after January 1, 2023

Additions since FY2022 Q2: None

Removals since FY2022 Q2: None

Vaccines Pipeline

Development code Brand name (country/region)	Type of vaccine (administration route)	Modality	Indications / additional formulations	Country/ Region	Stage
TAK-019/ NVX-CoV2373 ¹ <i>NUVAXOVID</i> <i>Intramuscular Injection</i> (Japan)	SARS-CoV-2 vaccine (injection)	Biologic and other	Active immunization for the prevention of COVID-19 (primary and booster)	Japan	Approved (Apr 2022)
			Active immunization for the prevention of COVID-19 (heterologous booster)	Japan	P-III
TAK-003 ² <i>QDENG</i> (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. QDENG (TAK-003) was approved by the Indonesia National Agency for Drug and Food Control, Badan Pengawas Obat dan Makanan (BPOM) in August 2022, for the prevention of dengue disease caused by any serotype in individuals six years to 45 years of age.

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 Q2: None

Removals since FY2022 Q2: 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>	IL 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-788 <mobocertinib>	Previously treated Non-Small Cell Lung Cancer with EGFR exon 20 insertion	China	Approved (Jan 2023)*
TAK-672	Acquired hemophilia A (AHA)	China	Filed (Jun 2022)
TAK-771 <IG Infusion 10% (Human) w/ Recombinant Human Hyaluronidase>	Pediatric indication for primary immunodeficiency	U.S.	Filed (Jul 2022)
TAK-438 <vonoprazan>	Acid related diseases (adjunct to <i>Helicobacter pylori</i> eradication)	China	Filed (Aug 2022)
TAK-743 <lanadelumab>	Pediatric Hereditary Angioedema	U.S.	Filed (Oct 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)*
<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-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 <zamaglutinase>	Celiac disease	-	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

* Event occurred after the end of the Q3 reporting period: Update after January 1, 2023

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.

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.

Oncology

Partner	Country of incorporation	Subject
Adimab	U.S.	Agreement for the discovery, development and commercialization of three mAbs and three CD3 Bi-Specific antibodies for oncology indications.
Crescendo Biologics	U.K	Collaboration and licensing agreement for the discovery, development and commercialization of Humabody®-based therapeutics for cancer indications.
Egle Therapeutics	France	Identify novel tumor-specific regulatory T cell targets and develop unique anti-suppressor-based immunotherapies.
Exelixis, Inc.	U.S.	Exclusive licensing agreement to commercialize and develop novel cancer therapy cabozantinib and all potential future cabozantinib indications in Japan, including advanced renal cell carcinoma and hepatocellular carcinoma.
GlaxoSmithKline	U.K.	Exclusive licensing agreement to develop and commercialize novel cancer therapy niraparib for the treatment of all tumor types in Japan, and all tumor types excluding prostate cancer in South Korea and Taiwan.
Heidelberg Pharma	Germany	Antibody-Drug-Conjugate (ADC) research collaboration on 2 targets and licensing agreement (α -amanitin payload and proprietary linker).
KSQ Therapeutics	U.S.	Strategic collaboration to research, develop and commercialize novel immune-based therapies for cancer using KSQ's CRISPRomics® technology.
MD Anderson Cancer Center (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.
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).
Code Bio	U.S.	Collaboration and license agreement for Takeda and Code Bio to design and develop a targeted gene therapy leveraging Code Bio's 3DNA platform for a liver-directed rare disease program, plus conduct additional studies for central nervous system-directed rare disease programs. Takeda has the right to exercise options for an exclusive license for four programs.
Codexis, Inc.	U.S.	Strategic collaboration and license for the research and development of novel gene therapies for certain disease indications, including the treatment of lysosomal storage disorders and blood factor deficiencies.
Ensoma	U.S.	Research collaboration and license provides Takeda with an exclusive worldwide license to Ensoma's Engenious™ vectors for up to five rare disease indication.
Evox Therapeutics	U.K.	Collaboration for developing novel protein replacement and mRNA therapies and targeted delivery using Evox's proprietary exosome technology. Partnership for up to five rare disease targets with Takeda assuming responsibility for its clinical development.
Evozyne	U.S.	Research collaboration and license agreement with Takeda to research and develop proteins that could be incorporated into next-generation gene therapies for up to four rare disease targets.
GlaxoSmithKline	U.K.	In-license agreement between GSK and University of Michigan for TAK-620 (maribavir) in the treatment of human cytomegalovirus.
JCR Pharmaceuticals	Japan	Exclusive collaboration and license agreement to commercialize TAK-141 (JR-141, pabinafusp alfa), applied with J-Brain Cargo®, JCR's proprietary blood-brain barrier (BBB) penetration technology, for the treatment of Hunter syndrome (MPS II). Takeda will exclusively commercialize TAK-141 outside of the United States, including Canada, Europe, and other regions (excluding Japan and certain other Asia-Pacific countries). Takeda receives an option under a separate option agreement, which allows Takeda to acquire an exclusive license to commercialize TAK-141 in the U.S. upon completion of the Phase 3 program. In March 2022, Takeda and JCR has entered into new exclusive license and collaboration agreement to develop gene therapies that apply J-Brain Cargo® BBB penetration technology for lysosomal storage disorders (LSDs); Takeda has the option to nominate additional rare disease and other disease indications.
Immusoft	U.S.	Research collaboration and license option agreement to discover, develop and commercialize cell therapies in rare inherited metabolic disorders with central nervous system (CNS) manifestations and complications using Immusoft's Immune System Programming (ISP™) technology platform.
IPSEN	France	Purchase agreement for the development of Obizur for the treatment of Acquired Hemophilia A including for patients with Congenital Hemophilia A with inhibitors indication in elective or emergency surgery.
KM Biologics	Japan	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. The collaboration will focus on developing non-viral in vivo gene therapy programs, including Poseida's Hemophilia A program.
Selecta Biosciences	U.S.	Research collaboration and license agreement to develop targeted, next-generation gene therapies for two indications within the field of lysosomal storage disorders using Selecta's ImmTOR platform.
Xenetic Biosciences	U.S.	Exclusive R&D license agreement for PolyXen delivery technology for hemophilia factors VII, VIII, IX, X.

Neuroscience

Partner	Country of incorporation	Subject
Anima Biotech	U.S.	Strategic collaboration to discover and develop mRNA translation modulators for genetically-defined neurological diseases.
AstraZeneca	UK	Agreement for the joint development and commercialization of MEDI1341/TAK-341, an alpha-synuclein antibody currently in development as a potential treatment for Multiple system atrophy (MSA) and Parkinson's disease.
BridGene Biosciences	U.S.	Research collaboration to discover small molecule drugs for "undruggable" targets using BridGene's chemoproteomics platform.
CNDAP (Cure Network Dolby Acceleration Partners)	U.S.	Research collaboration to develop small molecules targeting tau, a protein involved in Alzheimer's disease and other major brain disorders.
Denali Therapeutics	U.S.	Strategic option and collaboration agreement to develop and commercialize up to three specified therapeutic product candidates for neurodegenerative diseases, incorporating Denali's transport vehicle (TV) platform for increased exposure of biotherapeutic products in the brain; options exercised on DNL593/TAK-594 and DNL919/TAK-920 in Q3 FY2021.
Lundbeck	Denmark	Collaboration agreement to develop and commercialize vortioxetine.
Luxna Biotech	Japan	Exclusive worldwide license agreement for the use of Luxna's breakthrough xeno nucleic acid technology for multiple undisclosed target genes in the area of neurological diseases.
Neurocrine Biosciences	U.S.	Collaboration to develop and commercialize 7 compounds in Takeda's early-to-mid stage neuroscience pipeline, including TAK-041/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.
Skyhawk Therapeutics	U.S.	Collaboration and licensing agreement to develop and commercialize RNA modulation therapies targeting neurodegenerative diseases.
StrideBio	U.S.	Collaboration and license agreement to develop <i>in vivo</i> adeno-associated viruses (AAV) based therapies for Friedreich's Ataxia (FA) and two additional undisclosed targets.
Wave Life Sciences	Singapore	Multi-program option agreement to co-develop and co-commercialize antisense oligonucleotides for a range of neurological diseases.

Gastroenterology

Partner	Country of incorporation	Subject
Arrowhead Pharmaceuticals	U.S.	Collaboration and licensing agreement to develop fazirsiran (TAK-999; ARO-AAT), a Phase 2 investigational RNA interference (RNAi) therapy in development to treat alpha-1 antitrypsin-associated liver disease (AATLD). ARO-AAT is a potential first-in-class therapy designed to reduce the production of mutant alpha-1 antitrypsin protein, the cause of AATLD progression.
Beacon Discovery	U.S.	Collaboration agreement for the G-protein coupled receptor drug discovery and development program to identify drug candidates for a range of gastrointestinal disorders. The agreement grants Takeda worldwide rights to develop, manufacture and commercialize products resulting from the collaboration.
Cerevance	U.S.	Multi-year research alliance to identify novel target proteins expressed in the central nervous system and to develop new therapies against them for certain GI disorders. Goal of the collaboration is to select, confirm and validate targets from gene expression data sets generated by Cerevance's NETSeq 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.
Theravance Biopharma	U.S.	Global license, development and commercialization agreement for TAK-954, a selective 5-HT4 receptor agonist for motility disorders.
UCSD/Fortis Advisors	U.S.	Technology license for the development of oral budesonide formulation (TAK-721) for treatment of eosinophilic esophagitis.
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.

Plasma Derived Therapies

Partner	Country of incorporation	Subject
Halozyme	U.S.	Agreement for the in-license of Halozyme's proprietary ENHANZE™ platform technology to increase dispersion and absorption of HyQvia. Ongoing development work for a U.S. pediatric indication to treat primary immunodeficiencies and a Phase 3 indication in Chronic Inflammatory Demyelinating Polyradiculoneuropathy.
Kamada	Israel	In-license agreement to develop and commercialize IV Alpha-1 proteinase inhibitor (Glassia); Exclusive supply and distribution of Glassia in the U.S., Canada, Australia and New Zealand; work on post market commitments ongoing.
Johnson & Johnson/Momenta Pharmaceuticals	U.S.	In-licensing agreement with Momenta Pharmaceuticals, Inc. which was acquired by Johnson & Johnson for an investigational hypersialylated immunoglobulin (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.
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 neurosciences, oncology and GI as well as discovery efforts in additional areas of compelling iPSC translational science.
Charles River Laboratories	U.S.	Collaboration on multiple integrated programs across Takeda's core therapeutic areas using Charles River Laboratories' end-to-end drug discovery and safety assessment platform to progress these programs towards candidate status.
Evotec SE	Germany	Research alliance to support Takeda's growing number of research stage gene therapy discovery programs. Evotec and Takeda have also entered into a multi-RNA target alliance to discover and develop RNA targeting small molecule therapeutics for targets that are difficult to address via more conventional approaches.
Massachusetts Institute of Technology	U.S.	MIT-Takeda Program to fuel the development and application of artificial intelligence (AI) capabilities to benefit human health and drug development. Centered within the Abdul Latif Jameel Clinic for Machine Learning in Health (J-Clinic), the new program will leverage the combined expertise of both organizations, and is supported by Takeda's 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.

■ Clinical study protocol summaries

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

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

2. Supplementary Revenue Information

Revenue by region

Year to date

(Bn JPY)	Reported *1				Core CER Change *1*5
	FY21Q3 YTD	FY22Q3 YTD	YOY		YOY
Total revenue	2,695.7	3,071.3	375.6	13.9 %	4.5 %
Japan *2	530.2	389.8	(140.4)	(26.5)%	(2.3)%
% of revenue	19.7%	12.7%	(7.0)pt		
United States	1,297.0	1,621.8	324.8	25.0 %	2.6 %
% of revenue	48.1%	52.8%	4.7pt		
Europe and Canada	541.0	632.4	91.4	16.9 %	7.9 %
% of revenue	20.1%	20.6%	0.5pt		
Growth and Emerging Markets *3	327.5	427.3	99.8	30.5 %	14.5 %
% of revenue	12.1%	13.9%	1.8pt		
Asia (excluding Japan)	139.8	169.0	29.3	20.9 %	6.5 %
% of revenue	5.2%	5.5%	0.3pt		
Latin America	93.5	121.4	27.9	29.8 %	10.3 %
% of revenue	3.5%	4.0%	0.5pt		
Russia/CIS	43.6	66.7	23.1	53.0 %	15.6 %
% of revenue	1.6%	2.2%	0.6pt		
Other *4	50.6	70.2	19.6	38.7 %	43.4 %
% of revenue	1.9%	2.3%	0.4pt		
Of which royalty / service income *2	210.6	88.4	(122.1)	(58.0)%	5.6 %

*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 FY21Q3YTD.

*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

(Bn JPY)	Reported *1											
	FY21				FY22							
	Q1	Q2	Q3	Q4	Q1	YOY	Q2	YOY	Q3	YOY	Q4	YOY
Total revenue	949.6	844.8	901.3	873.3	972.5	2.4%	1,002.3	18.6%	1,096.6	21.7%		
Japan *2	259.0	131.9	139.4	128.7	140.5	(45.7%)	120.8	(8.4%)	128.5	(7.8%)		
% of revenue	27.3%	15.6%	15.5%	14.7%	14.5%		12.1%		11.7%			
United States	412.2	426.2	458.6	417.4	501.1	21.6%	531.5	24.7%	589.2	28.5%		
% of revenue	43.4%	50.4%	50.9%	47.8%	51.5%		53.0 %		53.7 %			
Europe and Canada	178.7	175.2	187.0	198.2	205.6	15.0%	203.4	16.1%	223.4	19.5%		
% of revenue	18.8%	20.7%	20.7%	22.7%	21.1%		20.3 %		20.4 %			
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%		
% of revenue	10.5%	13.2%	12.9%	14.8%	12.9%		14.6 %		14.2 %			
Asia (excluding Japan)	40.3	49.4	50.1	57.2	46.1	14.4%	59.6	20.7%	63.3	26.5%		
% of revenue	4.2%	5.8%	5.6%	6.5%	4.7%		5.9 %		5.8 %			
Latin America	30.1	31.3	32.2	34.9	40.3	34.0%	43.0	37.2%	38.2	18.6%		
% of revenue	3.2%	3.7%	3.6%	4.0%	4.1%		4.3 %		3.5 %			
Russia/CIS	12.3	12.8	18.5	18.5	17.4	40.8%	20.5	60.4%	28.9	56.2%		
% of revenue	1.3%	1.5%	2.1%	2.1%	1.8%		2.0 %		2.6 %			
Other *4	17.0	18.0	15.5	18.4	21.6	26.8%	23.6	30.7%	25.0	61.1%		
% of revenue	1.8%	2.1%	1.7%	2.1%	2.2%		2.4 %		2.3 %			
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%		

*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												
	FY21Q3 YTD	FY22Q3 YTD	YOY	US	YOY	Japan	YOY	EUCAN	YOY	GEM*5	YOY	Ex-US	YOY
GI	665.7	857.5	28.8 %	506.2	35.5 %	87.6	5.3 %	175.1	19.9 %	72.3	46.1 %	16.3	20.9 %
ENTYVIO	395.4	547.9	38.6 %	388.3	46.0 %	10.3	20.4 %	122.4	19.7 %	26.9	44.2 %		
TAKECAB/VOCINTI *1	78.4	84.5	7.9 %	—	-	72.3	(1.4)%	—	-	12.2	143.5 %		
GATTEX/REVESTIVE	56.6	78.2	38.1 %	59.2	27.5 %	4.2	461.1 %	10.3	25.5 %	4.5	251.7 %		
DEXILANT	40.1	55.1	37.3 %	31.6	36.0 %	—	-	10.3	33.9 %	13.2	43.5 %		
PANTOLOC/CONTROLOC*2	30.1	33.8	12.3 %	1.6	(8.9)%	—	-	23.0	16.9 %	9.2	6.1 %		
LIALDA/MEZAVANT *3	19.0	17.6	(7.4)%	1.3	(76.5)%							16.3	20.9 %
PENTASA	15.8	7.3	(53.7)%	7.3	(53.7)%								
RESOLOR/MOTTEGRITY	10.1	13.4	32.2 %	11.3	48.2 %	—	-	2.0	(17.5)%	—	-		
ALOFISEL	1.4	2.0	46.6 %	—	-	0.1	-	1.7	52.3 %	0.2	(15.1)%		
Others	18.8	17.7	(5.9)%	5.7	(21.9)%	0.7	36.9 %	5.3	15.7 %	6.0	(6.4)%		
Rare Diseases	462.9	553.6	19.6 %	256.2	25.3 %	28.6	12.8 %	149.1	5.0 %	119.7	31.4 %		
Rare Hematology	211.6	232.6	10.0 %	98.7	8.3 %	18.0	(7.6)%	50.3	(4.0)%	65.6	35.1 %		
ADVATE	89.3	92.1	3.1 %	45.2	6.5 %	3.3	(28.5)%	16.8	(17.2)%	26.8	22.0 %		
ADYNOVATE/ADYNOVI	45.9	49.9	8.7 %	21.4	8.3 %	11.0	(3.9)%	12.4	17.1 %	5.1	24.5 %		
FEIBA *4	29.0	32.6	12.5 %	9.7	9.0 %	0.6	0.4 %	7.5	(5.9)%	14.8	28.4 %		
RECOMBIMATE	9.6	9.7	0.8 %	9.1	1.8 %	—	-	0.6	(5.8)%	0.0	(56.0)%		
HEMOFIL/IMMUNATE/IMMUNINE*4	13.5	14.9	9.7 %	2.5	(5.2)%	—	-	2.9	(18.9)%	9.5	28.9 %		
Other PDT Products *4	3.0	3.3	10.3 %	(0.0)	-	0.1	-	2.9	9.3 %	0.4	4.6 %		
Others	21.3	30.2	42.1 %	10.9	28.5 %	3.1	7.7 %	7.3	7.4 %	9.0	182.5 %		
Rare Genetics and Other	251.3	321.0	27.7 %	157.5	38.9 %	10.6	81.3 %	98.9	10.3 %	54.1	27.1 %		
TAKHZYRO	78.4	116.9	49.0 %	87.4	44.0 %	0.9	-	22.5	41.7 %	6.1	228.9 %		
ELAPRASE	57.7	65.0	12.6 %	19.4	28.1 %	0.6	(43.8)%	22.7	11.5 %	22.3	5.4 %		
REPLAGAL	39.6	50.6	27.8 %	—	-	6.8	208.7 %	28.9	9.8 %	14.8	34.3 %		
VPRIV	32.2	36.3	12.9 %	15.3	16.5 %	0.9	(15.6)%	12.2	3.5 %	8.0	28.0 %		
FIRAZYR	21.5	19.8	(7.7)%	12.0	12.0 %	1.4	(10.3)%	4.1	(44.8)%	2.3	31.3 %		
CINRYZE *4	14.7	14.8	0.7 %	10.9	5.5 %	—	-	3.5	(12.8)%	0.4	18.7 %		
LIVTENCITY	0.2	7.3	3,752.8 %	7.2	3,668.5 %	—	-	0.1	-	0.0	-		
Others	7.1	10.2	45.1 %	5.3	69.5 %	—	-	4.9	26.5 %	0.0	(52.3)%		

*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												
	FY21Q3 YTD	FY22Q3 YTD	YOY	US	YOY	Japan	YOY	EUCAN	YOY	GEM*5	YOY	Ex-US	YOY
PDT Immunology	363.2	502.4	38.3 %	335.2	40.3 %							167.2	34.5 %
immunoglobulin *1	278.3	390.5	40.3 %	297.2	43.3 %							93.2	31.5 %
albumin *1	61.5	85.5	39.1 %	17.5	30.8 %							68.0	41.4 %
Others *1	23.4	26.4	12.7 %	20.4	12.8 %							6.0	12.5 %
Oncology	359.1	345.0	(3.9)%	128.0	(25.3)%	70.6	5.3 %	68.2	14.0 %	71.9	33.7 %	6.2	(10.0)%
VELCADE *2	84.5	24.7	(70.7)%	23.1	(71.8)%							1.6	(39.3)%
LEUPLIN/ENANTONE	82.2	85.2	3.6 %	18.1	0.1 %	19.3	(17.0)%	26.2	6.4 %	21.5	32.9 %		
NINLARO	70.7	75.9	7.3 %	46.2	7.5 %	5.1	10.1 %	10.3	(1.0)%	14.3	12.7 %		
ADCETRIS	51.8	65.8	27.0 %			9.8	11.7 %	26.1	23.8 %	30.0	36.3 %		
ICLUSIG *2	26.7	35.5	33.1 %	30.9	37.7 %							4.6	8.9 %
VECTIBIX	19.4	20.1	3.8 %			20.1	3.8 %						
ALUNBRIG	10.1	15.8	55.7 %	6.1	18.6 %	1.3	63.4 %	4.5	64.6 %	3.8	166.1 %		
ZEJULA	5.8	9.8	70.9 %			8.2	69.1 %			1.7	80.2 %		
CABOMETYX	4.8	6.2	28.8 %			6.2	28.8 %						
EXKIVITY	0.4	2.2	406.2 %	2.2	400.1 %	—	-	0.0	-	0.0	745.8 %		
Others	2.7	3.7	34.5 %	1.4	126.9 %	0.6	4.1 %	1.1	8.8 %	0.5	8.9 %		
Neuroscience	362.6	477.1	31.6 %	368.5	31.0 %	29.2	15.4 %	64.3	32.9 %	15.1	98.5 %		
VYVANSE/ELVANSE	245.0	335.4	36.9 %	268.7	32.9 %	0.7	181.7 %	51.9	45.6 %	14.2	105.0 %		
TRINTELLIX	63.0	79.7	26.4 %	73.5	24.7 %	6.2	51.8 %			—	-		
INTUNIV	12.5	16.6	32.8 %	0.5	348.9 %	8.5	145.4 %	6.8	(18.2)%	0.8	35.8 %		
ADDERALL XR	16.0	19.1	19.6 %	17.4	20.7 %	—	-	1.7	8.8 %	—	-		
ROZEREM	9.4	7.8	(17.1)%	0.1	31.2 %	7.6	(17.7)%	0.0	219.7 %	0.1	20.9 %		
Others	16.7	18.5	10.6 %	8.3	49.1 %	6.2	(24.6)%	4.0	36.6 %	—	(100.0)%		
Others *3	482.2	335.7	(30.4)%										
AZILVA *4	60.1	56.6	(5.8)%	—	-	56.6	(5.8)%	—	-	—	-		
LOTRIGA	24.8	13.3	(46.2)%			13.3	(46.2)%						
FOSRENOL *2	10.2	10.9	7.1 %	1.1	(15.5)%							9.8	10.3 %
ACTOVEGIN	11.0	11.6	4.9 %	—	-	—	-	0.6	(7.6)%	11.0	5.6 %		

*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 FY21Q3YTD.

*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

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(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/MOTTEGRITY	3.2	3.9	21.8 %	3.2	42.1 %	—	-	0.7	(25.1)%	—	-		
ALOFISEL	0.4	0.6	59.3 %	—	-	0.0	-	0.5	58.6 %	0.1	40.5 %		
Others	6.7	6.1	(8.5)%	1.7	(38.8)%	0.3	73.7 %	2.0	34.1 %	2.1	(6.4)%		
Rare Diseases	155.5	181.6	16.8 %	82.6	16.0 %	9.7	17.1 %	51.0	7.5 %	38.3	34.5 %		
Rare Hematology	72.2	79.1	9.6 %	35.6	7.0 %	6.0	(7.0)%	17.1	(5.0)%	20.5	40.9 %		
ADVATE	30.7	32.1	4.7 %	16.7	10.8 %	1.0	(34.7)%	6.2	(12.1)%	8.1	17.7 %		
ADYNOVATE/ADYNOVI	15.4	17.5	13.9 %	8.2	19.4 %	3.6	(1.9)%	4.1	13.9 %	1.6	31.0 %		
FEIBA *4	11.4	10.5	(7.6)%	2.9	(26.5)%	0.3	19.8 %	2.1	(34.2)%	5.3	29.2 %		
RECOMBIMATE	3.7	3.2	(12.7)%	3.1	(12.0)%	—	-	0.2	(22.7)%	0.0	(23.5)%		
HEMOFIL/IMMUNATE/IMMUNINE*4	3.3	5.4	63.9 %	0.9	5.9 %	—	-	1.0	(1.6)%	3.5	148.1 %		
Other PDT Products *4	0.9	1.1	31.8 %	—	(100.0)%	—	-	1.0	18.3 %	0.2	441.4 %		
Others	6.9	9.2	33.3 %	3.9	24.4 %	1.0	14.1 %	2.5	22.6 %	1.8	115.2 %		
Rare Genetics and Other	83.3	102.5	23.1 %	47.0	23.9 %	3.7	100.0 %	34.0	15.1 %	17.8	27.7 %		
TAKHZYRO	25.5	34.0	33.7 %	24.8	24.6 %	0.3	-	7.4	49.3 %	1.6	153.3 %		
ELAPRASE	18.6	22.2	19.3 %	6.4	28.4 %	0.3	(39.5)%	7.7	15.0 %	7.8	20.7 %		
REPLAGAL	14.1	17.6	25.3 %	—	-	2.4	207.5 %	10.0	12.6 %	5.2	18.2 %		
VPRIV	10.5	11.9	13.5 %	5.0	13.9 %	0.3	(11.4)%	4.1	6.3 %	2.4	32.4 %		
FIRAZYR	6.9	6.8	(1.7)%	4.0	15.6 %	0.5	43.6 %	1.6	(38.5)%	0.7	35.8 %		
CINRYZE *4	5.6	4.7	(16.7)%	3.2	(23.5)%	—	-	1.4	4.4 %	0.1	(19.9)%		
LIVTENCITY	—	2.2	-	2.2	-	—	-	0.0	-	—	-		
Others	2.2	3.2	42.0 %	1.4	35.6 %	—	-	1.7	49.2 %	0.0	(25.8)%		

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

*2 generic name: pantoprazole

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

*4 PDT products

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

■ 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/MOTTEGRITY	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 %	—	(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/MOTTEGRITY	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 %		
RECOMBIMATE	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 *3	122.3	111.1	(9.2)%										
AZILVA *4	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

Product Sales Analysis (Reported & Core CER Change)

(Bn JPY)	FY21 Reported				FY22 Reported & Core CER Change*4															
	Q1	Q2	Q3	Q4	YOY			YOY				YOY				YOY				
					Q1	Reported (QTD)	Core@CER (QTD)	Q2	Reported (QTD)	Core@CER (QTD)	Core@CER (YTD)	Q3	Reported (QTD)	Core@CER (QTD)	Core@CER (YTD)	Q4	Reported (QTD)	Core@CER (QTD)	Core@CER (YTD)	
GI	210.5	218.6	236.6	210.0	270.4	28.4 %	15.4 %	276.0	26.3 %	8.2 %	11.7 %	311.1	31.5 %	9.8 %	11.1 %					
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 %					
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 %					
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 %					
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 %					
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 %					
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)%					
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)%					
RESOLOR/MOTTEGRITY	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 %					
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 %					
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)%					
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 %					
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)%					
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)%					
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)%					
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 %					
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)%					
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)%					
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 %					
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 %					
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 %					
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 %					
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 %					
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 %					
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 %					
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)%					
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)%					
LIVTENCITY	—	—	0.2	1.1	2.2	-	-	2.0	-	-	-	3.1	1,525.0 %	1,180.5 %	3,053.2 %					
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 %					

*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.

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(Bn JPY)	FY21 Reported				FY22 Reported & Core CER Change*4														
	Q1	Q2	Q3	Q4	YOY			YOY				YOY				YOY			
					Q1	Reported (QTD)	Core@CER (QTD)	Q2	Reported (QTD)	Core@CER (QTD)	Core@CER (YTD)	Q3	Reported (QTD)	Core@CER (QTD)	Core@CER (YTD)	Q4	Reported (QTD)	Core@CER (QTD)	Core@CER (YTD)
PDT Immunology	107.2	130.8	125.2	143.7	141.9	32.3 %	18.0 %	172.1	31.6 %	11.1 %	14.2 %	188.4	50.5 %	24.1 %	17.6 %				
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 %				
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 %				
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)%				
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)%				
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)%				
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)%				
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)%				
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 %				
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 %				
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 %				
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 %				
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 %				
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 %				
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 %				
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 %				
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 %				
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 %				
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 %				
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 %				
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)%				
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)%				
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 %				
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)%				
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)%				
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)%				
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)%				
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)%				

*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)	FY21 Reported Annual	Disclosed on May 11, 2022				Disclosed on October 27, 2022				Disclosed on February 2, 2023			
		FY22 Reported Forecasts		FY22 Core CER Forecasts*4		FY22 Reported Forecasts		FY22 Core CER Forecasts*4		FY22 Reported Forecasts		FY22 Core CER Forecasts*4	
		Annual	YOY			Annual	YOY			Annual	YOY		
GI	875.7	Mid-teen growth		Low-teen growth		Mid-twenties growth		Low-teen growth		Mid-twenties growth		Low-teen growth	
ENTYVIO	521.8	659.0	137.2	26 %	20 %	721.0	199.2	38 %	20 %	721.0	199.2	38 %	20 %
TAKECAB/VOCINTI *1	102.4	112.0	9.6	9 %	9 %	114.0	11.6	11 %	9 %	114.0	11.6	11 %	9 %
GATTEX/REVESTIVE	75.8	91.0	15.2	20 %	15 %	100.0	24.2	32 %	15 %	100.0	24.2	32 %	15 %
DEXILANT	50.8	40.0	(10.8)	(21)%	(26)%	52.0	1.2	2 %	(13)%	63.0	12.2	24 %	4 %
PANTOLOC/CONTROLOC*2	40.3	40.0	(0.3)	(1)%	(3)%	41.0	0.7	2 %	(3)%	41.0	0.7	2 %	(3)%
LIALDA/MEZAVANT	26.5	23.0	(3.5)	(13)%	(15)%	25.0	(1.5)	(6)%	(15)%	25.0	(1.5)	(6)%	(15)%
PENTASA	20.2	17.0	(3.2)	(16)%	(21)%	6.0	(14.2)	(70)%	(74)%	8.0	(12.2)	(60)%	(66)%
RESOLOR/MOTTEGRITY	13.0	14.0	1.0	8 %	4 %	16.0	3.0	23 %	4 %	16.0	3.0	23 %	4 %
ALOFISEL	1.8	4.0	2.2	117 %	102 %	4.0	2.2	117 %	102 %	4.0	2.2	117 %	102 %
Others	23.2	-25% to -20%		-30% to -25%		-25% to -20%		-30% to -25%		-25% to -20%		-30% to -25%	
Rare Diseases	611.2												
Rare Hematology	283.7	Low-single-digit growth		Low-single-digit decrease		Low-teen growth		Low-single-digit decrease		Low-teen growth		Low-single-digit decrease	
ADVATE	118.5	173.0	(6.2)	(3)%	(8)%	187.0	7.8	4 %	(8)%	187.0	7.8	4 %	(8)%
ADYNOVATE/ADYNOVI	60.7	38.0	(1.2)	(3)%	(7)%	41.0	1.8	5 %	(7)%	41.0	1.8	5 %	(7)%
FEIBA *3	39.2	13.0	0.7	6 %	4 %	15.0	2.7	22 %	4 %	15.0	2.7	22 %	4 %
RECOMBINATE	12.3	19.0	1.3	7 %	4 %	21.0	3.3	18 %	4 %	21.0	3.3	18 %	4 %
HEMOFIL/IMMUNATE/IMMUNINE*3	17.7	4.0	0.1	2 %	4 %	4.0	0.1	2 %	4 %	4.0	0.1	2 %	4 %
Other PDT Products *3	3.9	+25% to +30%		+20% to +25%		+>30%		+20% to +25%		+>30%		+20% to +25%	
Others	31.4												
Rare Genetics and Other	327.5	Low-teen growth		High-single-digit growth		High-teen growth		High-single-digit growth		Low-twenties growth		High-single-digit growth	
TAKHZYRO	103.2	125.0	21.8	21 %	15 %	137.0	33.8	33 %	15 %	137.0	33.8	33 %	15 %
ELAPRASE	73.1	77.0	3.9	5 %	4 %	84.0	10.9	15 %	4 %	84.0	10.9	15 %	4 %
REPLAGAL	51.7	68.0	16.3	31 %	30 %	71.0	19.3	37 %	30 %	71.0	19.3	37 %	30 %
VPRIV	42.4	46.0	3.6	8 %	6 %	50.0	7.6	18 %	6 %	50.0	7.6	18 %	6 %
FIRAZYR	26.7	21.0	(5.7)	(21)%	(25)%	23.0	(3.7)	(14)%	(25)%	23.0	(3.7)	(14)%	(25)%
CINRYZE *3	19.3	13.0	(6.3)	(33)%	(37)%	13.0	(6.3)	(33)%	(37)%	18.0	(1.3)	(7)%	(15)%
LIVTENCITY	1.3	+>200%		+>200%		+>200%		+>200%		+>200%		+>200%	
Others	9.7	-20% to -10%		-30% to -20%		-20% to -10%		-30% to -20%		-20% to -10%		-30% to -20%	

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

*2 Generic name: pantoprazole

*3 PDT products

*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 FY21: 1 USD = 112 JPY, 1 Euro = 131 JPY, 1 RUB = 1.5 JPY, 1 BRL = 20.9 JPY, 1 CNY = 17.4 JPY

Assumption of FX rates for FY22 Reported Forecasts (Disclosed on May 11, 2022) : 1 USD = 119 JPY, 1 Euro = 133 JPY, 1 RUB = 1.3 JPY, 1 BRL = 24.0 JPY, 1 CNY = 18.8 JPY

Assumption of FX rates for FY22 Reported Forecasts (Disclosed on October 27, 2022) : 1 USD = 132 JPY, 1 Euro = 138 JPY, 1 RUB = 2.1 JPY, 1 BRL = 26.4 JPY, 1 CNY = 19.8 JPY

Assumption of FX rates for FY22 Reported Forecasts (Disclosed on February 2, 2023) : 1 USD = 132 JPY, 1 Euro = 138 JPY, 1 RUB = 2.1 JPY, 1 BRL = 26.4 JPY, 1 CNY = 19.8 JPY

(Bn JPY)	FY21 Reported Annual	Disclosed on May 11, 2022				Disclosed on October 27, 2022				Disclosed on February 2, 2023			
		FY22 Reported Forecasts		FY22 Core CER Forecasts*3	FY22 Reported Forecasts		FY22 Core CER Forecasts*3	FY22 Reported Forecasts		FY22 Core CER Forecasts*3			
		Annual	YOY		Annual	YOY		Annual	YOY				
PDT Immunology	507.0	+20% to +30%		+10% to +20%	+30% to +40%		+10% to +20%	+30% to +40%		+10% to +20%			
immunoglobulin *1	385.9	+20% to +30%		+10% to +20%	+30% to +40%		+10% to +20%	+30% to +40%		+10% to +20%			
albumin *1	90.0	+20% to +30%		+10% to +20%	+30% to +40%		+10% to +20%	+30% to +40%		+10% to +20%			
Others *1	31.1	0% to +10%		0% to +10%	10% to +20%		0% to +10%	10% to +20%		0% to +10%			
Oncology	468.7	Low-single-digit decrease		Mid-single-digit decrease	Low-single-digit decrease		Approx. 10% decrease	Low-single-digit decrease		Approx. 10% decrease			
VELCADE	110.0	47.0	(63.0)	(57)%	(61)%	28.0	(82.0)	(75)%	(79)%	28.0	(82.0)	(75)%	(79)%
LEUPLIN/ENANTONE	106.5	106.0	(0.5)	(0)%	(3)%	116.0	9.5	9 %	4 %	116.0	9.5	9 %	4 %
NINLARO	91.2	103.0	11.8	13 %	8 %	104.0	12.8	14 %	0 %	104.0	12.8	14 %	0 %
ADCETRIS	69.2	75.0	5.8	8 %	7 %	81.0	11.8	17 %	7 %	81.0	11.8	17 %	7 %
ICLUSIG	34.9	41.0	6.1	18 %	10 %	45.0	10.1	29 %	10 %	45.0	10.1	29 %	10 %
VECTIBIX	24.7	24.0	(0.7)	(3)%	(3)%	24.0	(0.7)	(3)%	(3)%	24.0	(0.7)	(3)%	(3)%
ALUNBRIG	13.6	26.0	12.4	91 %	85 %	28.0	14.4	105 %	85 %	28.0	14.4	105 %	85 %
ZEJULA	8.0	12.0	4.0	50 %	50 %	12.0	4.0	50 %	50 %	12.0	4.0	50 %	50 %
CABOMETYX	6.4	8.0	1.6	26 %	26 %	8.0	1.6	26 %	26 %	8.0	1.6	26 %	26 %
EXKIVITY	1.0	+>300%		+>300%	+>300%	+>300%		+>300%	+>300%	+>300%		+>300%	
Others	3.3	+>30%		+>30%	+>30%	+>30%		+>30%	+>30%	+>30%		+>30%	
Neuroscience	482.3	High-single-digit growth		Low-single-digit growth	Mid-twenties growth		High-single-digit growth	Mid-twenties growth		High-single-digit growth			
VYVANSE/ELVANSE	327.1	372.0	44.9	14 %	7 %	436.0	108.9	33 %	14 %	436.0	108.9	33 %	14 %
TRINTELLIX	82.3	95.0	12.7	15 %	9 %	105.0	22.7	28 %	9 %	105.0	22.7	28 %	9 %
INTUNIV	18.9	19.0	0.1	0 %	(4)%	19.0	0.1	0 %	(4)%	19.0	0.1	0 %	(4)%
ADDERALL XR	20.9	9.0	(11.9)	(57)%	(59)%	17.0	(3.9)	(19)%	(32)%	22.0	1.1	5 %	(11)%
ROZEREM	11.7	8.0	(3.7)	(31)%	(30)%	8.0	(3.7)	(31)%	(30)%	8.0	(3.7)	(31)%	(30)%
Others	21.4	-10% to -5%		-10% to -5%	-10% to -5%	-5% to 0%		-10% to -5%	-10% to -5%	-5% to 0%		-10% to -5%	
Others	624.1	>30%		-20% to -10%	>30%		-20% to -10%	>30%		-20% to -10%			
AZILVA *2	76.3	73.0	(3.3)	(4)%	(4)%	73.0	(3.3)	(4)%	(4)%	73.0	(3.3)	(4)%	(4)%
LOTRIGA	32.7	13.0	(19.7)	(60)%	(60)%	13.0	(19.7)	(60)%	(60)%	15.0	(17.7)	(54)%	(54)%
FOSRENOL	13.6	11.0	(2.6)	(19)%	(20)%	12.0	(1.6)	(12)%	(20)%	12.0	(1.6)	(12)%	(20)%
ACTOVEGIN	13.4	12.0	(1.4)	(11)%	(3)%	16.0	2.6	19 %	(3)%	16.0	2.6	19 %	(3)%

*1 PDT products

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

*3 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 FY21: 1 USD = 112 JPY, 1 Euro = 131 JPY, 1 RUB = 1.5 JPY, 1 BRL = 20.9 JPY, 1 CNY = 17.4 JPY

Assumption of FX rates for FY22 Reported Forecasts (Disclosed on May 11, 2022) : 1 USD = 119 JPY, 1 Euro = 133 JPY, 1 RUB = 1.3 JPY, 1 BRL = 24.0 JPY, 1 CNY = 18.8 JPY

Assumption of FX rates for FY22 Reported Forecasts (Disclosed on October 27, 2022) : 1 USD = 132 JPY, 1 Euro = 138 JPY, 1 RUB = 2.1 JPY, 1 BRL = 26.4 JPY, 1 CNY = 19.8 JPY

Assumption of FX rates for FY22 Reported Forecasts (Disclosed on February 2, 2023) : 1 USD = 132 JPY, 1 Euro = 138 JPY, 1 RUB = 2.1 JPY, 1 BRL = 26.4 JPY, 1 CNY = 19.8 JPY

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

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

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

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

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

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

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

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



Definition of EBITDA/Adjusted EBITDA and Net Debt

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

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

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

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

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

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

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

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

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



FY2022 Q3 YTD Reported Results with Actual and CER % Change

(Billion JPY)	FY2021 Q3 YTD	FY2022 Q3 YTD		vs. PY	
				ACTUAL % CHANGE	CER % CHANGE* ¹
Revenue	2,695.7	3,071.3	375.6	13.9%	(0.7)%
Cost of sales	(798.5)	(934.3)	(135.8)	(17.0)%	(3.4)%
Gross profit	1,897.3	2,137.0	239.8	12.6%	(2.4)%
<i>Margin</i>	70.4 %	69.6 %		(0.8) pp	(1.2) pp
SG&A expenses	(662.9)	(742.5)	(79.6)	(12.0)%	2.2%
R&D expenses	(382.5)	(472.4)	(89.9)	(23.5)%	(4.9)%
Amortization of intangible assets associated with products	(309.1)	(370.6)	(61.5)	(19.9)%	(0.4)%
Impairment losses on intangible assets associated with products	(14.6)	(38.6)	(24.0)	(165.0)%	(112.2)%
Other operating income	34.3	16.7	(17.6)	(51.3)%	(54.4)%
Other operating expenses	(100.0)	(127.6)	(27.6)	(27.6)%	(8.6)%
Operating profit	462.5	401.9	(60.5)	(13.1)%	(20.3)%
<i>Margin</i>	17.2 %	13.1 %		(4.1) pp	(3.4) pp
Finance income	42.9	55.1	12.2	28.4%	17.6%
Finance expenses	(143.5)	(126.8)	16.8	11.7%	16.9%
Share of profit (loss) of investments accounted for using the equity method	(5.3)	(3.1)	2.1	40.4%	58.1%
Profit before tax	356.6	327.2	(29.4)	(8.3)%	(16.5)%
Income tax expenses	(115.1)	(41.3)	73.8	64.1%	61.3%
Net profit for the period	241.5	285.9	44.4	18.4%	4.8%
Non-controlling interests	(0.1)	(0.0)	0.1	84.4%	87.8%
Net profit attributable to owners of the Company	241.4	285.9	44.5	18.4%	4.9%
Basic EPS (yen)	154.09	184.32	30.23	19.6%	5.9%

*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 Q3 (Oct-Dec) Reported Results with Actual and CER % Change

(Billion JPY)	FY2021 Q3 (Oct-Dec)	FY2022 Q3 (Oct-Dec)		vs. PY	
				ACTUAL % CHANGE	CER % CHANGE* ¹
Revenue	901.3	1,096.6	195.3	21.7%	2.6%
Cost of sales	(281.4)	(336.0)	(54.6)	(19.4)%	(2.3)%
Gross profit	619.9	760.6	140.7	22.7%	2.7%
<i>Margin</i>	<i>68.8 %</i>	<i>69.4 %</i>		<i>0.6 pp</i>	<i>0.1 pp</i>
SG&A expenses	(231.1)	(262.3)	(31.2)	(13.5)%	3.8%
R&D expenses	(128.4)	(174.6)	(46.3)	(36.0)%	(11.9)%
Amortization of intangible assets associated with products	(105.0)	(129.8)	(24.8)	(23.6)%	0.9%
Impairment losses on intangible assets associated with products	(13.1)	(5.8)	7.3	55.8%	65.1%
Other operating income	14.7	3.2	(11.5)	(78.3)%	(77.7)%
Other operating expenses	(40.6)	(44.3)	(3.7)	(9.1)%	11.2%
Operating profit	116.5	147.0	30.5	26.2%	10.8%
<i>Margin</i>	<i>12.9 %</i>	<i>13.4 %</i>		<i>0.5 pp</i>	<i>1.0 pp</i>
Finance income	4.1	41.7	37.5	905.5%	918.1%
Finance expenses	(46.7)	(79.7)	(33.0)	(70.7)%	(57.1)%
Share of profit (loss) of investments accounted for using the equity method	(1.7)	(1.8)	(0.0)	(2.1)%	20.3%
Profit before tax	72.2	107.2	35.0	48.4%	33.6%
Income tax expenses	(14.4)	12.0	26.4	—	—
Net profit for the period	57.8	119.1	61.3	106.1%	87.1%
Non-controlling interests	(0.1)	(0.0)	0.0	56.3%	65.2%
Net profit attributable to owners of the Company	57.8	119.1	61.4	106.2%	87.2%
Basic EPS (yen)	36.91	76.63	39.72	107.6%	88.5%

*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 Q3 YTD Core Results with Actual and CER % Change

(Billion JPY)	FY2021 Q3 YTD	FY2022 Q3 YTD		vs. PY	
				ACTUAL % CHANGE	CER % CHANGE* ¹
Revenue	2,562.7	3,071.3	508.6	19.8%	4.5%
Cost of sales	(764.7)	(901.7)	(137.0)	(17.9)%	(4.2)%
Gross profit	1,798.0	2,169.6	371.7	20.7%	4.6%
<i>Margin</i>	70.2 %	70.6 %		0.5 pp	0.1 pp
SG&A expenses	(659.1)	(742.9)	(83.8)	(12.7)%	1.6%
R&D expenses	(380.9)	(472.1)	(91.2)	(23.9)%	(5.3)%
Operating profit	757.9	954.7	196.7	26.0%	9.7%
<i>Margin</i>	29.6 %	31.1 %		1.5 pp	1.5 pp
Finance income	25.2	9.2	(16.0)	(63.7)%	(69.4)%
Finance expenses	(114.2)	(114.2)	0.0	0.0%	4.9%
Share of profit (loss) of investments accounted for using the equity method	3.8	2.5	(1.3)	(34.2)%	(29.6)%
Profit before tax	672.7	852.1	179.4	26.7%	9.0%
Income tax expenses	(151.1)	(144.9)	6.2	4.1%	15.1%
Net profit for the period	521.6	707.2	185.6	35.6%	15.9%
Non-controlling interests	(0.1)	(0.0)	0.1	84.4%	87.8%
Net profit attributable to owners of the Company	521.5	707.2	185.7	35.6%	15.9%
Basic EPS (yen)	333	456	123	37.0%	17.1%

*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 Q3 (Oct-Dec) Core Results with Actual and CER % Change

(Billion JPY)	FY2021 Q3 (Oct-Dec)	FY2022 Q3 (Oct-Dec)		vs. PY	
				ACTUAL % CHANGE	CER % CHANGE* ¹
Revenue	901.3	1,096.6	195.3	21.7%	2.6%
Cost of sales	(270.6)	(330.1)	(59.5)	(22.0)%	(4.7)%
Gross profit	630.7	766.4	135.7	21.5%	1.7%
<i>Margin</i>	70.0 %	69.9 %		(0.1) pp	(0.6) pp
SG&A expenses	(230.4)	(262.4)	(32.0)	(13.9)%	3.5%
R&D expenses	(128.1)	(174.6)	(46.5)	(36.3)%	(12.1)%
Operating profit	272.2	329.5	57.3	21.0%	1.1%
<i>Margin</i>	30.2 %	30.0 %		(0.2) pp	(0.4) pp
Finance income	1.6	39.5	37.9	2,333.4%	2,395.0%
Finance expenses	(32.2)	(76.2)	(44.0)	(136.8)%	(119.3)%
Share of profit (loss) of investments accounted for using the equity method	0.9	(0.2)	(1.1)	—	—
Profit before tax	242.6	292.5	50.0	20.6%	1.0%
Income tax expenses	(56.9)	(32.0)	24.9	43.7%	56.7%
Net profit for the period	185.6	260.5	74.9	40.3%	18.7%
Non-controlling interests	(0.1)	(0.0)	0.0	56.3%	65.2%
Net profit attributable to owners of the Company	185.6	260.5	74.9	40.4%	18.7%
Basic EPS (yen)	119	168	49	41.3%	19.5%

*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 Q3 YTD 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	3,071.3					3,071.3
Cost of sales	(934.3)				32.6	(901.7)
Gross profit	2,137.0				32.6	2,169.6
SG&A expenses	(742.5)				(0.4)	(742.9)
R&D expenses	(472.4)				0.3	(472.1)
Amortization of intangible assets associated with products	(370.6)	370.6				—
Impairment losses on intangible assets associated with products	(38.6)		38.6			—
Other operating income	16.7			(16.7)		—
Other operating expenses	(127.6)			127.6		—
Operating profit	401.9	370.6	38.6	111.0	32.5	954.7
<i>Margin</i>	13.1 %					31.1%
Finance income and (expenses), net	(71.6)				(33.4)	(105.0)
Share of profit (loss) of investments accounted for using the equity method	(3.1)				5.6	2.5
Profit before tax	327.2	370.6	38.6	111.0	4.8	852.1
Tax expenses	(41.3)	(79.4)	(8.2)	(24.1)	8.0	(144.9)
Non-controlling interests	(0.0)					(0.0)
Net profit attributable to owners of the Company	285.9	291.2	30.4	86.9	12.8	707.2
EPS (yen)	184					456
Number of shares (millions)	1,551					1,551



FY2022 Q3 (Oct-Dec) 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	1,096.6					1,096.6
Cost of sales	(336.0)				5.9	(330.1)
Gross profit	760.6				5.9	766.4
SG&A expenses	(262.3)				(0.1)	(262.4)
R&D expenses	(174.6)				0.1	(174.6)
Amortization of intangible assets associated with products	(129.8)	129.8				—
Impairment losses on intangible assets associated with products	(5.8)		5.8			—
Other operating income	3.2			(3.2)		—
Other operating expenses	(44.3)			44.3		—
Operating profit	147.0	129.8	5.8	41.1	5.8	329.5
<i>Margin</i>	13.4 %					30.0%
Finance income and (expenses), net	(38.1)				1.3	(36.8)
Share of profit (loss) of investments accounted for using the equity method	(1.8)				1.6	(0.2)
Profit before tax	107.2	129.8	5.8	41.1	8.7	292.5
Tax expenses	12.0	(27.9)	(1.2)	(11.0)	(4.0)	(32.0)
Non-controlling interests	(0.0)					(0.0)
Net profit attributable to owners of the Company	119.1	101.9	4.6	30.1	4.7	260.5
EPS (yen)	77					168
Number of shares (millions)	1,555					1,555



FY2021 Q3 YTD 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	2,695.7				(133.0)				2,562.7
Cost of sales	(798.5)				0.6			33.1	(764.7)
Gross profit	1,897.3				(132.4)			33.1	1,798.0
SG&A expenses	(662.9)				1.0			2.8	(659.1)
R&D expenses	(382.5)							1.6	(380.9)
Amortization of intangible assets associated with products	(309.1)	309.1							—
Impairment losses on intangible assets associated with products	(14.6)		14.6						—
Other operating income	34.3			(33.2)			(1.1)		—
Other operating expenses	(100.0)			100.0					—
Operating profit	462.5	309.1	14.6	66.9	(131.4)		(1.1)	37.5	757.9
<i>Margin</i>	17.2 %								29.6%
Finance income and (expenses), net	(100.6)							11.6	(89.0)
Share of profit (loss) of investments accounted for using the equity method	(5.3)						6.6	2.4	3.8
Profit before tax	356.6	309.1	14.6	66.9	(131.4)		5.5	51.5	672.7
Tax expenses	(115.1)	(68.9)	(3.6)	(17.5)	40.2	64.6	(1.7)	(49.1)	(151.1)
Non-controlling interests	(0.1)								(0.1)
Net profit attributable to owners of the Company	241.4	240.2	10.9	49.4	(91.2)	64.6	3.8	2.3	521.5
EPS (yen)	154								333
Number of shares (millions)	1,567								1,567

*1 Tax charges of 64.6 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 Q3 (Oct-Dec) 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	901.3								901.3
Cost of sales	(281.4)							10.8	(270.6)
Gross profit	619.9							10.8	630.7
SG&A expenses	(231.1)							0.7	(230.4)
R&D expenses	(128.4)							0.3	(128.1)
Amortization of intangible assets associated with products	(105.0)	105.0							—
Impairment losses on intangible assets associated with products	(13.1)		13.1						—
Other operating income	14.7			(14.4)			(1.1)	0.7	—
Other operating expenses	(40.6)			40.6					—
Operating profit	116.5	105.0	13.1	26.2			(1.1)	12.5	272.2
<i>Margin</i>	12.9 %								30.2%
Finance income and (expenses), net	(42.6)							12.0	(30.6)
Share of profit (loss) of investments accounted for using the equity method	(1.7)						6.6	(4.0)	0.9
Profit before tax	72.2	105.0	13.1	26.2			5.5	20.5	242.6
Tax expenses	(14.4)	(23.4)	(3.1)	(6.0)		0.9	(1.7)	(9.2)	(56.9)
Non-controlling interests	(0.1)								(0.1)
Net profit attributable to owners of the Company	57.8	81.6	10.0	20.2		0.9	3.8	11.3	185.6
EPS (yen)	37								119
Number of shares (millions)	1,565								1,565

*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 Q3 YTD	FY2022 Q3 YTD	Change versus the previous year	
Net profit	241.5	285.9	44.4	18.4%
Depreciation, amortization and impairment loss	445.5	545.0	99.4	
Decrease (increase) in trade working capital	41.2	(172.4)	(213.5)	
Income taxes paid	(107.2)	(173.4)	(66.1)	
Tax refunds and interest on tax refunds received	6.1	8.3	2.2	
Other	120.3	190.0	69.7	
Net cash from operating activities	747.5	683.5	(64.1)	(8.6)%
Adjustment for cash temporarily held by Takeda on behalf of third parties ^{*1}	47.0	76.2	29.2	
Acquisition of PP&E	(87.7)	(104.9)	(17.2)	
Proceeds from sales of PP&E	0.4	0.1	(0.3)	
Acquisition of intangible assets	(46.5)	(84.7)	(38.2)	
Acquisition of investments	(7.6)	(5.4)	2.2	
Proceeds from sales and redemption of investments	16.1	20.6	4.5	
Proceeds from sales of business, net of cash and cash equivalents divested	2.1	—	(2.1)	
Free Cash Flow	671.3	585.2	(86.1)	(12.8)%

*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.

FY2022 Q3 YTD Net Debt to Adjusted EBITDA

NET DEBT/ADJUSTED EBITDA RATIO

(Billion JPY)	FY2022 Q3 YTD
Cash and cash equivalents ^{*1}	553.8
Book value debt on consolidated statements of financial position	(4,286.9)
Hybrid bond 50% equity credit	250.0
FX adjustment ^{*2}	67.4
Gross debt ^{*3}	(3,969.5)
Net cash (debt)	(3,415.7)
Net debt/Adjusted EBITDA ratio	2.5 x
Adjusted EBITDA (LTM)^{*4}	1,381.2

NET INCREASE (DECREASE) IN CASH

(Billion JPY)	FY2021 Q3 YTD	FY2022 Q3 YTD	Change versus the previous year	
Net cash from operating activities	747.5	683.5	(64.1)	(8.6)%
Acquisition of PP&E	(87.7)	(104.9)		
Proceeds from sales of PP&E	0.4	0.1		
Acquisition of intangible assets	(46.5)	(84.7)		
Acquisition of investments	(7.6)	(5.4)		
Proceeds from sales and redemption of investments	16.1	20.6		
Acquisition of business, net of cash and cash equivalents acquired	(49.7)	—		
Proceeds from sales of business, net of cash and cash equivalents divested	2.1	—		
Net decrease in short-term loans and commercial papers	(0.0)	—		
Repayment of long-term loans	(414.1)	(0.1)		
Proceeds from issuance of bonds	249.3	—		
Repayment of bonds	(220.9)	(281.5)		
Purchase of treasury shares	(52.5)	(26.9)		
Interest paid	(84.9)	(86.6)		
Dividends paid	(273.0)	(269.0)		
Others	(29.9)	(32.7)		
Net increase (decrease) in cash	(251.4)	(187.7)	63.7	(25.3)%

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

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

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

*4 LTM represents Last Twelve Months (January 2022 - December 2022). Calculated by subtracting FY2021 Q3 YTD from FY2021 Full Year and adding FY2022 Q3 YTD.

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



FY2022 Q3 YTD and FY2021 Q3 YTD Net Profit to Adjusted EBITDA Bridge

(Billion JPY)	FY2021 Q3 YTD	FY2022 Q3 YTD	Change versus the previous year	
Net profit	241.5	285.9	44.4	18.4%
Income tax expenses	115.1	41.3		
Depreciation and amortization	430.9	503.0		
Interest expense, net	86.7	86.0		
EBITDA	874.2	916.2	42.0	4.8%
Impairment losses	14.7	42.0		
Other operating expense (income), net, excluding depreciation and amortization and other miscellaneous expenses (non-cash item)	59.5	105.4		
Finance expense (income), net, excluding interest income and expense, net	13.9	(14.4)		
Share of loss on investments accounted for under the equity method	5.3	3.1		
Other adjustments:	(46.6)	77.2		
Non-core expense related to COVID-19	7.2	8.4		
Sales of Japan diabetes portfolio and other non-core product divestitures	(131.4)	—		
Impact on profit related to fair value step up of inventory in Shire acquisition	24.8	24.9		
Other costs ^{*1}	52.9	43.9		
Adjusted EBITDA	920.9	1,129.5	208.6	22.7%

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

FY2022 Q3 YTD Net Profit to Adjusted EBITDA LTM Bridge

(Billion JPY)	FY2021 Full Year (Apr-Mar)	FY2021 Q3 YTD (Apr - Dec)	FY2022 Q3 YTD (Apr - Dec)	FY2022 Q3 YTD LTM ^{*1} (Jan-Dec)
Net profit	230.2	241.5	285.9	274.5
Income tax expenses	72.4	115.1	41.3	(1.4)
Depreciation and amortization	583.2	430.9	503.0	655.3
Interest expense, net	117.8	86.7	86.0	117.2
EBITDA	1,003.6	874.2	916.2	1,045.6
Impairment losses	54.5	14.7	42.0	81.8
Other operating expense (income), net, excluding depreciation and amortization and other miscellaneous expenses (non-cash item)	106.3	59.5	105.4	152.1
Finance expense (income), net, excluding interest income and expense, net	25.1	13.9	(14.4)	(3.2)
Share of loss on investments accounted for under the equity method	15.4	5.3	3.1	13.2
Other adjustments:	(30.2)	(46.6)	77.2	93.6
Non-core expense related to COVID-19	10.4	7.2	8.4	11.6
Sale of Japan diabetes portfolio	(144.8)	(131.4)	—	(13.4)
Impact on profit related to fair value step up of inventory in Shire acquisition	31.9	24.8	24.9	32.0
Other costs ^{*2}	72.4	52.9	43.9	63.4
Adjusted EBITDA	1,174.5	920.9	1,129.5	1,383.2
EBITDA from divested products ^{*3}	(6.6)			(1.9)
Adjusted EBITDA (LTM)	1,168.0			1,381.2

*1 LTM represents Last Twelve Months (January 2022 - December 2022). Calculated by subtracting FY2021 Q3 YTD from FY2021 Full Year and adding FY2022 Q3 YTD.

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

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

FX Rates and FY2022 Currency Sensitivity

Average Exchange Rates vs. JPY			Impact of depreciation of yen from October 2022 to March 2023 on FY2022 forecast (100 million JPY)					
	FY2021 Actual (Apr-Dec)	FY2022 Actual (Apr-Dec)	FY2022 Assumption (Apr-Mar)		Revenue (IFRS)	Operating Profit (IFRS)	Net Profit (IFRS)	Core Operating Profit (non-IFRS)
USD	111	136	132	1% depreciation	86.9	14.0	10.5	31.4
				1 yen depreciation	66.1	10.7	8.0	23.9
EUR	131	140	138	1% depreciation	22.0	(14.7)	(15.5)	(11.7)
				1 yen depreciation	16.0	(10.6)	(11.2)	(8.5)
RUB	1.5	2.2	2.1	1% depreciation	2.9	1.6	1.6	1.8
CNY	17.2	19.8	19.8		8.6	5.1	5.1	5.1
BRL	20.7	26.5	26.4		3.9	2.4	2.4	2.5



CAPEX, Depreciation and Amortization and Impairment Losses

(Billion JPY)	FY2021	FY2021 Q3 YTD	FY2022 Q3 YTD	vs. PY		FY2022 Latest Forecast (Oct 27, 2022)
Capital expenditures ^{*1}	186.0	134.2	189.6	55.4	41.3%	260.0 to 310.0
Tangible assets	123.3	87.7	104.9	17.2	19.6%	
Intangible assets	62.8	46.5	84.7	38.2	82.0%	
*1 Cash flow base						
Depreciation and amortization	579.8	428.4	500.5	72.2	16.8%	640.0
Depreciation of tangible assets ^{*2} (A)	132.4	99.6	110.8	11.2	11.3%	
Amortization of intangible assets (B)	447.4	328.8	389.7	60.9	18.5%	
Of which Amortization associated with products (C)	418.8	309.1	370.6	61.5	19.9%	480.0
Of which Amortization excluding intangible assets associated with products (D)	28.6	19.7	19.1	(0.6)	(3.2)%	
*2 Excluding depreciation from investment properties						
Depreciation and amortization (excluding intangible assets associated with products) (A)+(D)	161.0	119.3	129.9	10.6	8.9%	160.0
Impairment losses	54.5	14.7	38.9	24.2	165.3%	
Impairment losses associated with products	54.1	14.6	38.6	24.0	165.0%	50.0
Amortization and impairment losses on intangible assets associated with products	472.9	323.6	409.2	85.6	26.4%	530.0

* Capital expenditures in the latest forecast do not include the impact of acquisitions that have been announced but not completed yet, including the upfront cash payment for the acquisition of NDI-034858 from Nimbus Therapeutics, LLC, for 4 billion USD, as the exact timing of cash payment is dependent upon deal close.

FY2022 Detailed Forecast



(BN JPY)	FY2021 Actual	FY2022 Latest Forecast (Oct 27, 2022)	FY2022 Latest Forecast % change vs. PY
Revenue	3,569.0	3,930.0	10.1%
R&D expenses	(526.1)	(620.0)	(17.9)%
Amortization of intangible assets associated with products	(418.8)	(480.0)	(14.6)%
Impairment losses on intangible assets associated with products	(54.1)	(50.0)	7.6%
Other operating income	43.1	13.0	(69.9)%
Other operating expenses	(159.1)	(100.0)	37.1%
Operating profit	460.8	530.0	15.0%
Finance income (expenses), net	(142.9)	(105.0)	26.5%
Profit before tax	302.6	426.0	40.8%
Net profit attributable to owners of the Company	230.1	307.0	33.4%
Basic EPS (yen)	147	198	34.4%
Core Revenue* ¹	3,420.5	3,930.0	14.9%
Core Operating Profit* ¹	955.2	1,180.0	23.5%
Core EPS (yen)	425	525	23.6%
USD/JPY (yen)	112	132	18.3%
EUR/JPY (yen)	131	138	5.9%

*1 Please refer to A-1 Definition of Core Financial Measures, Constant Exchange Rate change, and Free Cash Flow, for the definition and A-20 FY2022 Full Year Reconciliation from Reported Operating Profit to Core Operating Profit Forecast, for reconciliation.



FY2022 Core Operating Profit Adjustment Items & Cash Flow Forecast

CORE OPERATING PROFIT ADJUSTMENT ITEMS

(Billion JPY)	FY2022 Q3 YTD	FY2022 Latest Forecast (Oct 27, 2022)
Amortization of intangible assets associated with products	370.6	480.0
<i>Of which Shire-acquisition related</i>	<i>300.9</i>	<i>390.0</i>
Impairment losses on intangible assets associated with products	38.6	50.0
Other operating income	(16.7)	(13.0)
Other operating expenses	127.6	100.0
Other Core Operating Profit adjustments	32.5	33.0
<i>Of which Shire-acquisition related to unwind of inventories step-up</i>	<i>24.9</i>	<i>25.0</i>
Total core operating profit adjustments	552.7	650.0

CASH FLOW GUIDANCE

(Billion JPY)	FY2022 Q3 YTD	FY2022 Latest Forecast (Oct 27, 2022)
Free cash flow* ¹	585.2	650.0 to 750.0
CAPEX (cash flow base)* ¹	(189.6)	(260.0) to (310.0)
Depreciation and amortization (excluding intangible assets associated with products)	(129.9)	(160.0)
Cash tax rate on adjusted EBITDA (excluding divestitures)	N/A	mid-teen %

*¹ Free cash flow and capital expenditures in the latest forecast do not include the impact of acquisitions that have been announced but not completed yet, including the upfront cash payment for the acquisition of NDI-034858 from Nimbus Therapeutics, LLC, for 4 billion USD, as the exact timing of cash payment is dependent upon deal close.



FY2022 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)	Others	
Revenue	3,930.0					3,930.0
Cost of sales					28.0	
Gross Profit					28.0	
SG&A and R&D expenses					5.0	
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	13.0			(13.0)		—
Other operating expenses	(100.0)			100.0		—
Operating profit	530.0	480.0	50.0	87.0	33.0	1,180.0

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