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Financial Results of Astellas for Fiscal Year 2020

Japan, April 27, 2021 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, "the Company") today announced the financial results for fiscal year 2020 (FY2020) ended March 31, 2021.

Consolidated financial results for FY2020 (April 1, 2020 – March 31, 2021) (core basis)

(Millions of yen)

	FY2019	**FY2020**	Change (%)
Revenue	1,300,843	**1,249,528**	-51,315 (-3.9%)
Core operating profit	277,758	**251,375**	-26,383 (-9.5%)
Core profit for the year	223,178	**209,906**	-13,272 (-5.9%)

Cautionary Notes
In this material, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.
Information about pharmaceutical products (including products currently in development) which is included in this material is not intended to constitute an advertisement or medical advice.

1. Overview of business performance and others

(1) Overview of business performance for FY2020

1) Overview of consolidated financial results for FY2020

<Consolidated financial results (core basis[(Note)])>

Consolidated financial results (core basis) in FY2020 are shown in the table below.
Revenue, core operating profit and core profit for the year decreased across the board.

Consolidated financial results (core basis)

(Millions of yen)

	FY2019	**FY2020**	Change (%)
Revenue	1,300,843	**1,249,528**	-51,315 (-3.9%)
Cost of sales	276,739	**246,063**	-30,676 (-11.1%)
Selling, general and administrative expenses	499,295	**504,316**	+5,021 (+1.0%)
R&D expenses	224,226	**224,489**	+263 (+0.1%)
Amortisation of intangible assets	21,164	**23,763**	+2,598 (+12.3%)
Share of profit (loss) of investments accounted for using equity method	-1,660	**478**	+2,139 (-)
Core operating profit	277,758	**251,375**	-26,383 (-9.5%)
Core profit for the year	223,178	**209,906**	-13,272 (-5.9%)
Basic core earnings per share (yen)	118.95	**113.03**	-5.92 (-5.0%)

(Note) The Company discloses financial results on a core basis as an indicator of its recurring profitability. Certain items reported in financial results on a full basis that are deemed to be non-recurring items by the Company are excluded as non-core items from these financial results on a core basis. These adjusted items include impairment losses, gain/loss on sales of property, plant and equipment, restructuring costs, loss on disaster, a large amount of losses on compensation or settlement of litigations and other legal disputes, and other items that are deemed to be excluded based on the Company's judgment. A reconciliation table between results on a full basis and results on a core basis is provided in the "Supplementary Documents for FY2020 Financial Results."

Revenue

- Sales of main products XTANDI for the treatment of prostate cancer and XOSPATA for the treatment of acute myeloid leukemia continued to grow. In addition, growth of the co-promotion revenue of PADCEV for the treatment of urothelial cancer contributed to revenue.
- Moreover, sales of Betanis / Myrbetriq / BETMIGA for the treatment of overactive bladder ("OAB") showed steady progress, and new product group in Japan achieved sales growth, including those of EVENITY for the treatment of osteoporosis, Suglat and SUJANU Combination Tablets for the treatment of diabetes mellitus.
- However, revenue decreased mainly due to the loss of market exclusivity of Vesicare for the treatment of OAB in Europe, and the termination of sales agreements for Symbicort for the treatment of asthma, human vaccines of KM Biologics Co., Ltd., Micardis family for the treatment of hypertension, and Celecox for the treatment of inflammation and pain in Japan. Sales were also negatively impacted due to the spread of COVID-19.

As a result of the above, revenue in FY2020 decreased by 3.9% compared to those in the previous fiscal year ("year-on-year") to ¥1,249.5 billion.

Core operating profit/ Core profit for the year

- Gross profit decreased by 2.0% year-on-year to ¥1,003.5 billion. The cost-to-revenue ratio fell by 1.6 percentage points year-on-year to 19.7%, mainly due to changes in product mix.
- Selling, general and administrative expenses increased by 1.0% year-on-year to ¥504.3 billion. There were factors causing a decrease in expenses, including the promotion of the efficient use of expenses and optimization of resource allocation, and also refraining from promotional activities, etc. because of the spread of COVID-19. Overall, however, total selling, general and administrative expenses slightly increased due to the increase of co-promotion fees associated with the growth of sales of XTANDI in the United States, and also there was a one-off reducing factor on expenses from a reversal of loss allowances in the previous year.
- Research and development (R&D) expenses stayed almost flat, showing a 0.1% increase year-on-year to ¥224.5 billion. There was a decrease in development expenses due to the impact of the spread of COVID-19 on the execution of a portion of clinical trials, but total R&D expenses were in the same range as those for the previous fiscal year due to an increase in development expenses for key post-POC pipeline projects, and the addition of R&D expenses from Audentes Therapeutics, Inc. The R&D cost-to-revenue ratio was up 0.7 percentage points year-on-year to 18.0%.
- Amortisation of intangible assets increased by 12.3% year-on-year to ¥23.8 billion.

As a result of the above, core operating profit decreased by 9.5% year-on-year to ¥251.4 billion, and core profit for the year decreased by 5.9% year-on-year to ¥209.9 billion.

Impact of exchange rate on financial results

The exchange rates for the yen in FY2020 are shown in the table below. The resulting impacts were a ¥4.6 billion decrease in revenue and a ¥7.3 billion decrease in core operating profit compared with if the exchange rates of FY2019 were applied.

Average rate	FY2019	**FY2020**	Change
US$/¥	109	**106**	¥3 (Strengthening of yen)
€/¥	121	**124**	¥3 (Weakening of yen)

Change from beginning to end of period	As of March 31, 2020	**As of March 31, 2021**
US$/¥	¥2 (Strengthening of yen)	**¥2 (Weakening of yen)**
€/¥	¥5 (Strengthening of yen)	**¥10 (Weakening of yen)**

<Consolidated financial results (full basis)>

Consolidated financial results on a full basis in FY2020 are shown in the table below. Revenue, operating profit, profit before tax and profit for the year decreased across the board.

The full basis financial results include “Other income,” “Other expenses,” which are excluded from the core basis financial results. In FY2020, “Other income” was ¥7.6 billion (¥12.2 billion in the previous fiscal year) and “Other expenses” was ¥123.0 billion (¥45.9 billion in the previous fiscal year).
As “Other expenses,” the Company recorded impairment losses of ¥30.2 billion in relation to the termination of development for the anti-TIGIT antibody ASP8374/PTZ-201 in the second quarter of FY2020, and impairment losses of ¥58.8 billion in relation to a revision of the development plan for the gene therapy AT132 targeting patients with X-linked myotubular myopathy in the fourth quarter of FY2020, and as a result, in the financial results on a full basis, the decrease in profit was larger compared to the financial results on a core basis.

Consolidated financial results (full basis)

(Millions of yen)

	FY2019	**FY2020**	Change (%)
Revenue	1,300,843	**1,249,528**	-51,315 (-3.9%)
Operating profit	243,991	**136,051**	-107,940 (-44.2%)
Profit before tax	245,350	**145,324**	-100,026 (-40.8%)
Profit for the year	195,411	**120,589**	-74,822 (-38.3%)
Basic earnings per share (yen)	104.15	**64.93**	-39.22 (-37.7%)
Comprehensive income	156,692	**181,499**	+24,807 (+15.8%)

<Sales of Main Products>

(Billions of yen)

	FY2019	**FY2020**	Change
XTANDI	400.0	**458.4**	+14.6%
XOSPATA	14.3	**23.8**	+67.2%
PADCEV	1.8	**12.8**	+607.3%
Evrenzo	0.2	**1.1**	+371.2%
Betanis / Myrbetriq / BETMIGA	161.6	**163.6**	+1.2%
Prograf*	192.9	**182.7**	-5.3%

* Prograf: Includes Advagraf, Graceptor, and ASTAGRAF XL.

- Sales of XTANDI increased by 14.6% year-on-year to ¥458.4 billion. Sales increased in all regions of Japan, United States, Established Markets, Greater China, and International Markets.
- Sales of XOSPATA increased by 67.2% year-on-year to ¥23.8 billion. In addition to an increase in sales in Japan, United States and Established Markets, sales commenced in International Markets in August 2020, and in Greater China in December 2020.
- Co-promotion revenue of PADCEV grew significantly in United States, increasing by 607.3% year-on-year to ¥12.8 billion.
- Evrenzo for the treatment of renal anemia, which has been sales commenced in Japan since November 2019, steadily increased.
- Sales of Betanis / Myrbetriq / BETMIGA increased by 1.2% year-on-year to ¥163.6 billion. While sales decreased in United States due to decreased demand, etc. associated with the reduction of patient visits to hospitals/clinics as a result of the impact of the spread of COVID-19, sales grew in Japan, Established Markets, Greater China and International Markets.
- Sales of Prograf decreased by 5.3% year-on-year to ¥182.7 billion. Sales in Greater China increased, and sales in International Markets achieved similar levels year on year. On the other hand, sales decreased in other regions.
- In Japan, new product group sales continued to increase, including those of EVENITY, Suglat and SUJANU Combination Tablets. On the other hand, the main factor for the decrease in sales was the termination of sales agreements for Symbicort, human vaccines of KM Biologics Co., Ltd., Micardis family and Celecox.
- In United States, sales of pharmacologic stress agent Lexiscan decreased due to decreased demand associated with the reduction of patient visits to hospitals/clinics as a result of the impact of the spread of COVID-19, mainly in the first quarter of FY 2020.

<Revenue by region>

Revenue by region is shown in the table below. Revenue in United States increased, while in Japan, Established Markets, Greater China and International Markets decreased.

(Billions of yen)

	FY2019	**FY2020**	Change
Japan	345.4	**279.1**	-19.2%
United States	443.5	**473.2**	+6.7%
Established Markets	296.1	**293.2**	-1.0%
Greater China	60.4	**59.3**	-1.8%
International Markets	134.8	**111.1**	-17.6%

Established Markets: Europe, Canada, Australia.

Greater China: China, Hong Kong, Taiwan.

International Markets: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea, Export sales, etc.

2) Progress of initiatives for sustainable growth

The Company has been pursuing initiatives for sustainable growth over the mid to long term, based on its Strategic Plan 2018, the final year of which was FY2020, which set forth three main strategic goals toward: “Maximizing Product VALUE and Operational Excellence,” “Evolving How We Create VALUE - With Focus Area Approach” and “Developing Rx+ programs.”
The following are the main initiatives during the FY2020:

<Maximizing Product VALUE and Operational Excellence>

The Company has been developing and maximizing the product VALUE of the Company’s growth drivers such as the main products XTANDI for the treatment of prostate cancer and Betanis / Myrbetriq / BETMIGA for overactive bladder (OAB) treatment in addition to XOSPATA for the treatment of acute myeloid leukemia, PADCEV for the treatment of urothelial cancer and Evrenzo for the treatment of renal anemia, which were launched during the Strategic Plan 2018.

- With regard to XTANDI, the Company worked to further strengthen market access and further increase penetration of XTANDI amongst urologists, and has been making efforts to increase the market penetration of XTANDI to the patients with prostate cancer in earlier stages by utilizing robust data based on clinical trials accumulated after launch.
- With regard to Betanis / Myrbetriq / BETMIGA, the Company aimed to expand the market through continuous disease education activities, and worked to establish it as the first choice of therapy through the penetration of a balance of efficacy and safety.
- With regard to XOSPATA, the Company steadily expanded the number of countries/areas where it launched by launching it in Japan and the United States in December 2018, and Europe in November 2019. Furthermore, the Company worked to increase penetration of XOSPATA amongst hematologists/oncologists as a new option for acute myeloid leukemia, and established its position as market leader by increasing product awareness and the rate that testing for FMS-like tyrosine kinase 3 (FLT3) mutations is carried out.
- With regard to PADCEV, the Company worked to penetrate it into the market rapidly as a new treatment option for urothelial cancer by launching it in the United States in December 2019, and established its position as a preferred treatment option for patients with approved indications.
- With regard to Evrenzo, the Company launched it in Japan in November 2019, worked to penetrate it into the market by differentiating it through the spread of a new mechanism of action, and worked to expand its market share as a first-in-class HIF-PH inhibitor.

Including these products, the Company is steadily advancing product development by preferentially allocating management resources to key post-POC pipeline projects that will support sustainable growth over the mid- to long-term. Much progress was made in each project, including an application for approval with the aim of expanding indications of PADCEV in the United States, the obtaining of approval for XOSPATA in China, and the obtaining of approval for supplemental applications for Evrenzo in Japan.
The following are the main progress of each key post-POC pipeline project.

◇ XTANDI (enzalutamide) for the treatment of prostate cancer

May 2020	In Japan, the Company obtained approval for supplemental applications for distant metastatic prostate cancer.
June 2020	In Europe, the Company submitted an application for approval of its appended documentation giving data on overall survival found in the Phase 3 PROSPER trial on patients with non-metastatic castration-resistant prostate cancer.
October 2020	In the United States, the Company obtained approval of its appended documentation giving data on overall survival found in the Phase 3 PROSPER trial on patients with non-metastatic castration-resistant prostate cancer.
November 2020	In China, the Company obtained approval for supplemental applications for non-metastatic castration-resistant prostate cancer.
March 2021	In Europe, a positive CHMP (Committee for Medicinal Products for Human Use) opinion for supplemental applications for metastatic hormone-sensitive prostate cancer was adopted.

◇ XOSPATA (gilteritinib) for the treatment of acute myeloid leukemia

December 2020	The Company discontinued patient registration for the Phase 3 LACEWING trial for patients with untreated acute myeloid leukemia with *FLT3* mutation as it was unable to achieve longer overall survival, which is the primary endpoint.
January 2021	In China, the Company obtained conditional approval as a treatment for adult patients with relapsed/refractory acute myeloid leukemia with *FLT3* mutation.
March 2021	The Company announced that in the interim analysis of the Phase 3 COMMODORE trial, XOSPATA achieved a primary endpoint (overall survival) among patients with relapsed/refractory acute myeloid leukemia with *FLT3* mutation.

◇ PADCEV (enfortumab vedotin) for the treatment of urothelial cancer

September 2020	The Company announced that in the Phase 3 EV-301 trial, PADCEV statistically demonstrated significantly longer overall survival, which is a primary endpoint, than chemotherapy among patients with locally advanced or metastatic urothelial cancer, which had previously been treated with chemotherapy, including platinum-containing chemotherapy, and PD-1 or PD-L1 inhibitors.
October 2020	The Company announced satisfactory results for cohort 2 in the Phase 2 EV-201 trial among patients with locally advanced or metastatic urothelial cancer who have been treated with PD-1 or PD-L1 inhibitors, and have not been treated with platinum-containing chemotherapy and are ineligible for cisplatin.
February 2021	In the United States, the Company submitted a supplemental Biologics License Application with the aim of converting from accelerated approval to regular approval based on the results of the Phase 3 EV-301 trial among patients with locally advanced or metastatic urothelial cancer, which had previously been treated with chemotherapy, including platinum-containing chemotherapy, and PD-1 or PD-L1 inhibitors.
February 2021	In the United States, the Company submitted a supplemental Biologics License Application with the aim of expanding indications based on the results of cohort 2 in the Phase 2 EV-201 trial among patients with locally advanced or metastatic urothelial cancer who have been treated with PD-1 or PD-L1 inhibitors, and are ineligible for cisplatin.
March 2021	In Japan, the Company submitted an application for approval of PADCEV as a treatment for patients with locally advanced or metastatic urothelial cancer who have been treated.
March 2021	In Europe, the application for approval of PADCEV as a treatment for locally advanced or metastatic urothelial cancer, which had previously been treated with chemotherapy, including platinum-containing chemotherapy, and PD-1 or PD-L1 inhibitors, was designated for accelerated assessment.

◇ Evrenzo (roxadustat) for the treatment of renal anemia

April 2020	In Europe, the Company submitted an application for approval of Evrenzo as a treatment for renal anemia in adult patients.
November 2020	In Japan, the Company obtained approval for a supplemental application for Evrenzo as a treatment for renal anemia in patients on non-dialysis.

◇ Fezolinetant, a selective neurokinin-3 receptor antagonist

February 2021 In two Phase 3 trials in patients with moderate-to-severe vasomotor symptoms associated with menopause (SKYLIGHT 1 and SKYLIGHT 2), the Company announced that all primary endpoints were met with statistically significant improvements in the frequency and severity of vasomotor symptoms compared to placebo.

◇ Zolbetuximab, an anti-Claudin 18.2 monoclonal antibody

Phase 3 trials for gastric and gastroesophageal junction adenocarcinoma, and a Phase 2 trial for pancreatic adenocarcinoma is underway.

In addition to the above, the main developments, including approvals and applications for approvals, were as follows.

May 2020 The Company received approval in the United States for an additional indication of neurogenic bladder in pediatric patients aged two years and older for the OAB treatment Vesicare.

December 2020 The Company submitted an application in the United States for immunosuppressant agent Prograf for an additional indication of prevention of rejection in lung transplantation.

March 2021 The Company obtained the approval of a new formulation, granules for suspension (oral extended-release formulation) and existing tablets (extended-release formulation) for the additional indication of neurogenic detrusor overactivity in children aged three years and older for the OAB treatment Myrbetriq in the United States.

In FY2020, the Company transferred marketing, etc. as follows.

October 2020 The Company transferred the marketing authorizations and distribution of the psychotropic/medicine for the treatment of peptic ulcers Dogmatil to Nichi-Iko Pharmaceutical Co., Ltd. in Japan.

December 2020 With regard to the non-steroidal Celecox for the treatment of inflammation and pain, the Company has terminated the joint sales promotion activities in Japan with Viatris Pharmaceuticals Japan Inc. In addition, the Company plans to transfer the manufacturing and marketing authorization of Celecox from the Company to Viatris Pharmaceuticals Japan Inc. and transfer the distribution of the product to Viatris Pharmaceuticals Japan Inc. on July 31, 2021.

March 2021	In Japan, the Company has terminated the joint sales promotion activities of Acofide, a treatment for functional dyspepsia, with Zeria Pharmaceutical Co., Ltd. and transferred the distribution and marketing of the product to Zeria Pharmaceutical Co., Ltd.

As our approach to pursuit even greater Operational Excellence, the Company has taken a multifaceted approach to reviewing activities and has been working to strengthen its business base. The following are the main initiatives during the FY2020:

November 2020	The Company has decided to absorb and merge its wholly owned subsidiaries Astellas Pharma Tech Co., Ltd. and Astellas Green Supply, Inc. (effective date of absorption mergers: April 1, 2022 (planned))
November 2020	The Company has entered into an asset transfer agreement with Tillotts Pharma AG to transfer the manufacturing and marketing authorization of DIFICLIR tablets, a treatment of Clostridium difficile infection, to Tillotts Pharma AG in Europe, the Middle East, Africa, and some regions of the Commonwealth of Independent States, and is proceeding with the succession in the subject countries and regions.
January 2021	The Kyushu Distribution Center, the Company’s fourth distribution base in Japan, began operations in Kitakyushu City, Fukuoka Prefecture.
January 2021	The Company decided to newly construct a sterile drug production line in the Yaizu Technology Center of Astellas Pharma Tech Co., Ltd., a manufacturing subsidiary of the Company, and started construction.
January 2021	The Company returned to Tolmar International Limited the license for Eligard, a treatment for advanced prostate cancer, which had been marketed by Astellas Pharma Europe Ltd., a subsidiary of the Company, in Europe, the Middle East, the Commonwealth of Independent States, and Asia. In addition, the Company signed an agreement with Recordati Industria Chimica e Farmaceutica S.p.A., which sells Eligard under a new license from Tolmar International Limited, regarding the transfer of manufacturing and marketing authorization and the transfer of distribution, and is proceeding with the succession in the subject countries and regions.

<Evolving How We Create VALUE - With Focus Area Approach>

The Company has established a Focus Area approach to create VALUE. Under this approach, a Focus Area is defined as a set of combinations of three components: (1) biologies with high disease relevance, (2) versatile modalities and technologies and (3) diseases with high unmet medical needs with solutions that are expected from these two elements of biologies and modalities/technologies. By building up unique expertise and a platform for that Focus Area, the Company aims to continue creating innovative products. When multiple new drug candidates are generated and the lead compound advances to the clinical stage, we designate them as the Primary Focus, an area in which management resources are given the highest priority within the Company. As of March 2021, we have selected four Primary Focuses: "Blindness & Regeneration," "Mitochondria Biology," "Genetic Regulation," and "Immuno-Oncology." In addition, we have selected two new Primary Focus candidates: “proto-oncogene mutation” and “immune homeostasis.” Audentes Therapeutics, Inc. and Xyphos Biosciences, Inc. have been working to further advance the Primary Focus as the core centers for “genetic regulation” and “immuno-oncology,” respectively. Additionally, in April 2021, the Company reorganized the Audentes Division to establish a research and manufacturing division, a development division, and a commercial division (collectively referred to as Astellas Gene Therapies) that will specialize in the area of gene therapy.

In addition to the progress of each Primary Focus, Primary Focus which was originally independent is beginning to organically connect with each other. As the modalities/technologies that were studied in each Primary Focus are now being utilized in other Primary Focus, development for various biologies and diseases is progressing.

The following are the main progress during the FY2020:

◇ Genetic Regulation

December 2020	The Company received a notice from the United States Food and Drug Administration (FDA) lifting the clinical trial suspension on the clinical trial (ASPIRO trial) of gene therapy AT132 for patients with X-linked myotubular myopathy, which had been suspended as directed by the FDA.
March 2021	The Company announced that it will reorganize the Audentes Division and establish Astellas Gene Therapies, which will serve as a Center of Excellence for gene therapy, effective April 1, 2021.

◇ Blindness & Regeneration

September 2020	The Company announced the start of a joint research collaboration with the University of Pittsburgh in February 2020 on gene therapy using Adeno-associated viruses to create development candidates for the treatment of dry age-related macular degeneration, a disease of the posterior segment of the eye.

◇ Immuno-Oncology

December 2020	Entered into an exclusive worldwide license agreement with KaliVir Immunotherapeutics LLC for the collaboration, development and commercialization of VET2-L2, an intravenously administered oncolytic virus, as well as a second, follow-on development candidate.

◇ Mitochondria Biology

April 2020	The Company acquired Nanna Therapeutics Limited, a bio venture company focusing on drug discovery research for age-related diseases with high unmet needs, including mitochondria-related diseases, and made Nanna Therapeutics Limited a wholly-owned subsidiary of the Company. Through this acquisition, we acquired Nanna Therapeutics Limited's new DNA-encoded compound library technology and cutting-edge screening platform.
October 2020	ASP0367/MA-0211, a selective PPARδ modulator was granted Fast Track designation in the United States for development as a treatment for primary mitochondrial myopathy.

◇ Others

April 2020	The Company announced that it formed an alliance with Harvard University to establish a strategic research collaboration for the research and development of innovative treatments and technologies of mutual interest.
July 2020	The Company received a grant from the United States National Institute on Drug Abuse for two Phase 1 trials of ASP8062, a GABAB receptor positive allosteric modulator being developed for the additional maintenance treatment of opioid use disorder.
September 2020	The Company signed an agreement with the University of Tokyo's Institute for Life Science Research and Education and the University of Tokyo's Center of Innovation on collaborative efforts to create innovative new drugs and medical solutions.
October 2020	The Company has determined that the role of project creation for ASIM (Antigen-specific Immune Modulation) biology, which has been identified as a Primary Focus, is completed and announced that the Company will shift to research on next-generation immunomodulation technologies.

<Developing Rx+ programs>

The Company is taking on the challenge of developing Rx+ programs with the goal of realizing sustainable growth over the mid- to long-term. The Rx+ business is defined as a business that contributes to patients throughout the Patient Journey and is capable of generating profits on its own, by integrating cutting-edge medical technologies and advanced technologies from different fields, based on the strengths we have cultivated in the prescription pharmaceutical (Rx) business. Based on the Rx+ Story, which outlines the strategic direction for the creation of Rx+ businesses, the Company is focused on pursuing business creation activities with the aim of realizing “a society in which people can live their own lives in good physical and mental health through science-based healthcare solutions.” Below are the key initiatives in FY2020.

◇ Prevention of serious conditions of chronic diseases

April 2020	The Company announced that we have signed an agreement with BANDAI NAMCO Entertainment Inc. for the joint development, test marketing, etc. of an application for smartphones and other devices that supports the continuation of exercise through the provision of scientifically-based exercise programs that incorporate game-like features.
September 2020	The Company launched limited service of an exercise program for type 2 diabetes patients, which is based on scientific grounds and developed through an industry-government-academia collaboration between Yokohama City University and Yokohama City through fitness clubs in Kanagawa Prefecture.

◇ Supplementation and replacement of physical and motor functions

October 2020	The Company acquired Iota Biosciences, Inc., a company that specializes in bioelectronics technology and has a revolutionary technology for ultra-small implantable medical devices, which became a wholly owned subsidiary of the Company.

◇ Maximizing patient outcomes by improving surgical and diagnostic accuracy

October 2020	The Company received Fast Track designation from the United States Food and Drug Administration for the development of ASP5354, an investigational near-infrared fluorescence imaging agent for visualization of the ureter during abdominal and pelvic surgery.
January 2021	The Company announced that it initiated a collaboration with Actinium Pharmaceuticals, Inc. on molecular targeted radiotherapies as part of our efforts to develop theranostics that integrate diagnosis and treatment.

3) Efforts Against the Spread of the Coronavirus Disease (COVID-19)

With the continuing spread of COVID-19, we are, as part of our mission as a pharmaceutical company, taking various actions and measures to contribute to securing the safety of patients and alleviating strain on healthcare resources. The Company's main efforts against the spread of the COVID-19 as of April 27, 2021 are as follows.
The latest information is published on our website (https://www.astellas.com/jp/en/covid-19). Please refer to the website for details.

◇ Continuation of business and maintaining a stable supply of products

- We are currently advising our employees to combine working at an office and working from home in accordance with the situation in each country and region to secure the safety of our employees and to prevent the further spread of the disease.
- While placing the highest priority on the safety of our employees, in order to continue our social mission of ensuring a stable supply of drugs, quality control, managing safety, and providing information, our essential business continues to be carried out with strict measures taken to prevent infections.
- While taking measures to prevent the spread of the disease, we are continuing to gather and provide necessary information to medical institutions in regions around the world consistent with the rules of each respective institution with regards to sales activities.
- As for the supply of products, in particular, there are currently no issues caused by COVID-19, as we have been able to manage risks around procuring raw materials and distributing finished products by closely cooperating with suppliers and manufacturers taking into account business continuity and at stable supply.

◇ For ensuring patient safety and alleviating strain on healthcare resources

In an effort to help ensure patient safety and alleviate strain on healthcare resources during the COVID-19 pandemic, we are taking the following actions to our clinical trial operations.

- In countries and regions with continuing spread of COVID-19, we temporarily suspended start-up activities involving study sites for new interventional clinical studies. But we have started to reactivate clinical studies in all countries, following the benefit-risk assessment of each study.
- Consistent with the issued guidance from regulatory bodies of each country, we are assessing protocols and implementing measures to reduce the burden on healthcare systems while ensuring that the maintenance of patient safety.
- Furthermore, in order to prioritize patient safety, we are also providing measures, when applicable, such as remotely monitoring the safety of a patient via phone, conducting necessary medical exams at medical institutions close to a patient's home outside of the trial site, and/or sending investigational drug to a patient's home, in case a patient cannot visit the trial site designated in the protocol.

- We are building flexibility into the protocols to respond to changes related to the ongoing pandemic.
- We will be frequently reassessing this approach, which applies to all interventional clinical trials led by us and our group companies.
- We remain focused on ensuring patient safety, while maintaining regulatory compliance and data integrity across clinical development programs.

◇ Contributing to the R&D of drugs

- We have taken appropriate actions, such as provide drugs, by cooperating with bodies concerned in response to requests by the government.
- In Japan, we have provided compounds in response to a request from the Ministry of Health, Labour and Welfare and National Institute of Infectious Diseases to cooperate in the “Basic Screening Plan for Drugs for Coronavirus Disease.”
- We also responded to requests from the European Federation of Pharmaceutical Industries Associations (EFPIA) and the Innovative Medicines Initiative (IMI) to cooperate in the “Activities Aimed at Developing Drugs for the Novel Virus” and providing consultation on countermeasures.
- Astellas Pharma Europe Ltd. is a member of the CARE (Corona Accelerated R&D in Europe) Consortium, the largest initiative in Europe addressing the challenges of COVID-19. CARE is funded by IMI, a public-private partnership aiming to speed up the development of better and safer medicines for patients. The goal of the CARE consortium is to deliver treatments for the current COVID outbreak as well as future coronavirus outbreaks.
- Furthermore, as part of our membership of the non-profit organization, TransCelerate BioPharma Inc.1, Astellas is participating in the COVID-19 Task Force, alongside 20 other biopharmaceutical member companies, to share industry best practices in managing the continuity of clinical trial operations during the global COVID-19 pandemic while ensuring patient safety and maintaining study integrity.
- We are actively seeking various proposals from within or outside of Astellas for our owned technology and potential use of our drugs that are under development or on the market against COVID-19, and we are swiftly evaluating each of them.
- We continuously respond to requests from various governments to provide compounds for the research phase. While placing the highest priority on safety, we will at the same time continue to contribute in our efforts to swiftly evaluate various possibilities in research and development of drugs for COVID-19.

◇ Activities in each country and region

- We donated worth 5 million yen to Astellas Foundation for Research on Metabolic Disorders2 as a grant for COVID-19 related research in Japan. The foundation has used it to subsidize COVID-19 related research in the research funding applications for FY2020. Further, the foundation has provided to researchers who have been economically affected by COVID-19 participating in studying abroad program supported by the foundation.

- Astellas Pharma US, Inc. and the Astellas Global Health Foundation have each expanded support to local and global communities fighting COVID-19 by providing more than $2.7 million of financial assistance, in aggregate, to meet the urgent demand for resources to help patients, health care workers, and first responders.
  - At a national level in the United States, Astellas has provided support to help humanitarian organizations working to support communities affected by COVID-19. This includes Astellas' corporate donations to Americares, the American Red Cross, and Direct Relief to help their emergency efforts. Additionally, in the U.S., through its Corporate Charitable Donation process, Astellas issued a request for proposal (RFP) process and awarded funding to five non-profit healthcare organizations that align with the company's focus areas, to support patients and care partners during the pandemic. The company has also coordinated opportunities to mobilize equipment, personal protective equipment (PPE) donations, blood donations in alignment with the Centers for Disease Control and Prevention guidance, employee contributions, and volunteerism to meet the critical demand for time and resources where needs are most pressing. Locally at the Astellas- US headquarters in Illinois, Astellas is partnering with multiple state organizations, as a Founding Partner to the Governor's Illinois COVID-19 Response Fund and the Illinois Biotechnology Innovation Organization (iBIO) COVID-19 PPE Relief Fund.
  - The Astellas Global Health Foundation has provided a combined $2 million in new and redirected emergency relief focused on improved healthcare infrastructure, COVID-19 training and education impacting more than 725,000 lives in Kenya, Dominican Republic, South Sudan, Democratic Republic of the Congo (DRC), Ghana, Ethiopia and Nigeria. The funding addresses the urgent needs of partners seeking to prevent the immediate spread and combat the long-term effects of COVID-19 in particularly vulnerable and hard-to-reach communities.
- Furthermore, as part of the company's ongoing commitment to ensuring that patients have access to our products, we have implemented changes to our patient assistance programs in the US offered through Astellas Pharma Support Solutions, which offers support to patients needing access and reimbursement assistance. The changes were made to make the application and verification process easily accessible for patients who have lost their jobs or insurance coverage as a result of COVID-19 and increase customer service capacity in light of the influx of patients requiring assistance.
- In Italy, our group company, Astellas Pharma S.p.A., has made a donation worth 174,800 euros for the necessary supply of goods to public medical institutions and NPOs.
- In Spain, our group company, Astellas Pharma S.A., has made a donation worth 200,000 euros to the country's health ministry for the necessary supply of goods to medical institutions.
- Furthermore, to assist healthcare systems coping with increasing demands by government or non-profit organizations presented by the escalation of COVID-19

around the world, Astellas will authorize a maximum of 4 weeks of paid leave (in accordance with each country’s provision) to employees who are medically qualified and wish to contribute by participating in volunteer activities within their community.

The Company, upon accurately ascertaining situations that change from day to day, will continue to work in cooperation with relevant authorities and organizations of each country by quickly gathering information and promptly taking necessary measures.

(2) Financial position

1) Assets, equity and liabilities

In the first quarter of FY2020, the consolidated statement of financial position as of March 31, 2020 was retrospectively revised due to adjustments of fair value of assets acquired and liabilities assumed for Audentes Therapeutics, Inc., which was acquired in January 2020. As a result, goodwill increased, and intangible assets and deferred tax liabilities decreased in comparison to the figures prior to the retrospective adjustment. The Company completed the distribution of consideration paid as of March 31, 2021.

An overview of the consolidated statement of financial position as of March 31, 2021 and the main changes from the end of the previous fiscal year after the retrospective adjustment are shown below.

Assets

Total assets saw a decrease of ¥41.5 billion compared to the end of the previous fiscal year to ¥2,273.6 billion.

<Non-current assets> As of March 31, 2021: ¥1,401.0 billion (a decrease of ¥46.6 billion)

- Property, plant and equipment decreased by ¥4.0 billion compared to the end of the previous fiscal year to ¥264.6 billion.
- Goodwill increased by ¥5.8 billion compared to the end of the previous fiscal year to ¥284.0 billion, and intangible assets decreased by ¥73.3 billion compared to the end of the previous fiscal year to ¥651.4 billion. Intangible assets decreased in FY2020, mainly due to the recording of impairment losses in relation to the termination of development for the anti-TIGIT antibody ASP8374/PTZ-201, and impairment losses in relation to a revision of the development plan for the gene therapy AT132.

<Current assets> As of March 31, 2021: ¥872.6 billion (an increase of ¥5.1 billion)

- Cash and cash equivalents increased by ¥7.7 billion compared to the end of the previous fiscal year to ¥326.1 billion.

Equity

Total equity as of March 31, 2021 saw an increase of ¥96.9 billion compared to the end of the previous fiscal year to ¥1,386.1 billion, making the ratio of equity attributable to owners of the parent to gross assets 61.0%.

- While profit for the year stood at ¥120.6 billion, the Company paid ¥76.2 billion of dividends of surplus.

Liabilities

Total liabilities decreased by ¥138.5 billion compared to the end of the previous fiscal year to ¥887.5 billion.

<Non-current liabilities> As of March 31, 2021: ¥295.1 billion (an increase of ¥67.8 billion)

- Other financial liabilities increased by ¥69.7 billion compared to the end of the previous fiscal year to ¥199.0 billion. This was mainly due to converting ¥80.0 billion from short-term borrowings to long-term borrowings in the first quarter of FY2020.

<Current liabilities> As of March 31, 2021: ¥592.4 billion (a decrease of ¥206.3 billion)

- As of March 31, 2021, the balance of bonds amounted to ¥120.0 billion. Other financial liabilities decreased by ¥197.5 billion compared to the end of the previous fiscal year to ¥148.2 billion which is attributable to the decrease in short-term borrowings due to conversion to long-term borrowings stated above and repayments, etc.

2) Cash flow

Cash flows from operating activities

Net cash flows from operating activities in FY2020 increased year-on-year by ¥84.8 billion to ¥306.8 billion.

- Income tax paid decreased by ¥30.1 billion year-on-year to ¥17.9 billion.

Cash flows from investing activities

Net cash flows used in investing activities in FY2020 was ¥81.9 billion, a decrease in outflow of ¥307.9 billion year-on-year.

Cash flows from financing activities

Net cash flows used in financing activities in FY2020 was ¥229.5 billion, (inflow of ¥188.1 billion in the previous fiscal year).

- While proceeds from long-term borrowings amounted to ¥80.0 billion, the balance of bonds and short-term borrowings decreased by ¥206.0 billion. Dividends paid increased by ¥2.6 billion year-on-year to ¥76.2 billion.

As a result, cash and cash equivalents totaled ¥326.1 billion as of March 31, 2021, an increase of ¥7.7 billion compared to the end of the previous fiscal year.

(3) Consolidated business forecasts for FY2021 and other forward-looking statements

The Company's business forecasts for FY2021 are presented on a core basis and full basis.
The consolidated full-year business forecasts (core basis) are shown below.

Consolidated full–year business forecasts (core basis)

(Millions of yen)

	FY2020 Results	**FY2021 Forecasts**	Change (%)
Revenue	1,249,528	**1,323,000**	+73,472 (+5.9%)
Selling, general and administrative expenses	504,316	**541,000**	+36,684 (+7.3%)
R&D expenses	224,489	**242,000**	+17,511 (+7.8%)
Core operating profit	251,375	**270,000**	+18,625 (+7.4%)
Core profit for the year	209,906	**213,000**	+3,094 (+1.5%)
Basic core earnings per share (yen)	113.03	**114.95**	+1.92 (+1.7%)

(Note) The forecast of the basic core earnings per share is calculated based on the number of issued shares (excluding treasury shares) at the end of FY2020.

Expected exchange rate for

FY2021 (Forecast)	**¥110/US$**	**¥130/€**
FY2020 (Result)	¥106/US$	¥124/€

Revenue, core operating profit and core profit for the year are anticipated to increase across the board.
In FY2021, revenue is expected to decrease due to the termination of sales agreements related to licensed products, the loss of exclusivity of Vesicare and the impact of the NHI drug price revisions in Japan. In addition, the reversal following the transfer of products overseas and the recording of revenue from consideration for transfer in FY2020 are anticipated to be the main factors in decrease in revenue. On the other hand, profit is anticipated to increase since we anticipate the impact of the above factors to be absorbed by continuing to significantly grow our main products.
The fluctuations in the exchange rate is anticipated to cause a ¥26.5 billion increase in revenue and a ¥12.8 billion increase in core operating profit compared with if the exchange rates of FY2020 were applied, as the exchange rate for FY2021 is anticipated to weaken against both the U.S. dollar and the euro compared with FY2020 results.

Revenue

- The main factors for the decrease in revenue are due to the termination of sales agreements for Celecox, Lipitor, etc., the loss of exclusivity of Vesicare and the impact of the NHI drug price revisions carried out in April 2021 in Japan. In addition, the reversal following the transfer of Eligard, a treatment for prostate cancer, and long-listed products in Europe, and the recording of revenue in FY2020 from consideration for the transfer of DIFICLIR, a treatment of Clostridium difficile infection, are anticipated to be the main factors in decrease in revenue.
- On the other hand, we expect the main products XTANDI, XOSPATA and PADCEV to continue to grow significantly, and Evrenzo to contribute to revenue. Revenue is anticipated to increase since we anticipate the growth of the main products to absorb the factors stated above regarding the decrease in revenue.

As a result of the above, the revenue forecast is ¥1,323.0 billion (up 5.9% year on year).

Core operating profit/ Core profit for the year

- Cost-of-goods ratio to revenue will be lowered mainly due to changes in product mix.
- Regarding selling, general and administrative expenses, we will pursue cost efficiency by thoroughly reviewing costs that do not contribute to our competitiveness or the increase of our VALUE. On the other hand, due to the allocation of investment to maximize the VALUE of new products and growth products as well as increases in XTANDI co-promotion fees in the United States, it is forecasted at ¥541.0 billion (up 7.3% year on year).
- We project R&D expenses of ¥242.0 billion (up 7.8% year on year) which account for 18.3% to revenue (FY2020 ratio to revenue: 18.0%) reflecting the continuation of enhanced investment into our Primary Focus, despite a decrease in investment into some key post-POC pipeline projects that have come to an end phase in the development stage.

As a result of the above, we project core operating profit of ¥270.0 billion (up 7.4% year on year).
Core profit for the year is forecasted at ¥213.0 billion (up 1.5% year on year) and basic core earnings per share is forecasted at ¥114.95 (up 1.7 % year on year).

<Sales of Main Products>

(Billions of yen)

	FY2020 Results	**FY2021 Forecasts**	Change
XTANDI	458.4	**557.2**	+21.5%
XOSPATA	23.8	**36.7**	+53.8%
PADCEV	12.8	**20.1**	+57.1%
Evrenzo	1.1	**8.6**	+661.0%
Betanis / Myrbetriq / BETMIGA	163.6	**175.2**	+7.1%
Prograf*	182.7	**192.6**	+5.5%

* Prograf: Includes Advagraf, Graceptor, and ASTAGRAF XL.

The consolidated full-year business forecasts (full basis) are shown below.

Consolidated full-year business forecasts (full basis)

(Millions of yen)

	FY2020 Results	**FY2021 Forecasts**	Change (%)
Revenue	1,249,528	**1,323,000**	+73,472 (+5.9%)
Operating profit	136,051	**265,000**	+128,949 (+94.8%)
Profit before tax	145,324	**263,000**	+117,676 (+81.0%)
Profit for the year	120,589	**209,000**	+88,411 (+73.3%)
Basic earnings per share (yen)	64.93	**112.79**	+47.86 (+73.7%)

(Note) The forecast of the basic earnings per share is calculated based on the number of issued shares (excluding treasury shares) at the end of FY2020.

Expected exchange rate for

FY2021 (Forecast)	**¥110/US$**	**¥130/€**
FY2020 (Result)	¥106/US$	¥124/€

In FY2020, the Company recorded “Other expense” that is excluded from its core basis financial results, with the result that operating profit is ¥115.3 billion lower than core operating profit. In FY2021, we do not currently expect major expenses to be incurred, and we therefore anticipate increases in operating profit, profit before tax, and profit for the year.

(4) Capital allocation policy and dividends for FY2020 and FY2021

The Company strives to sustainably increase enterprise value while proactively making returns to shareholders. While putting priority on business investment to assure future growth, the Company strives to increase dividend payments stably and continuously, based on medium- to long-term profit growth on a consolidated basis. In addition, the Company will flexibly acquire its own shares whenever necessary to further increase capital efficiency and earnings per share.

The annual dividend for FY2020 is ¥42 per share (including a year-end dividend of ¥21 per share) to shareholders.

The Company anticipates that the annual dividend in FY2021 will be ¥50 per share (composed of interim dividend of ¥25 per share and a year-end dividend of ¥25 per share).

2. Consolidated Financial Statements and Notes to Consolidated Financial Statements

(1) Consolidated Statement of Income

(Millions of yen)

	Fiscal year ended 31 March 2020	Fiscal year ended 31 March 2021
Revenue	1,300,843	1,249,528
Cost of sales	(276,739)	(246,063)
Gross profit	1,024,104	1,003,465
Selling, general and administrative expenses	(499,295)	(504,316)
Research and development expenses	(224,226)	(224,489)
Amortisation of intangible assets	(21,164)	(23,763)
Share of profit (loss) of investments accounted for using equity method	(1,660)	478
Other income	12,154	7,639
Other expenses	(45,921)	(122,963)
Operating profit	243,991	136,051
Finance income	4,363	11,608
Finance expenses	(3,004)	(2,335)
Profit before tax	245,350	145,324
Income tax expense	(49,939)	(24,734)
Profit	195,411	120,589
Profit attributable to:		
Owners of the parent	195,411	120,589
Earnings per share:		
Basic (Yen)	104.15	64.93
Diluted (Yen)	104.08	64.90

(2) Consolidated Statement of Comprehensive Income

(Millions of yen)

	Fiscal year ended 31 March 2020	Fiscal year ended 31 March 2021
Profit	195,411	120,589
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	(7,611)	5,374
Remeasurements of defined benefit plans	1,271	1,788
Subtotal	(6,339)	7,162
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	(32,380)	53,748
Subtotal	(32,380)	53,748
Other comprehensive income	(38,719)	60,910
Total comprehensive income	156,692	181,499
Total comprehensive income attributable to:		
Owners of the parent	156,692	181,499

(3) Consolidated Statement of Financial Position

(Millions of yen)

	As of 31 March 2020	As of 31 March 2021
Assets		
Non-current assets		
Property, plant and equipment	268,600	264,623
Goodwill	278,253	284,011
Intangible assets	724,773	651,427
Trade and other receivables	34,014	33,924
Investments accounted for using equity method	4,692	7,117
Deferred tax assets	52,876	54,176
Other financial assets	74,264	95,850
Other non-current assets	10,184	9,913
Total non-current assets	1,447,655	1,401,040
Current assets		
Inventories	151,017	164,080
Trade and other receivables	347,042	343,178
Income tax receivable	23,556	13,984
Other financial assets	9,459	5,560
Other current assets	18,049	19,658
Cash and cash equivalents	318,391	326,128
Total current assets	867,514	872,588
Total assets	2,315,169	2,273,628

(Millions of yen)

	As of 31 March 2020	As of 31 March 2021
Equity and liabilities		
Equity		
Share capital	103,001	103,001
Capital surplus	177,506	177,830
Treasury shares	(7,178)	(15,377)
Retained earnings	905,851	953,289
Other components of equity	109,989	167,373
Total equity attributable to owners of the parent	1,289,168	1,386,115
Total equity	1,289,168	1,386,115
Liabilities		
Non-current liabilities		
Trade and other payables	3,142	400
Deferred tax liabilities	24,670	18,161
Retirement benefit liabilities	38,074	38,982
Provisions	6,135	5,796
Other financial liabilities	129,272	199,021
Other non-current liabilities	25,999	32,782
Total non-current liabilities	227,293	295,141
Current liabilities		
Trade and other payables	171,954	124,777
Income tax payable	4,009	8,395
Provisions	14,241	22,187
Other financial liabilities	345,707	148,163
Other current liabilities	262,797	288,851
Total current liabilities	798,708	592,372
Total liabilities	1,026,001	887,513
Total equity and liabilities	2,315,169	2,273,628

(4) Consolidated Statement of Changes in Equity

(Millions of yen)

	Equity attributable to owners of the parent					
					Other components of equity	
	Share capital	Capital surplus	Treasury shares	Retained earnings	Subscription rights to shares	Exchange differences on translation of foreign operations
As of 1 April 2019	103,001	177,301	(164,629)	991,957	1,127	125,656
Comprehensive income						
Profit	—	—	—	195,411	—	—
Other comprehensive income	—	—	—	—	—	(32,380)
Total comprehensive income	—	—	—	195,411	—	(32,380)
Transactions with owners						
Acquisition of treasury shares	—	—	(52,899)	—	—	—
Disposals of treasury shares	—	(313)	954	(413)	(228)	—
Cancellation of treasury shares	—	—	209,396	(209,396)	—	—
Dividends	—	—	—	(73,539)	—	—
Share-based payments	—	518	—	—	—	—
Transfers	—	—	—	1,831	—	—
Total transactions with owners	—	205	157,451	(281,517)	(228)	—
As of 31 March 2020	103,001	177,506	(7,178)	905,851	899	93,277
Comprehensive income						
Profit	—	—	—	120,589	—	—
Other comprehensive income	—	—	—	—	—	53,748
Total comprehensive income	—	—	—	120,589	—	53,748
Transactions with owners						
Acquisition of treasury shares	—	—	(9,163)	—	—	—
Disposals of treasury shares	—	(444)	964	(365)	(154)	—
Dividends	—	—	—	(76,157)	—	—
Share-based payments	—	768	—	—	—	—
Transfers	—	—	—	3,371	—	—
Total transactions with owners	—	324	(8,199)	(73,151)	(154)	—
As of 31 March 2021	103,001	177,830	(15,377)	953,289	745	147,024

(Millions of yen)

	Equity attributable to owners of the parent				Total equity
	Other components of equity			Total	
	Financial assets measured at fair value through other comprehensive income	Remeasurements of defined benefit plans	Total		
As of 1 April 2019	23,984	—	150,767	1,258,396	1,258,396
Comprehensive income					
Profit	—	—	—	195,411	195,411
Other comprehensive income	(7,611)	1,271	(38,719)	(38,719)	(38,719)
Total comprehensive income	(7,611)	1,271	(38,719)	156,692	156,692
Transactions with owners					
Acquisition of treasury shares	—	—	—	(52,899)	(52,899)
Disposals of treasury shares	—	—	(228)	1	1
Cancellation of treasury shares	—	—	—	—	—
Dividends	—	—	—	(73,539)	(73,539)
Share-based payments	—	—	—	518	518
Transfers	(560)	(1,271)	(1,831)	—	—
Total transactions with owners	(560)	(1,271)	(2,059)	(125,920)	(125,920)
As of 31 March 2020	15,813	—	109,989	1,289,168	1,289,168
Comprehensive income					
Profit	—	—	—	120,589	120,589
Other comprehensive income	5,374	1,788	60,910	60,910	60,910
Total comprehensive income	5,374	1,788	60,910	181,499	181,499
Transactions with owners					
Acquisition of treasury shares	—	—	—	(9,163)	(9,163)
Disposals of treasury shares	—	—	(154)	1	1
Dividends	—	—	—	(76,157)	(76,157)
Share-based payments	—	—	—	768	768
Transfers	(1,583)	(1,788)	(3,371)	—	—
Total transactions with owners	(1,583)	(1,788)	(3,525)	(84,552)	(84,552)
As of 31 March 2021	19,604	—	167,373	1,386,115	1,386,115

(5) Consolidated Statement of Cash Flows

(Millions of yen)

	Fiscal year ended 31 March 2020	Fiscal year ended 31 March 2021
Cash flows from operating activities		
Profit before tax	245,350	145,324
Depreciation and amortisation	66,396	72,652
Impairment losses (reversal of impairment losses)	13,796	100,348
Finance income and expenses	(1,359)	(9,273)
(Increase) decrease in inventories	(6,038)	(2,318)
(Increase) decrease in trade and other receivables	(16,391)	22,161
Increase (decrease) in trade and other payables	(21,363)	(51,569)
Other	(10,400)	47,389
Subtotal	269,991	324,714
Income tax paid	(47,993)	(17,870)
Net cash flows from operating activities	221,998	306,843
Cash flows from investing activities		
Purchases of property, plant and equipment	(41,267)	(31,384)
Proceeds from sales of property, plant and equipment	6,924	6,831
Purchase of intangible assets	(36,621)	(46,057)
Payments for acquisition of subsidiaries	(320,764)	(14,916)
Interest and dividends received	2,062	1,037
Other	(127)	2,594
Net cash flows provided by (used in) investing activities	(389,793)	(81,894)
Cash flows from financing activities		
Increase (decrease) in bonds and short-term borrowings	326,000	(206,000)
Proceeds from long-term borrowings	—	80,000
Acquisition of treasury shares	(52,899)	(9,163)
Dividends paid to owners of the parent	(73,539)	(76,157)
Repayments of lease liabilities	(17,660)	(15,891)
Other	(847)	(2,268)
Net cash flows provided by (used in) financing activities	181,055	(229,479)
Effect of exchange rate changes on cash and cash equivalents	(5,942)	12,267
Net increase (decrease) in cash and cash equivalents	7,317	7,737
Cash and cash equivalents at the beginning of the year	311,074	318,391
Cash and cash equivalents at the end of the year	318,391	326,128

(6) Notes to consolidated financial statements

Notes on going concern assumption

Not applicable.

Business Combinations

For the fiscal year ended 31 March 2020

Acquisition of Xyphos Biosciences, Inc.

(1) Outline of the business combination

(i) Name and business description of the acquiree

Name of the acquiree: Xyphos Biosciences, Inc. (“Xyphos”)

Business description: Research and development of pharmaceuticals utilizing immuno-oncology therapeutics technology

(ii) Acquisition date

26 December 2019, U.S. Pacific Time

(iii) Percentage of voting equity interests acquired

100%

(iv) Acquisition method

Acquisition of all shares of stock in cash with contingent consideration to be paid when certain milestones are achieved in the future.

(v) Primary reasons for the business combination

Xyphos is a biotechnology company founded in 2017 and has novel and proprietary ACCEL (Advanced Cellular Control through Engineered Ligands) cell therapy technology platform, as well as industry-leading immuno-oncology talent.

The Group will combine the technology platform obtained through the acquisition with its capabilities in regenerative and cell therapy that it has been working on so far, so that it can create next-generation high-function cells in the field of immune-oncology and maximise the value of its technology.

(2) The fair values of assets acquired, liabilities assumed and purchase consideration transferred as at the acquisition date are as follows:

(Millions of yen)

Intangible assets	17,670
Cash and cash equivalents	27
Other assets	368
Deferred tax liabilities	(3,445)
Other liabilities	(2,580)
Fair value of assets acquired and liabilities assumed (net)	12,040
Goodwill	3,800
Total	15,841
Cash	9,577
Contingent consideration	6,263
Total fair value of purchase consideration transferred	15,841

Certain items had reflected provisional amounts as of 31 March 2020, however, the Group completed the purchase price allocation during the fiscal year ended 31 March 2021.

Goodwill mainly comprises the value of expected synergies arising from the acquisition and future economic benefits, which is not separately recognised.

(3) Contingent consideration

The contingent consideration relates to certain milestones depending on the progress of development. The maximum potential future cash outflows associated with the contingent consideration total 545 million U.S. dollars (59,312 million yen).

(4) Cash flow information

(Millions of yen)

Total fair value of purchase consideration transferred	15,841
Fair value of contingent consideration included in purchase consideration transferred	(6,263)
Cash and cash equivalents held by the acquiree	(27)
Acquisition of subsidiaries, net of cash acquired	9,550

(5) Acquisition-related costs

Immaterial

(6) Effect on the consolidated statement of income

(i) Profit (loss) before tax of the acquiree since the acquisition date included in the consolidated statement of income for the fiscal year ended 31 March 2020: Immaterial

(ii) Profit (loss) before tax of the combined entity for the fiscal year ended 31 March 2020 assuming the acquisition date had been at the beginning of the fiscal year: Immaterial

Acquisition of Audentes Therapeutics, Inc.

(1) Outline of the business combination

(i) Name and business description of the acquiree

Name of the acquiree: Audentes Therapeutics, Inc. (“Audentes”)

Business description: Research and development of pharmaceuticals based on gene therapy technology

(ii) Acquisition date

15 January 2020, U.S. Eastern Standard Time

(iii) Percentage of voting equity interests acquired

100%

(iv) Acquisition method

Cash tender offer followed by a merger

(v) Primary reasons for the business combination

Audentes is a leading Adeno-associated virus (AAV)-based genetic medicines company, founded in 2012, focused on developing and commercialising gene therapy products for serious and rare neuromuscular diseases with its proprietary AAV-based technology platform and in-house capability for manufacturing gene therapy product candidates. Also, Audentes has established a robust pipeline consisting of promising gene therapy programs, including, its lead program, AT132 for the treatment of X-linked myotubular myopathy, or XLMTM, which is in Phase I/II study.

Through the acquisition, the Group is establishing a leading position in the field of gene therapy with the goal of addressing the unmet medical needs of patients living with serious, rare diseases.

(2) The fair values of assets acquired, liabilities assumed and purchase consideration transferred as at the acquisition date are as follows:

(Millions of yen)

	Provisional fair value as of 31 March 2020	Fair value adjustments	Fair value (as adjusted)
Property, plant and equipment	8,964	—	8,964
Intangible assets	284,944	(13,723)	271,221
Financial assets at FVTOCI (debt instruments)	22,248	—	22,248
Cash and cash equivalents	9,320	—	9,320
Other assets	1,708	—	1,708
Trade and other payables	(6,092)	—	(6,092)
Deferred tax liabilities	(41,517)	2,989	(38,528)
Other liabilities	(6,488)	—	(6,488)
Fair value of assets acquired and liabilities assumed (net)	273,085	(10,734)	262,351
Goodwill	42,497	10,734	53,230
Total	315,582	—	315,582
Total fair value of purchase consideration transferred	315,582	—	315,582

Certain items had reflected provisional amounts as of 31 March 2020, however, the Group completed the purchase price allocation during the fiscal year ended 31 March 2021. Along with this, the Group retrospectively revised the corresponding balances in the consolidated statement of financial position as of 31 March 2020. As a result, intangible assets and deferred tax liabilities decreased by 13,734 million yen and 2,992 million yen respectively, and goodwill increased by 10,743 million yen.

Goodwill mainly comprises the value of expected synergies arising from the acquisition and future economic benefits, which is not separately recognised.

Financial assets at FVTOCI (debt instruments) are included in “Other financial assets” in the consolidated statement of financial position.

(3) Cash flow information

(Millions of yen)

Total fair value of purchase consideration transferred	315,582
Cash and cash equivalents held by the acquiree	(9,320)
Acquisition of subsidiaries, net of cash acquired	306,262

In addition, the Group separated Audentes’ payment for unvested share-based payments, such as share options from the business combination, and recognised 7,744 million yen as "Other Expenses" in the consolidated statement of income.

(4) Acquisition-related costs

Acquisition-related costs: 1,687 million yen

Acquisition-related costs were recognised in “Selling, general and administrative expenses” in the consolidated statement of income.

(5) Effect on the consolidated statement of income

(i) Profit (loss) before tax of the acquiree since the acquisition date included in the consolidated statement of income for the fiscal year ended 31 March 2020: (5,895) million yen

(ii) Profit (loss) before tax of the combined entity for the fiscal year ended 31 March 2020 assuming the acquisition date had been at the beginning of the fiscal year: (25,723) million yen

Note: This effect is calculated based on Audentes' financial results for the period from 1 April 2019 to the acquisition date.

Segment information

The main activities of the Group are the research and development, manufacture and sale of pharmaceutical products, and there are no separate operating segments. Therefore, the Group has a single reporting segment, “Pharmaceutical”.

Information about products and services

Revenue by type of product and service is as follows:

(Millions of yen)

	Fiscal year ended 31 March 2020	Fiscal year ended 31 March 2021
XTANDI	399,989	458,434
Prograf	192,926	182,650
Betanis/Myrbetriq/BETMIGA	161,564	163,569
Other	546,364	444,875
Total	1,300,843	1,249,528

Information about geographical areas

Revenue and non-current assets by geographical areas are as follows:

Revenue by geographical areas

(Millions of yen)

	Fiscal year ended 31 March 2020	Fiscal year ended 31 March 2021
Japan	375,174	297,230
United States	448,083	478,768
Others	477,586	473,530
Total	1,300,843	1,249,528

(Note) Revenue by geographical areas is categorised based on the geographical location of each Group company.

Non-current assets (property, plant and equipment, goodwill and intangible assets) by geographical areas

(Millions of yen)

	As of 31 March 2020	As of 31 March 2021
Japan	462,132	452,144
United States	708,401	640,120
Others	101,092	107,796
Total	1,271,625	1,200,060

Information about major customers

The following external customer accounts for 10% or more of the consolidated revenue of the Group

(Millions of yen)

	Segment	Fiscal year ended 31 March 2020	Fiscal year ended 31 March 2021
McKesson Group	Pharmaceutical	162,361	193,182

Earnings per share

The basis of calculation of basic earnings per share and diluted earnings per share is as follows:

(Millions of yen, except as otherwise indicated)

	Fiscal year ended 31 March 2020	Fiscal year ended 31 March 2021
Basis of calculating basic earnings per share		
Profit attributable to owners of the parent	195,411	120,589
Profit not attributable to ordinary shareholders of the parent	—	—
Profit used to calculate basic earnings per share	195,411	120,589
Weighted average number of ordinary shares (Thousands of shares)	1,876,193	1,857,125
Basis of calculating diluted earnings per share		
Profit used to calculate basic earnings per share	195,411	120,589
Adjustment	—	—
Profit used to calculate diluted earnings per share	195,411	120,589
Weighted average number of ordinary shares (Thousands of shares)	1,876,193	1,857,125
Increase in the number of ordinary shares due to exercise of subscription rights to shares (Thousands of shares)	1,355	1,068
Weighted average number of diluted ordinary shares (Thousands of shares)	1,877,548	1,858,193
Earnings per share (attributable to owners of the parent):		
Basic (Yen)	104.15	64.93
Diluted (Yen)	104.08	64.90

Significant subsequent events

Not applicable.