



Takeda Quarterly Financial Report

For the Quarter Ended September 30, 2021

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Financial Highlights

Selected Financial Results

Results of Operation

(JPY millions)	September 30,		Change versus the previous year	
	2020	2021	JPY	%
Revenue	1,590,785	1,794,423	203,638	12.8 %
Operating profit	215,588	345,979	130,391	60.5 %
Profit before tax	125,561	284,425	158,864	126.5 %
Net profit for the period	86,589	183,721	97,131	112.2 %
Net profit attributable to owners of the Company	86,548	183,648	97,100	112.2 %
Earnings per share (JPY)				
Basic earnings per share	55.45	117.08	61.64	111.2 %
Diluted earnings per share	55.13	116.40	61.27	111.1 %

Non-IFRS Measures

Results of Operations

(JPY billions)	September 30,		Change versus the previous year	
	2020	2021	JPY	%
Underlying:				
Revenue Growth	+ 0.5 %	+ 6.8%		
Core operating profit margin	29.3 %	29.1 %		
Core Operating Profit	507.6	485.7	(21.8)	(4.3) %
Core EPS (yen)	221	214	(7)	(3.3) %
Free Cash Flow	425.5	315.6	(109.9)	(25.8) %

Leverage

(JPY billions)	As of	
	March 31, 2021	September 30, 2021
Net debt	(3,429.4)	(3,449.3)
Adjusted EBITDA (Last 12 months)	1,083.5	1,112.2
Net debt/Adjusted EBITDA ratio	3.2 x	3.1

Takeda uses certain non-IFRS measures to supplement the analysis of results of operations under International Financial Reporting Standards ("IFRS"). Refer to *Supplementary Information "3. Reconciliation"* for reconciliations of non-IFRS Measures.

Consolidated Cash Flows

(JPY millions)	September 30,		Change versus the previous year	
	2020	2021	JPY	%
Cash flows from (used in) operating activities	392,011	400,011	8,000	2.0 %
Cash flows from (used in) investing activities	28,224	(103,349)	(131,573)	—
Cash flows from (used in) financing activities	(418,210)	(658,405)	(240,195)	57.4 %

Consolidated Financial Position

(JPY millions)	As of		Change versus the previous year	
	March 31, 2021	September 30, 2021	JPY	%
Non-current Assets	10,199,400	10,103,919	(95,481)	(0.9) %
Current Assets	2,712,893	2,456,353	(256,540)	(9.5) %
Total Assets	12,912,293	12,560,273	(352,020)	(2.7) %
Non-current Liabilities	5,961,940	5,317,162	(644,778)	(10.8) %
Current Liabilities	1,773,176	1,918,750	145,574	8.2 %
Total Liabilities	7,735,116	7,235,912	(499,204)	(6.5) %
Equity	5,177,177	5,324,361	147,184	2.8 %
Total liabilities and equity	12,912,293	12,560,273	(352,020)	(2.7) %

Forecast and Management Guidance

Forecast*

(JPY billions)	Previous Forecast (July 30, 2021)	Revised Forecast (October 28, 2021)	vs. Previous Forecast	
Reported:				
Revenue	3,370.0	3,370.0	—	— %
Operating profit	488.0	488.0	—	— %
Profit before tax	352.0	352.0	—	— %
Net profit for the year (attributable to owners of the Company)	250.0	184.3	(65.7)	(26.3)%
EPS (JPY)	159.91	117.35	(42.56)	(26.6)%
Non-IFRS Measures				
Core Operating Profit	930.0	930.0	—	— %
Core EPS (JPY)	394	394	—	— %
Free cash flow (including announced divestitures)	600.0 - 700.0	600.0 - 700.0		
Dividends per share (Yen)	180	180	—	— %

*Refer to *Analysis of Results of Operations, Financial Position, and Cash Flow "Outlook for the Fiscal Year Ending March 31, 2022"* for details.

Management Guidance*

	Guidance as of July 30, 2021	Guidance as of October 28, 2021
Underlying Revenue Growth	Mid-single-digit growth	Mid-single-digit growth
Underlying Core Operating Profit Growth	Mid-single-digit growth	Mid-single-digit growth
Underlying Core Operating Profit Margin	~30% margin	~30% margin
Underlying Core EPS Growth	Mid-single-digit growth	Mid-single-digit growth

*Underlying growth adjusts for divestitures (assets divested in FY2020 and disclosed divestitures expected to close in FY2021) and applies a constant exchange rate. Please refer to *Analysis of Results of Operations, Financial Position, and Cash Flow "Results of Operations (Underlying)"* for definition of underlying growth.

Revenue by Region

		JPY (millions)							
		Six-month Period Ended September 30,							
		Japan	United States	Europe and Canada	Asia (excluding Japan)	Latin America	Russia/CIS	Other	Total
	2020	282,383	786,118	327,161	78,291	58,969	21,661	36,202	1,590,785
	2021	390,868	838,376	353,970	89,706	61,372	25,088	35,041	1,794,423
Change versus the previous year	JPY	108,485	52,259	26,809	11,415	2,403	3,428	(1,161)	203,638
	%	38.4 %	6.6 %	8.2 %	14.6 %	4.1 %	15.8 %	(3.2)%	12.8 %

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

Revenue by Therapeutic Area and Product

	JPY (millions)			
	Six-month Period Ended September 30,		Change versus the previous year	
	2020	2021	JPY	%
Gastroenterology:				
ENTYVIO	206,974	255,908	48,934	23.6 %
TAKECAB-F ⁽¹⁾	39,952	49,111	9,159	22.9 %
GATTEX/REVESTIVE	33,219	36,835	3,616	10.9 %
DEXILANT	28,403	25,704	(2,699)	(9.5)%
PANTOLOC/CONTROLOC ⁽²⁾	21,465	19,861	(1,604)	(7.5)%
LIALDA/MEZAVANT	11,625	11,721	96	0.8 %
PENTASA	11,678	10,040	(1,638)	(14.0)%
AMITIZA	12,443	3,901	(8,542)	(68.6)%
RESOLOR/MOTEGRITY	4,956	6,379	1,423	28.7 %
ALOFISEL	281	798	517	184.6 %
Other	8,829	8,830	1	0.0 %
Total Gastroenterology	379,823	429,088	49,265	13.0 %
Rare Diseases:				
Rare Metabolic:				
ELAPRASE	34,316	34,813	497	1.4 %
REPLAGAL	24,967	25,933	966	3.9 %
VPRIV	18,834	20,988	2,154	11.4 %
NATPARA/NATPAR	1,506	2,480	974	64.7 %
Total Rare Metabolic	79,623	84,214	4,591	5.8 %
Rare Hematology:				
ADVATE	63,408	61,289	(2,119)	(3.3)%
ADYNOVATE/ADYNOVI	29,501	29,967	466	1.6 %
FEIBA	20,572	20,174	(398)	(1.9)%
RECOMBINATE	6,922	6,298	(624)	(9.0)%
HEMOFIL/IMMUNATE/IMMUNINE	9,369	8,382	(987)	(10.5)%
Other PDT Products	1,694	1,941	247	14.6 %
Other	11,344	13,536	2,192	19.3 %
Total Rare Hematology	142,809	141,587	(1,222)	(0.9)%
Hereditary Angioedema:				
TAKHZYRO	43,742	47,530	3,788	8.7 %
FIRAZYR	15,148	14,345	(803)	(5.3)%
CINRYZE	12,033	10,213	(1,820)	(15.1)%
KALBITOR	2,007	2,168	161	8.0 %
Total Hereditary Angioedema	72,930	74,256	1,326	1.8 %
Total Rare Diseases	295,362	300,057	4,695	1.6 %
PDT Immunology:				
immunoglobulin	162,667	181,317	18,650	11.5 %
albumin	28,571	41,744	13,173	46.1 %
Other	14,662	14,967	305	2.1 %
Total PDT Immunology	205,900	238,028	32,128	15.6 %

	JPY (millions)			
	Six-month Period Ended September 30,		Change versus the previous year	
	2020	2021	JPY	%
Oncology:				
VELCADE	50,012	55,109	5,097	10.2 %
LEUPLIN/ENANTONE	49,866	53,853	3,987	8.0 %
NINLARO	44,357	45,805	1,448	3.3 %
ADCETRIS	30,570	34,142	3,572	11.7 %
ICLUSIG	16,845	17,861	1,016	6.0 %
VECTIBIX	11,914	12,783	869	7.3 %
ALUNBRIG	4,268	6,239	1,971	46.2 %
Other	2,218	7,925	5,707	257.3 %
Total Oncology	210,050	233,716	23,666	11.3 %
Neuroscience:				
VYVANSE/ELVANSE	132,620	159,280	26,660	20.1 %
TRINTELLIX	34,955	40,050	5,095	14.6 %
INTUNIV	8,988	7,477	(1,511)	(16.8)%
ADDERALL XR	8,973	9,629	656	7.3 %
ROZEREM	5,942	6,315	373	6.3 %
Other	16,314	10,968	(5,346)	(32.8)%
Total Neuroscience	207,791	233,719	25,928	12.5 %
Other:				
AZILVA-F ⁽¹⁾	39,927	40,352	425	1.1 %
LOTRIGA	15,658	16,063	405	2.6 %
AIPHAGAN	7,654	8,375	721	9.4 %
FOSRENOL	6,518	6,999	481	7.4 %
ACTOVEGIN	4,916	6,699	1,783	36.3 %
Others ⁽³⁾	217,187	281,326	64,139	29.5 %
Total Other	291,860	359,814	67,954	23.3 %
Total Revenue by Product	1,590,785	1,794,423	203,638	12.8 %

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

⁽²⁾ Generic name: pantoprazole

⁽³⁾ The figure for the six-month period ended September 30, 2020 includes the revenue of Takeda Consumer Healthcare Company Limited, which was divested on March 31, 2021. The figure for the six-month period ended September 30, 2021 includes the 133,043 million JPY selling price on sales of four diabetes products (NESINA, LIOVEL, INISYNC and ZAFATEK) in Japan to Teijin Pharma Limited recorded as revenue.

Recent Developments

Business Development

During the three-month period ended September 30, 2021 and through the issuance of its earnings release dated October 28, 2021, Takeda Pharmaceutical Company Limited ("Takeda", or the "Company") divested certain businesses and assets in non-core areas as part of its efforts to deleverage toward its target of 2x (i.e. "low-twos") net debt/adjusted EBITDA within March 2022 - March 2024. Major divestment activities during the period are as follows:

- In April 2021, we completed the asset transfer associated with a portfolio of select non-core products in Japan to Teijin Pharma Limited for a total value of 133.0 billion JPY.

Pipeline and R&D Activities

Research and development expenses for the six-month period ended September 30, 2021 were 254.1 billion JPY.

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

Takeda's pipeline is positioned to support both near-term and sustained growth of the company. Once first approval is achieved, there is ongoing R&D support for geographical expansion and 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 2021 are listed as follows:

R&D pipeline

Oncology

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

NINLARO / Generic name: ixazomib

- In May 2021, Takeda announced that it received approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) for a partial amendment to the manufacturing and marketing approval of NINLARO to expand the eligible patient population for this medicine to those requiring a maintenance therapy after first-line treatment for multiple myeloma without prior stem cell transplant. The approval is based primarily on the results of the TOURMALINE-MM4 study, a randomized and placebo-controlled double-blind multicenter international Phase III clinical trial. The study achieved its primary endpoint, demonstrating a statistically significant improvement in progression-free survival (PFS) in adult patients with multiple myeloma receiving NINLARO maintenance who had

not undergone stem cell transplantation. The safety profile of NINLARO as a maintenance therapy is similar to its established safety profile in the monotherapy setting, and, notably, no new concerns were identified in the TOURMALINE-MM4 study.

ICLUSIG / Generic name: ponatinib

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

ALUNBRIG / Generic name: brigatinib

- In June 2021, Takeda announced that ALUNBRIG can be used for first-line treatment of patients with non-small cell lung cancer (NSCLC) who are ALK fusion gene positive (ALK-positive) as determined by the companion diagnostic ALK fusion protein kit, Ventana OptiView ALK (D5F3) ("Ventana") in Japan. Ventana, developed by Roche Diagnostics, which uses as its assay principle the immunohistochemical staining method (IHC method), received an additional indication through a partial change of the drug's manufacturing and marketing approval to include its use to ALUNBRIG. The additional approval of ALUNBRIG for the indication of Ventana, in addition to the Fluorescence *In Situ* Hybridization (FISH) diagnostic, will provide a wider range of ALK-positive NSCLC patients with the opportunity to be treated with ALUNBRIG.

ADCETRIS / Generic name: brentuximab vedotin

- In September 2021, Takeda announced that it submitted a Supplemental New Drug Application (sNDA) of ADCETRIS in the first-line treatment of CD30-positive Hodgkin lymphoma in pediatric patients in Japan. This application is based on the results of a global Phase 1/2 trial (C25004 Trial) evaluating the efficacy and safety of ADCETRIS in combination with AVD (doxorubicin, vinblastine and dacarbazine) as a first-line therapy in pediatric patients with previously untreated advanced-stage Hodgkin lymphoma.

CABOMETRYX / Generic name: cabozantinib

- In August 2021, Takeda and Ono Pharmaceutical (Ono) announced that the companies received an approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) for CABOMETRYX and Ono's OPDIVO (nivolumab), a human anti-human PD-1 monoclonal antibody, in combination therapy for the treatment of unresectable or metastatic renal cell carcinoma (RCC), for a partial change in approved items of the manufacturing and marketing approval. This approval is based on results from the global, multi-center, randomized, open-label Phase 3 CheckMate-9ER study, evaluating OPDIVO and CABOMETRYX combination therapy versus sunitinib alone in patients with previously untreated advanced or metastatic RCC. In this study, OPDIVO and CABOMETRYX combination therapy demonstrated a significant and clinically meaningful improvement in the primary endpoint of progression-free survival (PFS) as assessed by the blind independent central review (BICR), compared to sunitinib alone at the final analysis, as well as the secondary endpoints of overall survival (OS) and objective response rate (ORR) as assessed by the BICR. The safety profiles of OPDIVO and CABOMETRYX combination therapy observed in the study were consistent with the previously reported safety profile of each product.

ZEJULA / Generic name: niraparib

- In September 2021, Takeda announced that it has received approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) to manufacture and market ZEJULA tablets 100mg (hereinafter "ZEJULA tablets") as an additional formulation for ZEJULA capsules 100mg (hereinafter "ZEJULA capsules"), an oral poly (ADP-ribose) polymerase (PARP) inhibitor. The approval was granted based on the results of a human bioequivalence trial (3000-01-004 trial) and an dissolution study that confirmed the equivalence of ZEJULA capsules and ZEJULA tablets. ZEJULA capsules require refrigerated storage, however the newly approved ZEJULA tablets can be stored at room temperature.

EXKIVITY / Generic name: mobocertinib

- In May 2021, Takeda announced updated data from the Phase 1/2 trial of mobocertinib in patients with epidermal growth factor receptor (EGFR) Exon20 insertion mutation-positive (insertion+) metastatic non-small cell lung cancer (mNSCLC) who received prior platinum-based chemotherapy. The results showed mobocertinib continued to demonstrate clinically meaningful benefit after over a year of follow up and were presented at the virtual 57th American Society of Clinical Oncology (ASCO) Annual Meeting. Results showed a median overall survival (OS) of 24 months with a median follow up of 14 months, and responses were observed across diverse EGFR Exon20 insertion variants. Other key data points such as confirmed objective response rate (ORR), a median duration of response (DoR) and a disease control rate (DCR), remained consistent with previously reported data. The safety profile observed was manageable and consistent with previous findings.
- In July 2021, Takeda announced that Center for Drug Evaluation (CDE) of the National Medical Products Administration of China (NMPA) has accepted the New Drug Application (NDA) for mobocertinib and granted priority review for this Class-1 innovative drug, for the treatment of adult patients with non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) Exon20 insertion mutations.
- In September 2021, Takeda announced that the U.S. Food and Drug Administration (FDA) has approved EXKIVITY for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy. The FDA approval is based on results from the platinum-pretreated population in the Phase 1/2 trial of EXKIVITY, which consisted of 114 patients with EGFR Exon20 insertion+ NSCLC who received prior platinum-based therapy and were treated at the 160 mg dose once- daily. EXKIVITY, which was granted priority review and received Breakthrough Therapy Designation, Fast Track Designation and Orphan Drug Designation from the FDA, is the first and only approved oral therapy specifically designed to target EGFR Exon20 insertion mutations. This indication is approved under Accelerated Approval based on overall response rate (ORR) and duration of response (DoR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. The FDA simultaneously approved Thermo Fisher Scientific's OncoPrint Dx Target Test as a next-generation sequencing (NGS) companion diagnostic for EXKIVITY to identify NSCLC patients with EGFR Exon20 insertions.

Development code: TAK-924 / Generic name: pevonedistat

- In September 2021, Takeda announced the Phase 3 PANTHER (Pevonedistat-3001) study did not achieve pre-defined statistical significance for the primary endpoint of event-free survival (EFS). The trial evaluated whether the combination of pevonedistat plus azacitidine as first-line treatment for patients with higher-risk myelodysplastic syndromes (MDS), chronic myelomonocytic leukemia (CMML) and low-blast acute myeloid leukemia (AML) improved EFS versus azacitidine alone. An event in the trial was defined as death or transformation to AML in participants with higher-risk MDS or CMML, whichever occurred first, and death in participants with AML.

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

VONVENDI / Generic name: von Willebrand factor (Recombinant)

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

Development code: TAK-620 / Generic name: maribavir

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

difference [95% CI]: 30.5% [17.3, 43.6]). The results presented showed consistent efficacy in SOT recipients receiving maribavir in heart, lung and kidney transplants.

- In October 2021, Takeda announced that the U.S. Food and Drug Administration (FDA) Antimicrobial Drugs Advisory Committee (AMDAC) voted unanimously to recommend use of maribavir for the treatment of refractory cytomegalovirus (CMV) infection and disease with genotypic resistance to ganciclovir, valganciclovir, foscarnet or cidofovir in transplant recipients. The committee also voted unanimously to recommend use of maribavir for the treatment of refractory CMV infection and disease without genotypic resistance to ganciclovir, valganciclovir, foscarnet or cidofovir in transplant recipients. Both recommendations were based on the results of the Phase 2 and Phase 3 TAK-620-303 (SOLSTICE) trials. The New Drug Application (NDA) for maribavir is currently under Priority Review by the FDA. The FDA will consider the vote as part of its review of the NDA and is not bound by the AMDAC's recommendation.

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-994, TAK-925, TAK-861, etc.), and rare epilepsies with soticlestat (TAK-935). Other rare neurology diseases of focus include Amyotrophic Lateral Sclerosis, Huntington's disease and other ataxias. Takeda also makes targeted investments to potentially address well-defined segments of neurodegenerative diseases (e.g., Parkinson's Disease).

Development code: TAK-994

- In July 2021, Takeda announced that the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation (BTD) to TAK-994, its Phase 2 investigational oral orexin agonist, which is designed to selectively target orexin 2 receptors. TAK-994 is currently being studied in an ongoing Phase 2 (TAK-994-1501) study for the treatment of excessive daytime sleepiness (EDS) in patients with narcolepsy type 1 (NT1), a chronic neurological disorder that alters the sleep-wake cycle. The TAK-994 BTD was based, in part, on early phase and preliminary clinical data that indicates Takeda's investigational oral orexin agonist may demonstrate substantially improved objective and subjective measurements of daytime wakefulness in NT1 patients.
- In October 2021, Takeda announced that a safety signal has emerged in Phase 2 studies of TAK-994 (TAK-994-1501 study and TAK-994-1504 study). As an immediate precautionary measure, Takeda has suspended dosing of patients and has decided to stop both Phase 2 studies early. This allows for the timely interpretation of the benefit/risk profile of TAK-994 and to determine next steps for the program.

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 as well as a needle free device. Takeda is also expanding its position with GATTEX / REVESTIVE, and ALOFISEL, which is in ongoing P-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.

GATTEX / REVESTIVE / Generic name: teduglutide

- In June 2021, Takeda announced that it obtained approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) to manufacture and market REVESTIVE 3.8 mg for subcutaneous injection as a treatment for short bowel syndrome. The approval is mainly based on the results of several trials conducted overseas, as well as Phase 3 clinical trials (SHP633-302, SHP633-305, SHP633-306, and SHP633-307) conducted in pediatric and adult patients in Japan.

ALOFISEL / Generic name: darvadstrocel

- In September 2021, Takeda announced that it has received approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) to manufacture and market ALOFISEL for the treatment of complex perianal fistulas in patients with non-active or mildly active luminal Crohn's disease (CD). This product is indicated for the treatment of patients who have shown an inadequate response to at least one existing medicinal treatment. The approval is based on data from two trials, the Japanese Study Darvadstrocel-3002 and the ADMIRE-CD trial, conducted in Europe and Israel. ALOFISEL is the first expanded human allogeneic adipose-derived mesenchymal stem cell therapy to be approved in Japan, which exhibits immunomodulatory and local anti-inflammatory effects at the site of inflammation.

Plasma-Derived Therapies (PDT)

Takeda created a dedicated PDT business unit with a focus to manage the business end-to-end, from plasma collection to manufacturing, 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 that would add to our diversified commercial portfolio of more than 20 therapeutic products distributed worldwide.

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

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

complications. Analyses remain ongoing and NIAID and the INSIGHT Network intend to publish the full results of the trial soon. Following the outcome of the ITAC trial, the CoVIg-19 Plasma Alliance's work has now concluded.

Vaccines

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

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

- In May 2021, Takeda announced positive interim results from the ongoing Phase 1/2 immunogenicity and safety clinical trial of TAK-919 in Japan have been submitted to the Japan Pharmaceuticals and Medical Devices Agency (PMDA). Takeda currently has a three-way agreement with Moderna and the Government of Japan's Ministry of Health Labour and Welfare (MHLW) to import and distribute 50 million doses of TAK-919 in Japan. This interim analysis showed binding antibody and neutralizing antibody titres were elevated at 28 days after the second dose in 100% of people vaccinated with two 0.5ml doses of TAK-919 given 28 days apart. The vaccine candidate was generally well-tolerated with no significant safety concerns reported. The study results were submitted to the Japan Pharmaceuticals and Medical Devices Agency (PMDA) to be evaluated as part of the New Drug Application submitted in March 2021, which also includes safety and efficacy results from Moderna's pivotal Phase 3 COVE trial conducted in the U.S.
- In May 2021, Takeda announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) granted special approval under article 14-3 of the Pharmaceuticals and Medical Devices Act for emergency use of COVID-19 Vaccine Moderna Intramuscular Injection (TAK-919) in Japan. The approval is based on positive clinical data from Takeda's Phase 1/2 immunogenicity and safety clinical trial of COVID-19 Vaccine Moderna Intramuscular Injection in Japan, which showed an immune response consistent with results from Moderna's pivotal Phase 3 COVE trial conducted in the United States. Takeda has started distribution in Japan.
- In July 2021, Takeda announced an additional agreement with Moderna and the Government of Japan's Ministry of Health, Labour and Welfare (MHLW) to import and distribute an additional 50 million doses of COVID-19 Vaccine Moderna Intramuscular Injection in Japan from as early as the beginning of 2022. This agreement includes the potential to secure and supply vaccines corresponding to COVID-19 variants or booster products, should they be successfully developed by Moderna and licensed by the MHLW. Takeda will import and distribute the totaling 100 million doses including the additional 50 million doses in 2022 and 50 million doses announced in October, 2020.
- In July 2021, Takeda announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) accepted the change in age indication in the package insert for COVID-19 Vaccine Moderna Intramuscular Injection to expand to 12 years of age and older. This change is based on the results of Moderna's Phase 2/3 study conducted in 3,732 subjects aged 12 to 17 years in the United States. The serum neutralizing antibody titer and neutralizing antibody titer response rate 28 days after the second vaccination of adolescents (12 to 17 years old), which are the primary endpoints, showed non-inferiority to young adults (18 to 25 years old) in the overseas phase 3 study (mRNA-1273-P301 study). Additionally, the results indicating a high preventive effect at the vaccine efficacy rate 2 weeks after the second vaccination, which was set as a secondary endpoint. No significant safety concerns were reported, as was the case with the results of clinical studies in patients aged 18 years or older.

Development code: NVX-CoV2373 (Japanese development code: TAK-019) / Generic name: COVID-19 vaccine

- In September 2021, Takeda announced the agreement that the Japanese Ministry of Health, Labour and Welfare (MHLW) will purchase 150 million doses of Novavax' vaccine candidate (TAK-019 in Japan) manufactured in Japan by Takeda subject to licensing and approval. Takeda is establishing the capability to manufacture TAK-019 at its facilities in Japan and aims to begin distribution in early calendar year 2022. Novavax is licensing and transferring manufacturing technologies to enable Takeda to manufacture the vaccine antigen and is supplying the Matrix-M™ adjuvant to Takeda for fill/finish together with the antigen. Takeda is responsible for the Japanese clinical trial and regulatory submission and will distribute TAK-019 in Japan should it be approved by the MHLW.

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

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

Building a sustainable research platform / Enhancing R&D collaboration

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

- In July 2021, Takeda and PeptiDream Inc. announced an expansion of its research collaboration and exclusive license agreement, announced in December 2020, to create peptide-drug conjugates (PDCs) for several central nervous system (CNS) targets, which play important roles in chronic neurodegenerative diseases. This new collaboration expands the use of the TfR1 binding peptide ligands for CNS targets associated with neurodegeneration allowing Takeda to conjugate the peptides with therapeutic cargoes optimized to cross the blood-brain barrier (BBB). A significant challenge to the development of effective medicines for neurodegenerative diseases is the ability to deliver therapeutic molecules across the BBB into the brain. Peptide carriers that bind to TfR1 when conjugated to various therapeutic payloads facilitate the transport of the payload across the BBB into the brain, and thereby significantly improve functional benefit. This TfR1 BBB shuttle approach has the potential to accelerate the development of therapies for which BBB penetration remains challenging. This approach may also enable broad brain region biodistribution that is frequently needed to effectively treat many neurodegenerative diseases for which few, if any, effective drugs currently exist.
- In July 2021, Takeda and Frazier Healthcare Partners announced a collaboration to launch HilleVax, Inc. (HilleVax), a biopharmaceutical company to develop and commercialize Takeda's norovirus vaccine candidate. Takeda has granted a license to HilleVax for the exclusive development and commercialization rights to its norovirus vaccine candidate, HIL-214 (formerly TAK-214), worldwide outside of Japan, in exchange for upfront consideration, as well as future cash milestones and royalties on net sales. Takeda will retain commercialization rights in Japan and HilleVax will integrate certain Japan development activities into its global development. HIL-214, which is a virus-like particle (VLP) based vaccine candidate, completed a randomized, placebo-controlled Phase 2b field efficacy study in 4,712 adult subjects in which HIL-214 was well-tolerated and demonstrated clinical proof of concept in preventing

moderate-to-severe cases of acute gastroenteritis from norovirus infection.¹ To date, the candidate has been studied in nine human clinical trials with safety data from over 4,500 subjects and immunogenicity data from over 2,000 subjects.

- In September 2021, Takeda and Mirum Pharmaceuticals, Inc. (Mirum) announced that the companies have entered into an exclusive licensing agreement for the development and commercialization of maralixibat chloride (maralixibat) (US trade name: LIVMARLI), an apical sodium dependent bile acid transporter (ASBT) inhibitor, in Japan for Alagille syndrome (ALGS), progressive familial intrahepatic cholestasis (PFIC), and biliary atresia (BA). Maralixibat, an investigational, orally administered medication, is being evaluated globally in ALGS, PFIC, and BA. Under the terms of the agreement, Takeda will be responsible for regulatory approval and commercialization of maralixibat in Japan. Takeda will also be responsible for development, including conducting clinical studies in cholestatic indications.
- In September 2021, Takeda and JCR Pharmaceuticals Co., Ltd. (JCR) announced a geographically-focused exclusive collaboration and license agreement to commercialize JR-141 (INN: pabinafusp alfa), an investigational, next-generation recombinant fusion protein of an antibody against the human transferrin receptor and iduronate-2-sulfatase (IDS) enzyme for the treatment of Hunter syndrome (also known as Mucopolysaccharidosis type II or MPS II). JR-141, applied with J-Brain Cargo, JCR’s proprietary blood-brain barrier (BBB) technology, is engineered to transport the therapeutic enzyme across the BBB to directly reach the brain and address both the somatic and neuronopathic manifestations of the disease, which can lead to progressive cognitive decline. Under the terms of the exclusive collaboration and license agreement, Takeda will exclusively commercialize JR-141 outside of the United States, including Canada, Europe, and other regions (excluding Japan and certain other Asia-Pacific countries). The two companies will collaborate to bring this therapy to patients as quickly as possible upon completion of the global Phase 3 program, which will be conducted by JCR. Takeda receives an option under a separate option agreement, which allows Takeda to acquire an exclusive license to commercialize JR-141 in the U.S. upon completion of the Phase 3 program.
- In October 2021, Takeda announced the exercise of its option to acquire GammaDelta Therapeutics Limited (“GammaDelta”), a company focused on exploiting the unique properties of gamma delta ($\gamma\delta$) T cells for immunotherapy. Through the acquisition, Takeda will obtain GammaDelta’s allogeneic variable delta 1 (V δ 1) gamma-delta ($\gamma\delta$) T cell therapy platforms, which includes both blood-derived and tissue-derived platforms, in addition to early-stage cell therapy programs. The deal is expected to be finalized in Q1 of Takeda’s fiscal year 2022. Closing of the transaction is contingent on completion of review under antitrust laws, including the Hart-Scott-Rodino (HSR) Antitrust Improvements Act of 1976 in the U.S.

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

Results of Operations (Reported)

Consolidated Financial Results (April 1 to September 30, 2021)

	Billion JPY or percentage			
	FY2020 H1	FY2021 H1	Change versus the same period of the previous fiscal year	
Revenue	1,590.8	1,794.4	203.6	12.8 %
Cost of sales	(487.7)	(517.1)	(29.3)	6.0 %
Selling, general and administrative expenses	(418.6)	(431.9)	(13.2)	3.2 %
Research and development expenses	(225.0)	(254.1)	(29.1)	12.9 %
Amortization and impairment losses on intangible assets associated with products	(208.1)	(205.5)	2.6	(1.2)%
Other operating income	69.5	19.5	(49.9)	(71.9)%
Other operating expenses	(105.2)	(59.4)	45.8	(43.5)%
Operating profit	215.6	346.0	130.4	60.5 %
Finance income and (expenses), net	(81.1)	(58.0)	23.1	(28.4)%
Share of loss of investments accounted for using the equity method	(8.9)	(3.5)	5.4	(60.5)%
Profit before tax	125.6	284.4	158.9	126.5 %
Income tax expenses	(39.0)	(100.7)	(61.7)	158.4 %
Net profit for the period	86.6	183.7	97.1	112.2 %

Revenue. Revenue for the six-month period ended September 30, 2021 was 1,794.4 billion JPY, an increase of 203.6 billion JPY, or 12.8%, compared to the same period of the previous fiscal year. Excluding the impact from fluctuations in foreign exchange rates, which was calculated by translating revenue of the six-month period ended September 30, 2021 using corresponding exchange rates in the same period of the previous fiscal year, the increase in revenue was 8.7%. In April 2021, Takeda completed the sale of a portfolio of diabetes products in Japan to Teijin Pharma Limited for 133.0 billion JPY, which was recorded as revenue and accounted for 8.4 percentage points (“pp”) of the increase in revenue. Excluding this selling price from revenue for the six-month period ended September 30, 2021, the increase was 4.4%.

Each of our core therapeutic areas (i.e. Gastroenterology (“GI”), Rare Diseases, Plasma-Derived Therapies (“PDT”) Immunology, Oncology, and Neuroscience) contributed to positive revenue growth; however, Rare Diseases would have declined if not for the positive impact of the depreciation of the yen. Intensified competition impacted some products in this area, especially treatments for Rare Hematology. Overall, the global spread of COVID-19 did not have a material effect on our revenue for the six-month period ended September 30, 2021.

Revenue outside of our core therapeutic areas increased by 68.0 billion JPY, or 23.3%, compared to the same period of the previous fiscal year to 359.8 billion JPY, largely due to the 133.0 billion JPY selling price of the diabetes portfolio in Japan, offsetting the impact from divestitures.

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

- *GI.* In Gastroenterology, revenue was 429.1 billion JPY, a year-on-year increase of 49.3 billion JPY, or 13.0%. Growth was driven by Takeda’s top-selling product ENTYVIO (for ulcerative colitis (“UC”) and Crohn’s disease (“CD”)), with sales of 255.9 billion JPY, a year-on-year increase of 48.9 billion JPY, or 23.6%. Sales in the U.S. increased by 28.2 billion JPY, or 19.7%, to 171.3 billion JPY and sales in Europe and Canada increased by 15.1 billion JPY, or 29.3%, to 66.6 billion JPY, due to an increase in demand. In the Growth and Emerging Markets, the increase in sales was primarily driven by Brazil and China. Sales of TAKECAB (for acid-related diseases) were 49.1 billion JPY, an increase of 9.2 billion JPY, or 22.9%, versus the same period of the previous fiscal year. This increase was mainly driven by the expansion of new prescriptions in the Japanese market due to TAKECAB’s efficacy in reflux esophagitis and the prevention of recurrence of gastric and duodenal ulcers during low-dose aspirin administration. Sales of GATTEX/REVESTIVE (for short bowel syndrome) were 36.8 billion JPY, an increase of 3.6 billion JPY, or 10.9%. In August 2021, REVESTIVE was launched as the first therapy to treat this disease in Japan. Sales of AMITIZA (for chronic constipation) decreased by 8.5 billion JPY, or 68.6%, to 3.9 billion JPY, due to generic entrants in the U.S. in January 2021.
- *Rare Diseases.* In Rare Diseases, revenue was 300.1 billion JPY, a year-on-year increase of 4.7 billion JPY, or 1.6%.

Revenue in Rare Metabolic increased by 4.6 billion JPY, or 5.8%, compared to the same period of the previous fiscal year to 84.2 billion JPY. Sales of enzyme replacement therapies VPRIV (for Gaucher disease), REPLAGAL (for Fabry disease) and ELAPRASE (for Hunter syndrome) increased primarily in Europe and Growth and Emerging Markets.

Revenue in Rare Hematology decreased by 1.2 billion JPY, or 0.9%, to 141.6 billion JPY. Sales of ADVATE decreased by 2.1 billion JPY, or 3.3%, to 61.3 billion JPY. Sales of ADYNOVATE increased by 0.5 billion JPY, or 1.6%, to 30.0 billion JPY, helped by the positive impact of the depreciation of the yen. Both products were impacted by the competitive landscape in the hemophilia A non-inhibitors market in the U.S. FEIBA sales decreased by 0.4 billion JPY, or 1.9%, to 20.2 billion JPY.

Revenue in Hereditary Angioedema (“HAE”) was 74.3 billion JPY, a year-on-year increase of 1.3 billion JPY, or 1.8%. Sales of TAKHZYRO were 47.5 billion JPY, an increase of 3.8 billion JPY, or 8.7%, versus the same period of the previous fiscal year primarily due to new launches including prefilled syringe administration in Europe. Sales of FIRAZYR decreased by 0.8 billion JPY, or 5.3%, to 14.3 billion JPY, primarily due to the continued impact of generic entrants in the U.S.

- *PDT Immunology.* In Plasma-Derived Therapies (“PDT”) Immunology, revenue increased by 32.1 billion JPY, or 15.6%, compared to the same period of the previous fiscal year to 238.0 billion JPY. Aggregate sales of immunoglobulin products were 181.3 billion JPY, an increase of 18.7 billion JPY, or 11.5%, compared to the same period of the previous fiscal year. In particular, sales of GAMMAGARD LIQUID (for the treatment of primary immunodeficiency (“PID”) and multifocal motor neuropathy (“MMN”)) increased due to higher demand versus the same period of the previous fiscal year. In addition, CUVITRU, a SCIG (subcutaneous immunoglobulin) therapy continued to mark double digit growth. Aggregate sales of albumin products including HUMAN ALBUMIN and FLEXBUMIN (primarily used for hypovolemia and hypoalbuminemia) were 41.7 billion JPY, an increase of 13.2 billion JPY, or 46.1%, versus the same period of the previous fiscal year driven by higher China sales following the resolution of the supply interruption which impacted HUMAN ALBUMIN for release in China in the second half of the previous fiscal year.
- *Oncology.* In Oncology, revenue was 233.7 billion JPY, a year-on-year increase of 23.7 billion JPY, or 11.3%. Sales of VELCADE (for multiple myeloma) increased by 5.1 billion JPY, or 10.2% versus the same period of the previous fiscal year to 55.1 billion JPY. While royalty income outside the U.S. decreased due to continued generic erosion, sales in the U.S. increased by 5.9 billion JPY, or 12.3%, versus the same period of the previous fiscal year. This reflects a rebound in demand after lower sales in the previous fiscal year, particularly in the first quarter, when prescribers favored orally administered products over infusions or injections early in the COVID-19 pandemic. In addition, increased use of VELCADE as part of initial treatment for new patients contributed to the growth this year in the U.S. Sales of NINLARO (for multiple myeloma) were 45.8 billion JPY, an increase of 1.4 billion JPY, or 3.3%, versus the same period of the previous fiscal year. In the U.S., NINLARO’s profile as an effective oral treatment led to a temporary increase in demand early in the COVID-19 pandemic in 2020 because its oral administration facilitated treatment in the at-home setting. This benefit has been less impactful in the U.S. this year; however, there have been strong demand increases in other countries, particularly in China. Sales of LEUPLIN/ENANTONE (generic name: leuprorelin) (for endometriosis, uterine fibroids, premenopausal breast cancer, prostatic cancer, etc.), an off-patented product, increased by 4.0 billion JPY, or 8.0%, versus the same period of the previous fiscal year to 53.9 billion JPY mainly driven by an increased supply in the U.S. which was partially offset by a decrease in Japan due to generic erosion and competition. Sales of ADCETRIS (for malignant lymphomas) increased by 3.6 billion JPY, or 11.7% versus the same period of the previous fiscal year to 34.1 billion JPY, led by strong growth in sales in the Growth and Emerging Markets, particularly in China where it was approved in May 2020. Sales of ALUNBRIG (for non-small cell lung cancer) were 6.2 billion JPY, an increase of 2.0 billion JPY, or 46.2% due to new launches and market penetration in Europe and Growth and Emerging Markets.
- *Neuroscience.* In Neuroscience, revenue was 233.7 billion JPY, a year-on-year increase of 25.9 billion JPY, or 12.5%. Sales of VYVANSE/ELVANSE (for attention deficit hyperactivity disorder (“ADHD”)) were 159.3 billion JPY, an increase of 26.7 billion JPY, or 20.1%, versus the same period of the previous fiscal year. VYVANSE/ELVANSE has been negatively affected by COVID-19 during the course of the pandemic, most notably during periods when stay-at-home restrictions have been in place reducing patient visits, subsequent diagnoses and creating temporary discontinuation of medication. The trend has been fluctuating throughout 2020 and into 2021; however, there has been a positive impact from increasing prescriptions versus the same period of the previous fiscal year. Sales of TRINTELLIX (for major depressive disorder (“MDD”)) were 40.0 billion JPY, an increase of 5.1 billion JPY, or 14.6%, versus the same period of the previous fiscal year, primarily due to increasing prescriptions in the U.S. and in Japan. The increase of these products was partially offset by the decrease of other neuroscience products such as REMINYL (for Alzheimer's disease), attributable to the continued impact of competition from generic products.

Revenue by Geographic Region:

Revenue:	Billion JPY; percentages are portion of total revenue			
	FY2020 H1		FY2021 H1	
Japan ^{*1}	282.4	17.8 %	390.9	21.8 %
United States	786.1	49.4 %	838.4	46.7 %
Europe and Canada	327.2	20.6 %	354.0	19.7 %
Asia (excluding Japan)	78.3	4.9 %	89.7	5.0 %
Latin America	59.0	3.7 %	61.4	3.4 %
Russia/CIS	21.7	1.4 %	25.1	1.4 %
Other ^{*2}	36.2	2.3 %	35.0	2.0 %
Total	1,590.8	100.0 %	1,794.4	100.0 %

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

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

Cost of Sales. Cost of Sales increased by 29.3 billion JPY, or 6.0%, to 517.1 billion JPY. The increase was primarily due to the depreciation of the yen and a sales increase of the products with higher cost of sales ratio as compared to same period of the previous fiscal year. The increase was partially offset by a 28.4 billion JPY decrease in non-cash charges related to the unwind of the fair value step up on acquired inventory recognized in connection with the acquisition of Shire plc. The Cost of Sales Ratio decreased by 1.8pp compared to the same period of the previous fiscal year to 28.8%. The main reason for the decrease in the Cost of Sales Ratio was the effect of the sale of a portfolio of diabetes products in Japan with the selling price of 133.0 billion JPY being recorded in revenue.

Selling, General and Administrative (SG&A) expenses. SG&A expenses increased by 13.2 billion JPY, or 3.2%, to 431.9 billion JPY compared to the same period of the previous fiscal year, mainly due to the impact from the depreciation of the yen in the current period.

Research and Development (R&D) expenses. R&D expenses increased by 29.1 billion JPY, or 12.9%, to 254.1 billion JPY compared to the same period of the previous fiscal year, mainly due to further investment in prioritized new molecular entities as well as the impact from the depreciation of the yen in the current period.

Amortization and Impairment Losses on Intangible Assets Associated with Products. Amortization and Impairment Losses on Intangible Assets Associated with Products decreased by 2.6 billion JPY, or 1.2%, to 205.5 billion JPY compared to the same period of the previous fiscal year.

Other Operating Income. Other Operating Income was 19.5 billion JPY, a decrease of 49.9 billion JPY, or 71.9%, compared to the same period of the previous fiscal year, mainly driven by a 60.2 billion JPY revaluation gain recorded in the same period of the previous fiscal year triggered by an update to previously recognized liabilities for pipeline compound SHP647 and certain associated rights ("SHP647"), to reflect management's decision to terminate the clinical trial program following the European Commission's decision in May 2020 to release Takeda's obligation to divest SHP647. This decrease was partially offset by a 8.4 billion JPY change in fair value of financial assets and liabilities associated with contingent consideration arrangements recognized in the current period.

Other Operating Expenses. Other Operating Expenses were 59.4 billion JPY, a decrease of 45.8 billion JPY, or 43.5%, compared to the same period of the previous fiscal year. This is mainly attributable to a 26.0 billion JPY decrease in restructuring expenses mainly attributable to lower Shire integration costs. There was also a 18.6 billion JPY loss recognized in the same period of the previous year from changes in the fair value of financial assets associated with contingent consideration arrangements from the divestment of XIIDRA.

Operating Profit. As a result of the above factors, Operating Profit increased by 130.4 billion JPY, or 60.5% compared to the same period of the previous fiscal year to 346.0 billion JPY.

Net Finance Expenses. Net Finance Expenses were 58.0 billion JPY in the current period, a decrease of 23.1 billion JPY compared to the same period of the previous fiscal year. The decrease is mainly due to a gain on prior equity method investments related to the acquisition of Maverick Therapeutics, Inc. in April 2021 and a decrease in interest expense primarily driven by reduction in outstanding balances of bond and loans.

Share of Loss of Investments Accounted for Using the Equity Method. Share of Loss of Investments Accounted for Using the Equity Method was 3.5 billion JPY, a decrease of 5.4 billion JPY compared to the same period of the previous fiscal year. This

was mainly due to Takeda's shareholding ratio of impairment loss recognized by Teva Takeda Pharma Ltd. for the same period of the previous fiscal year resulting from the reassessment of the recoverable amount of relevant assets triggered by the decision to divest a part of its generics business and a manufacturing plant.

Income Tax Expenses. Income Tax Expenses were 100.7 billion JPY, an increase of 61.7 billion JPY compared to the same period of the previous year. This increase was primarily due to a tax charge of 63.7 billion JPY for tax and interest, net of 0.5 billion JPY of associated tax benefit, arising from tax assessment involving Irish taxation of the break fee Shire received from AbbVie in connection with the terminated offer to acquire Shire made by AbbVie in 2014 as well as higher pretax earnings in the current period. These increases were partially offset by the tax benefits from internal entity restructuring transactions in the current period.

Net Profit for the Period. Net Profit for the Period increased by 97.1 billion JPY, or 112.2%, compared to the same period of the previous fiscal year to 183.7 billion JPY.

Results of Operations (Underlying) (April 1 to September 30, 2021)

Definition of Core and Underlying Growth

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

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

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

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

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

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

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

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

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

Underlying Results

FY2021 H1

Underlying Revenue Growth	+6.8%
Underlying Core Operating Profit Growth	+6.4%
Underlying Core Operating Profit Margin	29.1%
Underlying Core EPS Growth	+9.1%

Underlying Revenue Growth was 6.8% compared to the same six-month period of the previous fiscal year. Underlying revenue attributable to Takeda's 14 global brands* grew by 11.4%, which constitute approximately 42% of the total Underlying revenue, led by ENTYVIO, HUMAN ALBUMIN/FLEXBUMIN and GAMMAGARD LIQUID/KIOVIG.

* Takeda's 14 global brands

GI: ENTYVIO, GATTEX/REVESTIVE, ALOFISEL

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

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

Oncology: NINLARO, ALUNBRIG

Underlying Revenue Growth by Therapeutic Area

GI	+8.3%
Rare Diseases	-2.2%
Rare Metabolic	+2.1%
Rare Hematology	-4.6%
Hereditary Angioedema	-1.9%
PDT Immunology	+11.1%
Oncology	+7.8%
Neuroscience	+9.1%
Other	+9.7%
Total	+6.8%

(Note) Underlying Revenue represents revenue on a constant currency basis and excluding non-recurring items and the impact of divestitures. Please refer to "[Results of Operations \(Reported\)](#)" for the revenue of each core therapeutic areas and sales of major products before underlying adjustments.

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

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

Underlying Core Operating Profit Growth was 6.4% over the same six-month period of the previous fiscal year, attributable to Underlying Revenue Growth.

Core Operating Profit for the current period, which excludes items unrelated to Takeda's core operations such as the sale of a portfolio of diabetes products in Japan, was 485.7 billion JPY.

Underlying Core Operating Profit Margin for the current period was 29.1%.

Underlying Core EPS Growth for the current period was 9.1%.

Consolidated Financial Position

Assets. Total Assets as of September 30, 2021 were 12,560.3 billion JPY, reflecting a decrease of 352.0 billion JPY compared to the previous fiscal year-end. Cash and Cash Equivalents decreased by 358.3 billion JPY, and Intangible Assets decreased by 125.4 billion JPY mainly due to amortization. These decreases were partially offset by an increase in Trade and Other Receivables of 60.5 billion JPY.

Although there was a decline in share price after September 30, 2021 that eliminated our surplus in market capitalization compared to the carrying value of our one cash-generating unit (CGU), we concluded there was no indication of goodwill impairment through the issuance date of this report.

Liabilities. Total Liabilities as of September 30, 2021 were 7,235.9 billion JPY, reflecting a decrease of 499.2 billion JPY compared to the previous fiscal year-end. Bonds and Loans decreased by 404.0 billion JPY to 4,231.4 billion JPY* primarily as a result of the repayment of loans and the redemption of bonds. In addition, Provisions decreased by 59.4 billion JPY and Other Financial Liabilities decreased by 53.7 billion JPY.

* The carrying amount of Bonds was 3,344.7 billion JPY and Loans was 886.7 billion JPY as of September 30, 2021. 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 (1,520 million USD)	June 2015	June 2022 ~ June 2045	170.2
Unsecured US dollar denominated senior notes (5,500 million USD)	September 2016	September 2023 ~ September 2026	588.3
Unsecured Euro denominated senior notes (3,750 million EUR)	November 2018	November 2022 ~ November 2030	484.3
Unsecured US dollar denominated senior notes (3,250 million USD)	November 2018	November 2023 ~ November 2028	362.0
Hybrid bonds (subordinated bonds)	June 2019	June 2079	497.8
Unsecured US dollar denominated senior notes (7,000 million USD)	July 2020	March 2030 ~ July 2060	778.0
Unsecured Euro denominated senior notes (3,600 million EUR)	July 2020	July 2027 ~ July 2040	464.1
Total			<u>3,344.7</u>

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	167.7
Japan Bank for International Cooperation (1,700 million USD)	January 2019	December 2025	190.3
Bilateral loans	March 2016 ~ April 2017	March 2023 ~ March 2026	210.0
Other			5.2
Total			<u>886.7</u>

On May 17, 2021, Takeda redeemed the remaining 200 million USD of unsecured U.S. dollar-denominated senior notes issued in July 2017 in advance of their original maturity date of January 18, 2022. Following this, on June 11, 2021, Takeda prepaid 2,000 million USD of the Japan Bank for International Cooperation loan (“JBIC Loan”) amount of 3,700 million USD (that was entered into on December 3, 2018) in advance of its original maturity date of December 11, 2025. On August 10, 2021, Takeda redeemed 1,500 million EUR of unsecured senior notes issued in November 2018 in advance of their original maturity date of November 21, 2022. On September 3, 2021, Takeda provided a formal notice of prepayment to the Japan Bank for International Cooperation committing the company to prepay the remaining 1,700 million USD outstanding JBIC Loan amount on December 13, 2021.

Equity. Total Equity as of September 30, 2021 was 5,324.4 billion JPY, an increase of 147.2 billion JPY compared to the previous fiscal year-end. This was mainly due to an increase of 85.0 billion JPY in Other Components of Equity mainly due to fluctuation in currency translation adjustments reflecting the depreciation of yen as well as an increase of 41.2 billion JPY in Retained Earnings resulting from Net Profit for the Period partially offset by dividends payment of 141.9 billion JPY.

Consolidated Cash Flow

	Billion JPY	
	FY2020 H1	FY2021 H1
Net cash from (used in) operating activities	392.0	400.0
Net cash from (used in) investing activities	28.2	(103.3)
Net cash from (used in) financing activities	(418.2)	(658.4)
Net increase (decrease) in cash and cash equivalents	2.0	(361.7)
Cash and cash equivalents at the beginning of the year	637.6	966.2
Effects of exchange rate changes on cash and cash equivalents	(8.6)	3.4
Net increase (decrease) in cash and cash equivalents resulting from a transfer from (to) assets held for sale	(0.2)	—
Cash and cash equivalents at the end of the period	<u>630.9</u>	<u>607.9</u>

Net cash from operating activities was 400.0 billion JPY for the current period compared to 392.0 billion JPY for the same period of the previous year. The increase of 8.0 billion JPY was primarily driven by higher net profit for the period adjusted for non-cash items and other adjustments, including the income relating to the release from the obligation to divest the pipeline compound SHP 647 and certain associated rights in the same period of the previous year. It was partially offset by a decrease in provisions and an increase in trade and other receivables.

Net cash used in investing activities was 103.3 billion JPY for the current period compared to net cash from investing activities of 28.2 billion JPY for the same period of the previous year. This increase in net cash used of 131.6 billion JPY was mainly due to a decrease of 40.6 billion JPY in proceeds from sales and redemption of investments, a decrease of 38.1 billion JPY in proceeds from sales of property, plant and equipment, and a decrease of 29.3 billion JPY in proceeds from sales of business, net of cash and cash equivalents divested.

Net cash used in financing activities was 658.4 billion JPY for the current period compared to 418.2 billion JPY for the same period of the previous year. This increase in net cash used of 240.2 billion JPY was mainly due to a decrease in proceeds from issuance of bonds and long-term loans of 1,179.5 billion JPY. This was partially offset by a decrease in repayments of bonds and long-term loans of 824.6 billion JPY as well as the favorable impact from short-term loans and commercial papers of 89.9 billion JPY.

Outlook for the Fiscal Year Ending March 31, 2022

The full year consolidated reported forecast for the fiscal year ending March 31, 2022 (FY2021) has been revised from the previous forecast (announced on July 30, 2021), reflecting a tax charge arising from a tax assessment involving Irish taxation of the break fee Shire received from AbbVie in connection with the terminated offer to acquire Shire made by AbbVie in 2014.

For the details, please refer to the press release, "[Takeda Receives Decision by the Irish Tax Appeals Commission Relating to Tax Assessment on Break Fee Shire Received from AbbVie](#)", announced on August 2, 2021.

Full Year Reported Forecast for the Fiscal Year Ending March 31, 2022 (FY2021)

	Billion JPY or percentage			
	Previous Forecast (July 30, 2021)	Revised Forecast (October 28, 2021)	vs. Previous Forecast	
Revenue	3,370.0	3,370.0	—	— %
Operating profit	488.0	488.0	—	— %
Profit before tax	352.0	352.0	—	— %
Net profit for the year (attributable to owners of the Company)	250.0	184.3	(65.7)	(26.3)%
EPS (JPY)	159.91	117.35	(42.56)	(26.6)%
Core Operating Profit	930.0	930.0	—	— %
Core EPS (JPY)	394	394	—	— %

Net profit for the year attributable to owners of the Company has been decreased by 65.7 billion JPY, or 26.3%, to 184.3 billion JPY. This reflects an estimated full year impact of the aforementioned tax charge, including interest expected to be accrued through March 31, 2022.

The forecast for EPS has been decreased by 42.56 JPY, or 26.6%, to 117.35 JPY. Core EPS remains unchanged as the tax charge is adjusted to be excluded from the Core financial results as a non-recurring item unrelated to Takeda's ongoing operations.

Major assumptions used in preparing the FY2021 Revised Reported Forecast

There are no changes in the major assumptions.

	Previous Forecast (July 30, 2021)	Revised Forecast (October 28, 2021)
		Billion JPY or percentage
FX rates	1 USD = 108 JPY 1 Euro = 131 JPY 1 RUB = 1.4 JPY 1 BRL = 19.9 JPY 1 CNY = 16.8 JPY	1 USD = 108 JPY 1 Euro = 131 JPY 1 RUB = 1.4 JPY 1 BRL = 19.9 JPY 1 CNY = 16.8 JPY
R&D expenses	(522.0)	(522.0)
Amortization of intangible assets associated with products	(406.0)	(406.0)
Of which Shire acquisition related	(328.0)	(328.0)
Impairment of intangible assets associated with products	(50.0)	(50.0)
Other operating income	23.0	23.0
Other operating expenses	(100.0)	(100.0)
Japan diabetes portfolio divestiture gain	130.0	130.0
Other Core Operating Profit adjustments	(39.0)	(39.0)
Of which Shire acquisition related to unwind of inventories step-up	(31.1)	(31.1)
Finance income and (expenses), net	(130.0)	(130.0)
Free cash flow (including announced divestitures)	600.0-700.0	600.0-700.0
Capital expenditures (cash flow base)	(210.0 - 260.0)	(210.0 - 260.0)
Depreciation and amortization (excluding intangible assets associated with products)	(150.0)	(150.0)
Cash tax rate on adjusted EBITDA (excluding divestitures)	Mid-teen%	Mid-teen%

Management Guidance*

The management guidance for the fiscal year ending March 31, 2022 (FY2021) has not been changed from the previous guidance (announced on July 30, 2021). The tax charge arising from a tax assessment involving Irish taxation is adjusted to be excluded from the Core financial results as a non-recurring item unrelated to Takeda's ongoing operations, and therefore, it does not impact the Underlying financial results.

	Guidance as of July 30, 2021	Guidance as of October 28, 2021
Underlying Revenue Growth	Mid-single-digit growth	Mid-single-digit growth
Underlying Core Operating Profit Growth	Mid-single-digit growth	Mid-single-digit growth
Underlying Core Operating Profit Margin	~30% margin	~30% margin
Underlying Core EPS Growth	Mid-single-digit growth	Mid-single-digit growth

* Please refer to "[Results of Operations \(Underlying\) \(April 1 to September 30, 2021\)](#)", Definition of Core and Underlying Growth.

Other assumptions used in preparing the FY2021 Reported Forecast and the Management Guidance

- To date, Takeda has not experienced a material effect on its financial results as a result of the global spread of the novel coronavirus infectious disease (COVID-19). Based on currently available information, Takeda believes that its financial results for FY2021 will not be materially affected by COVID-19 and, accordingly, Takeda's FY2021 forecast reflects this belief. However, the situation surrounding COVID-19 remains highly fluid, and future COVID-19-related developments in FY2021, including new or additional COVID-19 outbreaks and additional or extended lockdowns, shelter-in-place orders or other government action in major markets, could result in further or more serious disruptions to Takeda's business, such as slowdowns in demand for Takeda's products, supply chain related issues or significant delays in its clinical trial programs. These events, if they occur, could result in an additional impact on Takeda's business, results of operations or financial condition, as well as result in significant deviations from Takeda's FY2021 forecast.
- Takeda expects at least one 505(b)2 competitor for subcutaneous VELCADE to launch in the U.S. around mid FY2021.
- Takeda does not expect to restart sales of NATPARA in the U.S. market in FY2021.
- The forecast and the guidance do not include the impact of any potential further divestitures beyond what has already been disclosed by Takeda.

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.

Impact of the Spread of the Novel Coronavirus Infectious Disease (COVID-19) and Takeda's Initiatives in Response

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

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

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

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

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

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

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

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

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

- We spent several months evaluating new ways of working to ensure we consider the long-term effects of virtual and hybrid working on our overall people experience and to build an exceptional working environment in a "post-COVID-19" world. Now we are rolling out a new hybrid working model in parts of Takeda on a regional and local level. To ensure all Takeda working environments remain safe, we have created core principles, global guidelines and toolkits to help Takeda leaders and managers determine and implement new hybrid working models for their teams post-COVID. Implementation of this guidance varies on the local level, given differences in public health guidance and regulations, changes in population and epidemiology over time and standards of practice in the community.
- Takeda has undertaken a number of efforts to help the world respond to COVID-19. One example is to bring COVID-19 vaccines to Japan through two partnerships. The first partnership is with Novavax, for the development, manufacturing with production capacity of 250 million doses per year and commercialization of its COVID-19 vaccine candidate, NVX-CoV2373 (development code in Japan: TAK-019) in Japan. In September 2021, Takeda concluded the agreement with the Government of Japan's Ministry of Health, Labour and Welfare (MHLW) to provide 150 million doses of Novavax' COVID-19 vaccine candidate manufactured in Japan by Takeda subject to licensing and approval, starting in early calendar year 2022. The second partnership is with Moderna and the MHLW to import and distribute Moderna's mRNA COVID-19 vaccine (COVID-19 Vaccine Moderna Intramuscular Injection) in Japan. In May 2021, Takeda obtained approval from the MHLW for Moderna's COVID-19 vaccine following positive interim results in Takeda's Phase 1/2 immunogenicity and safety clinical trial, and has since commenced distribution in Japan. Takeda initially entered a three-way agreement with Moderna and MHLW to distribute 50 million doses of TAK-919 in Japan, and in July 2021, Takeda announced an additional three-way agreement to import and distribute an additional 50 million doses from as early as the beginning of 2022, totaling 100 million doses between the two agreements. The

July 2021 agreement includes the potential to secure and supply vaccines corresponding to COVID-19 variants or booster products, should they be successfully developed by Moderna and licensed by the MHLW.

In October 2021, Takeda and Moderna published an investigation report prompted by the recall of three lots of the Moderna COVID-19 vaccine in Japan based on the observation of foreign particles in unpunctured vials from a single lot. The joint report concluded that the rare presence of 316L stainless steel particles – observed in one of the recalled lots – presented no undue risk to patient safety and did not adversely affect the benefit/risk profile of the product. It also concluded that the most probable cause of the particles identified in one of the recalled lots is related to friction between two pieces at the production line at ROVI, Moderna’s third party manufacturer. The investigation conducted and actions taken specific to the impacted lots confirm that no other lots were impacted by the equipment event described in the investigation report.

(iii) FY2021 H1 financial impact from COVID-19

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

Interim Dividend for Fiscal 2021

Takeda maintains its annual dividend policy of 180 JPY per share.

For the six-month period ended September 30, 2021, Takeda’s Board of Directors approved the payment of an interim dividend of 90 JPY per share. The dividend will be paid on December 1, 2021.

Consolidated Financial Statements [IFRS]

(1) Consolidated Statements of Profit or Loss

	JPY (millions, except per share data)		USD (millions) ^(*)
	Six-month Period Ended September 30,		Six-month Period Ended September 30,
	2020	2021	2021
Revenue	¥ 1,590,785	¥ 1,794,423	\$ 16,093
Cost of sales	(487,720)	(517,061)	(4,637)
Selling, general and administrative expenses	(418,631)	(431,854)	(3,873)
Research and development expenses	(224,978)	(254,081)	(2,279)
Amortization and impairment losses on intangible assets associated with products	(208,097)	(205,545)	(1,843)
Other operating income	69,463	19,535	175
Other operating expenses	(105,234)	(59,438)	(533)
Operating profit	215,588	345,979	3,103
Finance income	29,628	46,912	421
Finance expenses	(110,720)	(104,940)	(941)
Share of loss of investments accounted for using the equity method	(8,935)	(3,525)	(32)
Profit before tax	125,561	284,425	2,551
Income tax expenses	(38,972)	(100,704)	(903)
Net profit for the period	86,589	183,721	1,648
Attributable to:			
Owners of the Company	86,548	183,648	1,647
Non-controlling interests	41	73	1
Net profit for the period	86,589	183,721	1,648
Earnings per share (JPY)			
Basic earnings per share	55.45	117.08	1.05
Diluted earnings per share	55.13	116.40	1.04

(*) Consolidated statements of profit or loss have been translated solely for the convenience of the reader at an exchange rate of 1USD = 111.50 JPY, the Noon Buying Rate certified by the Federal Reserve Bank of New York on September 30, 2021. 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 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) Consolidated Statements of Comprehensive Income

	JPY (millions)		USD (millions) ^(*)
	Six-month Period Ended September 30,		Six-month Period Ended September 30,
	2020	2021	2021
Net profit for the period	¥ 86,589	¥ 183,721	\$ 1,648
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	31,352	4,269	38
Remeasurement of defined benefit pension plans	(2,759)	(1,702)	(15)
	28,593	2,568	23
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	(31,403)	66,700	598
Cash flow hedges	(5,889)	11,553	104
Hedging cost	(13,544)	5,785	52
Share of other comprehensive income (loss) of investments accounted for using the equity method	97	(37)	(0)
	(50,739)	84,000	753
Other comprehensive income (loss) for the period, net of tax	(22,146)	86,568	776
Total comprehensive income for the period	64,443	270,288	2,424
Attributable to:			
Owners of the Company	64,272	270,198	2,423
Non-controlling interests	171	90	1
Total comprehensive income for the period	64,443	270,288	2,424

(*) Consolidated statements of comprehensive income have been translated solely for the convenience of the reader at an exchange rate of 1USD = 111.50 JPY, the Noon Buying Rate certified by the Federal Reserve Bank of New York on September 30, 2021. 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 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) Consolidated Statements of Financial Position

	JPY (millions)		USD (millions) ^(*)
	As of March 31, 2021	As of September 30, 2021	As of September 30, 2021
ASSETS			
Non-current assets:			
Property, plant and equipment	¥ 1,453,917	¥ 1,459,919	\$ 13,093
Goodwill	4,033,917	4,078,369	36,577
Intangible assets	3,909,106	3,783,677	33,934
Investments accounted for using the equity method	112,468	115,247	1,034
Other financial assets	235,882	236,844	2,124
Other non-current assets	100,341	94,289	846
Deferred tax assets	353,769	335,575	3,010
Total non-current assets	10,199,400	10,103,919	90,618
Current assets:			
Inventories	753,881	783,476	7,027
Trade and other receivables	783,091	843,625	7,566
Other financial assets	36,598	25,742	231
Income taxes receivable	29,623	43,670	392
Other current assets	122,789	131,842	1,182
Cash and cash equivalents	966,222	607,881	5,452
Assets held for sale	20,689	20,118	180
Total current assets	2,712,893	2,456,353	22,030
Total assets	12,912,293	12,560,273	112,648
LIABILITIES AND EQUITY			
LIABILITIES			
Non-current liabilities:			
Bonds and loans	4,613,218	4,016,473	36,022
Other financial liabilities	517,677	464,505	4,166
Net defined benefit liabilities	158,857	164,638	1,477
Income taxes payable	33,690	29,393	264
Provisions	38,748	35,581	319
Other non-current liabilities	56,898	59,226	531
Deferred tax liabilities	542,852	547,345	4,909
Total non-current liabilities	5,961,940	5,317,162	47,688
Current liabilities:			
Bonds and loans	22,153	214,886	1,927
Trade and other payables	343,838	336,600	3,019
Other financial liabilities	248,053	247,558	2,220
Income taxes payable	145,203	188,065	1,687
Provisions	471,278	415,076	3,723
Other current liabilities	542,651	516,565	4,633
Total current liabilities	1,773,176	1,918,750	17,209
Total liabilities	7,735,116	7,235,912	64,896

	JPY (millions)		USD (millions) ^(*)
	As of March 31, 2021	As of September 30, 2021	As of September 30, 2021
<u>EQUITY</u>			
Share capital	1,668,145	1,676,263	15,034
Share premium	1,688,424	1,686,493	15,125
Treasury shares	(59,552)	(41,037)	(368)
Retained earnings	1,509,906	1,551,150	13,912
Other components of equity	366,114	451,066	4,045
Equity attributable to owners of the company	5,173,037	5,323,935	47,748
Non-controlling interests	4,140	426	4
Total equity	5,177,177	5,324,361	47,752
Total liabilities and equity	12,912,293	12,560,273	112,648

(*) Consolidated statements of financial position have been translated solely for the convenience of the reader at an exchange rate of 1USD = 111.50 JPY, the Noon Buying Rate certified by the Federal Reserve Bank of New York on September 30, 2021. 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 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

Six-month period ended September 30, 2020 (From April 1 to September 30, 2020)

	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, 2020	1,668,123	1,680,287	(87,463)	1,369,972	91,848	22,891
Net profit for the period				86,548		
Other comprehensive income (loss)					(31,402)	31,318
Comprehensive income (loss) for the period	—	—	—	86,548	(31,402)	31,318
Transaction with owners:						
Issuance of new shares	22	22				
Acquisition of treasury shares			(2,135)			
Disposal of treasury shares		(0)	2			
Dividends				(141,858)		
Transfers from other components of equity				22,403		(25,162)
Share-based compensation		18,098				
Exercise of share-based awards		(29,535)	30,031			
Total transactions with owners	22	(11,415)	27,898	(119,455)	—	(25,162)
As of September 30, 2020	1,668,145	1,668,872	(59,565)	1,337,065	60,446	29,047

	Equity attributable to owners of the company				Other components of equity		
	Cash flow hedges	Hedging cost	Remeasurements of defined benefit pension plans	Total	Total	Non-controlling interests	Total equity
	As of April 1, 2020	(22,730)	555	—	92,564	4,723,483	4,003
Net profit for the period				—	86,548	41	86,589
Other comprehensive income (loss)	(5,889)	(13,544)	(2,759)	(22,276)	(22,276)	130	(22,146)
Comprehensive income (loss) for the period	(5,889)	(13,544)	(2,759)	(22,276)	64,272	171	64,443
Transaction with owners:							
Issuance of new shares				—	44		44
Acquisition of treasury shares				—	(2,135)		(2,135)
Disposal of treasury shares				—	2		2
Dividends				—	(141,858)	(77)	(141,935)
Transfers from other components of equity			2,759	(22,403)	—		—
Share-based compensation				—	18,098		18,098
Exercise of share-based awards				—	496		496
Total transactions with owners	—	—	2,759	(22,403)	(125,353)	(77)	(125,430)
As of September 30, 2020	(28,619)	(12,989)	—	47,885	4,662,402	4,097	4,666,499

Six-month period ended September 30, 2021 (From April 1 to September 30, 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				183,648		
Other comprehensive income (loss)					66,578	4,337
Comprehensive income (loss) for the period	—	—	—	183,648	66,578	4,337
Transaction with owners:						
Issuance of new shares	8,118	14,036				
Acquisition of treasury shares			(4,468)			
Disposal of treasury shares		(0)	1			
Dividends				(141,859)		
Changes in ownership				(2,143)		
Transfers from other components of equity				1,599		(3,301)
Share-based compensation		20,972				
Exercise of share-based awards		(36,938)	22,982			
Total transactions with owners	8,118	(1,931)	18,515	(142,404)	—	(3,301)
As of September 30, 2021	1,676,263	1,686,493	(41,037)	1,551,150	467,376	43,019

	Equity attributable to owners of the company				Other components of equity		
	Cash flow hedges	Hedging cost	Remeasurements of defined benefit pension plans	Total	Total	Non-controlling interests	Total equity
	As of April 1, 2021	(68,075)	(8,592)	—	366,114	5,173,037	4,140
Net profit for the period				—	183,648	73	183,721
Other comprehensive income (loss)	11,553	5,785	(1,702)	86,551	86,551	17	86,568
Comprehensive income (loss) for the period	11,553	5,785	(1,702)	86,551	270,198	90	270,288
Transaction with owners:							
Issuance of new shares				—	22,154		22,154
Acquisition of treasury shares				—	(4,468)		(4,468)
Disposal of treasury shares				—	1		1
Dividends				—	(141,859)		(141,859)
Changes in ownership				—	(2,143)	(3,804)	(5,948)
Transfers from other components of equity			1,702	(1,599)	—		—
Share-based compensation				—	20,972		20,972
Exercise of share-based awards				—	(13,956)		(13,956)
Total transactions with owners	—	—	1,702	(1,599)	(119,300)	(3,804)	(123,104)
As of September 30, 2021	(56,522)	(2,807)	—	451,066	5,323,935	426	5,324,361

(5) Consolidated Statements of Cash Flows

	JPY (millions)		USD (millions)(*)
	Six-month Period Ended September 30,		Six-month Period Ended September 30,
	2020	2021	2021
Cash flows from operating activities:			
Net profit for the period	¥ 86,589	¥ 183,721	\$ 1,648
Depreciation and amortization	280,531	283,595	2,543
Impairment losses	8,303	1,489	13
Equity-settled share-based compensation	18,098	20,972	188
Change in estimate of liabilities related to SHP647	(60,179)	—	—
Loss on sales and disposal of property, plant and equipment	323	219	2
Gain on divestment of business and subsidiaries	(730)	(730)	(7)
Change in fair value of financial assets and liabilities associated with contingent consideration arrangements, net	19,937	(8,099)	(73)
Finance (income) and expenses, net	81,092	58,028	520
Share of loss of investments accounted for using the equity method	8,935	3,525	32
Income tax expenses	38,972	100,704	903
Changes in assets and liabilities:			
Increase in trade and other receivables	(1,542)	(55,190)	(495)
Decrease (increase) in inventories	3,010	(24,965)	(224)
Decrease in trade and other payables	(26,336)	(9,043)	(81)
Increase (decrease) in provisions	41,490	(63,512)	(570)
Increase in other financial liabilities	13,722	1,023	9
Other, net	(40,099)	(17,856)	(160)
Cash generated from operations	472,116	473,883	4,250
Income taxes paid	(103,775)	(78,707)	(706)
Tax refunds and interest on tax refunds received	23,670	4,835	43
Net cash from operating activities	392,011	400,011	3,588
Cash flows from investing activities:			
Interest received	577	2,126	19
Dividends received	177	142	1
Acquisition of property, plant and equipment	(50,479)	(60,601)	(544)
Proceeds from sales of property, plant and equipment	38,535	389	3
Acquisition of intangible assets	(30,413)	(25,182)	(226)
Acquisition of investments	(6,219)	(3,591)	(32)
Proceeds from sales and redemption of investments	50,650	10,070	90
Acquisition of businesses, net of cash and cash equivalents acquired	—	(27,549)	(247)
Proceeds from sales of business, net of cash and cash equivalents divested	31,400	2,138	19
Other, net	(6,004)	(1,292)	(12)
Net cash from (used in) investing activities	28,224	(103,349)	(927)

	JPY (millions)		USD
	Six-month Period Ended		Six-month
	2020	2021	Period Ended
			September 30,
			2021
Cash flows from financing activities:			
Net decrease in short-term loans and commercial papers	(89,917)	(1)	(0)
Proceeds from issuance of bonds and long-term loans	1,179,515	—	—
Repayments of bonds and long-term loans	(1,265,629)	(441,072)	(3,956)
Payments for settlement of forward rate agreement related to bonds	(34,830)	—	—
Acquisition of treasury shares	(2,135)	(2,542)	(23)
Interest paid	(47,562)	(52,668)	(472)
Dividends paid	(141,754)	(141,573)	(1,270)
Repayments of lease liabilities	(15,779)	(20,536)	(184)
Other, net	(119)	(13)	(0)
Net cash used in financing activities	(418,210)	(658,405)	(5,905)
Net increase (decrease) in cash and cash equivalents	2,025	(361,743)	(3,244)
Cash and cash equivalents at the beginning of the year			
(Consolidated statements of financial position)	637,614	966,222	8,666
Effects of exchange rate changes on cash and cash equivalents	(8,570)	3,402	31
Cash and cash equivalents at the end of the period	631,069	607,881	5,452
Cash and cash equivalents reclassified to assets held for sale	(201)	—	—
Cash and cash equivalents at the end of the period			
(Consolidated statements of financial position)	630,868	607,881	5,452

(*) Consolidated statements of cash flows have been translated solely for the convenience of the reader at an exchange rate of 1USD = 111.50 JPY, the Noon Buying Rate certified by the Federal Reserve Bank of New York on September 30, 2021. 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 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)

On October 14, 2021, Takeda issued a 0.40%, 250 billion JPY 10-year unsecured senior bond maturing on October 14, 2031. Takeda intends to use the proceeds from the bond offering primarily to prepay the remaining 1,700 million USD outstanding JBIC Loan amount on December 13, 2021 in advance of its original maturity date of December, 2025. The remaining bond issuance proceeds will be used for the redemption of bonds or be deployed towards the working capital needs of Takeda.

On October 28, 2021, Takeda resolved to engage in the acquisition of its own shares at the Board of Directors Meeting pursuant to the provision of its Articles of Incorporation in accordance with Article 459, paragraph 1 of the Companies Act of Japan.

1. Reason for acquisition of its own shares
To enhance capital efficiency and improve shareholder returns
2. Details of acquisition

Class of shares to be acquired:	Shares of common stock
Number of shares to be acquired:	Up to 35 million shares (equivalent to 2.23% of the total number of shares outstanding excluding treasury shares)
Total amount of shares to be acquired:	Up to 100 billion JPY
Schedule of acquisition:	From November 2, 2021 to April 29, 2022
Method of acquisition:	Open-market repurchase through a trust bank

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1. Pipeline

I. Clinical Development Activities

- The following table lists the pipeline assets that we are developing as of October 28, 2021. The assets in our pipeline are in various stages of development, and the contents of the pipeline may change as compounds currently under development drop out and new compounds are introduced. Whether the compounds 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 will actively pursue approval. 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 in the "Stage" column denote where a 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', 'microbiome' or 'biologic and other.'

• Oncology Pipeline

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Stage	
SGN-35¹ <brentuximab vedotin> <i>ADCETRIS</i> (EU, Japan, China)	CD30 monoclonal antibody-drug conjugate (injection)	Biologic and other	Cutaneous T cell lymphoma	China	Approved (Apr 2021)
<brigatinib> <i>ALUNBRIG</i> (Global)	ALK inhibitor (oral)	Small molecule	1L & 2L ALK-positive Non-Small Cell Lung Cancer	China	Filed (Dec 2020)
			2L ALK-positive Non-Small Cell Lung Cancer (head-to-head with alectinib)	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	Japan U.S. EU China	Approved (May 2021) P-III P-III P-III
			Maintenance therapy in patients with newly diagnosed Multiple Myeloma following autologous stem cell transplant	U.S. EU	P-III P-III
<cabozantinib> ² <i>CABOMETYX</i> (Japan)	Multi-targeted kinase inhibitor (oral)	Small molecule	1L Renal cell carcinoma in combination with nivolumab	Japan	Approved (Aug 2021)
			2L metastatic Non-Small Cell Lung Cancer in combination with atezolizumab ³	Japan	P-III
			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
TAK-788 <mobocertinib> <i>EXKIVITY</i> (U.S.)	EGFR/HER2 exon 20 inhibitor (oral)	Small molecule	Treatment Naïve Non-Small Cell Lung Cancer with EGFR exon 20 insertion	Global	P-III
			Previously treated Non-Small Cell Lung Cancer with EGFR exon 20 insertion ⁵	U.S. China Japan EU	Approved (Sep 2021) Filed (Jul 2021) P-III P-III
TAK-385 <relugolix>	LH-RH antagonist (oral)	Small molecule	Prostate cancer	Japan China	P-III P-III
TAK-981 <subsumstat>	SUMO inhibitor (injection)	Small molecule	Multiple cancers	-	P-II

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TAK-007 ⁶	CD19 CAR-NK (injection)	Cell and gene therapy	Relapsed/refractory B cell malignancies	-	P-I/II
TAK-102 ⁷	GPC3 CAR-T (injection)	Cell and gene therapy	Solid tumors	-	P-I
TAK-573 ⁸ <modakafusp alpha>	Anti-CD38-targeted IgG4 genetically fused with an attenuated IFN α (injection)	Biologic and other	Relapsed/refractory Multiple Myeloma	-	P-I
TAK-605 ⁹	Oncolytic virus (intra-tumoral administration)	Biologic and other	Solid tumors	-	P-I
TAK-676	STING agonist (injection)	Small molecule	Solid tumors	-	P-I
TAK-940 ¹⁰	CD19 1XX CAR-T (injection)	Cell and gene therapy	Relapsed/refractory B cell malignancies	-	P-I
TAK-252 / SL-279252 ¹¹	PD-1-Fc-OX40L (injection)	Biologic and other	Solid tumors or lymphomas	-	P-I
TAK-186 ¹²	T Cell Engager (Injection)	Biologic and other	EGFR expressing solid tumors	-	P-I

1. Partnership with Seagen, Inc.
2. Partnership with Exelixis, Inc.
3. Partnership with Chugai Pharmaceutical. Chugai operates Phase 3 development
4. Partnership with Chugai Pharmaceutical. Takeda operates Phase 3 development
5. 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 such as the UK, Brazil and Australia.
6. Partnership with The University of Texas MD Anderson Cancer Center
7. Partnership with Noile-Immune Biotech, Inc.
8. Partnership with Teva Pharmaceutical Industries Ltd.
9. Partnership with Turnstone Biologics
10. Partnership with Memorial Sloan Kettering Cancer Center
11. Partnership with Shattuck Labs, Inc.
12. Acquired Maverick Therapeutics, Inc. including TAK-186.

Additions since FY2021 Q1: None

Removals since FY2021 Q1: TAK-924 for High-risk Myelodysplastic Syndrome and Unfit Acute Myelogenous Leukemia (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	Stage	
TAK-743 <lanadelumab> <i>TAKHZYRO</i> (U.S., EU, China)	Plasma kallikrein inhibitor (injection)	Biologic and other	Hereditary Angioedema	Japan	Filed (Mar 2021)
			Pediatric Hereditary Angioedema	Global	P-III
			Bradykinin-Mediated Angioedema	Global	P-III
TAK-577 <i>VONVENDI</i> (U.S., Japan), <i>VEYVONDI</i> (EU)	von Willebrand factor [recombinant] (injection)	Biologic and other	Adult prophylactic treatment of von Willebrand disease	U.S. Japan EU China	Filed (May 2021) P-III 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-755¹	Replacement of the deficient-ADAMTS13 enzyme (injection)	Biologic and other	Congenital Thrombotic Thrombocytopenic Purpura	U.S. EU	P-III P-III
			Immune Thrombotic Thrombocytopenic Purpura	U.S. EU	P-II P-II
			Sickle cell disease	U.S.	P-I
TAK-620² <maribavir>	Benzimidazole riboside inhibitor (oral)	Small molecule	Cytomegalovirus infection in post-transplant patients	U.S. EU	Filed (May 2021) P-III
TAK-607	Insulin-like Growth Factor / IGF Binding Protein (injection)	Biologic and other	Complications of prematurity	-	P-II
TAK-609	Recombinant human iduronate-2-sulfatase for intrathecal administration (injection)	Biologic and other	Hunter syndrome CNS	U.S. EU	P-II P-II
TAK-611	Recombinant human arylsulfatase A for intrathecal administration (injection)	Biologic and other	Metachromatic leukodystrophy	-	P-II
TAK-079³ <mezagitamab>	Anti-CD38 monoclonal antibody (injection)	Biologic and other	Myasthenia gravis	-	P-II
			Immune thrombocytopenic purpura	-	P-II
			Systemic lupus erythematosus	-	P-I/II
TAK-834 <i>NATPARA</i> (U.S.), <i>NATPAR</i> (EU)	Parathyroid hormone (injection)	Biologic and other	Hypoparathyroidism	Japan	P-I ⁴

- Partnership with KM Biologics for co-exclusive license for commercialization in Japan only
- Partnership with GlaxoSmithKline
- Relapsed/refractory Multiple Myeloma will continue until trial completion.
- P-I study in Japan completed; P-III study start timing under review.

Additions since FY2021 Q1: None

Removals since FY2021 Q1: None

• **Neuroscience Pipeline**

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Stage	
TAK-935 <soficostat>	CH24H inhibitor (oral)	Small molecule	Dravet syndrome	-	P-III
			Lennox-Gastaut syndrome	-	P-III
TAK-994	Orexin 2R agonist (oral)	Small molecule	Narcolepsy	-	P-II
TAK-071	M1 positive allosteric modulator (M1PAM) (oral)	Small molecule	Parkinson's disease	-	P-II
TAK-041 ¹	GPR139 agonist (oral)	Small molecule	Anhedonia in major depressive disorder (MDD)	-	P-I
TAK-341/MEDI1341 ²	Alpha-synuclein antibody (injection)	Biologic and other	Parkinson's disease	-	P-I
TAK-653 ¹	AMPA receptor potentiator (oral)	Small molecule	Inadequate response to treatment in major depressive disorder (MDD)	-	P-I
TAK-861	Orexin 2R agonist (oral)	Small molecule	Sleep disorders, other disorders	-	P-I
TAK-925	Orexin 2R agonist (injection)	Small molecule	Hospital setting, narcolepsy	-	P-I

1. 50:50 co-development and co-commercialization with Neurocrine
2. Partnership with AstraZeneca. AstraZeneca leads Phase 1 development

Additions since FY2021 Q1: None

Removals since FY2021 Q1: TAK-935 for 15q duplication syndrome, CDKL5 deficiency disorder (P-II, discontinued)

• **GI Pipeline**

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Stage	
MLN0002 <vedolizumab> <i>ENTYVIO</i> (Global)	Humanized monoclonal antibody against $\alpha 4\beta 7$ integrin (injection)	Biologic and other	Subcutaneous formulation for ulcerative colitis	U.S.	CRL received (Dec 2019) ⁹
				Japan	Filed (Aug 2019)
			Subcutaneous formulation for Crohn's disease	U.S.	P-III
				Japan	P-III
			Antibiotic-refractory Pouchitis	EU	Filed (Jul 2021)
TAK-438 <vonoprazan> <i>TAKECAB</i> (Japan) <i>VOCINTI</i> (China)	Potassium-competitive acid blocker (oral)	Small molecule	Graft-versus-Host Disease prophylaxis in patients undergoing allogeneic hematopoietic stem cell transplantation	EU	P-III
				Japan	P-III
			Pediatrics Study (ulcerative colitis, Crohn's disease)	Global	P-II
			Acid related diseases (Reflux Esophagitis Maintenance)	China	Approved (Oct 2021)*
TAK-438 <vonoprazan> <i>TAKECAB</i> (Japan) <i>VOCINTI</i> (China)	Potassium-competitive acid blocker (oral)	Small molecule	Acid related diseases (Duodenal Ulcer)	China	Filing withdrawn (Jun 2021) ¹⁰
			Oral disintegrated tablet formulation	Japan	Filed (Mar 2021)
			Acid related diseases (adjunct to Helicobacter pylori eradication)	China	P-III

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TAK-633 <teduglutide> <i>GATTEX</i> (U.S.) <i>REVESTIVE</i> (EU, Japan)	GLP-2 analogue (injection)	Peptide/ Oligo- nucleotide	Short bowel syndrome (pediatric indication)	Japan	Approved (Jun 2021)
			Short bowel syndrome (in adults)	Japan	Approved (Jun 2021)
TAK-721¹ <budesonide>	Glucocorticosteroid (oral)	Small molecule	Eosinophilic esophagitis	U.S.	Filed (Dec 2020)
Cx601 <darvadstrocel> <i>ALOFISEL</i> (EU)	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. Japan	P-III Approved (Sep 2021)
TAK-906	Dopamine D2/D3 receptor antagonist (oral)	Small molecule	Gastroparesis	-	P-II (b)
TAK-954²	5-HT ₄ - hydroxytryptamine receptor agonist (injection)	Small molecule	Post-operative gastrointestinal dysfunction	-	P-II (b)
TAK-999³	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-101⁴	Tolerizing Immune Modifying nanoParticle (TIMP) (injection)	Biologic and other	Celiac disease	-	P-II (a)
TAK-018/EB8018⁵ <sibofimloc>	FimH antagonist (oral)	Small molecule	Crohn's disease (post-operative and ileitis)	-	P-II (a)
TAK-951	Peptide agonist (sub- cutaneous)	Peptide/ Oligo- nucleotide	Nausea and vomiting	-	P-II
TAK-510	Peptide agonist (sub- cutaneous)	Peptide/ Oligo- nucleotide	Nausea and vomiting	-	P-I
TAK-105	Peptide agonist (sub- cutaneous)	Peptide/ Oligo- nucleotide	Nausea and vomiting	-	P-I
TAK-062⁶	Glutenase (oral)	Biologic and other	Celiac disease	-	P-I
TAK-039⁷	Bacterial consortium (oral)	Microbiome	Clostridium difficile infections ⁸	-	P-I

1. Partnership with UCSD and Fortis Advisors
2. Partnership with Theravance Biopharma, Inc.
3. Partnership with Arrowhead Pharmaceuticals, Inc.
4. Acquired development and commercialization license for TAK-101 from Cour Pharmaceutical Development Company. Previously known as TIMP-GLIA.
5. Partnership with Enterome Bioscience SA
6. Previously known as Kuma062.
7. Partnership with with NuBiyota
8. Phase 1 study in clostridium difficile infections completed; strategic intention is to take the program forward in hepatic encephalopathy.
9. In active discussions with the FDA. Timelines under review; potential approval anticipated FY23.
10. The sNDA withdrawal was filed to leave a room for further negotiations with Chinese CDE (Center for Drug Evaluation) to update study designs and agree on efficacy data points that need to be derived from an updated study design. This withdrawal is not related to product safety.

* Event after the Q2 reporting period: Update after October 1, 2021

Additions since FY2021 Q1: TAK-105 for Nausea and vomiting (P-I)

Removals since FY2021 Q1: None

• **Plasma-Derived Therapies Pipeline**

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Stage
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-664 <i>CUVITRU</i> (U.S., EU)	Immunoglobulin 20% [human] (subcutaneous)	Biologic and other	Primary immunodeficiencies	Japan P-III
TAK-771¹ <IG Infusion 10% (Human) w/ Recombinant Human Hyaluronidase> <i>HYQVIA</i> (U.S., EU)	Immunoglobulin (IgG) + recombinant hyaluronidase replacement therapy (injection)	Biologic and other	Pediatric indication for primary immunodeficiency	U.S. P-III
			Chronic inflammatory demyelinating polyradiculoneuropathy	U.S. P-III EU P-III

1. Partnership with Halozyme

Additions since FY2021 Q1: TAK-662 for severe congenital protein C deficiency (P-I/II study initiated, Japan)

Removals since FY2021 Q1: None

• **Vaccines Pipeline**

Development code Brand name (country/region)	Type of vaccine (administration route)	Modality	Indications / additional formulations	Stage
TAK-919/mRNA-1273¹ <i>COVID-19 Vaccine Moderna Intramuscular Injection</i> (Japan)	SARS-CoV-2 vaccine (injection)	Biologic and other	Active immunization for the prevention of COVID-19	Japan Approved (May 2021) ⁴
TAK-003	Tetravalent dengue vaccine (injection)	Biologic and other	For the prevention of dengue fever of any severity, due to any serotype, in individuals aged 4 up to 60 years of age	EU and EU-M4all - P-III Filed (Mar 2021) ⁵
TAK-019/ NVX-CoV2373²	SARS-CoV-2 vaccine (injection)	Biologic and other	Active immunization for the prevention of COVID-19	Japan P-I/II
TAK-426³	Zika vaccine (injection)	Biologic and other	Active immunization for the prevention of disease caused by Zika virus	- P-I

1. Partnership with Moderna and MHLW to bring Moderna’s COVID-19 vaccine candidate to Japan

2. Partnership with Novavax, Inc. to bring Novavax’ COVID-19 vaccine candidate to Japan with funding from the Government of Japan’s Ministry of Health, Labour and Welfare (MHLW) and Agency for Medical Research and Development (AMED)

3. Partnership with The Biomedical Advanced Research and Development Authority (BARDA) - U.S. Government

4. Change in age indication to expand to 12 years of age and older (July 2021).

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

Additions since FY2021 Q1: None

Removals since FY2021 Q1: HIL-214 (TAK-214) for active immunization for the prevention of acute gastroenteritis caused by norovirus (P-II (b), externalization ex-JP)

II. Recent Progress in stage [Progress in stage since April 1st, 2021]

Development code <generic name>	Indications / additional formulations	Country/Region	Progress in stage
SGN-35 <brentuximab vedotin>	Cutaneous T cell lymphoma	China	Approved (Apr 2021)
MLN9708 <ixazomib>	Maintenance therapy in patients with newly diagnosed Multiple Myeloma not treated with stem cell transplant	Japan	Approved (May 2021)
TAK-919/mRNA-1273	Active immunization for the prevention of COVID-19	Japan	Approved (May 2021)
TAK-633 <teduglutide>	Short bowel syndrome (pediatric indication and in adults)	Japan	Approved (Jun 2021)
<cabozantinib>	1L Renal cell carcinoma in combination with nivolumab	Japan	Approved (Aug 2021)
TAK-788 <mobocertinib>	Previously treated Non-Small Cell Lung Cancer with EGFR exon 20 insertion	U.S.	Approved (Sep 2021)
Cx601 <darvadstrocel>	Refractory complex perianal fistulas in patients with Crohn's disease	Japan	Approved (Sep 2021)
TAK-438 <vonoprazan>	Acid related diseases (Reflux Esophagitis Maintenance)	China	Approved (Oct 2021)*
TAK-577	Adult prophylactic treatment of von Willebrand disease	U.S.	Filed (May 2021)
TAK-620 <maribavir>	Cytomegalovirus infection in post-transplant patients	U.S.	Filed (May 2021)
TAK-788 <mobocertinib>	Previously treated Non-Small Cell Lung Cancer with EGFR exon 20 insertion	China	Filed (Jul 2021)
MLN0002 <vedolizumab>	Antibiotic-refractory Pouchitis	EU	Filed (Jul 2021)
TAK-981	Multiple cancers	-	P-II
TAK-662	Severe congenital protein C deficiency	Japan	P-I/II
TAK-861	Sleep disorders, other disorders	-	P-I
TAK-105	Nausea and vomiting	-	P-I

* Event after the Q2 reporting period: Update after October 1, 2021

III. Discontinued projects [Update since April 1st, 2021]

Development code <generic name>	Indications (Stage)	Reason
CoVIg-19	Treatment of adult hospitalized patients at onset of clinical progression of COVID-19 (U.S., EU, Japan, P-III)	Phase 3 Inpatient Treatment with Anti-Coronavirus Immunoglobulin (ITAC) clinical trial sponsored and funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), did not meet its endpoints.
TAK-169	Relapse/refractory multiple myeloma (P-I)	Takeda has communicated its decision to turn over full rights of TAK-169 to Molecular Templates. Molecular Templates will continue to develop TAK-169.
TAK-831 <luvadaxistat>	Negative symptoms and/or cognitive impairment associated with schizophrenia (P-II)	Based on clinical data, our partner Neurocrine announced the discontinuation of development in Schizophrenia Negative Symptoms. Neurocrine will continue developing TAK-831 in Cognitive Impairment Associated with Schizophrenia and Takeda decided not to co-fund a supplemental study with Neurocrine, which resulted in TAK-831 remaining a Royalty Bearing Product.
TAK-671	Acute Pancreatitis (P-I)	Takeda has opted out of further development based on a business decision, and the right to continue developing the asset falls under Samsung Bioepis.
TAK-924 <pevonedistat>	High-risk Myelodysplastic Syndrome (P-III), Unfit Acute Myelogenous Leukemia (P-III)	Phase 3 PANTHER study did not meet its primary endpoint. The result did not support further development in Phase 3 HR MDS trial and Unfit AML trial. The Phase 1/2 AML trial in combination with venetoclax is ongoing but not recruiting new patients and is not registrational.
TAK-935 <socticestat>	15q duplication syndrome, CDKL5 deficiency disorder (P-II)	The Phase 2 result did not support further development in these indications.

IV. Main Research & Development collaborations [not a comprehensive list of all Takeda R&D collaborations]

• **Oncology**

Partner	Country	Subject
Adimab	U.S.	Agreement for the discovery, development and commercialization of three mAbs and three CD3 Bi-Specific antibodies for oncology indications.
Centre d'Immunologie de Marseille-Luminy	France	Collaboration agreement to bring together expertise and knowledge in innate biology with Takeda's BacTrap capabilities to identify novel targets and pathways in myeloid cells.
ASKA Pharmaceutical Co., Ltd	Japan	Takeda granted exclusive commercialization rights for uterine fibroids and exclusive development and commercialization rights for endometriosis for Japan to maximize the product value of relugolix (TAK-385).
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.
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.
GlaxoSmithKline	U.K.	Exclusive licensing agreement to develop and commercialize novel cancer therapy niraparib for the treatment of all tumor types in Japan, and all tumor types excluding prostate cancer in South Korea and Taiwan.
Heidelberg Pharma	Germany	Antibody-Drug-Conjugate (ADC) research collaboration on 2 targets and licensing agreement (α -amanitin payload and proprietary linker).
KSQ Therapeutics	U.S.	Strategic collaboration to research, develop and commercialize novel immune-based therapies for cancer using KSQ's CRISPRomics® technology.
MD Anderson Cancer Center	U.S.	Exclusive license and research agreement to develop cord blood-derived chimeric antigen receptor-directed natural killer (CAR NK) cell therapies, 'armored' with IL-15, for the treatment of B cell malignancies and other cancers.
Memorial Sloan Kettering Cancer Center	U.S.	Strategic research collaboration and license to develop novel chimeric antigen receptor T cell (CAR-T) products for the treatment of multiple myeloma, acute myeloid leukemia and additional solid tumor indications. The collaboration is co-led by Michel Sadelain, who is currently head of the Center for Cell Engineering at Memorial Sloan Kettering
Molecular Templates	U.S.	Research collaboration to apply Molecular Templates' engineered toxin bodies (ETB) technology platform to potential therapeutic targets provided by Takeda, who has rights to exercise exclusive options to obtain license rights to products resulting from the collaboration.
Myovant Sciences	Switzerland	Takeda granted Myovant an exclusive, worldwide license (excluding Japan and certain other Asian countries) to relugolix (TAK-385) and an exclusive, worldwide license to MVT-602 (TAK-448).
National Cancer Center of Japan	Japan	Partnership agreement to develop basic research to clinical development by promoting exchanges among researchers, physicians, and others engaged in anti-cancer drug discovery and cancer biology research.
Noile-Immune Biotech	Japan	Collaboration agreement for the development of next generation CAR-T cell therapy, developed by Professor Koji Tamada at Yamaguchi University. Takeda has exclusive options to obtain licensing rights for the development and commercialization of Noile-Immune Biotech's pipeline and products resulting from this partnership. Due to the success of the collaboration, Takeda licensed NIB-102 and NIB-103.
Presage Biosciences	U.S.	Research collaboration and license for multiple programs using Presage's proprietary platform CIVO to evaluate patients' unique responses to microdoses of cancer drugs.
Seagen	U.S.	Agreement for the joint development of ADCETRIS, an ADC technology which targets CD30 for the treatment of HL. Approved in 67 countries with ongoing clinical trials for additional indications.
Shattuck Labs	U.S.	Collaboration agreement to explore and develop checkpoint fusion proteins utilizing Shattuck's unique Agonist Redirected Checkpoint (ARC) TM platform which enables combination immunotherapy with a single product. Takeda will have the option to take an exclusive license to further develop and commercialize TAK-252/SL-279252
Teva	Israel	Agreement for worldwide License to TEV-48573 (TAK-573) (modakafusp alpha, Anti-CD38-Atenukine TM) and multi-target discovery collaboration accessing Teva's attenukine platform.
Turnstone Biologics	U.S.	Collaboration to co-develop TAK-605 (RIVAL-01) (novel oncolytic virus expressing aCTLA4, IL12-mb, flt3L) via a worldwide partnership and also conduct collaborative discovery efforts to identify additional novel product candidates based on a Turnstone's vaccinia virus platform.

Rare Genetics and Hematology

Partner	Country	Subject
Asklepios Biopharmaceuticals	U.S.	Agreement for multiple research and development collaborations using FVIII Gene Therapy for the treatment of Hemophilia A and B.
BioMarin	U.S.	Agreement for the in-license of enabling technology for the exogenous replacement of iduronate-2-sulfatase with Idursulfase-IT in patients via direct delivery to the CNS for the long-term treatment of Hunter Syndrome in patients with cognitive impairment in order to slow progression of cognitive impairment (TAK-609).
Carmine Therapeutics	Singapore	Research collaboration agreement to discover, develop and commercialize transformative non-viral gene therapies for two rare disease targets using Carmine's REGENT(TM) technology, based on red blood cell extracellular vesicles.
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
GlaxoSmithKline	U.K.	In-license agreement between GSK and University of Michigan for TAK-620 (marabivir) in the treatment of human cytomegalovirus.
JCR Pharmaceuticals†	Japan	Exclusive collaboration and license agreement to commercialize JR-141 (pabinafusp alfa), applied with J-Brain Cargo®, JCR's proprietary blood-brain barrier (BBB) technology, for the treatment of Hunter syndrome (MPS II). Takeda will exclusively commercialize 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 JR-141 in the U.S. upon completion of the Phase 3 program.
ImmuSoft**	U.S.	Research collaboration and license option agreement to discover, develop and commercialize cell therapies in rare inherited metabolic disorders with central nervous system (CNS) manifestations and complications using ImmuSoft's Immune System Programming (ISP™) technology platform.
IPSEN	France	Purchase agreement for the development of Obizur for the treatment of Acquired Hemophilia A including for patients with Congenital Hemophilia A with inhibitors indication in elective or emergency surgery.
KM Biologics	Japan	Agreement for the development collaboration of TAK-755 to overcome the ADAMTS13 deficiency in TTP.
Poseida Therapeutics**	U.S.	Research collaboration and exclusive license agreement to utilize Poseida's piggyBac, Cas-CLOVER, biodegradable DNA and RNA nanoparticle delivery technology and other proprietary genetic engineering platforms for up to eight gene therapies. The collaboration will focus on developing non-viral in vivo gene therapy programs, including Poseida's Hemophilia A program.
Rani Therapeutics	U.S.	Research collaboration agreement to evaluate a micro tablet pill technology for oral delivery of FVIII therapy in hemophilia.
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.

‡ Executed since April 1, 2021

* Event after the Q2 reporting period: Update after October 1, 2021

• **Neuroscience**

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

‡ Executed since April 1, 2021

• **Gastroenterology**

Partner	Country	Subject
Ambys Medicines	U.S.	Collaboration agreement for the application of novel modalities, including cell and gene therapy and gain-of-function drug therapy, to meet the urgent need for treatments that restore liver function and prevent the progression to liver failure across multiple liver diseases. Under the terms of the agreement, Takeda has an option to ex-U.S. commercialization rights for the first 4 products that reach an investigational new drug application.
Arcturus	U.S.	Collaboration agreement to develop RNA-based therapeutics for the treatment of non-alcoholic steatohepatitis and other gastrointestinal related disorders using Arcturus’ wholly-owned LUNAR™ lipid-mediated delivery systems and UNA Oligomer chemistry.
Arrowhead Pharmaceuticals	U.S.	Collaboration and licensing agreement to develop TAK-999 (ARO-AAT), a Phase 2 investigational RNA interference (RNAi) therapy in development to treat alpha-1 antitrypsin-associated liver disease (AATLD). ARO-AAT is a potential first-in-class therapy designed to reduce the production of mutant alpha-1 antitrypsin protein, the cause of AATLD progression.
Beacon Discovery	U.S.	Collaboration agreement for the G-protein coupled receptor drug discovery and development program to identify drug candidates for a range of gastrointestinal disorders. The agreement grants Takeda worldwide rights to develop, manufacture and commercialize products resulting from the collaboration.
Cerevance	U.S.	Multi-year research alliance to identify novel target proteins expressed in the central nervous system and to develop new therapies against them for certain GI disorders. Goal of the collaboration is to select, confirm and validate targets from gene expression data sets generated by Cerevance’s NETSseq technology.
Cour Pharmaceutical Development Company	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 liver fibrosis platform to conduct research activities and to nominate, confirm, and validate potential targets against which Takeda may advance new therapeutic programs.
Enterome	France	Collaboration agreement to research and develop microbiome targets thought to play crucial roles in gastrointestinal disorders, including inflammatory bowel diseases (e.g. ulcerative colitis). The agreement includes a global license and co-development of EB8018/TAK-018 in Crohn’s disease.
Finch Therapeutics	U.S.	Global agreement to develop TAK-524, a live biotherapeutic product composed of cultured bacterial strains linked to favorable clinical outcomes in studies of microbiota transplantations in inflammatory bowel disease. Under the terms of the agreement, Takeda has the exclusive worldwide rights to develop and commercialize TAK-524 and rights to follow-on products in inflammatory bowel diseases. Following a contract amendment in Aug 2021, Takeda assumes sole responsibility for development of TAK-524, prior to the start of clinical development.

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Genevant Sciences Corporation	U.S.	Collaboration and License Agreement 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.
Hemoshear Therapeutics	U.S.	Collaboration agreement for novel target and therapeutic development for liver diseases, using Hemoshear's proprietary REVEAL-Tx drug discovery platform.
NuBiyota	Canada	Agreement for the development of Microbial Ecosystem Therapeutic products for gastroenterology indications.
Mirum Pharmaceuticals [‡]	U.S.	Exclusive licensing agreement for the development and commercialization of maralixibat in Japan for Alagille syndrome (ALGS), progressive familial intrahepatic cholestasis (PFIC), and biliary atresia (BA).
Phathom Pharmaceuticals	U.S.	Takeda has granted a license to Phathom Pharmaceuticals for the development and exclusive commercialization rights to vonoprazan in the U.S., Europe and Canada in exchange for upfront cash and equity, as well as future cash milestones and royalties on net sales.
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.

[‡] Executed since April 1, 2021

• Plasma Derived Therapies

Partner	Country	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.
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.

• Vaccines

Partner	Country	Subject
Biological E. Limited	India	Takeda agreed to transfer existing measles and acellular pertussis vaccine bulk production technology to develop low-cost combination vaccines for India, China and low- and middle-income countries.
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.
HilleVax, Inc. [‡]	U.S.	Collaboration with Frazier Healthcare Partners to launch HilleVax, Inc., a biopharmaceutical company to advance the development and commercialization of norovirus vaccine candidate HIL-214 (formerly TAK-214). HilleVax will have exclusive global development rights and commercialization rights worldwide outside of Japan in exchange for upfront consideration, as well as future cash milestones and royalties on net sales (Takeda retains commercialization rights in Japan).
Novavax	U.S.	Partnership for the development, manufacturing and commercialization of over 250 million doses per year of TAK-019 (NVX-CoV2373), Novavax' COVID-19 vaccine candidate, 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 recently announced that the MHLW will purchase 150 million doses of Novavax' vaccine candidate, subject to licensing and approval.
Moderna	U.S.	Three-way agreement with Moderna and the Government of Japan's Ministry of Health Labour & Welfare (MHLW) to import and distribute 50 million doses of TAK-919 (mRNA-1273) Moderna's COVID-19 vaccine (The MHLW granted special approval in May 2021). Takeda also had an agreement to import and distribute the additional 50 million doses from as early as the beginning of 2022, and will distribute totaling 100 million doses between the two agreements. This includes the potential to secure and supply vaccines corresponding to COVID-19 variants or booster products, should they be successfully developed by Moderna and licensed by the MHLW.

[‡] Executed since April 1, 2021

• **Other / Multiple Therapeutic Area**

Partner	Country	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.
HiFiBio	U.S.	Collaboration agreement for functional therapeutics high-throughput antibody discovery platform that enables identification of antibodies for rare events for discovery of therapeutic antibodies for GI therapeutic areas.
Massachusetts Institute of Technology	U.S.	MIT-Takeda Program to fuel the development and application of artificial intelligence (AI) capabilities to benefit human health and drug development. Centered within the Abdul Latif Jameel Clinic for Machine Learning in Health (J-Clinic), the new program will leverage the combined expertise of both organizations, and is supported by Takeda’s three-year investment (with the potential for a two-year extension).
Portal Instruments	U.S.	Agreement for the development and commercialization of Portal’s jet injector drug delivery device for potential use with Takeda’s investigational or approved biologic medicines.
Schrödinger	U.S.	Agreement for the multi-target research collaboration combining Schrödinger’s in silico platform-driven drug discovery capabilities with Takeda’s deep therapeutic area knowledge and expertise in structural biology.
Seattle Collaboration	U.S.	Agreement for SPRInT (Seattle Partnership for Research on Innovative Therapies) to accelerate the translation of Fred Hutchinson Cancer Research Center’s and University of Washington’s cutting-edge discoveries into treatments for human disease (focusing on Oncology, GI and Neuroscience).
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, 2021]**

Partner	Country	Subject
CoVIg-19 Plasma Alliance	-	Alliance formed by Takeda and CSL Behring to develop a potential plasma-derived therapy for treating COVID-19. The alliance goal is the development of a non-branded hyperimmune globulin medicine (CoVIg-19) with the potential to treat hospitalized adult patients with COVID-19.
Maverick Therapeutics	U.S.	Collaboration agreement for the development of Maverick Therapeutics’ T-cell engagement platform created specifically to improve the utility of T-cell redirection therapy for the treatment of cancer. Under the agreement, Takeda has the exclusive option to acquire Maverick Therapeutics 5 years after partnership initiation in 2017 which was exercised April 2021.
Samsung Bioepis	Korea	Strategic collaboration agreement to jointly fund and co-develop multiple novel biologic therapies in unmet disease areas. The program’s first therapeutic candidate is TAK-671, which is intended to treat severe acute pancreatitis.
Silence Therapeutics	U.K.	Technology Evaluation Agreement with Silence Therapeutics to access their GalNAc-siRNA technology platform. The objective of the evaluation is to identify a GalNAc-conjugated siRNA that inhibits expression of a proprietary Takeda target.

■ **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 Financial Information

Revenue by region

Year to date

(Bn JPY)	Reported *1				Underlying *1
	FY20Q2 YTD	FY21Q2 YTD	YOY		YOY
Total revenue	1,590.8	1,794.4	203.6	12.8%	6.8%
Japan *2	282.4	390.9	108.5	38.4%	7.3%
% of revenue	17.8%	21.8%	4.0pt		
United States	786.1	838.4	52.3	6.6%	3.9%
% of revenue	49.4%	46.7%	-2.7pt		
Europe and Canada	327.2	354.0	26.8	8.2%	9.1%
% of revenue	20.6%	19.7%	-0.8pt		
Growth and Emerging Markets *3	195.1	211.2	16.1	8.2%	16.0%
% of revenue	12.3%	11.8%	-0.5pt		
Asia (excluding Japan)	78.3	89.7	11.4	14.6%	19.4%
% of revenue	4.9%	5.0%	0.1pt		
Latin America	59.0	61.4	2.4	4.1%	26.8%
% of revenue	3.7%	3.4%	-0.3pt		
Russia/CIS	21.7	25.1	3.4	15.8%	1.8%
% of revenue	1.4%	1.4%	0.0pt		
Other *4	36.2	35.0	-1.2	-3.2%	4.4%
% of revenue	2.3%	2.0%	-0.3pt		
Of which royalty / service income *2	46.3	183.1	136.9	295.7%	

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

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

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

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

Quarterly

(Bn JPY)	Reported *1											
	FY20				FY21							
	Q1	Q2	Q3	Q4	Q1	YOY	Q2	YOY	Q3	YOY	Q4	YOY
Total revenue	801.9	788.9	836.8	770.3	949.6	18.4%	844.8	7.1%				
Japan *2	144.0	138.3	152.7	124.6	259.0	79.8%	131.9	-4.6%				
% of revenue	18.0%	17.5%	18.3%	16.2%	27.3%		15.6%					
United States	402.6	383.5	402.8	379.0	412.2	2.4%	426.2	11.1%				
% of revenue	50.2%	48.6%	48.1%	49.2%	43.4%		50.4 %					
Europe and Canada	157.6	169.6	172.8	166.2	178.7	13.4%	175.2	3.3%				
% of revenue	19.6%	21.5%	20.7%	21.6%	18.8%		20.7 %					
Growth and Emerging Markets *3	97.6	97.5	108.4	100.5	99.7	2.1%	111.5	14.4%				
% of revenue	12.2%	12.4%	13.0%	13.0%	10.5%		13.2 %					
Asia (excluding Japan)	36.9	41.4	40.9	37.1	40.3	9.3%	49.4	19.3%				
% of revenue	4.6%	5.2%	4.9%	4.8%	4.2%		5.8 %					
Latin America	30.8	28.2	36.4	26.2	30.1	-2.3%	31.3	11.1%				
% of revenue	3.8%	3.6%	4.4%	3.4%	3.2%		3.7 %					
Russia/CIS	13.0	8.6	17.1	18.8	12.3	-5.4%	12.8	48.0%				
% of revenue	1.6%	1.1%	2.0%	2.4%	1.3%		1.5 %					
Other *4	16.9	19.3	14.0	18.3	17.0	0.3%	18.0	-6.3%				
% of revenue	2.1%	2.4%	1.7%	2.4%	1.8%		2.1 %					
Of which royalty / service income *2	18.1	28.2	22.8	23.4	157.7	773.2%	25.4	-9.8%				

*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)	FY20Q2 YTD	Reported		US	YOY	Japan	YOY	EUCAN	YOY	GEM*5	YOY	Ex-US	YOY
		FY21Q2 YTD	YOY										
GI	379.8	429.1	13.0%	240.8	7.3%	51.9	18.8%	95.1	25.6%	33.2	15.2%	8.2	13.4%
ENTYVIO	207.0	255.9	23.6%	171.3	19.7%	5.4	34.4%	66.6	29.3%	12.6	52.0%		
TAKECAB-F *1	40.0	49.1	22.9%	—	-	46.0	17.1%	—	-	3.1	381.3%		
GATTEX/REVESTIVE	33.2	36.8	10.9%	30.6	6.8%	0.1	-	5.3	27.3%	0.8	86.2%		
DEXILANT	28.4	25.7	-9.5%	14.7	-17.5%	—	-	4.8	14.7%	6.2	-3.1%		
PANTOLOC/CONTROLOC*2	21.5	19.9	-7.5%	1.1	6.0%	—	-	12.8	12.6%	6.0	-34.1%		
LIALDA/MEZAVANT *3	11.6	11.7	0.8%	3.6	-19.6%							8.2	13.4%
PENTASA	11.7	10.0	-14.0%	10.0	-14.0%								
AMITIZA	12.4	3.9	-68.6%	3.5	-71.6%			—	-	0.4	104.7%		
RESOLOR/MOTTEGRITY	5.0	6.4	28.7%	4.6	34.2%	—	-	1.8	21.1%	—	-100.0%		
ALOFISEL	0.3	0.8	184.6%	—	-	—	-	0.6	179.3%	0.2	210.0%		
Other	8.8	8.8	0.0%	1.4	-30.9%	0.3	-3.9%	3.1	12.6%	4.0	7.7%		
Rare Diseases	295.4	300.1	1.6%	133.3	-3.0%	14.1	-10.0%	76.4	10.5%	50.3	4.6%	25.9	3.9%
Rare Metabolic	79.6	84.2	5.8%	18.5	3.6%	1.0	-31.3%	23.8	14.5%	15.0	2.9%	25.9	3.9%
ELAPRASE	34.3	34.8	1.4%	9.9	-3.0%	0.4	-53.4%	13.4	10.6%	11.1	-0.6%		
REPLAGAL *3	25.0	25.9	3.9%	—	-							25.9	3.9%
VPRIV	18.8	21.0	11.4%	8.6	10.2%	0.6	-4.7%	7.9	13.1%	3.9	13.8%		
NATPARA/NATPAR	1.5	2.5	64.7%	0.0	-	—	-	2.4	50.2%	0.0	28.1%		
Rare Hematology	142.8	141.6	-0.9%	61.3	-0.3%	12.4	-7.9%	35.0	-3.5%	32.8	4.1%		
ADVATE	63.4	61.3	-3.3%	28.4	-7.9%	3.0	-9.6%	14.1	-13.5%	15.7	22.1%		
ADYNOVATE/ADYNOVI	29.5	30.0	1.6%	13.4	2.0%	7.3	-8.1%	6.7	0.4%	2.6	45.5%		
FEIBA *4	20.6	20.2	-1.9%	6.1	22.3%	0.4	-15.4%	6.0	13.6%	7.7	-21.9%		
RECOMBINATE	6.9	6.3	-9.0%	5.9	-3.3%	—	-	0.4	-26.2%	0.1	-84.8%		
HEMOFIL/IMMUNATE/IMMUNINE*4	9.4	8.4	-10.5%	1.7	-5.7%	—	-	2.3	-10.8%	4.4	-12.2%		
Other PDT Products *4 *6	1.7	1.9	14.6%	0.0	-	—	-	1.7	17.5%	0.2	-4.8%		
Other *7	11.3	13.5	19.3%	5.9	25.0%	1.7	-2.0%	3.8	9.6%	2.1	49.8%		
Hereditary Angioedema	72.9	74.3	1.8%	53.5	-8.0%	0.7	-5.8%	17.6	45.7%	2.5	24.4%		
TAKHZYRO	43.7	47.5	8.7%	36.5	-4.1%	—	-	10.0	89.5%	1.1	158.4%		
FIRAZYR	15.1	14.3	-5.3%	7.6	-17.0%	0.7	-5.8%	4.9	24.9%	1.1	-14.6%		
CINRYZE *4	12.0	10.2	-15.1%	7.2	-18.7%	—	-	2.7	-6.1%	0.3	10.1%		
KALBITOR	2.0	2.2	8.0%	2.2	8.0%	—	-	—	-	—	-		

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

*2 generic name: pantoprazole

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

*4 PDT products

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

*6 Other PDT products in Rare Hematology include BEBULIN, PROTHROMPLEX and Factor VII.

*7 Other in Rare Hematology include VONVENDI, OBIZUR, RIXUBIS, AGRYLIN/XAGRID and Other Hemophilia.

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(Bn JPY)	Reported			US	YOY	Japan	YOY	EUCAN	YOY	GEM*5	YOY	Ex-US	YOY
	FY20Q2 YTD	FY21Q2 YTD	YOY										
PDT Immunology	205.9	238.0	15.6%	157.1	10.9%							80.9	26.0%
immunoglobulin *1	162.7	181.3	11.5%	135.5	9.3%							45.8	18.5%
albumin *1	28.6	41.7	46.1%	10.0	58.5%							31.8	42.6%
Other *1 *6	14.7	15.0	2.1%	11.7	2.4%							3.3	1.0%
Oncology	210.0	233.7	11.3%	111.5	10.7%	42.7	3.1%	40.4	10.0%	34.8	31.8%	4.3	-10.3%
VELCADE *2	50.0	55.1	10.2%	53.4	12.3%							1.7	-31.3%
LEUPLIN/ENANTONE	49.9	53.9	8.0%	11.8	100.8%	15.1	-25.6%	16.9	9.0%	10.1	22.0%		
NINLARO	44.4	45.8	3.3%	27.4	-8.0%	3.0	22.4%	6.9	7.2%	8.5	49.8%		
ADCETRIS	30.6	34.1	11.7%			5.7	0.5%	14.2	7.2%	14.3	22.2%		
ICLUSIG *2	16.8	17.9	6.0%	15.2	5.2%							2.6	11.2%
VECTIBIX	11.9	12.8	7.3%			12.8	7.3%						
ALUNBRIG	4.3	6.2	46.2%	3.1	4.6%	0.5	-	1.7	80.2%	0.9	161.3%		
Other	2.2	7.9	257.3%	0.5	-	5.8	360.6%	0.7	17.6%	1.0	146.7%		
Neuroscience	207.8	233.7	12.5%	181.8	13.6%	16.0	-18.0%	30.8	25.2%	5.1	42.2%		
VYVANSE/ELVANSE	132.6	159.3	20.1%	131.9	16.7%	0.2	-	22.5	38.2%	4.7	41.3%		
TRINTELLIX	35.0	40.0	14.6%	37.6	9.6%	2.4	281.6%			—	-100.0%		
INTUNIV	9.0	7.5	-16.8%	-0.0	-	1.8	-58.5%	5.3	33.2%	0.4	62.5%		
ADDERALL XR	9.0	9.6	7.3%	8.7	6.2%	—	-	1.0	18.8%	—	-		
ROZEREM	5.9	6.3	6.3%	0.2	60.6%	6.1	4.9%	0.0	-	0.1	45.5%		
Other *7	16.3	11.0	-32.8%	3.5	-11.6%	5.5	-38.0%	1.9	-43.9%	0.0	-56.2%		
Other *3	291.9	359.8	23.3%										
AZILVA-F *4	39.9	40.4	1.1%	—	-	40.4	1.1%	—	-	—	-		
LOTRIGA	15.7	16.1	2.6%			16.1	2.6%						
AIPHAGAN	7.7	8.4	9.4%	—	-	8.4	9.4%	—	-	—	-		
FOSRENOL *2	6.5	7.0	7.4%	1.3	42.4%							5.7	1.7%
ACTOVEGIN	4.9	6.7	36.3%	—	-	—	-	0.4	74.6%	6.3	34.3%		

*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

*6 Other in PDT Immunology include ARALAST, GLASSIA, CEPROTIN, ANTITHROMBIN III, KENKTSU-NONTHRON and others

*7 Other in Neuroscience include REMINYL, COPAXONE, AZILECT, MYDAYIS, BUCCOLAM, EQUASYM and CARBATROL

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- Quarterly
- Q1

(Bn JPY)	Reported			US	YOY	Japan	YOY	EUCAN	YOY	GEM*5	YOY	Ex-US	YOY
	FY20 Q1	FY21 Q1	YOY										
GI	186.9	210.5	12.6%	117.6	3.3%	25.6	15.9%	47.1	36.1%	16.0	23.6%	4.2	20.5%
ENTYVIO	101.2	125.4	23.9%	83.7	17.1%	2.5	26.6%	32.7	35.6%	6.4	78.9%		
TAKECAB-F *1	20.2	24.3	20.1%	—	-	22.9	15.0%	—	-	1.4	346.2%		
GATTEX/REVESTIVE	17.5	18.1	3.7%	15.2	-1.1%	—	-	2.7	43.5%	0.2	3.6%		
DEXILANT	13.6	10.8	-20.7%	6.0	-31.3%	—	-	2.2	18.3%	2.5	-14.3%		
PANTOLOC/CONTROLOC*2	9.2	10.4	13.8%	0.7	39.8%	—	-	6.7	37.4%	3.1	-19.1%		
LIALDA/MEZAVANT *3	5.5	6.4	16.2%	2.2	8.6%							4.2	20.5%
PENTASA	6.2	4.8	-21.6%	4.8	-21.6%								
AMITIZA	6.3	2.1	-65.8%	2.0	-67.8%			—	-	0.1	133.0%		
RESOLOR/MOTTEGRITY	2.7	3.2	16.9%	2.2	10.2%	—	-	1.0	43.4%	—	-100.0%		
ALOFISEL	0.0	0.4	3,556.0%	—	-	—	-	0.3	4,796.0%	0.1	1,513.3%		
Other	4.5	4.5	0.0%	0.7	-41.8%	0.2	-7.1%	1.5	26.6%	2.1	10.8%		
Rare Diseases	155.0	155.5	0.3%	71.2	-3.9%	7.5	-2.4%	38.6	11.8%	24.1	-9.0%	14.1	15.2%
Rare Metabolic	39.9	44.3	10.9%	9.4	5.5%	0.7	-2.6%	11.8	17.1%	8.3	3.7%	14.1	15.2%
ELAPRASE	17.6	18.6	5.5%	5.0	0.1%	0.4	-5.1%	6.7	13.9%	6.4	2.5%		
REPLAGAL *3	12.2	14.1	15.2%	—	-							14.1	15.2%
VPRIV	9.3	10.5	11.9%	4.4	13.8%	0.3	0.8%	3.9	12.7%	1.8	7.9%		
NATPARA/NATPAR	0.7	1.2	56.8%	-0.0	-	—	-	1.2	64.6%	0.0	45.1%		
Rare Hematology	76.8	72.2	-5.9%	33.3	-0.4%	6.4	-2.6%	18.0	-6.0%	14.6	-17.6%		
ADVATE	33.7	30.7	-8.9%	15.1	-11.1%	1.6	-5.4%	7.1	-13.0%	6.9	0.6%		
ADYNOVATE/ADYNOVI	15.3	15.4	0.6%	6.8	-5.5%	3.7	-3.4%	3.6	6.1%	1.2	50.6%		
FEIBA *4	12.9	11.4	-11.3%	3.9	60.3%	0.2	-8.8%	3.2	-2.3%	4.1	-40.7%		
RECOMBINATE	3.7	3.7	-0.9%	3.5	4.9%	—	-	0.2	-8.0%	0.0	-91.1%		
HEMOFIL/IMMUNATE/IMMUNINE*4	4.4	3.3	-25.6%	0.9	12.8%	—	-	1.0	-36.7%	1.4	-31.4%		
Other PDT Products *4 *6	0.9	0.9	-1.1%	0.0	-	—	-	0.8	15.6%	0.0	-81.4%		
Other *7	5.9	6.9	16.4%	3.1	15.1%	0.9	8.5%	2.1	16.3%	0.8	32.8%		
Hereditary Angioedema	38.3	39.0	1.8%	28.5	-10.1%	0.4	2.9%	8.9	64.8%	1.3	48.2%		
TAKHZYRO	23.2	25.5	9.6%	19.9	-5.7%	—	-	4.9	140.6%	0.6	572.2%		
FIRAZYR	8.1	6.9	-15.1%	3.4	-34.7%	0.4	2.9%	2.6	36.1%	0.5	-15.7%		
CINRYZE *4	5.9	5.6	-5.7%	4.1	-4.9%	—	-	1.3	-5.8%	0.1	-26.9%		
KALBITOR	1.1	1.1	2.8%	1.1	2.8%	—	-	—	-	—	-		

*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

*6 Other PDT products in Rare Hematology include BEBULIN, PROTHROMPLEX and Factor VII.

*7 Other in Rare Hematology include VONVENDI, OBIZUR, RIXUBIS, AGRYLIN/XAGRID and Other Hemophilia.

■ Q1

(Bn JPY)	Reported			US	YOY	Japan	YOY	EUCAN	YOY	GEM*5	YOY	Ex-US	YOY
	FY20 Q1	FY21 Q1	YOY										
PDT Immunology	105.3	107.2	1.8%	70.3	-5.4%							36.9	19.2%
immunoglobulin *1	85.1	81.6	-4.1%	59.0	-10.7%							22.6	19.0%
albumin *1	13.0	17.8	36.8%	5.3	100.9%							12.5	20.6%
Other *1 *6	7.2	7.8	9.1%	6.0	7.8%							1.8	13.5%
Oncology	108.0	121.4	12.4%	60.4	20.7%	21.0	-11.0%	21.2	15.4%	16.6	23.7%	2.1	-15.9%
VELCADE *2	24.2	30.1	24.6%	29.4	27.3%							0.8	-30.8%
LEUPLIN/ENANTONE	27.4	26.2	-4.3%	4.8	128.5%	7.5	-41.4%	9.7	17.7%	4.2	-1.7%		
NINLARO	22.9	24.4	6.3%	15.4	-1.3%	1.5	19.3%	3.5	3.5%	4.1	46.0%		
ADCETRIS	15.1	17.2	14.2%			2.8	-2.4%	7.0	13.2%	7.5	22.9%		
ICLUSIG *2	9.2	10.4	12.3%	9.1	15.0%							1.3	-3.6%
VECTIBIX	6.2	6.2	0.1%			6.2	0.1%						
ALUNBRIG	2.0	3.1	54.4%	1.7	18.0%	0.2	-	0.8	89.6%	0.4	160.4%		
Other	0.9	3.8	300.0%	0.1	-	2.8	418.7%	0.3	25.9%	0.5	231.1%		
Neuroscience	106.9	113.4	6.1%	87.3	8.7%	7.5	-39.9%	15.9	37.0%	2.8	10.1%		
VYVANSE/ELVANSE	66.0	79.2	20.0%	65.2	16.6%	0.0	-	11.5	48.3%	2.5	7.8%		
TRINTELLIX	16.9	17.9	5.9%	16.7	0.9%	1.1	273.0%						
INTUNIV	5.6	3.3	-42.5%	-0.0	-	0.4	-89.1%	2.7	44.6%	0.2	59.1%		
ADDERALL XR	5.3	3.9	-24.9%	3.5	-27.5%			0.4	4.0%				
ROZEREM	3.0	3.2	6.9%	0.1	485.1%	3.1	4.1%			0.0	8.5%		
Other *7	10.0	5.9	-41.2%	1.8	-29.7%	2.9	-51.1%	1.2	-21.7%	0.0	-51.2%		
Other *3	139.8	241.6	72.8%										
AZILVA-F *4	20.9	22.6	8.6%			22.6	8.6%						
LOTRIGA	8.1	7.8	-3.0%			7.8	-3.0%						
AIPHAGAN	4.0	4.6	15.0%			4.6	15.0%						
FOSRENOL *2	3.2	3.4	4.7%	0.5	-30.2%							2.8	15.9%
ACTOVEGIN	1.7	3.2	87.2%					0.2	222.9%	3.0	81.8%		

*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

*6 Other in PDT Immunology include ARALAST, GLASSIA, CEPROTIN, ANTITHROMBIN III, KENKTSU-NONTHRON and others

*7 Other in Neuroscience include REMINYL, COPAXONE, AZILECT, MYDAYIS, BUCCOLAM, EQUASYM and CARBATROL

■ Q2

(Bn JPY)	Reported			US	YOY	Japan	YOY	EUCAN	YOY	GEM*5	YOY	Ex-US	YOY
	FY20 Q2	FY21 Q2	YOY										
GI	192.9	218.6	13.3%	123.2	11.3%	26.3	21.9 %	48.0	16.7 %	17.2	8.3%	3.9	6.5%
ENTYVIO	105.7	130.5	23.4%	87.6	22.3%	2.9	42.1 %	33.9	23.7 %	6.2	31.5%		
TAKECAB-F *1	19.7	24.8	25.9%	—	-	23.1	19.2 %	—	-	1.7	413.4%		
GATTEX/REVESTIVE	15.7	18.7	18.8%	15.4	16.1%	0.1	-	2.6	14.3 %	0.6	176.0%		
DEXILANT	14.8	14.9	0.8%	8.7	-4.1%	—	-	2.6	11.7 %	3.6	6.6%		
PANTOLOC/CONTROLOC*2	12.3	9.4	-23.4%	0.4	-22.4%	—	-	6.1	-5.9 %	2.9	-45.2%		
LIALDA/MEZAVANT *3	6.1	5.3	-13.1%	1.4	-42.9%							3.9	6.5%
PENTASA	5.5	5.2	-5.6%	5.2	-5.6%								
AMITIZA	6.2	1.8	-71.6%	1.5	-75.5%			—	-	0.3	92.2%		
RESOLOR/MOTTEGRITY	2.2	3.2	43.3%	2.4	68.4%	—	-	0.8	1.8 %	—	-100.0%		
ALOFISEL	0.3	0.4	52.2%	—	-	—	-	0.3	43.9 %	0.1	93.5%		
Other	4.3	4.3	-0.0%	0.7	-13.9%	0.2	-0.4 %	1.6	1.9 %	1.9	4.4%		
Rare Diseases	140.4	144.6	3.0%	62.1	-2.1%	6.6	-17.3 %	37.8	9.2 %	26.2	21.4%	11.9	-7.0%
Rare Metabolic	39.7	40.0	0.6%	9.1	1.6%	0.3	-62.8 %	12.0	12.1 %	6.7	1.9%	11.9	-7.0%
ELAPRASE	16.7	16.2	-2.8%	4.9	-6.0%	-0.1	-	6.7	7.4 %	4.6	-4.5%		
REPLAGAL *3	12.8	11.9	-7.0%	—	-							11.9	-7.0%
VPRIV	9.5	10.5	11.0%	4.2	6.7%	0.3	-9.8 %	4.0	13.5 %	2.1	19.7%		
NATPARA/NATPAR	0.8	1.3	72.1%	0.0	-	—	-	1.3	39.0 %	0.0	7.6%		
Rare Hematology	66.1	69.4	5.0%	28.1	-0.1%	6.0	-13.0 %	17.1	-0.9 %	18.2	31.9%		
ADVATE	29.8	30.6	2.9%	13.3	-4.0%	1.4	-13.7 %	7.1	-13.9 %	8.8	46.9%		
ADYNOVATE/ADYNOVI	14.2	14.6	2.6%	6.5	11.4%	3.6	-12.5 %	3.2	-5.3 %	1.4	41.0%		
FEIBA *4	7.7	8.8	13.7%	2.2	-13.5%	0.2	-23.3 %	2.8	39.2 %	3.6	22.7%		
RECOMBINATE	3.2	2.6	-18.5%	2.4	-13.2%	—	-	0.2	-39.5 %	0.0	-76.2%		
HEMOFIL/IMMUNATE/IMMUNINE*4	4.9	5.1	3.0%	0.8	-19.5%	—	-	1.3	32.8 %	3.0	1.2%		
Other PDT Products *4 *6	0.8	1.1	31.3%	0.0	-	—	-	0.9	19.5 %	0.2	124.3%		
Other *7	5.4	6.6	22.5%	2.8	38.2%	0.8	-11.7 %	1.7	2.3 %	1.3	62.7%		
Hereditary Angioedema	34.6	35.2	1.8%	24.9	-5.4%	0.4	-12.9 %	8.7	30.3 %	1.3	7.2%		
TAKHZYRO	20.5	22.1	7.6%	16.6	-2.2%	—	-	5.0	56.7 %	0.4	36.7%		
FIRAZYR	7.1	7.5	5.9%	4.1	7.1%	0.4	-12.9 %	2.4	14.7 %	0.6	-13.8%		
CINRYZE *4	6.1	4.6	-24.3%	3.1	-31.9%	—	-	1.3	-6.5 %	0.2	54.2%		
KALBITOR	0.9	1.1	14.0%	1.1	14.0%	—	-	—	-	—	-		

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

*2 generic name: pantoprazole

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

*4 PDT products

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

*6 Other PDT products in Rare Hematology include BEBULIN, PROTHROMPLEX and Factor VII.

*7 Other in Rare Hematology include VONVENDI, OBIZUR, RIXUBIS, AGRYLIN/XAGRID and Other Hemophilia.

■ Q2

(Bn JPY)	Reported			US	YOY	Japan	YOY	EUCAN	YOY	GEM*5	YOY	Ex-US	YOY
	FY20 Q1	FY21 Q1	YOY										
PDT Immunology	100.6	130.8	30.0%	86.8	28.9%							44.0	32.3%
immunoglobulin *1	77.6	99.7	28.6%	76.5	32.1%							23.2	18.1%
albumin *1	15.6	24.0	53.8%	4.7	28.0%							19.3	61.7%
Other *1 *6	7.5	7.1	-4.6%	5.7	-2.8%							1.5	-11.2%
Oncology	102.1	112.3	10.0%	51.0	0.8%	21.7	21.8%	19.1	4.6%	18.2	40.2%	2.2	-4.4%
VELCADE *2	25.8	25.0	-3.3%	24.1	-1.8%							0.9	-31.7%
LEUPLIN/ENANTONE	22.5	27.6	23.0%	7.0	85.4%	7.6	1.5%	7.2	-0.9%	5.9	47.5%		
NINLARO	21.4	21.4	0.0%	12.0	-15.4%	1.5	25.6%	3.5	11.1%	4.5	53.4%		
ADCETRIS	15.5	16.9	9.3%			2.9	3.5%	7.2	1.9%	6.8	21.5%		
ICLUSIG *2	7.6	7.5	-1.6%	6.2	-6.6%							1.3	30.9%
VECTIBIX	5.7	6.6	15.0%			6.6	15.0%						
ALUNBRIG	2.3	3.1	38.8%	1.4	-8.0%	0.3	-	0.9	72.7%	0.5	162.1%		
Other	1.3	4.1	225.6%	0.4	-	2.9	315.5%	0.4	11.4%	0.5	95.0%		
Neuroscience	100.9	120.3	19.2%	94.6	18.4%	8.5	21.1%	14.9	14.6%	2.3	117.6%		
VYVANSE/ELVANSE	66.6	80.1	20.2%	66.7	16.8%	0.2	-	11.0	29.0%	2.1	126.2%		
TRINTELLIX	18.1	22.2	22.7%	20.9	17.7%	1.3	289.6%			—	-100.0%		
INTUNIV	3.3	4.2	26.6%	0.0	-78.6%	1.4	44.8%	2.6	23.0%	0.2	66.1%		
ADDERALL XR	3.7	5.7	52.9%	5.2	54.8%	—	-	0.5	35.9%	—	-		
ROZEREM	2.9	3.1	5.7%	0.1	-13.4%	3.0	5.8%	0.0	-	0.0	91.5%		
Other *7	6.3	5.1	-19.3%	1.7	21.4%	2.6	-11.0%	0.8	-60.7%	—	-100.0%		
Other *3	152.0	118.2	-22.3%										
AZILVA-F *4	19.1	17.7	-7.2%	—	-	17.7	-7.2%	—	-	—	-		
LOTRIGA	7.6	8.2	8.5%			8.2	8.5%						
AIPHAGAN	3.7	3.8	3.3%	—	-	3.8	3.3%	—	-	—	-		
FOSRENOL *2	3.3	3.6	9.9%	0.7	479.3%							2.9	-9.1%
ACTOVEGIN	3.2	3.5	8.8%	—	-	—	-	0.2	20.0%	3.3	8.1%		

*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

*6 Other in PDT Immunology include ARALAST, GLASSIA, CEPROTIN, ANTITHROMBIN III, KENKTSU-NONTHRON and others

*7 Other in Neuroscience include REMINYL, COPAXONE, AZILECT, MYDAYIS, BUCCOLAM, EQUASYM and CARBATROL

Product Sales Analysis (Reported & Underlying Growth)

(Bn JPY)	FY20 Reported				FY21 Reported & Underlying Growth															
	Q1	Q2	Q3	Q4	YOY			YOY				YOY				YOY				
					Q1	Reported	Underlying	Q2	Reported	Underlying	YTD Underlying	Q3	Reported	Underlying	YTD Underlying	Q4	Reported	Underlying	YTD Underlying	
GI	186.9	192.9	209.0	189.0	210.5	12.6%	7.9%	218.6	13.3%	8.7%	8.3%									
ENTYVIO	101.2	105.7	112.3	110.0	125.4	23.9%	18.2%	130.5	23.4%	18.1%	18.1%									
TAKECAB-F *1	20.2	19.7	24.2	20.7	24.3	20.1%	19.5%	24.8	25.9%	25.2%	22.3%									
GATTEX/REVESTIVE	17.5	15.7	16.9	14.4	18.1	3.7%	0.3%	18.7	18.8%	14.1%	6.9%									
DEXILANT	13.6	14.8	15.1	12.1	10.8	-20.7%	-24.6%	14.9	0.8%	-4.8%	-14.3%									
PANTOLOC/CONTROLOC*2	9.2	12.3	10.9	10.7	10.4	13.8%	4.4%	9.4	-23.4%	-28.1%	-14.0%									
LIALDA/MEZAVANT	5.5	6.1	7.1	6.8	6.4	16.2%	7.0%	5.3	-13.1%	-18.5%	-6.3%									
PENTASA	6.2	5.5	6.2	5.3	4.8	-21.6%	-23.2%	5.2	-5.6%	-9.0%	-16.4%									
AMITIZA	6.3	6.2	6.4	2.4	2.1	-65.8%	-66.5%	1.8	-71.6%	-72.7%	-69.6%									
RESOLOR/MOTTEGRITY	2.7	2.2	3.6	2.7	3.2	16.9%	11.4%	3.2	43.3%	37.0%	22.8%									
ALOFISEL	0.0	0.3	0.3	0.2	0.4	3,556.0%	3,222.0%	0.4	52.2%	42.8%	166.8%									
Other	4.5	4.3	6.1	3.7	4.5	0.0%	-6.2%	4.3	-0.0%	-4.2%	-5.2%									
Rare Diseases	155.0	140.4	151.3	145.0	155.5	0.3%	-3.5%	144.6	3.0%	-0.7%	-2.2%									
Rare Metabolic	39.9	39.7	42.2	40.8	44.3	10.9%	6.6%	40.0	0.6%	-2.5%	2.1%									
ELAPRASE	17.6	16.7	17.2	17.3	18.6	5.5%	2.5%	16.2	-2.8%	-5.8%	-1.5%									
REPLAGAL	12.2	12.8	13.9	12.9	14.1	15.2%	10.2%	11.9	-7.0%	-9.6%	0.2%									
VPRIV	9.3	9.5	10.0	9.7	10.5	11.9%	6.9%	10.5	11.0%	7.6%	7.2%									
NATPARA/NATPAR	0.7	0.8	1.0	1.0	1.2	56.8%	39.1%	1.3	72.1%	61.5%	50.4%									
Rare Hematology	76.8	66.1	75.8	71.2	72.2	-5.9%	-9.6%	69.4	5.0%	1.1%	-4.6%									
ADVATE	33.7	29.8	33.7	31.4	30.7	-8.9%	-12.9%	30.6	2.9%	-1.5%	-7.6%									
ADYNOVATE/ADYNOVI	15.3	14.2	14.3	14.3	15.4	0.6%	-3.3%	14.6	2.6%	-0.9%	-2.1%									
FEIBA *3	12.9	7.7	13.7	10.3	11.4	-11.3%	-12.6%	8.8	13.7%	10.1%	-4.0%									
RECOMBINATE	3.7	3.2	3.5	2.9	3.7	-0.9%	-3.7%	2.6	-18.5%	-21.6%	-12.0%									
HEMOFIL/IMMUNATE/ IMMUNINE*3	4.4	4.9	3.9	5.4	3.3	-25.6%	-29.4%	5.1	3.0%	2.4%	-13.1%									
Other PDT Products *3 *4	0.9	0.8	0.9	0.9	0.9	-1.1%	-10.2%	1.1	31.3%	24.6%	6.4%									
Other *5	5.9	5.4	5.8	6.0	6.9	16.4%	10.4%	6.6	22.5%	17.2%	13.6%									
Hereditary Angioedema	38.3	34.6	33.4	33.0	39.0	1.8%	-1.7%	35.2	1.8%	-2.2%	-1.9%									
TAKHZYRO	23.2	20.5	22.1	20.8	25.5	9.6%	6.0%	22.1	7.6%	3.2%	4.7%									
FIRAZYR	8.1	7.1	5.0	6.7	6.9	-15.1%	-18.3%	7.5	5.9%	2.1%	-8.8%									
CINRYZE *3	5.9	6.1	5.2	4.6	5.6	-5.7%	-9.2%	4.6	-24.3%	-27.3%	-18.4%									
KALBITOR	1.1	0.9	1.1	0.8	1.1	2.8%	0.8%	1.1	14.0%	9.9%	5.1%									

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

*2 Generic name: pantoprazole

*3 PDT products

*4 Other PDT products in Rare Hematology include BEBULIN, PROTHROMPLEX and Factor VII.

*5 Other in Rare Hematology include VONVENDI, OBIZUR, RIXUBIS, AGRYLIN/XAGRI and Other Hemophilia.

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(Bn JPY)	FY20 Reported				FY21 Reported & Underlying Growth														
	Q1	Q2	Q3	Q4	YOY			YOY				YOY				YOY			
					Q1	Reported	Underlying	Q2	Reported	Underlying	YTD Underlying	Q3	Reported	Underlying	YTD Underlying	Q4	Reported	Underlying	YTD Underlying
PDT Immunology	105.3	100.6	107.1	107.3	107.2	1.8%	-1.8%	130.8	30.0%	24.6%	11.1%								
immunoglobulin *1	85.1	77.6	85.4	86.8	81.6	-4.1%	-6.9%	99.7	28.6%	24.2%	8.0%								
albumin *1	13.0	15.6	15.0	14.0	17.8	36.8%	26.4%	24.0	53.8%	42.2%	35.0%								
Other *1 *4	7.2	7.5	6.7	6.5	7.8	9.1%	6.0%	7.1	-4.6%	-8.1%	-1.2%								
Oncology	108.0	102.1	108.4	98.0	121.4	12.4%	8.9%	112.3	10.0%	6.5%	7.8%								
VELCADE	24.2	25.8	25.9	25.2	30.1	24.6%	22.1%	25.0	-3.3%	-6.7%	7.1%								
LEUPLIN/ENANTONE	27.4	22.5	25.4	20.1	26.2	-4.3%	-8.8%	27.6	23.0%	18.8%	3.6%								
NINLARO	22.9	21.4	23.5	19.5	24.4	6.3%	2.0%	21.4	0.0%	-4.4%	-1.1%								
ADCETRIS	15.1	15.5	13.8	15.0	17.2	14.2%	8.8%	16.9	9.3%	5.7%	7.2%								
ICLUSIG	9.2	7.6	9.4	7.9	10.4	12.3%	10.0%	7.5	-1.6%	-5.0%	3.2%								
VECTIBIX	6.2	5.7	6.5	5.4	6.2	0.1%	0.1%	6.6	15.0%	15.0%	7.3%								
ALUNBRIG	2.0	2.3	2.2	2.3	3.1	54.4%	47.3%	3.1	38.8%	33.0%	39.7%								
Other	0.9	1.3	1.7	2.4	3.8	300.0%	495.2%	4.1	225.6%	278.1%	357.6%								
Neuroscience	106.9	100.9	107.3	102.2	113.4	6.1%	2.9%	120.3	19.2%	15.7%	9.1%								
VYVANSE/ELVANSE	66.0	66.6	69.8	69.1	79.2	20.0%	15.6%	80.1	20.2%	14.9%	15.2%								
TRINTELLIX	16.9	18.1	17.7	16.2	17.9	5.9%	4.0%	22.2	22.7%	18.7%	11.6%								
INTUNIV	5.6	3.3	5.9	5.6	3.3	-42.5%	-49.5%	4.2	26.6%	17.8%	-25.1%								
ADDERALL XR	5.3	3.7	4.4	4.4	3.9	-24.9%	-27.4%	5.7	52.9%	46.8%	3.5%								
ROZEREM	3.0	2.9	3.6	2.5	3.2	6.9%	7.1%	3.1	5.7%	5.9%	6.5%								
Other *5	10.0	6.3	6.0	4.4	5.9	-41.2%	-41.1%	5.1	-19.3%	-3.5%	-27.7%								
Other *2	139.8	152.0	153.5	128.7	241.6	72.8%	9.5%	118.2	-22.3%	10.0%	9.7%								
AZILVA-F *3	20.9	19.1	22.9	19.4	22.6	8.6%	8.6%	17.7	-7.2%	-7.2%	1.1%								
LOTRIGA	8.1	7.6	8.8	7.3	7.8	-3.0%	-3.0%	8.2	8.5%	8.2%	2.4%								
AIPHAGAN	4.0	3.7	4.6	3.7	4.6	15.0%	15.0%	3.8	3.3%	3.3%	9.4%								
FOSRENOL	3.2	3.3	3.7	3.3	3.4	4.7%	-3.2%	3.6	9.9%	4.5%	0.7%								
ACTOVEGIN	1.7	3.2	3.4	2.4	3.2	87.2%	83.3%	3.5	8.8%	3.8%	31.8%								

*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 Other in PDT Immunology include ARALAST, GLASSIA, CEPROTIN, ANTITHROMBIN III, KENKTSU-NONTHRON and others

*5 Other in Neuroscience include REMINYL, COPAXONE, AZILECT, MYDAYIS, BUCCOLAM, EQUASYM and CARBATROL

Product Forecasts

(Bn JPY)	FY20 Reported	Disclosed on May 11, 2021				FY21 Underlying Growth Forecasts	Disclosed on October 28, 2021			
		FY21 Reported Forecasts			Annual		FY21 Reported Forecasts			Annual
		Annual	YOY				Annual	YOY		
GI	777.8	878.0	100.2	13 %	10%	870.0	92.2	12 %	9%	
ENTYVIO	429.3	538.0	108.7	25 %	22 %	538.0	108.7	25 %	22 %	
TAKECAB-F *1	84.8	94.0	9.2	11 %	11 %	100.0	15.2	18 %	17 %	
GATTEX/REVESTIVE	64.6	79.0	14.4	22 %	20 %	74.0	9.4	15 %	12 %	
DEXILANT	55.6	54.0	-1.6	-3 %	-6 %	42.0	-13.6	-24 %	-27 %	
PANTOLOC/ CONTROLOC*2	43.1	37.0	-6.1	-14 %	-19 %	37.0	-6.1	-14 %	-19 %	
LIALDA/MEZAVANT	25.5	19.0	-6.5	-25 %	-25 %	19.0	-6.5	-25 %	-25 %	
PENTASA	23.1	19.0	-4.1	-18 %	-20 %	19.0	-4.1	-18 %	-20 %	
AMITIZA	21.2	5.0	-16.2	-76 %	-79 %	5.0	-16.2	-76 %	-79 %	
RESOLOR/MOTEGRITY	11.2	12.0	0.8	7 %	-1 %	12.0	0.8	7 %	-1 %	
ALOFISEL	0.8	3.0	2.2	283 %	238 %	3.0	2.2	283 %	238 %	
Other	18.6	18.0	-0.6	-3 %	-8 %	21.0	2.4	13 %	6 %	
Rare Diseases	591.7									
Rare Metabolic	162.6	173.0	10.4	6 %	2%	173.0	10.4	6 %	2%	
ELAPRASE	68.8	71.0	2.2	3 %	-1 %	71.0	2.2	3 %	-1 %	
REPLAGAL	51.8	56.0	4.2	8 %	3 %	56.0	4.2	8 %	3 %	
VPRIV	38.5	41.0	2.5	6 %	5 %	41.0	2.5	6 %	5 %	
NATPARANATPAR	3.6	5.0	1.4	41 %	38 %	5.0	1.4	41 %	38 %	
Rare Hematology	289.8	273.0	-16.8	-6 %	-10%	273.0	-16.8	-6 %	-10%	
ADVATE	128.5									
ADYNOVATE/ ADYNOVI	58.1	176.0	-10.6	-6 %	-10 %	176.0	-10.6	-6 %	-10 %	
FEIBA *3	44.5	35.0	-9.5	-21 %	-26 %	35.0	-9.5	-21 %	-26 %	
RECOMBINATE	13.4	12.0	-1.4	-10 %	-10 %	12.0	-1.4	-10 %	-10 %	
HEMOFIL/IMMUNATE/ IMMUNINE*3	18.7	17.0	-1.7	-9 %	-13 %	17.0	-1.7	-9 %	-13 %	
Other PDT Products *3 *4	3.5	5.0	1.5	44 %	41 %	5.0	1.5	44 %	41 %	
Other *5	23.2	28.0	4.8	21 %	15 %	28.0	4.8	21 %	15 %	
Hereditary Angioedema	139.3		0% to +10%		0% to +10%		0% to +10%		0% to +10%	
TAKHZYRO	86.7		+20% to +30%		+20% to +30%		+20% to +30%		+20% to +30%	
FIRAZYR	26.8	15.0	-11.8	-44 %	-46 %	21.0	-5.8	-22 %	-24 %	
CINRYZE *3	21.9	17.0	-4.9	-22 %	-23 %	17.0	-4.9	-22 %	-23 %	
KALBITOR	3.9	2.0	-1.9	-49 %	-40 %	2.0	-1.9	-49 %	-40 %	

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

*2 Generic name: pantoprazole

*3 PDT products

*4 Other PDT products in Rare Hematology include BEBULIN, PROTHROMPLEX and Factor VII.

*5 Other in Rare Hematology include VONVENDI, OBIZUR, RIXUBIS, AGRYLIN/XAGRID, OCTOFACTOR, COAGIL-VII, INNONAFACOR, and Other Hemophilia.

Average FX rates for FY2020: 1 USD = 106 JPY, 1 Euro = 123 JPY, 1 RUB = 1.4 JPY, 1 BRL = 19.6 JPY, 1 CNY = 15.5 JPY

Assumption of FX rates for FY2021 Reported Forecasts: 1 USD = 108 JPY, 1 Euro = 131 JPY, 1 RUB = 1.4 JPY, 1 BRL = 19.9 JPY, 1 CNY = 16.8 JPY

Assumption of FX rates for FY2021 Underlying Forecasts: 1 USD = 106 JPY, 1 Euro = 123 JPY, 1 RUB = 1.4 JPY, 1 BRL = 19.6 JPY, 1 CNY = 15.5 JPY

(Bn JPY)	FY20 Reported	Disclosed on May 11, 2021				Disclosed on October 28, 2021			
		FY21 Reported Forecasts			FY21 Underlying Growth Forecasts	FY21 Reported Forecasts			FY21 Underlying Growth Forecasts
		Annual	YOY			Annual	YOY		
PDT Immunology	420.4	+10% to +20%			+10% to +20%	+10% to +20%			+10% to +20%
immunoglobulin *1	334.9	+5% to +10%			+5% to +10%	+5% to +10%			+5% to +10%
albumin *1	57.6	+>30%			+>30%	+>30%			+>30%
Other *1 *4	27.9	0% to +10%			0% to +10%	0% to +10%			0% to +10%
Oncology	416.5	455.0	38.5	9%	7%	461.0	44.5	11%	8%
VELCADE	101.1	83.0	-18.1	-18%	-20%	95.0	-6.1	-6%	-7%
LEUPLIN/ENANTONE	95.4	104.0	8.6	9%	7%	104.0	8.6	9%	7%
NINLARO	87.4	97.0	9.6	11%	8%	93.0	5.6	6%	4%
ADCETRIS	59.4	70.0	10.6	18%	14%	70.0	10.6	18%	14%
ICLUSIG	34.2	39.0	4.8	14%	11%	39.0	4.8	14%	11%
VECTIBIX	23.8	22.0	-1.8	-8%	-7%	22.0	-1.8	-8%	-7%
ALUNBRIG	8.8	16.0	7.2	82%	80%	16.0	7.2	82%	80%
Other	6.4	24.0	17.6	276%	256%	22.0	15.6	245%	226%
Neuroscience	417.3	434.0	16.7	4%	2%	450.0	32.7	8%	6%
VYVANSE/ELVANSE	271.5	293.0	21.5	8%	5%	309.0	37.5	14%	11%
TRINTELLIX	68.9	82.0	13.1	19%	17%	82.0	13.1	19%	17%
INTUNIV	20.4	17.0	-3.4	-17%	-20%	17.0	-3.4	-17%	-20%
ADDERALL XR	17.8	10.0	-7.8	-44%	-45%	13.0	-4.8	-27%	-28%
ROZEREM	12.0	11.0	-1.0	-8%	-3%	11.0	-1.0	-8%	-3%
Other *5	26.7	21.0	-5.7	-21%	-17%	18.0	-8.7	-33%	-30%
Other *2	574.1	-10% to 0%			-10% to 0%	-10% to 0%			-10% to 0%
AZILVA-F *3	82.2	68.0	-14.2	-17%	-16%	68.0	-14.2	-17%	-16%
LOTRIGA	31.8	29.0	-2.8	-9%	-8%	29.0	-2.8	-9%	-8%
AIPHAGAN	15.9	12.0	-3.9	-25%	-22%	12.0	-3.9	-25%	-22%
FOSRENOL	13.5	11.0	-2.5	-18%	-17%	11.0	-2.5	-18%	-17%
ACTOVEGIN	10.7	11.0	0.3	3%	7%	11.0	0.3	3%	7%

*1 PDT products

*2 The 133.0 billion JPY selling price of the sale of diabetes portfolio in Japan is included in FY21 Reported.

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

*4 Other in PDT Immunology include ARALAST, GLASSIA, CEPROTIN, ANTITHROMBIN III, KENKTSU-NONTHRON and others

*5 Other in Neuroscience include REMINYL, COPAXONE, AZILECT, MYDAYIS, BUCCOLAM, EQUASYM and CARBATROL

Average FX rates for FY2020: 1 USD = 106 JPY, 1 Euro = 123 JPY, 1 RUB = 1.4 JPY, 1 BRL = 19.6 JPY, 1 CNY = 15.5 JPY

Assumption of FX rates for FY2021 Reported Forecasts: 1 USD = 108 JPY, 1 Euro = 131 JPY, 1 RUB = 1.4 JPY, 1 BRL = 19.9 JPY, 1 CNY = 16.8 JPY

Assumption of FX rates for FY2021 Underlying Forecasts: 1 USD = 106 JPY, 1 Euro = 123 JPY, 1 RUB = 1.4 JPY, 1 BRL = 19.6 JPY, 1 CNY = 15.5 JPY

Exchange Rate

No changes in FY21 currency assumptions and impact of 1% depreciation of yen from April 2021 to March 2022 from those disclosed on May 11, 2021

(yen)				(100 million yen)			
Average Exchange Rates vs. JPY				Impact of 1% depreciation of yen from April 2021 to March 2022 (Disclosed on May 11, 2021)			
CURRENCY	FY20Q2 YTD (Apr-Sep)	FY21Q2 YTD (Apr-Sep)	FY21 Assumption (Apr-Mar) (Disclosed on May 11, 2021)	Revenue	Core Operating Profit	Operating Profit	Net Profit
USD	107	110	108	+170.7	+69.2	+29.4	+16.7
EUR	121	131	131	+45.0	-19.5	-31.4	-27.0
RUB	1.5	1.5	1.4	+3.7	+2.5	+2.1	+1.7
CNY	15.2	17.0	16.8	+10.7	+6.0	+5.9	+4.4
BRL	20.1	20.9	19.9	+5.8	+3.8	+3.7	+2.5

CAPEX, depreciation and amortization and impairment losses

No changes in FY21 Forecasts for capex, depreciation and amortization and impairment losses from those disclosed on May 11, 2021

(Bn JPY)	FY20	FY20Q2 YTD	FY21Q2 YTD	YOY		FY21 Forecasts (Disclosed on May 11, 2021)
Capital expenditures*	236.5	80.9	85.8	4.9	6.0%	210.0 -260.0
Tangible assets	111.2	50.5	60.6	10.1	20.1%	
Intangible assets	125.3	30.4	25.2	-5.2	-17.2%	
* Cash flow base						
Depreciation and amortization	558.0	280.5	281.9	1.4	0.5%	556.0
Depreciation of tangible assets* (A)	124.4	63.2	65.2	2.0	3.1%	
Amortization of intangible assets (B)	433.6	217.3	216.7	-0.6	-0.3%	
Of which Amortization associated with products (C)	405.3	206.0	204.1	-1.9	-0.9%	406.0
Of which Amortization excluding intangible assets associated with products (D)	28.3	11.3	12.6	1.3	11.6%	
* Excluding depreciation for investment assets.						
Depreciation and amortization (excluding intangible assets associated with products) (A)+(D)	152.7	74.5	77.8	3.3	4.4%	150.0
Impairment losses	25.5	8.3	1.5	-6.8	-82.1%	
Impairment losses associated with products	16.6	2.1	1.5	-0.7	-30.9%	50.0
Amortization and impairment losses on intangible assets associated with products	421.9	208.1	205.5	-2.6	-1.2%	456.0

3. Reconciliation

FY2021 H1 Reconciliation from Reported Revenue to Core/Underlying Revenue

(Billion JPY)	H1		vs. PY	
	FY2020	FY2021		
Reported Revenue	1,590.8	1,794.4	+203.6	+ 12.8%
Sale of Japan diabetes portfolio* ²	—	(133.0)	(133.0)	-8.4pp
Core Revenue	1,590.8	1,661.4	+70.6	+ 4.4%
FX effects* ¹				-3.9pp
Divestitures* ²				+6.3pp
Regional portfolio				+4.6pp
Japan diabetes portfolio				+1.0pp
TACHOSIL				+0.5pp
Others				+0.2pp
Underlying Revenue Growth				+ 6.8%

*1 FX adjustment applies plan rate to both periods.

*2 Major adjustments are as follows:

- Revenue of select over-the-counter and non-core products in Asia Pacific is excluded from FY2020 H1 as the divestiture was completed in November 2020.
- Revenue of select non-core prescription pharmaceutical products predominantly in Europe is excluded from FY2020 H1 as the divestiture was completed in December 2020.
- Revenue of select over-the-counter and non-core products in Latin America is excluded from FY2020 H1 as the divestiture was completed in January 2021.
- Net sales from TACHOSIL, a surgical patch, are excluded from FY2020 H1 as the divestiture was completed in January 2021.
- Revenue of select over-the-counter and non-core products predominantly in Europe is excluded from FY2020 H1 as the divestiture was completed in March 2021.
- Revenue of the former subsidiary, Takeda Consumer Healthcare Company Limited is excluded from FY2020 H1 as the divestiture was completed in March 2021.
- Net sales from a portfolio of diabetes products in Japan (NESINA, LIOVEL, INISYNC and ZAFATEK) are excluded from FY2020 H1 as the divestiture was completed at the beginning of April 2021. In addition, the non-recurring item of the 133.0 billion JPY selling price as the result of the completion of the divestiture is excluded from FY2021 H1.
- Revenue of select non-core prescription pharmaceutical products in China is excluded from both FY2021 H1 and FY2020 H1 as the divestiture was publicly announced and had been expected to complete within FY2021 H1. It is now expected to complete in FY2021 H2.

FY2021 H1 Reconciliation from Reported to Core/Underlying Core
FY2021 H1

(Billion JPY)	REPORTED	REPORTED TO CORE ADJUSTMENTS						CORE	CORE TO UNDERLYING CORE ADJ.		UNDERLYING GROWTH
		Amortization of intangible assets	Impairment of intangible assets	Other operating income/expenses	Sale of Japan diabetes portfolio	Irish Tax Assessment *1	Others		FX	Divestitures	
Revenue	1,794.4				(133.0)			1,661.4	(64.8)	(8.9)	+6.8 %
Cost of sales	(517.1)				0.6		22.3	(494.1)	21.8	2.6	
Gross Profit	1,277.4				(132.4)		22.3	1,167.2	(43.0)	(6.2)	
SG&A expenses	(431.9)				1.0		2.1	(428.7)	17.0		
R&D expenses	(254.1)						1.3	(252.8)	8.7		
Amortization of intangible assets	(204.1)	204.1						—			
Impairment losses on intangible assets	(1.5)		1.5					—			
Other operating income	19.5			(18.8)			(0.7)	—			
Other operating expenses	(59.4)			59.4				—			
Operating profit	346.0	204.1	1.5	40.6	(131.4)		25.0	485.7	(17.2)	(6.2)	+6.4 %
Margin	19.3 %							29.2 %			29.1 %*2
Financial income/expenses	(58.0)						(0.4)	(58.5)	5.2		
Equity income/loss	(3.5)						6.4	2.8	0.1		
Profit before tax	284.4	204.1	1.5	40.6	(131.4)		31.0	430.1	(11.9)	(6.2)	
Tax expenses	(100.7)	(45.5)	(0.5)	(11.5)	40.2	63.7	(39.9)	(94.2)	2.5	1.9	
Non-controlling interests	(0.1)							(0.1)	—		
Net profit	183.6	158.6	0.9	29.2	(91.2)	63.7	(9.0)	335.9	(9.4)	(4.3)	
EPS (yen)	117							214	(5)	(3)	+9.1 %
Number of shares (millions)	1,568							1,568			1,563

*1 A tax charge of 63.7 billion JPY for tax and interest, net of 0.5 billion JPY of associated tax benefit, arising from tax assessment involving Irish taxation of the break fee Shire received from AbbVie in connection with the terminated offer to acquire Shire made by AbbVie in 2014.

*2 Underlying Core Operating Profit Margin.

FY2020 H1 Reconciliation from Reported to Core/ Underlying Core
FY2020 H1

(Billion JPY)	REPORTED	REPORTED TO CORE ADJUSTMENTS					CORE	CORE TO UNDERLYING CORE ADJ.		UNDERLYING GROWTH
		Amortization of intangible assets	Impairment of intangible assets	Other operating income/expenses	TEVA JV related accounting adjustments	Others		FX	Divestitures	
Revenue	1,590.8						1,590.8	(2.6)	(102.2)	+0.5 %
Cost of sales	(487.7)					47.3	(440.4)	(7.7)	28.5	
Gross Profit	1,103.1					47.3	1,150.4	(10.4)	(73.7)	
SG&A expenses	(418.6)			0.0		(0.6)	(419.2)	2.0	7.8	
R&D expenses	(225.0)			(0.2)		1.6	(223.6)	0.9	0.4	
Amortization of intangible assets	(206.0)	206.0					—			
Impairment losses on intangible assets	(2.1)		2.1				—			
Other operating income	69.5			(8.6)	(0.7)	(60.2)	—			
Other operating expenses	(105.2)			86.7		18.6	—			
Operating profit	215.6	206.0	2.1	78.0	(0.7)	6.7	507.6	(7.4)	(65.5)	+1.9 %
Margin	13.6 %						31.9 %			29.3 %*
Financial income/expenses	(81.1)					17.2	(63.9)	3.5	(0.0)	
Equity income/loss	(8.9)					11.0	2.1	(0.0)		
Profit before tax	125.6	206.0	2.1	78.0	10.3	23.9	445.8	(3.9)	(65.5)	
Tax expenses	(39.0)	(42.2)	(0.3)	(13.5)	(3.2)	(2.1)	(100.2)	0.9	18.3	
Non-controlling interests	(0.0)						(0.0)	(0.0)	0.0	
Net profit	86.5	163.8	1.8	64.5	7.2	21.8	345.5	(3.1)	(47.2)	
EPS (yen)	55						221	(2)	(30)	(0.4) %
Number of shares (millions)	1,561						1,561			1,558

* Underlying Core Operating Profit Margin.

Free Cash Flow

(BN JPY)	FY2020 H1	FY2021 H1	vs. PY	
Net profit	86.6	183.7	97.1	+112.2%
Depreciation, amortization and impairment loss	288.8	285.1	(3.8)	
Decrease (increase) in trade working capital	(24.9)	(89.2)	(64.3)	
Income taxes paid	(103.8)	(78.7)	25.1	
Tax refunds and interest on tax refunds received	23.7	4.8	(18.8)	
Other	121.6	94.3	(27.3)	
Net cash from operating activities	392.0	400.0	8.0	+2.0%
Adjustment for deposits restricted to certain vaccines operations	—	(7.6)	(7.6)	
Acquisition of PP&E	(50.5)	(60.6)	(10.1)	
Proceeds from sales of PP&E	38.5	0.4	(38.1)	
Acquisition of intangible assets	(30.4)	(25.2)	5.2	
Acquisition of investments	(6.2)	(3.6)	2.6	
Proceeds from sales and redemption of investments	50.6	10.1	(40.6)	
Proceeds from sales of business, net of cash and cash equivalents divested	31.4	2.1	(29.3)	
Free Cash Flow	425.5	315.6	(109.9)	-25.8%

FY2021 H1 NET PROFIT TO ADJUSTED EBITDA BRIDGE

(BN JPY)	FY2020 Full Year (Apr-Mar)	FY2020 H1	FY2021 H1	FY2021 H1 LTM*1 (Oct-Sep)
Net profit	376.2	86.6	183.7	473.3
Income tax expenses	(9.9)	39.0	100.7	51.8
Depreciation and amortization	559.7	280.5	283.6	562.7
Interest expense, net	129.0	68.2	58.9	119.8
EBITDA	1,054.9	474.3	627.0	1,207.6
Impairment losses	25.5	8.3	1.5	18.6
Other operating expense (income), net, excluding depreciation and amortization and other miscellaneous expenses (non-cash item)	(74.5)	27.5	36.8	(65.2)
Finance expense (income), net, excluding interest income and expense, net	14.1	12.9	(0.9)	0.2
Share of loss on investments accounted for under the equity method	(0.1)	8.9	3.5	(5.5)
Other adjustments:	131.4	65.1	(72.9)	(6.6)
Non-core expense related to COVID-19	14.0	—	5.5	19.5
Sale of Japan diabetes portfolio	—	—	(131.4)	(131.4)
Impact on profit related to fair value step up of inventory in Shire acquisition	79.4	46.6	17.8	50.6
Acquisition costs related to Shire	1.9	0.0	—	1.9
Other costs*2	36.1	18.5	35.2	52.8
Adjusted EBITDA	1,151.3	597.1	595.0	1,149.2
EBITDA from divested products*3				(37.0)
Adjusted EBITDA (LTM)				1,112.2

*1 LTM represents Last Twelve Months (October 2020 - September 2021). Calculated by subtracting FY2020 H1 from FY2020 Full Year and adding FY2021 H1.

*2 Includes adjustments for non-cash equity-based compensation expense and non-recurring wind-down costs related to pipeline de-prioritization after Shire acquisition.

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

Net Debt to Adjusted EBITDA

FY2021 H1

NET DEBT/ADJUSTED EBITDA RATIO

(BN JPY)	FY2021 H1
Cash and cash equivalents*1	424.8
Book value debt on the balance sheet	(4,231.4)
Hybrid bond 50% equity credit	250.0
FX adjustment*2	107.3
Gross debt*3	(3,874.1)
Net cash (debt)	(3,449.3)
Net debt/Adjusted EBITDA ratio	3.1x
Adjusted EBITDA	1,112.2

NET INCREASE (DECREASE) IN CASH

(BN JPY)	FY2020 H1	FY2021 H1	vs. PY	
Net cash from operating activities	392.0	400.0	8.0	+2.0 %
Acquisition of PP&E	(50.5)	(60.6)		
Proceeds from sales of PP&E	38.5	0.4		
Acquisition of intangible assets	(30.4)	(25.2)		
Acquisition of investments	(6.2)	(3.6)		
Proceeds from sales and redemption of investments	50.6	10.1		
Acquisition of business, net of cash and cash equivalents acquired	—	(27.5)		
Proceeds from sales of business, net of cash and cash equivalents divested	31.4	2.1		
Net increase (decrease) in short-term loans and commercial papers	(89.9)	(0.0)		
Repayment of long-term loans	(792.5)	(220.1)		
Proceeds from issuance of bonds	1,179.5	—		
Repayment of bonds	(473.1)	(220.9)		
Interest paid	(47.6)	(52.7)		
Dividends paid	(141.8)	(141.6)		
Others	(58.1)	(22.1)		
Net increase (decrease) in cash	2.0	(361.7)	(363.8)	—

*1 Includes short-term investments which mature or become due within one year from the reporting date and excludes deposits restricted to certain vaccines operations.

*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 cash and non cash adjustments to debt book-value. Non cash adjustments include changes dues to debt amortization and FX impact.

FY2020 Q4 (Full Year)

NET DEBT/ADJUSTED EBITDA RATIO	
(BN JPY)	FY2020
Cash and cash equivalents*1	790.7
Book value debt on the balance sheet	(4,635.4)
Hybrid bond 50% equity credit	250.0
FX adjustment*2	165.2
Gross debt*3	(4,220.2)
Net cash (debt)	(3,429.4)
Net debt/Adjusted EBITDA ratio	3.2 x
Adjusted EBITDA	1,083.5

NET INCREASE (DECREASE) IN CASH			
(BN JPY)	FY2019	FY2020	vs. PY
Net cash from operating activities	669.8	1,010.9	+341.2 +50.9%
Acquisition of PP&E	(127.1)	(111.2)	
Proceeds from sales of PP&E	12.6	46.5	
Acquisition of intangible assets	(90.6)	(125.3)	
Acquisition of investments	(7.6)	(12.6)	
Proceeds from sales and redemption of investments	49.4	74.6	
Acquisition of business, net of cash and cash equivalents acquired	(4.9)	—	
Proceeds from sales of business, net of cash and cash equivalents divested	461.5	530.4	
Net increase (decrease) in short-term loans and commercial papers	(351.2)	(149.0)	
Repayment of long-term loans	(137.4)	(792.5)	
Proceeds from issuance of bonds	496.2	1,179.5	
Repayment of bonds	(563.6)	(859.2)	
Interest paid	(127.2)	(107.3)	
Dividends paid	(282.6)	(283.4)	
Others	(40.6)	(85.3)	
Net increase (decrease) in cash	(43.3)	316.1	+359.4 —

*1 Includes short-term investments which mature or become due within one year from the reporting date and excludes deposits restricted to certain vaccines operations.

*2 FX adjustment refers to change from month-end rate to average rate used for non-JPY debt calculation, to match with adjusted EBITDA calculation.

*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 cash and non cash adjustments to debt book-value. Non cash adjustments include changes dues to debt amortization and FX impact.

Reconciliation from Reported Operating Profit to Core Operating Profit - FY2021 Forecast

(BN JPY)	REPORTED	REPORTED TO CORE ADJUSTMENTS					CORE
		Amortization of intangible assets	Impairment of intangible assets	Other operating income/expenses	Sale of Japan diabetes portfolio	Others	
Revenue	3,370.0				(133.0)		3,237.0
Cost of sales					3.0	35.0	
Gross Profit					(130.0)	35.0	
SG&A and R&D expenses						4.0	
Amortization of intangible assets	(406.0)	406.0					—
Impairment losses on intangible assets	(50.0)		50.0				—
Other operating income	23.0			(23.0)			—
Other operating expenses	(100.0)			100.0			—
Operating profit	488.0	406.0	50.0	77.0	(130.0)	39.0	930.0

Important Notice

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