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Takeda Quarterly Financial Report

For the Quarter Ended June 30, 2021

Table of Contents

Financial Highlights	3
Selected Financial Results	3
Revenue by Region	4
Revenue by Therapeutic Area and Product	5
Recent Developments	7
Business Development	7
Pipeline and R&D Activities	7
Analysis of results of operations, financial position, and cash flow	13
Results of Operations (Reported)	13
Results of Operations (Underlying)	17
Consolidated Financial Position	19
Consolidated Cash Flow	20
Outlook for the Fiscal Year Ending March 31, 2022	21
Impact of the Spread of the Novel Coronavirus Infectious Disease (COVID-19) and Takeda's Initiatives in Response	23
Consolidated Financial Statements	25
(1) Consolidated Statements of Profit or Loss	25
(2) Consolidated Statements of Comprehensive Income	26
(3) Consolidated Statements of Financial Position	27
(4) Consolidated Statements of Changes in Equity	29
(5) Consolidated Statements of Cash Flows	31
(6) Other Information	33
Supplementary Information	34
1. Pipeline	35
• I. Clinical Development Activities	35
• II. Recent Progress in stage	42
• III. Discontinued projects	42
• IV. Main Research & Development collaborations	43
2. Supplementary Financial Information	48
• Revenue by region	48
◦ Year to date	48
◦ Quarterly	49
• Product Sales Analysis	50
◦ Year to date	50
• Product Sales Analysis (Reported & Underlying Growth)	52
• Product Forecast	54
• Exchange Rate	56
• CAPEX, depreciation and amortization and impairment losses	57
3. Reconciliation	58
• FY2021 Q1 Reconciliation from Reported Revenue to Core/Underlying Revenue	58
• FY2021 Q1 Reconciliation from Reported to Core/Underlying Core	59
• FY2020 Q1 Reconciliation from Reported to Core/Underlying Core	60
• Free Cash Flow	61
• FY2021 Q1 LTM Net Profit to Adjusted EBITDA Bridge	62

- [FY2021 Q1 Net Debt to Adjusted EBITDA](#) [63](#)
- [FY2020 Net Debt to Adjusted EBITDA](#) [64](#)
- [Reconciliation from Reported Operating Profit to Core Operating Profit - FY2021 Forecast](#) [65](#)
- [**Important Notice**](#) [66](#)

Financial Highlights

Selected Financial Results

Results of Operation

(JPY millions)	Three-month Period Ended June 30,		Change versus the previous year	
	2020	2021	JPY	%
Revenue	801,850	949,603	147,753	18.4 %
Operating profit	167,285	248,552	81,267	48.6 %
Profit before tax	130,291	222,978	92,687	71.1 %
Net profit for the period	82,519	137,726	55,207	66.9 %
Net profit attributable to owners of the Company	82,511	137,684	55,173	66.9 %
Earnings per share (JPY)				
Basic earnings per share	52.93	87.96	35.03	66.2 %
Diluted earnings per share	52.69	87.45	34.76	66.0 %

Non-IFRS Measures

Results of Operations

(JPY billions)	Three-month Period Ended June 30,		Change versus the previous year	
	2020	2021	JPY	%
Underlying:				
Revenue Growth	+ 0.9 %	+ 3.8%		
Core operating profit margin	32.4 %	30.5 %		
Core Operating Profit	280.9	248.9	(32.0)	(11.4) %
Core EPS (yen)	122	113	(9)	(7.4) %
Free Cash Flow	146.3	129.9	(16.4)	(11.2) %

Leverage

(JPY billions)	As of	
	March 31, 2021	June 30, 2021
Net debt	(3,429.4)	(3,537.6)
Adjusted EBITDA (Last 12 months)	1,083.5	1,057.1
Net debt/Adjusted EBITDA ratio	3.2 x	3.3 x

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)	Three-month Period Ended June 30,		Change versus the previous year	
	2020	2021	JPY	%
Cash flows from (used in) operating activities	145,861	166,858	20,997	14.4 %
Cash flows from (used in) investing activities	662	(70,445)	(71,107)	—
Cash flows from (used in) financing activities	(192,765)	(411,038)	(218,273)	113.2 %

Consolidated Financial Position

(JPY millions)	As of		Change versus the previous year	
	March 31, 2021	June 30, 2021	JPY	%
Non-current Assets	10,199,400	10,180,777	(18,623)	(0.2) %
Current Assets	2,712,893	2,476,458	(236,435)	(8.7) %
Total Assets	12,912,293	12,657,234	(255,059)	(2.0) %
Non-current Liabilities	5,961,940	5,711,809	(250,131)	(4.2) %
Current Liabilities	1,773,176	1,706,782	(66,394)	(3.7) %
Total Liabilities	7,735,116	7,418,591	(316,525)	(4.1) %
Equity	5,177,177	5,238,643	61,466	1.2 %
Total liabilities and equity	12,912,293	12,657,234	(255,059)	(2.0) %

Forecast and Management Guidance

<i>Forecast*</i> (JPY billions)	FY2020	FY2021	Change over the previous year	
Reported:				
Revenue	3,197.8	3,370.0	172.2	5.4 %
Operating profit	509.3	488.0	(21.3)	(4.2)%
Profit before tax	366.2	352.0	(14.2)	(3.9)%
Net profit for the year (attributable to owners of the Company)	376.0	250.0	(126.0)	(33.5)%
EPS (JPY)	240.72	159.91	(80.81)	(33.6)%
Non-IFRS Measures				
Core Operating Profit	967.9	930.0	(37.9)	(3.9)%
Core EPS (JPY)	420	394	(26)	(6.2)%
Free cash flow (including announced divestitures)	1,237.8	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**

	FY2021
Underlying Revenue Growth	Mid-single-digit growth
Underlying Core Operating Profit Growth	Mid-single-digit growth
Underlying Core Operating Profit Margin	~30% margin
Underlying Core EPS 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)							
		Three-month Period Ended June 30,							
	Japan	United States	Europe and Canada	Asia (excluding Japan)	Latin America	Russia/CIS	Other	Total	
2020	144,045	402,606	157,559	36,879	30,774	13,044	16,943	801,850	
2021	258,963	412,220	178,742	40,292	30,059	12,336	16,991	949,603	
Change versus the previous year	JPY 114,918	9,614	21,184	3,413	(714)	(707)	47	147,753	
	%	79.8 %	2.4 %	13.4 %	9.3 %	(2.3)%	(5.4)%	0.3 %	18.4 %

“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)			
	Three-month Period Ended June 30,		Change versus the previous year	
	2020	2021	JPY	%
Gastroenterology:				
ENTYVIO	101,224	125,370	24,146	23.9 %
TAKECAB-F ⁽¹⁾	20,214	24,268	4,054	20.1 %
GATTEX/REVESTIVE	17,474	18,123	649	3.7 %
DEXILANT	13,609	10,788	(2,821)	(20.7)%
PANTOLOC/CONTROLOC ⁽²⁾	9,177	10,446	1,269	13.8 %
LIALDA/MEZAVANT	5,528	6,423	895	16.2 %
PENTASA	6,167	4,836	(1,331)	(21.6)%
AMITIZA	6,267	2,144	(4,123)	(65.8)%
RESOLOR/MOTEGRITY	2,738	3,200	462	16.9 %
ALOFISEL	11	388	377	3556.0 %
Other	4,519	4,520	1	0.0 %
Total Gastroenterology	186,928	210,505	23,577	12.6 %
Rare Diseases:				
Rare Metabolic:				
ELAPRASE	17,637	18,599	962	5.5 %
REPLAGAL	12,193	14,050	1,857	15.2 %
VPRIV	9,343	10,452	1,109	11.9 %
NATPARA/NATPAR	734	1,150	416	56.8 %
Total Rare Metabolic	39,907	44,251	4,344	10.9 %
Rare Hematology:				
ADVATE	33,652	30,663	(2,989)	(8.9)%
ADYNOVATE/ADYNOVI	15,280	15,373	93	0.6 %
FEIBA	12,859	11,402	(1,457)	(11.3)%
RECOMBINATE	3,721	3,688	(33)	(0.9)%
HEMOFIL/IMMUNATE/IMMUNINE	4,430	3,294	(1,136)	(25.6)%
Other PDT Products	873	863	(10)	(1.1)%
Other	5,940	6,916	976	16.4 %
Total Rare Hematology	76,755	72,199	(4,556)	(5.9)%
Hereditary Angioedema:				
TAKHZYRO	23,245	25,469	2,224	9.6 %
FIRAZYR	8,095	6,873	(1,222)	(15.1)%
CINRYZE	5,922	5,585	(337)	(5.7)%
KALBITOR	1,060	1,090	30	2.8 %
Total Hereditary Angioedema	38,321	39,017	696	1.8 %
Total Rare Diseases	154,983	155,467	484	0.3 %
PDT Immunology:				
immunoglobulin	85,106	81,608	(3,498)	(4.1)%
albumin	12,979	17,759	4,780	36.8 %
Other	7,179	7,831	652	9.1 %
Total PDT Immunology	105,264	107,197	1,933	1.8 %

	JPY (millions)			
	Three-month Period Ended June 30,		Change versus the previous year	
	2020	2021	JPY	%
Oncology:				
VELCADE	24,181	30,129	5,948	24.6 %
LEUPLIN/ENANTONE	27,400	26,213	(1,187)	(4.3) %
NINLARO	22,931	24,370	1,439	6.3 %
ADCETRIS	15,090	17,228	2,138	14.2 %
ICLUSIG	9,233	10,369	1,136	12.3 %
VECTIBIX	6,177	6,185	8	0.1 %
ALUNBRIG	2,017	3,113	1,096	54.4 %
Other	944	3,775	2,831	300.0 %
Total Oncology	107,973	121,382	13,409	12.4 %
Neuroscience:				
VYVANSE/ELVANSE	66,009	79,212	13,203	20.0 %
TRINTELLIX	16,880	17,868	988	5.9 %
INTUNIV	5,649	3,250	(2,399)	(42.5) %
ADDERALL XR	5,257	3,949	(1,308)	(24.9) %
ROZEREM	3,021	3,228	207	6.9 %
Other	10,041	5,905	(4,136)	(41.2) %
Total Neuroscience	106,857	113,411	6,554	6.1 %
Other:				
AZILVA-F ⁽¹⁾	20,855	22,646	1,791	8.6 %
LOTRIGA	8,065	7,826	(239)	(3.0) %
AIPHAGAN	3,971	4,569	598	15.0 %
FOSRENOL	3,210	3,363	153	4.7 %
ACTOVEGIN	1,726	3,230	1,504	87.2 %
Others ⁽³⁾	102,019	200,007	97,988	96.0 %
Total Other	139,846	241,641	101,795	72.8 %
Total Revenue by Product	801,850	949,603	147,753	18.4 %

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

⁽²⁾ Generic name: pantoprazole

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

Recent Developments

Business Development

During the three-month period ended June 30, 2021 and through the issuance of its earnings release dated July 30, 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 three-month period ended June 30, 2021 were 122.5 billion JPY.

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

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

R&D pipeline

Oncology

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

NINLARO / Generic name: ixazomib

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

ICLUSIG / Generic name: ponatinib

- In June 2021, Takeda presented primary analysis data from the Phase II OPTIC (Optimizing Ponatinib Treatment in CML) trial during an oral session at the virtual 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.

Development code: TAK-788 / Generic name: mobocertinib

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

Rare Genetics & Hematology

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

TAKHZYRO / Generic name: lanadelumab

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

VONVENDI / Generic name: von Willebrand factor (Recombinant)

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

Development code: TAK-620 / Generic name: maribavir

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

Neuroscience

In Neuroscience, Takeda is focusing its R&D investments on potentially transformative treatments for neurological and neuromuscular diseases of high unmet need, and building its pipeline through a combination of in-house expertise and partnerships. By harnessing advances in disease biology understanding, translational tools, and innovative modalities, Takeda is primarily focusing on rare neurology (e.g., narcolepsy, Amyotrophic Lateral Sclerosis, Huntington's disease and other ataxias), as well as making targeted investments to potentially address well-defined segments of neurodegenerative diseases (e.g., Parkinson's Disease).

Development code: TAK-994

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

Gastroenterology (GI)

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

GATTEX / REVESTIVE / Generic name: teduglutide

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

Plasma-Derived Therapies (PDT)

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

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

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

Vaccines

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

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

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

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

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

Building a sustainable research platform / Enhancing R&D collaboration

In addition to our concentrated efforts to increase our in-house R&D capabilities, external partnerships with third-party partners are a key component of our strategy for enhancing our R&D pipeline. Our strategy to expand and diversify our

external partnerships allows us to take part in research of a wide variety of new products and increases the chances that we will be able to take part in a major research-related breakthrough.

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

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

Results of Operations (Reported)

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

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

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

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

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

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

- **GI.** In Gastroenterology, revenue was 210.5 billion JPY, a year-on-year increase of 23.6 billion JPY, or 12.6%. Growth was driven by Takeda’s top-selling product ENTYVIO (for ulcerative colitis (“UC”) and Crohn’s disease (“CD”)), with sales of 125.4 billion JPY, a year-on-year increase of 24.1 billion JPY, or 23.9%. Sales in the U.S. increased by 12.2 billion JPY, or 17.1%, to 83.7 billion JPY and sales in Europe and Canada increased by 8.6 billion JPY, or 35.6%, to 32.7 billion JPY, due to an increase in demand. In the Growth and Emerging Markets, the increase in sales was primarily driven by Brazil and China. Sales of TAKECAB (for acid-related diseases) were 24.3 billion JPY, an increase of 4.1 billion JPY, or 20.1%, versus the same period of the previous fiscal year. This increase was driven by the expansion of new prescriptions in the Japanese market due to TAKECAB’s efficacy in reflux esophagitis and the prevention of recurrence of gastric and duodenal ulcers during low-dose aspirin administration. Sales of AMITIZA (for chronic constipation) decreased by 4.1 billion JPY, or 65.8%, to 2.1 billion JPY, due to generic entrants in the U.S. in January 2021.
- **Rare Diseases.** In Rare Diseases, revenue was 155.5 billion JPY, a slight year-on-year increase of 0.5 billion JPY, or 0.3%. Revenue in Rare Metabolic increased by 4.3 billion JPY, or 10.9%, compared to the same period of the previous fiscal year to 44.3 billion JPY. Sales of enzyme replacement therapies REPLAGAL (for Fabry disease), VPRIV (for Gaucher disease)

and ELAPRASE (for Hunter syndrome) increased due to higher demand coupled with the positive impact of the depreciation of the yen.

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

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

- *PDT Immunology*. In Plasma-Derived Therapies (“PDT”) Immunology, revenue increased by 1.9 billion JPY, or 1.8%, compared to the same period of the previous fiscal year to 107.2 billion JPY. Aggregate sales of immunoglobulin products were 81.6 billion JPY, a decrease of 3.5 billion JPY, or 4.1%, compared to the same period of the previous fiscal year. In particular, GAMMAGARD LIQUID (for the treatment of primary immunodeficiency (“PID”) and multifocal motor neuropathy (“MMN”)) decreased in sales mainly due to shipment timing, as the last three-month period of the previous fiscal year saw higher sales. On the other hand, CUVITRU, a SCIG (subcutaneous immunoglobulin) therapy continued to mark double digit growth. Aggregate sales of albumin products including HUMAN ALBUMIN and FLEXBUMIN (primarily used for hypovolemia and hypoalbuminemia) were 17.8 billion JPY, an increase of 4.8 billion JPY, or 36.8%, versus the same period of the previous fiscal year driven by the resolution of the temporary supply interruption impacting HUMAN ALBUMIN for release in China which impacted the second half of the previous fiscal year.
- *Oncology*. In Oncology, revenue was 121.4 billion JPY, a year-on-year increase of 13.4 billion JPY, or 12.4%. Sales of VELCADE (for multiple myeloma) increased by 5.9 billion JPY, or 24.6% versus the same period of the previous fiscal year to 30.1 billion JPY. While royalty income outside the U.S. decreased by 0.3 billion JPY, or 30.8%, due to continued generic erosion, sales in the U.S. increased by 6.3 billion JPY, or 27.3%, versus the same period of the previous fiscal year, reflecting a rebound in demand after lower sales in the same period of the prior year when prescribers favored orally administered products over infusions or injections, as a result of the COVID-19 outbreak. Sales of NINLARO (for multiple myeloma) were 24.4 billion JPY, an increase of 1.4 billion JPY, or 6.3%, versus the same period of the previous fiscal year. NINLARO’s convenient profile as an orally administered treatment led to a temporary increase in demand in light of the spread of COVID-19, especially in the first few months of the previous fiscal year, because its administration reduced some of the logistical burden for patients visiting a hospital, clinic or physician’s office to get an infusion or injection. This benefit has since normalized in the U.S.; however, there have been strong demand increases in other countries, particularly in China. Sales of ADCETRIS (for malignant lymphomas) increased by 2.1 billion JPY, or 14.2% versus the same period of the previous fiscal year to 17.2 billion JPY, led by strong growth in sales in the Growth and Emerging Markets, particularly in China where it was approved in May 2020. Sales of LEUPLIN/ENANTONE (generic name: leuprorelin) (for endometriosis, uterine fibroids, premenopausal breast cancer, prostatic cancer, etc.), an off-patented product, decreased by 1.2 billion JPY, or 4.3%, versus the same period of the previous fiscal year to 26.2 billion JPY mainly due to generic erosion and competition in Japan.
- *Neuroscience*. In Neuroscience, revenue was 113.4 billion JPY, a year-on-year increase of 6.6 billion JPY, or 6.1%. Sales of VYVANSE/ELVANSE (for attention deficit hyperactivity disorder (“ADHD”)) were 79.2 billion JPY, an increase of 13.2 billion JPY, or 20.0%, versus the same period of the previous fiscal year. VYVANSE/ELVANSE has been negatively affected by COVID-19 during the course of the pandemic, most notably during periods when stay-at-home restrictions have been in place reducing patient visits, subsequent diagnoses and creating temporary discontinuation of medication. The trend has been fluctuating throughout 2020 and into 2021; however, when comparing the three-month period of the current fiscal year with the same period of the previous fiscal year, there has been a positive impact from increasing prescriptions. Sales of TRINTELLIX (for major depressive disorder (“MDD”)) were 17.9 billion JPY, an increase of 1.0 billion JPY, or 5.9%, versus the same period of the previous fiscal year, primarily due increasing market penetration in Japan. The increase of these products was partially offset by the decrease of other neuroscience products such as REMINYL (for Alzheimer’s disease) and ADDERALL XR (for ADHD), attributable to the continued impact of competition from generic products.

Revenue by Geographic Region:

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

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

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

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

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

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

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

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

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

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

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

Share of Loss of Investments Accounted for Using the Equity Method. Share of Loss of Investments Accounted for Using the Equity Method was 0.4 billion JPY, a decrease of 9.4 billion JPY compared to the same period of the previous fiscal year. This was mainly due to Takeda's shareholding ratio of impairment loss recognized by Teva Takeda Pharma Ltd. for the same period

of the previous fiscal year resulting from the reassessment of the recoverable amount of relevant assets triggered by the decision to divest a part of its generics business and a manufacturing plant.

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

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

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

Definition of Core and Underlying Growth

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

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

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

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

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

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

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

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

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

Underlying Results

FY2021Q1

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

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

* Takeda's 14 global brands

GI: ENTYVIO, GATTEX/REVESTIVE, ALOFISEL

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

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

Oncology: NINLARO, ALUNBRIG

Underlying Revenue Growth by Therapeutic Area

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

(Note) Underlying Revenue represents revenue on a constant currency basis and excluding non-recurring items and the impact of divestitures. Please refer to [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.

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

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

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

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

Consolidated Financial Position

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

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

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

Bonds:

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	167.9
Unsecured US dollar denominated senior notes (5,500 million USD)	September 2016	September 2023 ~ September 2026	578.8
Unsecured Euro denominated senior notes (5,250 million EUR)	November 2018	November 2022 ~ November 2030	685.8
Unsecured US dollar denominated senior notes (3,250 million USD)	November 2018	November 2023 ~ November 2028	357.1
Hybrid bonds (subordinated bonds)	June 2019	June 2079	497.6
Unsecured US dollar denominated senior notes (7,000 million USD)	July 2020	March 2030 ~ July 2060	767.7
Unsecured Euro denominated senior notes (3,600 million EUR)	July 2020	July 2027 ~ July 2040	469.1
Total			<u>3,524.0</u>

Loans:

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	165.4
Japan Bank for International Cooperation (1,700 million USD)	January 2019	December 2025	187.8
Bilateral loans	March 2016 ~ April 2017	March 2023 ~ March 2026	210.0
Other			5.1
Total			<u>881.9</u>

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

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

Consolidated Cash Flow

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

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

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

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

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 not been changed from the original forecast (announced at the FY2020 financial results announcement on May 11, 2021). In the three-month period ended June 30, 2021, Takeda recorded a tax charge of 62.7 billion JPY for tax and interest, net of 0.5 billion JPY of associated tax benefit, arising from tax assessment involving Irish taxation of the break fee Shire received from AbbVie in connection with the terminated offer to acquire Shire made by AbbVie in 2014. Takeda will update its FY2021 forecast at the appropriate timing by taking this event as well as other factors into consideration.

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

	Billion JPY or percentage			
	FY2020	FY2021	Change over the previous year	
Revenue	3,197.8	3,370.0	+172.2	+5.4 %
Operating profit	509.3	488.0	(21.3)	(4.2)%
Profit before tax	366.2	352.0	(14.2)	(3.9)%
Net profit for the year (attributable to owners of the Company)	376.0	250.0	(126.0)	(33.5)%
EPS (JPY)	240.72	159.91	(80.81)	(33.6)%
Core Operating Profit	967.9	930.0	(37.9)	(3.9)%
Core EPS (JPY)	420	394	(26)	(6.2)%

Major assumptions used in preparing the FY2021 Reported Forecast

	Billion JPY or percentage	
	FY2020	FY2021
FX rates	1 USD = 106 JPY 1 Euro = 123 JPY 1 RUB = 1.4 JPY 1 BRL = 19.6 JPY 1 CNY = 15.5 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	(455.8)	(522.0)
Amortization of intangible assets associated with products	(405.3)	(406.0)
Of which Shire acquisition related	(319.5)	(328.0)
Impairment of intangible assets associated with products	(16.6)	(50.0)
Other operating income	318.0	23.0
Other operating expenses	(258.9)	(100.0)
Japan diabetes portfolio divestiture gain	—	130.0
Other Core Operating Profit adjustments	(95.9)	(39.0)
Of which Shire acquisition related to unwind of inventories step-up	(79.4)	(31.1)
Finance income and (expenses), net	(143.1)	(130.0)
Free cash flow (including announced divestitures)	1,237.8	600.0-700.0
Capital expenditures (cash flow base)	(236.5)	(210.0 - 260.0)
Depreciation and amortization (excluding intangible assets associated with products)	(152.6)	(150.0)
Cash tax rate on adjusted EBITDA (excluding divestitures)	~16 %	Mid-teen%

Management Guidance*

The management guidance for the fiscal year ending March 31, 2022 (FY2021) has not been changed from the original guidance (announced at the FY2020 financial results announcement on May 11, 2021). The tax charge arising from tax assessment involving Irish taxation is adjusted to exclude 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.

	FY2021
Underlying Revenue Growth	Mid-single-digit growth
Underlying Core Operating Profit Growth	Mid-single-digit growth
Underlying Core Operating Profit Margin	~30% margin
Underlying Core EPS Growth	Mid-single-digit growth

* Please refer to [Results of Operations \(Underlying\) \(April 1 to June 30, 2021\)](#), 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

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

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

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

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

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

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

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

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

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

(iii) FY2021 Q1 financial impact from COVID-19

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

Consolidated Financial Statements [IFRS]

(1) Consolidated Statements of Profit or Loss

	JPY (millions, except per share data)		USD (millions) ^(*)
	Three-month Period Ended June 30,		Three-month Period Ended June 30,
	2020	2021	2021
Revenue	¥ 801,850	¥ 949,603	\$ 8,551
Cost of sales	(238,078)	(241,264)	(2,173)
Selling, general and administrative expenses	(202,374)	(219,843)	(1,980)
Research and development expenses	(106,821)	(122,480)	(1,103)
Amortization and impairment losses on intangible assets associated with products	(104,250)	(102,824)	(926)
Other operating income	63,732	11,118	100
Other operating expenses	(46,774)	(25,758)	(232)
Operating profit	167,285	248,552	2,238
Finance income	19,611	45,851	413
Finance expenses	(46,846)	(71,068)	(640)
Share of loss of investments accounted for using the equity method	(9,759)	(357)	(3)
Profit before tax	130,291	222,978	2,008
Income tax expenses	(47,772)	(85,252)	(768)
Net profit for the period	82,519	137,726	1,240
Attributable to:			
Owners of the Company	82,511	137,684	1,240
Non-controlling interests	8	43	0
Net profit for the period	82,519	137,726	1,240
Earnings per share (JPY)			
Basic earnings per share	52.93	87.96	0.79
Diluted earnings per share	52.69	87.45	0.79

(*) Consolidated statements of profit or loss have been translated solely for the convenience of the reader at an exchange rate of 1USD = 111.05 JPY, the Noon Buying Rate certified by the Federal Reserve Bank of New York on June 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) ^(*)
	Three-month Period Ended June 30,		Three-month Period Ended June 30,
	2020	2021	2021
Net profit for the period	¥ 82,519	¥ 137,726	\$ 1,240
Other comprehensive income (loss)			
Items that will not be reclassified to profit or loss:			
Changes in fair value of financial assets measured at fair value through other comprehensive income	25,518	15,877	143
Remeasurement of defined benefit pension plans	(2,286)	(57)	(1)
	23,232	15,819	142
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	1,997	28,280	255
Cash flow hedges	(5,126)	12,948	117
Hedging cost	(5,357)	2,230	20
Share of other comprehensive income (loss) of investments accounted for using the equity method	(7)	2	0
	(8,493)	43,460	391
Other comprehensive income for the period, net of tax	14,739	59,279	534
Total comprehensive income for the period	97,258	197,005	1,774
Attributable to:			
Owners of the Company	97,183	196,956	1,774
Non-controlling interests	75	49	0
Total comprehensive income for the period	97,258	197,005	1,774

(*) Consolidated statements of comprehensive income have been translated solely for the convenience of the reader at an exchange rate of 1USD = 111.05 JPY, the Noon Buying Rate certified by the Federal Reserve Bank of New York on June 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 June 30, 2021	As of June 30, 2021
ASSETS			
Non-current assets:			
Property, plant and equipment	¥ 1,453,917	¥ 1,452,172	\$ 13,077
Goodwill	4,033,917	4,058,935	36,551
Intangible assets	3,909,106	3,856,432	34,727
Investments accounted for using the equity method	112,468	115,751	1,042
Other financial assets	235,882	258,908	2,331
Other non-current assets	100,341	95,022	856
Deferred tax assets	353,769	343,557	3,094
Total non-current assets	10,199,400	10,180,777	91,677
Current assets:			
Inventories	753,881	779,148	7,016
Trade and other receivables	783,091	827,253	7,449
Other financial assets	36,598	29,930	270
Income taxes receivable	29,623	31,704	285
Other current assets	122,789	133,307	1,200
Cash and cash equivalents	966,222	654,920	5,898
Assets held for sale	20,689	20,195	182
Total current assets	2,712,893	2,476,458	22,300
Total assets	12,912,293	12,657,234	113,978
LIABILITIES AND EQUITY			
LIABILITIES			
Non-current liabilities:			
Bonds and loans	4,613,218	4,381,589	39,456
Other financial liabilities	517,677	496,546	4,471
Net defined benefit liabilities	158,857	160,871	1,449
Income taxes payable	33,690	29,006	261
Provisions	38,748	35,970	324
Other non-current liabilities	56,898	58,768	529
Deferred tax liabilities	542,852	549,059	4,944
Total non-current liabilities	5,961,940	5,711,809	51,435
Current liabilities:			
Bonds and loans	22,153	24,272	219
Trade and other payables	343,838	320,645	2,887
Other financial liabilities	248,053	233,170	2,100
Income taxes payable	145,203	200,926	1,809
Provisions	471,278	410,300	3,695
Other current liabilities	542,651	517,468	4,660
Total current liabilities	1,773,176	1,706,782	15,369
Total liabilities	7,735,116	7,418,591	66,804

	JPY (millions)		USD (millions) ^(*)
	As of March 31, 2021	As of June 30, 2021	As of June 30, 2021
<u>EQUITY</u>			
Share capital	1,668,145	1,669,125	15,030
Share premium	1,688,424	1,682,504	15,151
Treasury shares	(59,552)	(42,344)	(381)
Retained earnings	1,509,906	1,503,811	13,542
Other components of equity	366,114	425,163	3,829
Equity attributable to owners of the company	5,173,037	5,238,258	47,170
Non-controlling interests	4,140	385	3
Total equity	5,177,177	5,238,643	47,174
Total liabilities and equity	12,912,293	12,657,234	113,978

(*) Consolidated statements of financial position have been translated solely for the convenience of the reader at an exchange rate of 1USD = 111.05 JPY, the Noon Buying Rate certified by the Federal Reserve Bank of New York on June 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

Three-month period ended June 30, 2020 (From April 1 to June 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				82,511		
Other comprehensive income (loss)					1,957	25,484
Comprehensive income (loss) for the period	—	—	—	82,511	1,957	25,484
Transaction with owners:						
Issuance of new shares	22	22				
Acquisition of treasury shares			(2,132)			
Disposal of treasury shares		(0)	0			
Dividends				(141,858)		
Transfers from other components of equity				19,429		(21,715)
Share-based compensation		10,043				
Exercise of share-based awards		(28,878)	28,878			
Total transactions with owners	22	(18,813)	26,746	(122,429)	—	(21,715)
As of June 30, 2020	1,668,145	1,661,474	(60,717)	1,330,054	93,805	26,660

	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				—	82,511	8	82,519
Other comprehensive income (loss)	(5,126)	(5,357)	(2,286)	14,672	14,672	67	14,739
Comprehensive income (loss) for the period	(5,126)	(5,357)	(2,286)	14,672	97,183	75	97,258
Transaction with owners:							
Issuance of new shares				—	44		44
Acquisition of treasury shares				—	(2,132)		(2,132)
Disposal of treasury shares				—	0		0
Dividends				—	(141,858)	(77)	(141,935)
Transfers from other components of equity			2,286	(19,429)	—		—
Share-based compensation				—	10,043		10,043
Exercise of share-based awards				—	(0)		(0)
Total transactions with owners	—	—	2,286	(19,429)	(133,903)	(77)	(133,980)
As of June 30, 2020	(27,856)	(4,802)	—	87,807	4,686,763	4,001	4,690,764

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

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

	Equity attributable to owners of the company				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				—	137,684	43	137,726
Other comprehensive income (loss)	12,948	2,230	(57)	59,272	59,272	7	59,279
Comprehensive income (loss) for the period	12,948	2,230	(57)	59,272	196,956	49	197,005
Transaction with owners:							
Issuance of new shares				—	7,878		7,878
Acquisition of treasury shares				—	(4,464)		(4,464)
Disposal of treasury shares				—	0		0
Dividends				—	(141,859)		(141,859)
Changes in ownership				—	(2,143)	(3,804)	(5,948)
Transfers from other components of equity			57	(224)	—		—
Share-based compensation				—	8,547		8,547
Exercise of share-based awards				—	307		307
Total transactions with owners	—	—	57	(224)	(131,734)	(3,804)	(135,539)
As of June 30, 2021	(55,126)	(6,362)	—	425,163	5,238,258	385	5,238,643

(5) Consolidated Statements of Cash Flows

	JPY (millions)		USD (millions)(*)
	Three-month Period Ended June 30,		Three-month Period Ended June 30,
	2020	2021	2021
Cash flows from operating activities:			
Net profit for the period	¥ 82,519	¥ 137,726	\$ 1,240
Depreciation and amortization	141,587	142,948	1,287
Impairment losses	7,458	53	0
Equity-settled share-based compensation	10,043	8,547	77
Change in estimate of liabilities related to SHP647	(60,179)	—	—
Loss on sales and disposal of property, plant and equipment	300	94	1
Gain on divestment of business and subsidiaries	(365)	(365)	(3)
Change in fair value of financial assets and liabilities associated with contingent consideration arrangements, net	19,297	(934)	(8)
Finance (income) and expenses, net	27,235	25,216	227
Share of loss of investments accounted for using the equity method	9,759	357	3
Income tax expenses	47,772	85,252	768
Changes in assets and liabilities:			
Increase in trade and other receivables	(25,845)	(41,835)	(377)
Increase in inventories	(4,367)	(21,009)	(189)
Decrease in trade and other payables	(23,153)	(24,854)	(224)
Increase (decrease) in provisions	2,177	(65,217)	(587)
Increase (decrease) in other financial liabilities	685	(7,985)	(72)
Other, net	(37,579)	(35,236)	(317)
Cash generated from operations	197,344	202,760	1,826
Income taxes paid	(51,483)	(35,902)	(323)
Net cash from operating activities	145,861	166,858	1,503
Cash flows from investing activities:			
Interest received	308	349	3
Dividends received	177	139	1
Acquisition of property, plant and equipment	(23,135)	(29,838)	(269)
Proceeds from sales of property, plant and equipment	26	79	1
Acquisition of intangible assets	(17,342)	(12,454)	(112)
Acquisition of investments	(3,517)	(3,251)	(29)
Proceeds from sales and redemption of investments	44,437	483	4
Acquisition of businesses, net of cash and cash equivalents acquired	—	(27,549)	(248)
Proceeds from sales of business, net of cash and cash equivalents divested	—	2,138	19
Other, net	(292)	(543)	(5)
Net cash from (used in) investing activities	662	(70,445)	(634)

	JPY (millions)		USD (millions)(*)
	Three-month Period Ended June 30,		Three-month Period Ended June 30,
	2020	2021	2021
Cash flows from financing activities:			
Net increase (decrease) in short-term loans and commercial papers	(10,000)	1	0
Repayments of bonds and long-term loans	(9,979)	(242,919)	(2,187)
Acquisition of treasury shares	(2,132)	(2,542)	(23)
Interest paid	(30,207)	(23,218)	(209)
Dividends paid	(133,115)	(132,032)	(1,189)
Repayments of lease liabilities	(7,213)	(10,328)	(93)
Other, net	(119)	—	—
Net cash used in financing activities	(192,765)	(411,038)	(3,701)
Net decrease in cash and cash equivalents	(46,242)	(314,625)	(2,833)
Cash and cash equivalents at the beginning of the year			
(Consolidated statements of financial position)	637,614	966,222	8,701
Effects of exchange rate changes on cash and cash equivalents	(1,585)	3,324	30
Cash and cash equivalents at the end of the period			
(Consolidated statements of financial position)	589,787	654,920	5,898

(*) Consolidated statements of cash flows have been translated solely for the convenience of the reader at an exchange rate of 1USD = 111.05 JPY, the Noon Buying Rate certified by the Federal Reserve Bank of New York on June 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 July 9, 2021, Takeda provided a notice of redemption to the holders of 1,500 million EUR in unsecured senior notes issued in November 2018 in advance of their original maturity date of November 21, 2022. The redemption date of the unsecured senior notes will be August 10, 2021.

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

Supplementary Information

1. Pipeline
• I. Clinical Development Activities
• II. Recent Progress in stage
• III. Discontinued projects
• IV. Main Research & Development collaborations
2. Supplementary Financial Information
• Revenue by region
◦ Year to date
◦ Quarterly
• Product Sales Analysis
◦ Year to date
• Product Sales Analysis (Reported & Underlying Growth)
• Product Forecast
• Exchange Rate
• CAPEX, depreciation and amortization and impairment losses
3. Reconciliation
• FY2021 Q1 Reconciliation from Reported Revenue to Core/Underlying Revenue
• FY2021 Q1 Reconciliation from Reported to Core/Underlying Core
• FY2020 Q1 Reconciliation from Reported to Core/Underlying Core
• Free Cash Flow
• FY2021 Q1 LTM Net Profit to Adjusted EBITDA Bridge
• FY2021 Q1 Net Debt to Adjusted EBITDA
• FY2020 Net Debt to Adjusted EBITDA
• Reconciliation from Reported Operating Profit to Core Operating Profit - FY2021 Forecast

1. Pipeline

I. Clinical Development Activities

- The following table lists the pipeline assets that we are developing as of July 30, 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-35^{*1} <brentuximab vedotin> <i>ADCESTRIS</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	Filed (Oct 2020)
			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-924 <pevonedistat>	NEDD 8 activating enzyme inhibitor (injection)	Small molecule	High-risk Myelodysplastic Syndrome	Global	P-III
			Unfit Acute Myelogenous Leukemia	Global	P-III

[Table of Contents](#)

TAK-788 < mobocertinib >	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	Filed (Apr 2021) Filed (Jul 2021) ^{*13} P-III P-III
TAK-385 < relugolix >	LH-RH antagonist (oral)	Small molecule	Prostate cancer	Japan China	P-III P-III
TAK-981	SUMO inhibitor (injection)	Small molecule	Multiple cancers	-	P-II
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	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	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.

*13 Event after the Q1 reporting period: Update after July 1, 2021

Additions since FY2020 Q4: None

Removals since FY2020 Q4: TAK-169 for relapsed/ refractory multiple myeloma (P-I, 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> TAKHZYRO (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 VONVENDI (U.S., Japan), VEYVONDI (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 ADYNOVATE (U.S., Japan), ADYNOVI (EU)	Antihemophilic factor [recombinant], PEGylated (injection)	Biologic and other	Pediatric Hemophilia A	EU	P-III
TAK-755 ^{*1}	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/II
TAK-620 ^{*2} <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-079 ^{*3} <mezagitamab>	Anti-CD38 monoclonal antibody (injection)	Biologic and other	Myasthenia gravis	-	P-II
			Immune thrombocytopenic purpura	-	P-II
			Systemic lupus erythematosus	-	P-I/II
TAK-834 NATPARA (U.S.), NATPAR (EU)	Parathyroid hormone (injection)	Biologic and other	Hypoparathyroidism	Japan	P-I ^{*4}

*1 Partnership with KM Biologics for co-exclusive license for commercialization in Japan only

*2 Partnership with GlaxoSmithKline

*3 Relapsed/refractory Multiple Myeloma will continue until trial completion.

*4 P-I study in Japan completed; P-III study start timing under review.

Additions since FY2020 Q4: None

Removals since FY2020 Q4: None

• **Neuroscience Pipeline**

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Stage	
TAK-935 <soficicostat>	CH24H inhibitor (oral)	Small molecule	Dravet Syndrome, Lennox-Gastaut syndrome	-	P-II
			15q duplication syndrome, CDKL5 deficiency disorder	-	P-II
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	Narcolepsy, other sleep disorders	-	P-I

*1 50:50 co-development and co-commercialization with Neurocrine

*2 Partnership with AstraZeneca. AstraZeneca leads Phase 1 development

Additions since FY2020 Q4: None

Removals since FY2020 Q4: TAK-831 Schizophrenia negative symptoms (P-II (a), discontinued)

TAK-831 Cognitive impairment associated with schizophrenia (CIAS) (P-II (a), decided not to co-fund a supplemental study with Neurocrine)

• **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. Japan	CRL received (Dec 2019)* ⁹ Filed (Aug 2019)
			Subcutaneous formulation for Crohn's disease	U.S. Japan	P-III P-III
			Antibiotic-refractory Pouchitis	EU	Filed (Jul 2021) * ¹⁰
			Graft-versus-Host Disease prophylaxis in patients undergoing allogeneic hematopoietic stem cell transplantation	EU Japan	P-III P-III
			Pediatrics Study (ulcerative colitis, Crohn's disease)	Global	P-II
TAK-438 <vonoprazan> <i>TAKECAB</i> (Japan) <i>VOCINTI</i> (China)	Potassium-competitive acid blocker (oral)	Small molecule	Acid related diseases (Reflex Esophagitis Maintenance)	China	Filed (Mar 2020)
			Acid related diseases (Duodenal Ulcer)	China	Filing withdrawn (Jun 2021)* ¹¹
			Oral disintegrated tablet formulation	Japan	Filed (Mar 2021)
			Acid related diseases (adjunct to Helicobacter pylori eradication)	China	P-III
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-721 * ¹ <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 Filed (Feb 2021)
TAK-906	Dopamine D2/D3 receptor antagonist (oral)	Small molecule	Gastroparesis	-	P-II (b)
TAK-954 * ²	5-HT ₄ - hydroxytryptamine receptor agonist (injection)	Small molecule	Post-operative gastrointestinal dysfunction	-	P-II (b)
TAK-999 * ³	GalNAc based RNA interference (RNAi) (injection)	Peptide/ Oligo- nucleotide	Alpha-1 antitrypsin-deficiency associated liver disease	U.S. EU	P-II (b) P-II (b)
TAK-101 * ⁴	Tolerizing Immune Modifying nanoParticle (TIMP) (injection)	Biologic and other	Celiac disease	-	P-II (a)
TAK-018/EB8018 * ⁵ <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

[Table of Contents](#)

TAK-510	Peptide agonist (sub-cutaneous)	Peptide/ Oligo-nucleotide	Nausea and vomiting	-	P-I
TAK-062 *6	Glutenase (oral)	Biologic and other	Celiac disease	-	P-I
TAK-039 *7	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 Complete Response Letter (CRL) is unrelated to the clinical safety and efficacy data, and included queries related to the design and labelling of the SC device. In August 2020, Takeda had a productive meeting with the FDA to review the Company’s latest data and to seek guidance on additional data needs required to support the approval of vedolizumab SC. During the meeting, Takeda gained clarity on data needs for the device, and is moving forward to address them. Continued testing of the device will take time, and as a result, Takeda expects to potentially launch vedolizumab SC for moderate to severe ulcerative colitis in the U.S. in 2022, pending FDA approval.

*10 Event after the Q1 reporting period: Update after July 1, 2021

*11 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.

Additions since FY2020 Q4: None

Removals since FY2020 Q4: TAK-671 for acute pancreatitis (P-I, discontinued)

• **Plasma-Derived Therapies Pipeline**

Development code <generic name> Brand name (country/region)	Type of Drug (administration route)	Modality	Indications / additional formulations	Stage	
TAK-664 <i>CUVITRU</i> (U.S., EU)	Immunoglobulin 20% [human] (subcutaneous)	Biologic and other	Primary immunodeficiencies	Japan	P-III
TAK-771 *1 <IG Infusion 10% (Human) w/ Recombinant Human Hyaluronidase> <i>HYQVIA</i> (U.S., EU)	Immunoglobulin (IgG) + recombinant hyaluronidase replacement therapy (injection)	Biologic and other	Pediatric indication for primary immunodeficiency	U.S.	P-III
			Chronic inflammatory demyelinating polyradiculoneuropathy	U.S. EU	P-III P-III

*1 Partnership with Halozyme

Additions since FY2020 Q4: None

Removals since FY2020 Q4: None

• **Vaccines Pipeline**

Development code Brand name (country/region)	Type of vaccine (administration route)	Modality	Indications / additional formulations	Stage	
TAK-919/ mRNA-1273 ^{*1} <i>COVID-19 Vaccine Moderna Intramuscular Injection (Japan)</i>	SARS-CoV-2 vaccine (injection)	Biologic and other	Active immunization for the prevention of COVID-19	Japan	Approved (May 2021) ^{*5}
TAK-003	Tetravalent dengue vaccine (injection)	Biologic and other	For the prevention of dengue fever of any severity, due to any serotype, in individuals aged 4 up to 60 years of age	EU and EU- M4all -	Filed (Mar 2021) ^{*6} P-III
TAK-019/ NVX-CoV2373 ^{*2}	SARS-CoV-2 vaccine (injection)	Biologic and other	Active immunization for the prevention of COVID-19	Japan	P-I/II
TAK-214 ^{*3}	Norovirus vaccine (injection)	Biologic and other	Active immunization for the prevention of acute gastroenteritis caused by norovirus	-	P-II (b)
TAK-426 ^{*4}	Zika vaccine (injection)	Biologic and other	Active immunization for the prevention of disease caused by Zika virus	-	P-I

*1 Partnership with 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 HilleVax, Inc. HilleVax will have exclusive global development rights and commercialization rights worldwide outside of Japan and Takeda retains commercialization rights in Japan.

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

*5 Change in age indication to expand to 12 years of age and older (July 2021), event after the Q1 reporting period (Update after July 1, 2021).

*6 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 FY2020 Q4: None

Removals since FY2020 Q4: None

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)
TAK-788 <mobocertinib>	Previously treated Non-Small Cell Lung Cancer with EGFR exon 20 insertion	U.S.	Filed (Apr 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-861	Sleep disorders, other disorders	-	P-I

*Event after the Q1 reporting period: Update after July 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.

IV. Main Research & Development 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) (CD38-Attenukine) 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.

* List is not inclusive of all Takeda R&D collaborations.

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.
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.
Rani Therapeutics	U.S.	Research collaboration agreement to evaluate a micro tablet pill technology for oral delivery of FVIII therapy in hemophilia
Xenetic Biosciences	U.S.	Exclusive R&D license agreement for PolyXen delivery technology for hemophilia factors VII, VIII, IX, X.

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
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 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. At certain development events, Takeda may elect to opt in or out of a 50:50 profit share on all clinical programs on an asset-by-asset basis. For any asset in which Takeda is participating in a 50:50 profit share arrangement, Takeda will not be eligible to receive development or commercial milestones. For TAK-831, Takeda decided not to co-fund a supplemental study with Neurocrine, which resulted in TAK-831 remaining a Royalty Bearing Product.
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> AAV based therapies for Friedreich's Ataxia (FA) and two additional undisclosed targets.
Wave Life Sciences	Singapore	Research, development and commercial collaboration and multi-program option agreement to develop antisense oligonucleotides for a range of neurological diseases.

‡ Executed since April 1, 2021

*Event after the Q1 reporting period: Update after July 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 FIN-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 obtains the exclusive worldwide rights to develop and commercialize FIN-524 and rights to follow-on products in inflammatory bowel diseases.
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.
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.
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.
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.
Theravance Biopharma	U.S.	Global license, development and commercialization agreement for TAK-954, a selective 5-HT4 receptor agonist for motility disorders.
UCSD/Fortis Advisors	U.S.	Technology license for the development of oral budesonide formulation (TAK-721) for treatment of eosinophilic esophagitis.

• **Plasma Derived Therapies**

Partner	Country	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).
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

*Event after the Q1 reporting period: Update after July 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.

■ **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
	FY20Q1	FY21Q1	YOY		YOY
Total revenue	801.9	949.6	147.8	18.4%	3.8%
Japan *2	144.0	259.0	114.9	79.8%	1.0%
% of revenue	18.0%	27.3%	9.3pt		
United States	402.6	412.2	9.6	2.4%	0.5%
% of revenue	50.2%	43.4%	-6.8pt		
Europe and Canada	157.6	178.7	21.2	13.4%	11.1%
% of revenue	19.6%	18.8%	-0.8pt		
Growth and Emerging Markets *3	97.6	99.7	2.0	2.1%	10.8%
% of revenue	12.2%	10.5%	-1.7pt		
Asia (excluding Japan)	36.9	40.3	3.4	9.3%	13.6%
% of revenue	4.6%	4.2%	-0.4pt		
Latin America	30.8	30.1	-0.7	-2.3%	24.4%
% of revenue	3.8%	3.2%	-0.7pt		
Russia/CIS	13.0	12.3	-0.7	-5.4%	-14.9%
% of revenue	1.6%	1.3%	-0.3pt		
Other *4	16.9	17.0	0.0	0.3%	7.3%
% of revenue	2.1%	1.8%	-0.3pt		
Of which royalty / service income *2	18.1	157.7	139.6	773.2%	

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

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

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

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

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%						
Japan *2	144.0	138.3	152.7	124.6	259.0	79.8%						
% of revenue	18.0%	17.5%	18.3%	16.2%	27.3%							
United States	402.6	383.5	402.8	379.0	412.2	2.4%						
% of revenue	50.2%	48.6%	48.1%	49.2%	43.4%							
Europe and Canada	157.6	169.6	172.8	166.2	178.7	13.4%						
% of revenue	19.6%	21.5%	20.7%	21.6%	18.8%							
Growth and Emerging Markets *3	97.6	97.5	108.4	100.5	99.7	2.1%						
% of revenue	12.2%	12.4%	13.0%	13.0%	10.5%							
Asia (excluding Japan)	36.9	41.4	40.9	37.1	40.3	9.3%						
% of revenue	4.6%	5.2%	4.9%	4.8%	4.2%							
Latin America	30.8	28.2	36.4	26.2	30.1	-2.3%						
% of revenue	3.8%	3.6%	4.4%	3.4%	3.2%							
Russia/CIS	13.0	8.6	17.1	18.8	12.3	-5.4%						
% of revenue	1.6%	1.1%	2.0%	2.4%	1.3%							
Other *4	16.9	19.3	14.0	18.3	17.0	0.3%						
% of revenue	2.1%	2.4%	1.7%	2.4%	1.8%							
Of which royalty / service income *2	18.1	28.2	22.8	23.4	157.7	773.2%						

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

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

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

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

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

Year to date

(Bn JPY)	Reported			US	YOY	Japan	YOY	EUCAN	YOY	GEM*5	YOY	Ex-US	YOY
	FY20Q1	FY21Q1	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.

Table of Contents

(Bn JPY)	Reported			US	YOY	Japan	YOY	EUCAN	YOY	GEM*5	YOY	Ex-US	YOY
	FY20Q1	FY21Q1	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	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 and blister packs.

*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%													
ENTYVIO	101.2	105.7	112.3	110.0	125.4	23.9%	18.2%													
TAKECAB-F *1	20.2	19.7	24.2	20.7	24.3	20.1%	19.5%													
GATTEX/REVESTIVE	17.5	15.7	16.9	14.4	18.1	3.7%	0.3%													
DEXILANT	13.6	14.8	15.1	12.1	10.8	-20.7%	-24.5%													
PANTOLOC/CONTROLOC*2	9.2	12.3	10.9	10.7	10.4	13.8%	3.7%													
LIALDA/MEZAVANT	5.5	6.1	7.1	6.8	6.4	16.2%	7.0%													
PENTASA	6.2	5.5	6.2	5.3	4.8	-21.6%	-23.2%													
AMITIZA	6.3	6.2	6.4	2.4	2.1	-65.8%	-66.5%													
RESOLOR/MOTTEGRITY	2.7	2.2	3.6	2.7	3.2	16.9%	11.4%													
ALOFISEL	0.0	0.3	0.3	0.2	0.4	3,556.0%	3,222.0%													
Other	4.5	4.3	6.1	3.7	4.5	0.0%	-6.2%													
Rare Diseases	155.0	140.4	151.3	145.0	155.5	0.3%	-3.4%													
Rare Metabolic	39.9	39.7	42.2	40.8	44.3	10.9%	6.6%													
ELAPRASE	17.6	16.7	17.2	17.3	18.6	5.5%	2.5%													
REPLAGAL	12.2	12.8	13.9	12.9	14.1	15.2%	10.2%													
VPRIV	9.3	9.5	10.0	9.7	10.5	11.9%	6.9%													
NATPARA/NATPAR	0.7	0.8	1.0	1.0	1.2	56.8%	39.1%													
Rare Hematology	76.8	66.1	75.8	71.2	72.2	-5.9%	-9.4%													
ADVATE	33.7	29.8	33.7	31.4	30.7	-8.9%	-12.5%													
ADYNOVATE/ADYNOVI	15.3	14.2	14.3	14.3	15.4	0.6%	-3.3%													
FEIBA *3	12.9	7.7	13.7	10.3	11.4	-11.3%	-12.6%													
RECOMBINATE	3.7	3.2	3.5	2.9	3.7	-0.9%	-3.7%													
HEMOFIL/IMMUNATE/ IMMUNINE*3	4.4	4.9	3.9	5.4	3.3	-25.6%	-29.4%													
Other PDT Products *3 *4	0.9	0.8	0.9	0.9	0.9	-1.1%	-10.2%													
Other *5	5.9	5.4	5.8	6.0	6.9	16.4%	10.4%													
Hereditary Angioedema	38.3	34.6	33.4	33.0	39.0	1.8%	-1.7%													
TAKHZYRO	23.2	20.5	22.1	20.8	25.5	9.6%	6.0%													
FIRAZYR	8.1	7.1	5.0	6.7	6.9	-15.1%	-18.3%													
CINRYZE *3	5.9	6.1	5.2	4.6	5.6	-5.7%	-9.2%													
KALBITOR	1.1	0.9	1.1	0.8	1.1	2.8%	0.8%													

*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.

Table of Contents

(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%													
immunoglobulin *1	85.1	77.6	85.4	86.8	81.6	-4.1%	-6.9%													
albumin *1	13.0	15.6	15.0	14.0	17.8	36.8%	26.4%													
Other *1 *4	7.2	7.5	6.7	6.5	7.8	9.1%	6.0%													
Oncology	108.0	102.1	108.4	98.0	121.4	12.4%	8.9%													
VELCADE	24.2	25.8	25.9	25.2	30.1	24.6%	22.1%													
LEUPLIN/ENANTONE	27.4	22.5	25.4	20.1	26.2	-4.3%	-8.8%													
NINLARO	22.9	21.4	23.5	19.5	24.4	6.3%	2.0%													
ADCETRIS	15.1	15.5	13.8	15.0	17.2	14.2%	8.8%													
ICLUSIG	9.2	7.6	9.4	7.9	10.4	12.3%	10.0%													
VECTIBIX	6.2	5.7	6.5	5.4	6.2	0.1%	0.1%													
ALUNBRIG	2.0	2.3	2.2	2.3	3.1	54.4%	47.3%													
Other	0.9	1.3	1.7	2.4	3.8	300.0%	495.2%													
Neuroscience	106.9	100.9	107.3	102.2	113.4	6.1%	2.9%													
VYVANSE/ELVANSE	66.0	66.6	69.8	69.1	79.2	20.0%	15.6%													
TRINTELLIX	16.9	18.1	17.7	16.2	17.9	5.9%	4.0%													
INTUNIV	5.6	3.3	5.9	5.6	3.3	-42.5%	-49.5%													
ADDERALL XR	5.3	3.7	4.4	4.4	3.9	-24.9%	-27.4%													
ROZEREM	3.0	2.9	3.6	2.5	3.2	6.9%	7.1%													
Other *5	10.0	6.3	6.0	4.4	5.9	-41.2%	-41.1%													
Other *2	139.8	152.0	153.5	128.7	241.6	72.8%	9.0%													
AZILVA-F *3	20.9	19.1	22.9	19.4	22.6	8.6%	8.6%													
LOTRIGA	8.1	7.6	8.8	7.3	7.8	-3.0%	-3.0%													
AIPHAGAN	4.0	3.7	4.6	3.7	4.6	15.0%	15.0%													
FOSRENOL	3.2	3.3	3.7	3.3	3.4	4.7%	-3.2%													
ACTOVEGIN	1.7	3.2	3.4	2.4	3.2	87.2%	81.9%													

*1 PDT products

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

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

*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

No changes in FY21 Product Forecasts (Reported and Underlying Growth) from those disclosed on May 11, 2021

(Bn JPY)	FY2020 Reported	FY2021 Reported Forecasts (Disclosed on May 11, 2021)		FY2021 Underlying Growth Forecasts (Disclosed on May 11, 2021)
	Annual	Annual	YOY	
GI	777.8	878.0	100.2 13 %	10%
ENTYVIO	429.3	538.0	108.7 25 %	22 %
TAKECAB-F *1	84.8	94.0	9.2 11 %	11 %
GATTEX/REVESTIVE	64.6	79.0	14.4 22 %	20 %
DEXILANT	55.6	54.0	-1.6 -3 %	-6 %
PANTOLOC/CONTROLOC*2	43.1	37.0	-6.1 -14 %	-19 %
LIALDA/MEZAVANT	25.5	19.0	-6.5 -25 %	-25 %
PENTASA	23.1	19.0	-4.1 -18 %	-20 %
AMITIZA	21.2	5.0	-16.2 -76 %	-79 %
RESOLOR/MOTTEGRITY	11.2	12.0	0.8 7 %	-1 %
ALOFISEL	0.8	3.0	2.2 283 %	238 %
Other	18.6	18.0	-0.6 -3 %	-8 %
Rare Diseases	591.7			
Rare Metabolic	162.6	173.0	10.4 6 %	2%
ELAPRASE	68.8	71.0	2.2 3 %	-1 %
REPLAGAL	51.8	56.0	4.2 8 %	3 %
VPRIV	38.5	41.0	2.5 6 %	5 %
NATPARANATPAR	3.6	5.0	1.4 41 %	38 %
Rare Hematology	289.8	273.0	-16.8 -6 %	-10%
ADVATE	128.5	176.0	-10.6 -6 %	-10 %
ADYNOVATE/ADYNOVI	58.1	35.0	-9.5 -21 %	-26 %
FEIBA *3	44.5	12.0	-1.4 -10 %	-10 %
RECOMBINATE	13.4	17.0	-1.7 -9 %	-13 %
HEMOFIL/IMMUNATE/ IMMUNINE*3	18.7	5.0	1.5 44 %	41 %
Other PDT Products *3 *4	3.5	28.0	4.8 21 %	15 %
Other *5	23.2			
Hereditary Angioedema	139.3		0% to +10%	0% to +10%
TAKHZYRO	86.7		+20% to +30%	+20% to +30%
FIRAZYR	26.8	15.0	-11.8 -44 %	-46 %
CINRYZE *3	21.9	17.0	-4.9 -22 %	-23 %
KALBITOR	3.9	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, INNONAFACTOR, 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)	FY2020 Reported	FY2021 Reported Forecasts (Disclosed on May 11, 2021)			FY2021 Underlying Growth Forecasts (Disclosed on May 11, 2021)
	Annual	Annual	YOY		
PDT Immunology	420.4		+10% to +20%		+10% to +20%
immunoglobulin *1	334.9		+5% to +10%		+5% to +10%
albumin *1	57.6		+>30%		+>30%
Other *1 *4	27.9		0% to +10%		0% to +10%
Oncology	416.5	455.0	38.5	9%	7%
VELCADE	101.1	83.0	-18.1	-18%	-20%
LEUPLIN/ENANTONE	95.4	104.0	8.6	9%	7%
NINLARO	87.4	97.0	9.6	11%	8%
ADCETRIS	59.4	70.0	10.6	18%	14%
ICLUSIG	34.2	39.0	4.8	14%	11%
VECTIBIX	23.8	22.0	-1.8	-8%	-7%
ALUNBRIG	8.8	16.0	7.2	82%	80%
Other	6.4	24.0	17.6	276%	256%
Neuroscience	417.3	434.0	16.7	4%	2%
VYVANSE/ELVANSE	271.5	293.0	21.5	8%	5%
TRINTELLIX	68.9	82.0	13.1	19%	17%
INTUNIV	20.4	17.0	-3.4	-17%	-20%
ADDERALL XR	17.8	10.0	-7.8	-44%	-45%
ROZEREM	12.0	11.0	-1.0	-8%	-3%
Other *5	26.7	21.0	-5.7	-21%	-17%
Other *2	574.1		-10% to 0%		-10% to 0%
AZILVA-F *3	82.2	68.0	-14.2	-17%	-16%
LOTRIGA	31.8	29.0	-2.8	-9%	-8%
AIPHAGAN	15.9	12.0	-3.9	-25%	-22%
FOSRENOL	13.5	11.0	-2.5	-18%	-17%
ACTOVEGIN	10.7	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 and blister packs.

*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	FY20 (Apr-Jun)	FY21 (Apr-Jun)	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	118	132	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	15.1	17.0	16.8	+10.7	+6.0	+5.9	+4.4
BRL	20.2	20.2	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	FY20Q1	FY21Q1	YOY		FY21 Forecasts (Disclosed on May 11, 2021)
Capital expenditures*	236.5	40.5	42.3	1.8	4.5%	210.0 -260.0
Tangible assets	111.2	23.1	29.8	6.7	29.0%	
Intangible assets	125.3	17.3	12.5	-4.9	-28.2%	
* Cash flow base						
Depreciation and amortization	558.0	141.6	142.0	0.5	0.3%	556.0
Depreciation of tangible assets* (A)	124.4	31.5	32.4	0.9	3.0%	
Amortization of intangible assets (B)	433.6	110.1	109.6	-0.5	-0.4%	
Of which Amortization associated with products (C)	405.3	102.3	102.8	0.5	0.5%	406.0
Of which Amortization excluding intangible assets associated with products (D)	28.3	7.8	6.8	-1.0	-12.5%	
* Excluding depreciation for investment assets.						
Depreciation and amortization (excluding intangible assets associated with products) (A)+(D)	152.7	39.2	39.2	-0.0	-0.1%	150.0
Impairment losses	25.5	7.5	0.1	-7.4	-99.3%	
Impairment losses associated with products	16.6	1.9	—	-1.9	-100.0%	50.0
Amortization and impairment losses on intangible assets associated with products	421.9	104.3	102.8	-1.4	-1.4%	456.0

3. Reconciliation

FY2021 Q1 Reconciliation from Reported Revenue to Core/Underlying Revenue

(Billion JPY)	Q1		vs. PY	
	FY2020	FY2021		
Reported Revenue	801.9	949.6	+147.8	+ 18.4%
Sale of Japan diabetes portfolio*2	—	(133.0)	(133.0)	-16.6pp
Core Revenue	801.9	816.6	+14.7	+ 1.8%
FX effects*1				-3.9pp
Divestitures*2				+5.8pp
Regional portfolio				+1.6pp
Japan diabetes portfolio				+1.1pp
TACHOSIL				+0.4pp
Others				+2.8pp
Underlying Revenue Growth				+ 3.8%

*1 FX adjustment applies plan rate to both periods.

*2 Major adjustments are as follow;

- Revenue of select over-the-counter and non-core products in Asia Pacific is excluded from FY2020 Q1 as the divestiture was completed in November 2020.
- Revenue of select non-core prescription pharmaceutical products predominantly in Europe is excluded from FY2020 Q1 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 Q1 as the divestiture was completed in January 2021.
- Net sales from TACHOSIL, a surgical patch, are excluded from FY2020 Q1 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 Q1 as the divestiture was completed in March 2021.
- Revenue of the former subsidiary, Takeda Consumer Healthcare Company Limited is excluded from FY2020 Q1 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 Q1 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 Q1.
- Revenue of select non-core prescription pharmaceutical products in China is excluded from both FY2021 Q1 and FY2020 Q1 as the divestiture was publicly announced and had been expected to complete within FY2021 H1.

FY2021 Q1 Reconciliation from Reported to Core/Underlying Core
FY2021Q1

(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/expense	Sale of Japan diabetes portfolio	Irish Tax Assessment *1	Others		FX	Divestitures	
Revenue	949.6				(133.0)			816.6	(31.5)	(3.9)	+3.8 %
Cost of sales	(241.3)				0.6		12.8	(227.9)	10.6	1.4	
Gross Profit	708.3				(132.4)		12.8	588.7	(20.9)	(2.5)	
SG&A expenses	(219.8)				1.0		0.9	(218.0)	8.7		
R&D expenses	(122.5)						0.7	(121.8)	4.1		
Amortization of intangible assets	(102.8)	102.8						—			
Impairment losses on intangible assets	—							—			
Other operating income	11.1			(10.8)			(0.4)	—			
Other operating expenses	(25.8)			25.1			0.7	—			
Operating profit	248.6	102.8		14.3	(131.4)		14.7	248.9	(8.1)	(2.5)	(2.1) %
Margin	26.2 %							30.5 %			30.5 %*2
Financial income/expenses	(25.2)						(2.5)	(27.7)	1.3		
Equity income/loss	(0.4)						2.3	2.0	0.1		
Profit before tax	223.0	102.8		14.3	(131.4)		14.5	223.2	(6.7)	(2.5)	
Tax expenses	(85.3)	(22.9)		(4.8)	40.2	62.7	(36.5)	(46.6)	1.4	0.8	
Non-controlling interests	(0.0)							(0.0)	0.0		
Net profit	137.7	79.9		9.5	(91.2)	62.7	(22.0)	176.6	(5.3)	(1.7)	
EPS (yen)	88							113	(3)	(1)	+3.9 %
Number of shares (millions)	1,565							1,565			1,563

*1 A tax charge of 62.7 billion JPY for tax and interest, net of 0.5 billion JPY of associated tax benefit, arising from tax assessment involving Irish taxation of the break fee Shire received from AbbVie in connection with the terminated offer to acquire Shire made by AbbVie in 2014.

*2 Underlying Core Operating Profit Margin.

FY2020 Q1 YTD Reconciliation from Reported to Core/ Underlying Core
FY2020Q1

(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/expense	TEVA JV related accounting adjustments	Others		FX	Divestitures	
Revenue	801.9						801.9	(0.7)	(48.7)	+0.9 %
Cost of sales	(238.1)					26.6	(211.5)	(6.5)	13.5	
Gross Profit	563.8					26.6	590.3	(7.1)	(35.2)	
SG&A expenses	(202.4)			0.0		(0.3)	(202.6)	0.5	3.5	
R&D expenses	(106.8)			(0.1)		0.1	(106.8)	0.8	0.2	
Amortization of intangible assets	(102.3)	102.3					—			
Impairment losses on intangible assets	(1.9)		1.9				—			
Other operating income	63.7			(3.2)	(0.4)	(60.2)	—			
Other operating expenses	(46.8)			28.2		18.6	—			
Operating profit	167.3	102.3	1.9	24.9	(0.4)	(15.2)	280.9	(5.9)	(31.5)	+11.2 %
Margin	20.9 %						35.0 %			32.4 %*
Financial income/expenses	(27.2)					(1.1)	(28.3)	(0.4)	(0.0)	
Equity income/loss	(9.8)					10.6	0.8	0.0		
Profit before tax	130.3	102.3	1.9	24.9	10.2	(16.3)	253.4	(6.2)	(31.5)	
Tax expenses	(47.8)	(19.7)	(0.3)	(2.6)	(3.1)	10.8	(62.7)	1.6	8.8	
Non-controlling interests	(0.0)						(0.0)	(0.0)		
Net profit	82.5	82.6	1.6	22.3	7.1	(5.5)	190.6	(4.7)	(22.7)	
EPS (yen)	53						122	(3)	(15)	+8.7 %
Number of shares (millions)	1,559						1,559			1,558

* Underlying Core Operating Profit Margin.

Free Cash Flow

(BN JPY)	FY2020 Q1 (Apr-Jun)	FY2021 Q1 (Apr-Jun)	vs. PY	
Net profit	82.5	137.7	+55.2	+66.9%
Depreciation, amortization and impairment loss	149.0	143.0	-6.0	
Decrease (increase) in trade working capital	-53.4	-87.7	-34.3	
Income taxes paid	-51.5	-35.9	+15.6	
Other	19.1	9.7	-9.4	
Net cash from operating activities	145.9	166.9	+21.0	+14.4%
Adjustment for deposits restricted to certain vaccines operations	—	5.9	+5.9	
Acquisition of PP&E	-23.1	-29.8	-6.7	
Proceeds from sales of PP&E	0.0	0.1	+0.1	
Acquisition of intangible assets	-17.3	-12.5	+4.9	
Acquisition of investments	-3.5	-3.3	+0.3	
Proceeds from sales and redemption of investments	44.4	0.5	-44.0	
Proceeds from sales of business, net of cash and cash equivalents divested	—	2.1	+2.1	
Free Cash Flow	146.3	129.9	-16.4	-11.2%

FY2021 Q1 NET PROFIT TO ADJUSTED EBITDA BRIDGE

(BN JPY)	FY2020 Full Year (Apr-Mar)	FY2020 Q1 (Apr-Jun)	FY2021 Q1 (Apr-Jun)	FY2021 Q1 LTM*1 (Jul-Jun)
Net profit	376.2	82.5	137.7	431.4
Income tax expenses	-9.9	47.8	85.3	27.5
Depreciation and amortization	559.7	141.6	142.9	561.0
Interest expense, net	129.0	30.7	29.9	128.2
EBITDA	1,054.9	302.6	395.9	1,148.2
Impairment losses	25.5	7.5	0.1	18.0
Other operating expense (income), net, excluding depreciation and amortization and other miscellaneous expenses (non-cash item)	-74.5	-24.4	12.6	-37.5
Finance expense (income), net, excluding interest income and expense, net	14.1	-3.5	-4.7	12.9
Share of loss on investments accounted for under the equity method	-0.1	9.8	0.4	-9.5
Other adjustments:	131.4	35.7	-108.6	-12.9
Non-core expense related to COVID-19	14.0	—	3.4	17.4
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	26.5	10.8	63.7
Acquisition costs related to Shire	1.9	0.0	—	1.9
Other costs*2	36.1	9.2	8.7	35.6
Adjusted EBITDA	1,151.3	327.6	295.6	1,119.2
EBITDA from divested products*3				-62.2
Adjusted EBITDA (LTM)				1,057.1

*1 LTM represents Last Twelve Months (July 2020 - June 2021). Calculated by subtracting FY2020 Q1 from FY2020 Full Year and adding FY2021 Q1.

*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 Q1

NET DEBT/ADJUSTED EBITDA RATIO	
(BN JPY)	FY2021 Q1 (Jun End)
Cash and cash equivalents*1	485.4
Book value debt on the balance sheet	-4,405.9
Hybrid bond 50% equity credit	250.0
FX adjustment*2	132.9
Gross debt*3	-4,023.0
Net cash (debt)	-3,537.6
Net debt/Adjusted EBITDA ratio	3.3 x
Adjusted EBITDA	1,057.1

NET INCREASE (DECREASE) IN CASH				
(BN JPY)	FY2020 Q1 (Apr-Jun)	FY2021 Q1 (Apr-Jun)	vs. PY	
Net cash from operating activities	145.9	166.9	+21.0	+14.4%
Acquisition of PP&E	-23.1	-29.8		
Proceeds from sales of PP&E	0.0	0.1		
Acquisition of intangible assets	-17.3	-12.5		
Acquisition of investments	-3.5	-3.3		
Proceeds from sales and redemption of investments	44.4	0.5		
Acquisition of business, net of cash and cash equivalents acquired	—	-27.5		
Proceeds from sales of business, net of cash and cash equivalents divested	—	2.1		
Net increase (decrease) in short-term loans and commercial papers	-10.0	0.0		
Repayment of long-term loans	-10.0	-220.1		
Repayment of bonds	—	-22.8		
Interest paid	-30.2	-23.2		
Dividends paid	-133.1	-132.0		
Others	-9.3	-12.9		
Net increase (decrease) in cash	-46.2	-314.6	-268.4	-580.4%

*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 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

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