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Financial Results of Astellas for Fiscal Year 2019

Japan, May 14, 2020 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, “the Company”) today announced the financial results for fiscal year 2019 (FY2019) ended March 31, 2020.

Consolidated financial results for FY2019 (April 1, 2019 – March 31, 2020) (core basis)

(Millions of yen)

	FY2018	FY2019	Change (%)
Revenue	1,306,348	1,300,843	-5,505 (-0.4%)
Core operating profit	278,514	277,758	-756 (-0.3%)
Core profit for the year	249,343	223,178	-26,165 (-10.5%)

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 FY2019

1) Overview of consolidated financial results for FY2019

<Consolidated financial results (core basis ^(Note))>

Consolidated financial results (core basis) in FY2019 are shown in the table below.

Revenue and core operating profit were in the same range as those for previous fiscal year. Meanwhile, core profit for the year decreased.

Consolidated financial results (core basis)

(Millions of yen)

	FY2018	FY2019	Change (%)
Revenue	1,306,348	1,300,843	-5,505 (-0.4%)
Cost of sales	292,050	276,739	-15,311 (-5.2%)
Selling, general and administrative expenses	490,263	499,295	+9,032 (+1.8%)
R&D expenses	208,682	224,226	+15,545 (+7.4%)
Amortisation of intangible assets	35,212	21,164	-14,048 (-39.9%)
Share of profit (loss) of investments accounted for using equity method	-1,627	-1,660	-33 (—)
Core operating profit	278,514	277,758	-756 (-0.3%)
Core profit for the year	249,343	223,178	-26,165 (-10.5%)
Basic core earnings per share (yen)	129.07	118.95	-10.11 (-7.8%)

(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 Results FY2019."

Revenue

Revenue in FY2019 decreased by 0.4% compared to those in the previous fiscal year (“year-on-year”) to ¥1,300.8 billion.

- Revenue increased by 2.4%, excluding the negative impact of exchange rates with respect to yen appreciation.
- Sales of main products XTANDI for the treatment of prostate cancer and Betanis / Myrbetriq / BETMIGA for the treatment of overactive bladder (“OAB”) continued to grow.
- XOSPATA for the treatment of acute myeloid leukemia was additionally launched in Europe and also achieved growth in Japan and the United States. Moreover, new product groups in Japan achieved sales growth, notably EVENITY for the treatment of osteoporosis.
- The sales growth of those products almost offset the revenue decline mainly due to the end of exclusivity for OAB treatment Vesicare and anticancer drug Tarceva, and the termination of agreements in Japan for asthma treatment Symbicort as well as products of KM Biologics Co., Ltd. such as vaccines.

Core operating profit / Core profit for the year

- Gross profit increased by 1.0% year-on-year to ¥1,024.1 billion. The cost-to-revenue ratio fell by 1.1 percentage points year-on-year to 21.3%, mainly owing to changes in product mix.
- Selling, general and administrative expenses increased by 1.8% year-on-year to ¥499.3 billion. The efficient use of expenses and optimization of resource allocation partially offset increases in XTANDI co-promotion fees in United States, which accompanied sales growth, and investment required to launch new products. In addition, the reversal of loss allowances performed during the second quarter of FY2019 was a one-time factor affecting expense reduction.
- Research and development (R&D) expenses increased by 7.4% year-on-year to ¥224.2 billion. Expenses increased in relation to key post-POC pipeline projects and enhanced investment in new areas and technologies, such as increase in R&D expenses incurred due to acquisition of Audentes Therapeutics, Inc. The R&D cost-to-revenue ratio was up 1.3 percentage points year-on-year to 17.2%.
- Amortisation of intangible assets decreased by 39.9% year-on-year to ¥21.2 billion.

As a result of the above, core operating profit decreased by 0.3% year-on-year to ¥277.8 billion. Meanwhile, core profit for the year decreased by 10.5% year-on-year to ¥223.2 billion due to an increase in income tax expense given that the rate of taxation was low in the previous fiscal year due to one-time factors. Core operating profit increased by 4.3%, excluding the negative impact of exchange rates with respect to yen appreciation.

Impact of exchange rate on financial results

The exchange rates for the yen in FY2019 are shown in the table below. The resulting impacts were a ¥36.7 billion decrease in revenue and a ¥12.6 billion decrease in core operating profit compared with if the exchange rates of FY2018 were applied.

Average rate	FY2018	FY2019	Change
US\$/¥	111	109	¥2 (Strengthening of yen)
€/¥	128	121	¥8 (Strengthening of yen)

Change from beginning to end of period	As of March 31, 2019	As of March 31, 2020
US\$/¥	¥5 (Weakening of yen)	¥2 (Strengthening of yen)
€/¥	¥6 (Strengthening of yen)	¥5 (Strengthening of yen)

<Consolidated financial results (full basis)>

Consolidated financial results on a full basis in FY2019 are shown in the table below.

The full basis financial results include “Other income” and “Other expense” (including impairment losses and net foreign exchange losses), which are excluded from the core basis financial results.

The Company recorded a gain on sales of property, plant and equipment and other amounts in the third quarter of FY2019 as “Other income.” On the other hand, the Company recorded net foreign exchange losses as “Other expense,” and in the first quarter of FY2019 also recorded an increase in fair value of contingent consideration paid to former shareholders of Ogeda SA, commensurately with progress made in developing selective neurokinin-3 (NK3) receptor antagonist fezolinetant. In addition, in the fourth quarter of FY2019, the Company recorded expenses related to liquidating unvested stock options, etc. of Audentes Therapeutics, Inc. upon its acquisition, and recorded impairment losses in relation to renegotiation of contracts with Cytokinetics, Inc.

As a result of the above, in FY2019, “Other income” was ¥12.2 billion (¥14.2 billion in the previous fiscal year) and “Other expense” was ¥45.9 billion (¥48.8 billion in the previous fiscal year).

Consolidated financial results (full basis)

(Millions of yen)

	FY2018	FY2019	Change (%)
Revenue	1,306,348	1,300,843	-5,505 (-0.4%)
Operating profit	243,912	243,991	+80 (+0.0%)
Profit before tax	248,967	245,350	-3,617 (-1.5%)
Profit for the year	222,265	195,411	-26,854 (-12.1%)
Basic earnings per share (yen)	115.05	104.15	-10.90 (-9.5%)
Comprehensive income	222,250	156,692	-65,558 (-29.5%)

<Sales of Main Products>

(Billions of yen)

	FY2018	FY2019	Change
XTANDI	333.1	400.0	+20.1%
XOSPATA	2.5	14.3	+467.6%
PADCEV	–	1.8	–
Betanis / Myrbetriq / BETMIGA	147.2	161.6	+9.8%
Vesicare	95.0	44.7	-52.9%
Prograf*	195.7	192.9	-1.4%

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

<XTANDI>

- Sales increased by 20.1% year-on-year to ¥400.0 billion. Sales grew in all regions of Japan, United States, Established Markets*¹, Greater China*², and International*³.

<XOSPATA>

- Adding to sales in Japan and United States, XOSPATA was launched in Europe in November 2019. Sales of XOSPATA increased by 467.6% year-on-year to ¥14.3 billion.

<OAB products in Urology>

- Sales of Betanis / Myrbetriq / BETMIGA increased by 9.8% year-on-year to ¥161.6 billion. Sales increased in all regions.
- Sales of Vesicare decreased by 52.9% year-on-year to ¥44.7 billion, impacted by the effect of generic drugs resulting from the end of exclusivity for the drug in United States and Europe.

<Prograf>

- Sales decreased by 1.4% year-on-year to ¥192.9 billion. While sales grew in Greater China and International, sales decreased in Japan, United States and Established Markets.

<Other new products and main products>

- In Japan, in addition to EVENITY, new product group sales continued to grow, including those of Suglat and SUJANU Combination Tablets for the treatment of diabetes mellitus, Linzess for the treatment of chronic constipation, and the antineoplastic drug BLINCYTO. In addition, Evrenzo for the treatment of renal anemia was launched in November 2019. On the other hand, sales of Symbicort and vaccines of KM Biologics Co., Ltd. decreased as a result of the Company having discontinued

sales amid the termination of agreements.

- In United States, sales of azole antifungal CRESEMBA grew. In addition, PADCEV for the treatment of urothelial cancer was launched, which is being jointly developed with Seattle Genetics, Inc. Meanwhile, revenue associated with Tarceva decreased due to loss of exclusivity.

<Revenue by region>

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

Although the revenue of Established Markets and Greater China decreased due to the foreign exchange rate impact, it increased when calculated excluding such adverse effects.

(Billions of yen)

	FY2018	FY2019	Change
Japan	369.5	345.4	-6.5%
United States	421.6	443.5	+5.2%
Established Markets	300.0	296.1	-1.3%
Greater China	62.4	60.4	-3.3%
International	122.7	134.8	+9.9%

*1 Established Markets: Europe, Canada, Australia.

*2 Greater China: China, Hong Kong, Taiwan.

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

2) Other

The Company has been pursuing initiatives geared towards achieving sustainable growth over the mid to long term, based on its Strategic Plan 2018 announced in May 2018 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 FY2019:

<Maximizing Product VALUE and Operational Excellence>

The Company has been developing and maximizing the product value of the Company’s growth drivers such as XTANDI for the treatment of prostate cancer and Betanis / Myrbetriq / BETMIGA for the treatment of overactive bladder (“OAB”).

With regard to XTANDI, the Company strived to further increase penetration of XTANDI amongst urologists, along with establishing it as the first choice of therapy by utilizing extensive data based on the clinical experience accumulated since its launch. Moreover, the Company has been making efforts to increase the market penetration of XTANDI to the patients with prostate cancer in earlier stages by obtaining approval for expanding indications.

With regard to Betanis / Myrbetriq / BETMIGA, to partially offset the decline in sales of the OAB treatment Vesicare in Europe and the U.S. due to the expiry of the marketing exclusivity, the Company worked on expanding its market share through education on its clinical profile, which feature a balance of efficacy and safety.

In addition to these products, the Company is steadily advancing product development by preferentially allocating management resources to six key post-POC pipeline projects that will support growth over the mid- to long-term. Much progress was made in each project,, including the launch of Evrenzo for the treatment of renal anemia in Japan and the launch of PADCEV for the treatment of urothelial cancer in the U.S., which is being jointly developed with Seattle Genetics, Inc.

The following are the main progress of the each key post-POC pipeline project.

- ◇ XTANDI (enzalutamide) for the treatment of prostate cancer
 - July 2019 In Europe and Japan, the Company filed a supplemental new drug application for approval for metastatic castration-sensitive prostate cancer.
 - December 2019 In the U.S., the Company obtained approval for supplemental applications for metastatic castration-sensitive prostate cancer.

- February 2020 The Company announced that, in the final overall survival analysis from the Phase 3 PROSPER trial on patients with non-metastatic castration-resistant prostate cancer, those who were treated with androgen deprivation therapy plus XTANDI demonstrated a statistically significant improvement in overall survival over those who were treated with androgen deprivation therapy plus a placebo.
- March 2020 In China, the Company launched XTANDI with metastatic castration-sensitive prostate cancer as an indication in cases with no symptoms or mild symptoms and where androgen deprivation therapy has failed and chemotherapy is not yet clinically indicated.
- ◇ XOSPATA (gilteritinib) for the treatment of acute myeloid leukemia
- April 2019 The Company announced that in the Phase 3 ADMIRAL trial, XOSPATA demonstrated longer overall survival than salvage chemotherapy among adult patients with relapsed/refractory acute myeloid leukemia with an FMS-like tyrosine kinase 3 (*FLT3*) mutation, thus achieving a primary endpoint.
- May 2019 In the U.S., the Company obtained approval of its appended documentation giving data on longer overall survival found in the Phase 3 ADMIRAL trial.
- November 2019 In Europe, the Company launched XOSPATA as an indication for adult patients with relapsed/refractory acute myeloid leukemia with *FLT3* mutation.
- ◇ Evrenzo (roxadustat) for the treatment of renal anemia
- November 2019 In Japan, the Company launched Evrenzo as an indication for renal anemia in patients on dialysis.
- January 2020 In Japan, the Company submitted a supplemental application for approval of Evrenzo as a treatment for renal anemia in patients on non-dialysis.
- ◇ PADCEV (enfortumab vedotin) for the treatment of urothelial cancer
- November 2019 The Company and Seattle Genetics, Inc. entered into a collaboration agreement with MSD International GmbH, regarding clinical trials on untreated patients with metastatic urothelial cancer to evaluate the use of PADCEV combined with pembrolizumab.
- December 2019 In the U.S., Seattle Genetics, Inc. launched PADCEV for the treatment of locally advanced or metastatic urothelial cancer, which had previously been treated with PD-1 or PD-L1 inhibitors and with supplemental platinum-containing chemotherapy before or after surgery or in a locally advanced or metastatic setting.

- February 2020 The U.S. FDA has granted the Breakthrough Therapy Designation for PADCEV for first-line therapy using PADCEV in combination with pembrolizumab to treat patients with unresectable locally advanced or metastatic urothelial cancer who are unable to receive cisplatin-based chemotherapy.
- ◇ Fezolinetant, a selective neurokinin-3 receptor antagonist
- August 2019 The Company announced the dosing of the first patient in the international joint Phase 3 trial for fezolinetant on patients with moderate-to-severe vasomotor symptoms associated with menopause.
- ◇ Zolbetuximab (IMAB362), an anti-Claudin 18.2 monoclonal antibody
- July 2019 The Company announced the dosing of the first patient in the Phase 2 trials of patients with pancreatic adenocarcinoma.

In addition to the above, the main developments in Japan, including approvals and new launches, were as follows.

- June 2019 The Company and its manufacturing partner, Toa Eiyo Ltd., launched BisoNo Tape 2 mg for tachycardiac atrial fibrillation, an additional dosage form of its hypertension and atrial fibrillation treatment BisoNo Tape.
- June 2019 The Company launched Gonax 240 mg, an additional dosage of its prostate cancer treatment Gonax that enables new maintenance dosage at 12-week intervals.
- June 2019 The Company's joint development partner, Amgen Astellas BioPharma K.K., received approval to amend its production and marketing terms indication for the hypercholesterolemia drug Repatha for treatment of hypercholesterolemia and familial hypercholesterolemia where HMG-CoA reductase inhibitor therapy is not suitable.
- July 2019 The Company launched Smyraf for the treatment of rheumatoid arthritis in cases where conventional therapies for rheumatoid arthritis (including prevention of structural joint damage) have been inadequate.

In Japan, the Company ceased transferred sale and distribution of products as below.

- July 2019 In accordance with the expiration of the sales and co-promotion agreement with AstraZeneca AB for the Symbicort Turbuhaler treatment for asthma and chronic obstructive pulmonary disease, the Company transferred the exclusive sale and distribution of this product in Japan to AstraZeneca K.K. and terminated the co-promotion activities it had been conducting with that company.

July 2019	In accordance with the expiration of the contract with KM Biologics Co., Ltd. to jointly market blood plasma products, the Company terminated all marketing of the applicable products as well as the provision and collection of information from medical institutions.
January 2020	The Company transferred the marketing authorizations and marketing of the Tiapride medication Gramalil and the digestive organ dysfunction medication Primperan to Nichi-Iko 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 is the main initiative during the FY2019:

November 2019	The Company transferred its manufacturing and marketing authorizations, trademark, and related contracts for South Korea, Thailand, the Philippines, Indonesia, China, and Taiwan relating to the Nasea antiemetic treatment, the Perdipine hypertension treatment, and the Oldeca hypertension treatment to Daiichi Sankyo Co., Ltd.
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<Evolving How We Create VALUE - With Focus Area Approach>

The Company is aiming to create innovative pharmaceuticals for diseases with high unmet medical needs by focusing on fields that have been carefully narrowed from elucidation of pathophysiology through advances in science (biology) and the utilization of treatment modalities and technologies (modality/technology), as creation of VALUE thorough Focus Area Approach. The Company has selected Primary Focus such as “regeneration and blindness,” “immuno-oncology,” “ASIM (Antigen-specific Immune Modulation) biology,” and “mitochondria biology” through the Focus Area approach, and in addition to them, “genetic regulation” has been defined as a new Primary Focus with the acquisition of Audentes Therapeutics, Inc. The Company allocate management resources to these Primary Focus and is embarking on research and development.

The following are the main progress during the FY2019:

◇ Immuno-oncology

September 2019	The Company entered into a worldwide exclusive license agreement with RIKEN for the cell therapy formulations applying RIKEN’s artificial adjuvant vector cell technology in oncology, and acquired the rights for the research, development and commercialization of cell therapy formulations that targets selected cancer antigens.
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December 2019 The Company acquired Xyphos Biosciences, Inc. and made it a wholly owned subsidiary of the Company. With the acquisition, the Company gained Xyphos' ACCEL (Advanced Cellular Control through Engineered Ligands) technology platform related to Chimeric Antigen Receptor (CAR) cell therapy, as well as industry-leading immuno-oncology talent.

January 2020 The Company entered into an agreement with Adaptimmune Therapeutics plc to co-develop and co-commercialize stem-cell derived allogeneic T-cell therapies to people with cancer. Based on the agreement, the Company and Adaptimmune agree on up to three targets and co-develop T-cell therapy candidates directed to those targets.

March 2020 The Company entered into a strategic collaboration agreement with CytomX Therapeutics, Inc. focused on the discovery, research, development and commercialization of novel T-cell engaging bispecific antibodies targeting CD3 and tumor cell surface antigens for the treatment of cancer. Based on the agreement, the Company aims to deliver innovative cancer treatments by utilizing the CytomX's Probody therapeutic technology platform, as well as its proprietary bispecific formats and CD3 modules.

◇ ASIM Biology

October 2019 The Company entered into a license collaboration agreement with Pandion Therapeutics, Inc. for research, development, and commercialization of locally acting immunomodulators for autoimmune diseases of the pancreas. By doing this, the Company aims to jointly develop treatments for autoimmune diseases by combining Pandion's expertise in biopharmaceutical engineering and immunology with the Company's wealth of experience in global business and research and development of innovative drugs.

◇ Mitochondria Biology

October 2019 The Company received Fast Track designation in the U.S. for its ongoing development of ASP1128 for patients who have an increased risk of developing moderate to severe acute kidney injury after coronary artery bypass and/or valve surgery.

◇ Genetic Regulation

January 2020 The Company acquired Audentes Therapeutics, Inc., and made it a wholly owned subsidiary of the Company. In addition to acquiring Audentes' original technological platform for gene therapy that uses Adeno-associated viruses and its strong capabilities in manufacturing therapies in-house, the Company has also obtained several gene therapy programs, including AT132 for the treatment of X-linked myotubular myopathy, which is currently in Phases 1/2 of clinical development stage. The Company is also aiming to create opportunities for expanding its pipeline and partnering in the field of gene therapy by integrating valuable human networks consisting of patient groups, academic partners, and the like.

◇ Others

July 2019 The Company entered into an exclusive license agreement with Frequency Therapeutics, Inc. and acquired rights regarding the development and commercialization of Frequency's regenerative therapeutic candidate, FX-322 outside of the U.S. for the treatment of sensorineural hearing loss.

July 2019 The Company announced that it began the Phase 2 part of the Phase 1 and 2 trials for ASP3772, a pneumococcus vaccine developed with the Multiple Antigen Presenting System technology of Affinivax, Inc.

<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 Company aims to create new healthcare solutions by combining expertise and experience cultivated through the prescription pharmaceutical (Rx) business with advanced medical technology, and technology and knowledge from different fields.

In FY2019, the Company established Rx+ Story™ as a strategic direction of the Rx+™ business with clarified focus and priority. This will enable Rx+™ business creation activities to transition from the stage of seeking a broad range of opportunities to the stage of establishing a solid ground for business acceleration.

Below are the key initiatives in FY2019.

August 2019 With Yokohama City University and the Tokyo University of the Arts, the Company launched "Health Mock Lab." as a virtual framework for industry-academia collaboration aimed at creating and commercializing new digital healthcare solutions using gamification.

- September 2019 The Company entered into a collaborative research and development agreement with Iota Biosciences, Inc. to explore new biosensing and treatment measures using ultra-small implantable medical devices. Under this agreement, the two companies will jointly design detailed specifications for implantable medical devices and will conduct preclinical studies for several diseases with high unmet medical needs.
- November 2019 The Company entered into a collaboration and license agreement with Welldoc, Inc. toward the development and commercialization of digital therapeutics. Under this agreement, the Company has obtained the rights in Japan and certain other Asian markets for joint development and commercialization of Welldoc's digital health product for diabetes BlueStar[®] as well as the right to collaborate in broadening the adoption of BlueStar[®] in the U.S. market. The Company will also jointly develop and commercialize digital therapeutics for other diseases besides diabetes on a global basis.

(2) Financial position

1) Assets, equity and liabilities

An overview of the consolidated statement of financial position as of March 31, 2020 and the main changes from the end of the previous fiscal year are shown below.

In January 2020, the Company acquired Audentes Therapeutics, Inc. and its subsidiaries and subsequently made them consolidated subsidiaries. The Company's assets and liabilities have been subject to substantial change associated with having arranged financing in the form of short-term bonds and short-term borrowings to finance the acquisition of Audentes Therapeutics, Inc.

Assets

Total assets saw an increase of ¥420.5 billion compared to the end of the previous fiscal year to ¥2,318.2 billion.

<Non-current assets> ¥1,450.6 billion (an increase of ¥410.2 billion)

- Due to the application of IFRS 16 "Leases," right-of-use assets of ¥83.1 billion was recognized at the beginning of the year. Consequently, property, plant and equipment increased by ¥95.1 billion compared to the end of the previous fiscal year to ¥268.6 billion.
- Goodwill increased by ¥41.6 billion compared to the end of the previous fiscal year to ¥267.5 billion, and intangible assets increased by ¥308.8 billion compared to the end of the previous fiscal year to ¥738.5 billion as a result of the acquisitions of Xyphos Biosciences, Inc. in December 2019 and Audentes Therapeutics, Inc. in January 2020, and other factor.

<Current assets> ¥867.5 billion (an increase of ¥10.4 billion)

- Cash and cash equivalents increased by ¥7.3 billion compared to the end of the previous fiscal year to ¥318.4 billion.

Equity

Total equity as of March 31, 2020 saw an increase of ¥30.8 billion compared to the end of the previous fiscal year to ¥1,289.2 billion, making the ratio of equity attributable to owners of the parent to gross assets 55.6%.

- While profit for the year stood at ¥195.4 billion, the Company paid ¥73.5 billion of dividends of surplus and executed a ¥52.9 billion acquisition of own shares.
- The Company canceled a total of 118.04 million own shares valued at ¥209.4 billion in the months of May 2019 and February 2020, combined.

Liabilities

Total liabilities increased by ¥389.7 billion compared to the end of the previous fiscal year to ¥1,029.0 billion.

<Non-current liabilities> ¥230.3 billion (an increase of ¥88.7 billion)

- Due to the application of IFRS 16 “Leases,” lease liabilities of ¥75.5 billion was recognized at the beginning of the year. Consequently, other financial liabilities increased by ¥76.4 billion compared to the end of the previous fiscal year to ¥129.3 billion.
- Deferred tax liabilities increased by ¥22.5 billion compared to the end of the previous fiscal year to ¥27.7 billion, due to acquisition of Audentes Therapeutics, Inc.

<Current liabilities> ¥798.7 billion (an increase of ¥301.0 billion)

- As of March 31, 2020, the balance of short-term bonds and short-term borrowings amounted to ¥186.0 billion and ¥140.0 billion, respectively, as a result of the Company having arranged such financing to finance the acquisition of Audentes Therapeutics, Inc. In addition, due to the application of IFRS 16 “Leases,” lease liabilities of ¥16.9 billion was recognized at the beginning of the year. Consequently, other financial liabilities increased by ¥331.6 billion compared to the end of the previous fiscal year to ¥345.7 billion.

2) Cash flow

Cash flows from operating activities

Net cash flows from operating activities in FY2019 decreased year-on-year by ¥36.6 billion to ¥222.0 billion.

- Income tax paid was ¥48.0 billion.

Cash flows from investing activities

Net cash flows used in investing activities in FY2019 was ¥389.8 billion, an increase in outflow of ¥348.0 billion year-on-year.

- Payments for acquisition of subsidiaries increased by ¥301.5 billion to ¥320.8 billion due to acquisitions including those of Audentes Therapeutics, Inc. and Xyphos Biosciences, Inc.

Cash flows from financing activities

Net cash flows provided by financing activities in FY2019 was ¥181.1 billion (outflow of ¥233.7 billion in the previous fiscal year).

- The net change in bonds and borrowings amounts to ¥326.0 billion as a result of having procured requisite funds for the acquisition of Audentes Therapeutics, Inc.
- Dividends paid increased by ¥1.5 billion year-on-year to ¥73.5 billion. Other outflow included cash of ¥52.9 billion (a decrease of ¥107.5 billion year-on-year) used for the acquisition of own shares.

As a result, cash and cash equivalents totaled ¥318.4 billion as of March 31, 2020, an increase of ¥7.3 billion compared to the end of the previous fiscal year.

(3) Consolidated business forecasts for FY2020 and other forward-looking statements

The Company's business forecasts for FY2020 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)

	FY2019 Results	FY2020 Forecasts	Change (%)
Revenue	1,300,843	1,282,000	-18,843 (-1.4%)
R&D expenses	224,226	239,000	+14,774 (+6.6%)
Core operating profit	277,758	257,000	-20,758 (-7.5%)
Core profit for the year	223,178	206,000	-17,173 (-7.7%)
Basic core earnings per share (yen)	118.95	110.90	-8.05 (-6.8%)

(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 FY2019.

Expected exchange rate for

FY2020 (Forecast)	¥110/US\$	¥120/€
FY2019 (Result)	¥109/US\$	¥121/€

Revenue, core operating profit and core profit for the year are anticipated to decrease compared with FY2019.

In FY2020, the decrease in revenue caused by the expiration of agreements related to licensed products in Japan and the loss of exclusivity, and the increase in R&D investment are anticipated to be the main factors in decrease in profit. Despite the core operating profit decrease in FY2020 guidance, we forecast growth in core operating profit excluding one-off factors to improve FY2019 profit by approximately 30.0 billion yen.

The yen is anticipated to slightly weaken against the U.S. dollar and slightly strengthen against the euro compared with FY2019 result. The fluctuations in the exchange rate is anticipated to cause a ¥3.5 billion increase in revenue and a ¥1.3 billion decrease in core operating profit compared with if the exchange rates of FY2019 were applied.

Revenue

The revenue forecast is ¥1,282.0 billion (down 1.4% year on year).

Mainstay products XTANDI and Betanis / Myrbetriq / BETMIGA are anticipated to see continued growth, while growth of XOSPATA, which has now been launched in Europe as well as Japan and the United States, and sales of PADCEV (U.S.) and Evrenzo (Japan), which were launched during FY2019, are also anticipated to contribute to earnings throughout the year.

However, declines in sales are anticipated due to a loss of exclusivity of Funguard / MYCAMINE, Vesicare in Europe, and Celecox in Japan. Above these, the impact of the termination of agreements in Japan for Micardis family, Symbicort, and products of KM Biologics Co., Ltd. will continue to be decreasing factors for revenue in FY2020.

As a result of these factors, revenues are anticipated to decrease.

Core operating profit/ Core profit for the year

Cost-of-goods ratio to revenue will be lowered mainly due to changes in product mix. Selling, general and administrative expenses are anticipated to increase year on year. We will pursue cost efficiency by allocating sufficient investment to maximizing the value of new products and growth products, while thoroughly reviewing other costs. However, co-promotion fees for XTANDI in the United States are to increase in association with sales expansion, and in FY2019 there was a one-off reducing factor on expenses from a reversal of loss allowances.

We project R&D expenses of ¥239.0 billion (up 6.6% year on year) which account for 18.6% to revenue (FY2019 ratio to revenue: 17.2%) reflecting increase in investment for steady development of key post-POC pipeline projects and new technologies including R&D expenses at Audentes Therapeutics, Inc. to be booked throughout the year.

As a result, we project core operating profit of ¥257.0 billion (down 7.5% year on year).

Core profit for the year is forecasted at ¥206.0 billion (down 7.7% year on year) and basic core earnings per share is forecasted at ¥110.85 (down 6.8 % year on year).

<Sales of Main Products>

(Billions of yen)

	FY2019 Results	FY2020 Forecasts	Change
XTANDI	400.0	459.3	+14.8%
XOSPATA	14.3	23.2	+62.6%
Betanis / Myrbetriq / BETMIGA	161.6	172.5	+6.8%
Vesicare	44.7	32.4	-27.5%
Prograf*	192.9	186.3	-3.4%

* 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)

	FY2019 Results	FY2020 Forecasts	Change (%)
Revenue	1,300,843	1,282,000	-18,843 (-1.4%)
Operating profit	243,991	252,000	+8,009 (+3.2%)
Profit before tax	245,350	251,000	+5,650 (+2.3%)
Profit for the year	195,411	202,000	+6,589 (+3.4%)
Basic earnings per share (yen)	104.15	108.75	+4.60 (+4.4%)

(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 FY2019.

Expected exchange rate for

FY2020 (Forecast)	¥110/US\$	¥120/€
FY2019 (Result)	¥109/US\$	¥121/€

In FY2019, the Company recorded “Other expense” that is excluded from its core basis financial results, with the result that operating profit is ¥33.8 billion lower than core operating profit. In FY2020, 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.

Impact of the Spread of Coronavirus Disease (COVID-19) on Financial Results

The impact of the spread of COVID-19 on the Company's financial results in FY2019 was immaterial; however, as it is difficult to assess properly the impact on financial results at this point, the impact has not been incorporated into the financial results forecasts for FY2020 disclosed here.

Effort against the spread of COVID-19

The Company's main efforts against the spread of the COVID-19 as of May 14, 2020 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 forbidding our employees in countries and regions with continuing spread of COVID-19, except those instructed by the company, to work in offices and instead are having them work from home by using online digital tools. While we are basically refraining from sales activities, we continue to gather and provide necessary information to medical institutions in regions around the world in accordance with rules of each institution.
 - 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, complying with laws and regulations, managing safety, and providing information, our essential business continues to be carried out by those who have been instructed by the company under the business continuity plan with strict measures taken to prevent infections.
 - As for the supply of products, in particular, there are currently no problems, as we have been able to manage risks of raw materials and finished products supply, by closely cooperating with outsourcing manufacturers and suppliers of raw materials taking into account the continuation of business and the stable supply of products.

- ◇ 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 implementing changes to our clinical trial operations.

 - In countries and regions with continuing spread of COVID-19, we are suspending start-up activities involving study sites for new interventional clinical studies. We are also suspending enrollment of new patients in ongoing studies.
 - In countries no longer experiencing a rapid growth of COVID-19 cases, we are resuming or continuing study activities.
 - Consistent with the recently issued guidance from authorities including US and EU regulatory bodies, we are assessing protocols and implementing measures to reduce the burden to healthcare systems while ensuring that patient safety is maintained.
 - In order to prioritize patient's safety, we are also providing measures, when applicable, such as remotely monitoring the safety of a patient via phone, conducting necessary medical exam 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 will frequently reassess this approach, which applies to all interventional clinical trials led by us and our subsidiaries and affiliates. A different approach may be implemented for some clinical trials led by our collaboration partners.

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 will continue to quickly take appropriate action by cooperating with bodies concerned in response to requests by the government such as the provisions of drugs.

- In Japan, we are providing 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 are also responding to requests from the European Federation of Pharmaceutical Industries Associations (EFPIA) and the Innovative Medicines Initiative (IMI) to cooperate in “Activities Aimed at Developing Drugs for the Novel Virus” and providing consultation on countermeasures.
- We receive various proposals from within or outside of the Company, for potential use of our drugs that are under development or in the market against COVID-19, and we are swiftly evaluating each of them.

We are also responding to the requests from various government to provide compounds in the research phase. While placing highest priority on the safety, we will at the same time continue to contribute in the efforts to swiftly evaluating various possibilities in research and development of drugs against COVID-19.

◇ Activities in regions where infection is spreading

- Astellas Pharma China, Inc. donated one million yuan to the Red Cross Society of China for purchasing protective clothing, masks, disinfecting solutions, and other equipment for healthcare professionals serving at hospitals in Wuhan, China, and procuring medical treatment equipment. In addition, it has donated up to approximately 300,000 yuan worth personal protective equipment to the same society, which have been distributed to hospitals in Wuhan City.
- Astellas Pharma US, Inc. and the Astellas Global Health Foundation are each expanding support for global and local communities fighting the COVID-19 by providing up to \$2 million of new 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, the Company is preparing to help humanitarian organizations working to support communities affected by the COVID-19 outbreak. This includes the Company’ corporate donations to the Americares, the American Red Cross, and Direct Relief to help their emergency efforts. The company is also coordinating 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 Company’ US-headquarters

in Illinois, the Company is partnering with multiple state organizations with their response to the COVID-19, 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 recently completed its COVID-19 request for proposal process, with funding to be awarded later this year to the selected national and global humanitarian organizations who are working tirelessly to fight COVID-19 in countries where the Company does not have a commercial presence.
- Furthermore, we have implemented changes to its patient assistance programs in the United States, Astellas Pharma Support SolutionsSM, which offers support to patients needing access and reimbursement assistance as part of the company's ongoing commitment to ensuring that patients have access to our products. 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 increased customer service capacity in light of the influx of patients requiring assistance.
- In Italy, our group company, Astellas Pharma S.p.A., has decided on a donation worth 150,000 euros for the necessary supply of goods to public medical institutions and NPOs.
- In Spain, our group company, Astellas Pharma S.A., has decided on a donation worth 200,000 euros to its country's health ministry for the necessary supply of goods to medical institutions.
- Furthermore, to assist health care systems coping with increasing demands by government or non-profit organization presented by the escalation of the COVID-19 around the world, the Company will authorize a maximum of 4 weeks of paid leave (in accordance with each country's provision) to employees who are medically qualified and wishes to contribute 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.

(4) Capital allocation policy and dividends for FY2019 and FY2020

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 FY2019 is ¥40 per share (including a year-end dividend of ¥20 per share) to shareholders.

In addition, the Company implemented acquisition of own shares from the stock market of 27.04 million shares, which amounted to ¥50.0 billion, during FY2019.

The Company anticipates that the annual dividend in FY2020 will be ¥42 per share (composed of interim dividend of ¥21 per share and a year-end dividend of ¥21 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 2019	Fiscal year ended 31 March 2020
Revenue	1,306,348	1,300,843
Cost of sales	(292,050)	(276,739)
Gross profit	1,014,299	1,024,104
Selling, general and administrative expenses	(490,263)	(499,295)
Research and development expenses	(208,682)	(224,226)
Amortisation of intangible assets	(35,212)	(21,164)
Share of profit (loss) of investments accounted for using equity method	(1,627)	(1,660)
Other income	14,152	12,154
Other expense	(48,755)	(45,921)
Operating profit	243,912	243,991
Finance income	6,358	4,363
Finance expense	(1,302)	(3,004)
Profit before tax	248,967	245,350
Income tax expense	(26,702)	(49,939)
Profit	222,265	195,411
Profit attributable to:		
Owners of the parent	222,265	195,411
Earnings per share		
Basic (Yen)	115.05	104.15
Diluted (Yen)	114.94	104.08

(2) Consolidated Statement of Comprehensive Income

(Millions of yen)

	Fiscal year ended 31 March 2019	Fiscal year ended 31 March 2020
Profit	222,265	195,411
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	5,060	(7,611)
Remeasurements of defined benefit plans	(2,553)	1,271
Subtotal	<u>2,508</u>	<u>(6,339)</u>
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	(2,523)	(32,380)
Subtotal	<u>(2,523)</u>	<u>(32,380)</u>
Other comprehensive income	<u>(15)</u>	<u>(38,719)</u>
Total comprehensive income	<u>222,250</u>	<u>156,692</u>
Total comprehensive income attributable to:		
Owners of the parent	222,250	156,692

(3) Consolidated Statement of Financial Position

(Millions of yen)

	As of 31 March 2019	As of 31 March 2020
Assets		
Non-current assets		
Property, plant and equipment	173,483	268,600
Goodwill	225,864	267,510
Intangible assets	429,707	738,507
Trade and other receivables	25,248	34,014
Investments accounted for using equity method	3,653	4,692
Deferred tax assets	92,958	52,876
Other financial assets	81,457	74,264
Other non-current assets	8,121	10,184
Total non-current assets	1,040,489	1,450,646
Current assets		
Inventories	151,511	151,017
Trade and other receivables	342,628	347,042
Income tax receivable	20,113	23,556
Other financial assets	2,607	9,459
Other current assets	25,080	18,049
Cash and cash equivalents	311,074	318,391
Subtotal	853,012	867,514
Assets held for sale	4,147	—
Total current assets	857,159	867,514
Total assets	1,897,648	2,318,160

(Millions of yen)

	As of 31 March 2019	As of 31 March 2020
Equity and liabilities		
Equity		
Share capital	103,001	103,001
Capital surplus	177,301	177,506
Treasury shares	(164,629)	(7,178)
Retained earnings	991,957	905,851
Other components of equity	150,767	109,989
Total equity attributable to owners of the parent	1,258,396	1,289,168
Total equity	1,258,396	1,289,168
Liabilities		
Non-current liabilities		
Trade and other payables	1,572	3,142
Deferred tax liabilities	5,175	27,661
Retirement benefit liabilities	40,163	38,074
Provisions	5,416	6,135
Other financial liabilities	52,882	129,272
Other non-current liabilities	36,379	25,999
Total non-current liabilities	141,587	230,284
Current liabilities		
Trade and other payables	185,280	171,954
Income tax payable	17,587	4,009
Provisions	22,843	14,241
Other financial liabilities	14,136	345,707
Other current liabilities	255,913	262,797
Subtotal	495,759	798,708
Liabilities directly associated with assets held for sale	1,906	—
Total current liabilities	497,665	798,708
Total liabilities	639,252	1,028,992
Total equity and liabilities	1,897,648	2,318,160

(4) Consolidated Statement of Changes in Equity

(Millions of yen)

	Equity attributable to owners of the parent					
	Share capital	Capital surplus	Treasury shares	Retained earnings	Other components of equity	
					Subscription rights to shares	Exchange differences on translation of foreign operations
As of 1 April 2018	103,001	177,219	(135,951)	976,076	1,477	128,179
Cumulative effect of accounting change	—	—	—	—	—	—
Restated balance	103,001	177,219	(135,951)	976,076	1,477	128,179
Comprehensive income						
Profit	—	—	—	222,265	—	—
Other comprehensive income	—	—	—	—	—	(2,523)
Total comprehensive income	—	—	—	222,265	—	(2,523)
Transactions with owners						
Acquisition of treasury shares	—	—	(160,442)	—	—	—
Disposals of treasury shares	—	(281)	1,345	(713)	(350)	—
Cancellation of treasury shares	—	—	130,419	(130,419)	—	—
Dividends	—	—	—	(72,066)	—	—
Share-based payments	—	364	—	—	—	—
Transfers	—	—	—	(3,187)	—	—
Total transactions with owners	—	82	(28,678)	(206,384)	(350)	—
As of 31 March 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

(Millions of yen)

	Equity attributable to owners of the parent					Total equity
	Other components of equity				Total	
	Fair value movements on available-for-sale financial assets	Financial assets measured at fair value through other comprehensive income	Remeasurements of defined benefit plans	Total		
As of 1 April 2018	18,289	—	—	147,945	1,268,289	1,268,289
Cumulative effect of accounting change	(18,289)	18,289	—	—	—	—
Restated balance	—	18,289	—	147,945	1,268,289	1,268,289
Comprehensive income						
Profit	—	—	—	—	222,265	222,265
Other comprehensive income	—	5,060	(2,553)	(15)	(15)	(15)
Total comprehensive income	—	5,060	(2,553)	(15)	222,250	222,250
Transactions with owners						
Acquisition of treasury shares	—	—	—	—	(160,442)	(160,442)
Disposals of treasury shares	—	—	—	(350)	1	1
Cancellation of treasury shares	—	—	—	—	—	—
Dividends	—	—	—	—	(72,066)	(72,066)
Share-based payments	—	—	—	—	364	364
Transfers	—	635	2,553	3,187	—	—
Total transactions with owners	—	635	2,553	2,837	(232,143)	(232,143)
As of 31 March 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

(5) Consolidated Statement of Cash Flows

(Millions of yen)

	Fiscal year ended 31 March 2019	Fiscal year ended 31 March 2020
Cash flows from operating activities		
Profit before tax	248,967	245,350
Depreciation and amortisation	63,458	66,396
Impairment losses (reversal of impairment losses)	11,446	13,796
Finance income and expense	(5,055)	(1,359)
(Increase) decrease in inventories	(5,480)	(6,038)
(Increase) decrease in trade and other receivables	(25,640)	(16,391)
Increase (decrease) in trade and other payables	40,828	(21,363)
Other	20	(10,400)
Subtotal	328,543	269,991
Income tax paid	(69,913)	(47,993)
Net cash flows from operating activities	258,630	221,998
Cash flows from investing activities		
Purchases of property, plant and equipment	(25,190)	(41,267)
Proceeds from sales of property, plant and equipment	20,949	6,924
Purchase of intangible assets	(26,938)	(36,621)
Payments for acquisition of subsidiaries	(19,292)	(320,764)
Interest and dividends received	2,798	2,062
Other	5,916	(127)
Net cash flows provided by (used in) investing activities	(41,757)	(389,793)
Cash flows from financing activities		
Increase (decrease) in bonds and borrowings	—	326,000
Acquisition of treasury shares	(160,442)	(52,899)
Dividends paid to owners of the parent	(72,066)	(73,539)
Repayments of lease liabilities	—	(17,660)
Other	(1,173)	(847)
Net cash flows provided by (used in) financing activities	(233,681)	181,055
Effect of exchange rate changes on cash and cash equivalents	(2,118)	(5,942)
Cash and cash equivalents reclassified to assets held for sale	(1,732)	—
Net increase (decrease) in cash and cash equivalents	(20,657)	7,317
Cash and cash equivalents at the beginning of the year	331,731	311,074
Cash and cash equivalents at the end of the year	311,074	318,391

(6) Notes to consolidated financial statements

Notes on going concern assumption

Not applicable.

Significant accounting policies

Astellas Pharma Inc. and its subsidiaries (collectively, the “Group”) has newly adopted the following standard from the fiscal year ended 31 March 2020:

IFRS		Summary of new or amended IFRS standard and interpretations
IFRS 16	Leases	Amendments related to accounting treatment for leases

With the application of IFRS 16, the Group adopts the practical expedient whereby the Group does not reassess whether a contract is, or contains, a lease at the date of initial application. The Group adopts the method whereby the cumulative effect of initially applying this standard is recognised at the date of initial application as a transitional measure.

At inception of a contract, the Group assesses whether the contract is, or contains, a lease based on the substance of the contract. The Group determines the lease term as the non-cancellable period of a lease, together with both periods covered by an option to extend the lease and periods covered by an option to terminate the lease, as well as using hindsight at the date of initial application. The Group applies a single discount rate to a portfolio of leases with reasonably similar characteristics. For short-term leases and leases for which the underlying asset is of low value, the Group may recognise the lease payments as an expense over the lease term instead of recognising a right-of-use asset and a lease liability.

1) Right-of-use asset

The right-of-use assets are initially measured at cost, which comprises the amount of the initial measurement of the corresponding lease liability adjusted for initial direct costs, etc.

Right-of-use assets are depreciated on a straight-line basis from the commencement date of the lease over the shorter of the useful life of the right-of-use asset or the end of the lease term.

2) Lease liability

The lease liabilities are initially measured at the present value of the lease payments that are not paid at the commencement date, which is discounted using the interest rate implicit in the lease. If that rate can not be readily determined, the Group uses its incremental borrowing rate.

After the commencement date, the lease liabilities are measured by increasing the carrying amount to reflect interest on the lease liability, reducing the carrying amount to reflect the lease payments made and remeasured to reflect any reassessment or lease modifications when necessary.

Due to the application of IFRS 16, the Group recognises right-of-use assets of 83,061 million yen as “Property, plant and equipment”, lease liabilities of 75,455 million yen and 16,859 million yen as “other financial liabilities” in non-current liabilities and current liabilities, respectively, in the consolidated statement of financial position at the date of initial application. There is no material impact on other assets and liabilities. There is no impact on the beginning balance of retained earnings. There is no material impact on the consolidated statement of income. The lease payments are recognised in the consolidated statement of cash flows mainly as cash flows from financing activities, whereas previously such payments were recognised as cash flows from operating activities.

Business Combinations

For the fiscal year ended 31 March 2019

Potenza Therapeutics, Inc.

(1) Outline of the business combination

(i) Name and business description of the acquiree

Name of the acquiree: Potenza Therapeutics, Inc. ("Potenza")

Business description: Research and development in various novel drugs to stimulate the immune system

(ii) Acquisition date

13 December 2018, U.S. Eastern Standard Time

(iii) Percentage of voting equity interests

The Group had owned 24% of voting equity interests before the acquisition. As a result of the acquisition, the Group owns 100% of voting equity interests.

(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

Potenza is a biotechnology company founded in 2014 and has discovered and developed various clinical stage novel immuno-oncology (IO) programs through the research and development collaboration over the past three and a half years.

Upon the closing of this transaction, the Group has added competitive clinical IO programs to its oncology pipeline, which also provide a platform for IO combinations with Astellas' existing non-IO programs and future novel IO combinations.

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

	(Millions of yen)
Property, plant and equipment	36
Intangible assets	31,609
Cash and cash equivalents	802
Other assets	191
Deferred tax liabilities	(5,232)
Other liabilities	(1,580)
Fair value of assets acquired and liabilities assumed (net)	25,827
Goodwill	5,518
Total	31,345
Cash	18,668
Contingent consideration	6,865
Fair value of previously held equity interests in Potenza	5,812
Total fair value of purchase consideration transferred	31,345

Certain items had reflected provisional amounts as of 31 March 2019, however, the Group completed the purchase price allocation during the fiscal year ended 31 March 2020.

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

As a result of remeasurement of the Group's previously held equity interests in Potenza at fair value as of the acquisition date, the Group recognised a 5,812 million yen gain on remeasurement related to a business combination achieved in stages. This gain was included as a component of "Other income" in the consolidated statement of income.

(3) Contingent consideration

The contingent consideration relates to certain milestones depending on the progress of various programs in clinical development. Maximum potential future cash outflows associated with the contingent consideration total 240 million U.S. dollars (26,651 million yen). The fair value of the contingent consideration is calculated based on the success probability of the clinical program adjusted for the time value of money.

(4) Cash flow information

	(Millions of yen)
Total fair value of purchase consideration transferred	31,345
Fair value of contingent consideration included in purchase consideration transferred	(6,865)
Fair value of previously held equity interests in Potenza included in purchase consideration transferred	(5,812)
Cash and cash equivalents held by the acquiree	(802)
Acquisition of subsidiaries, net of cash acquired	17,866

(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: Immaterial

(ii) Profit (loss) before tax of the combined entity for the fiscal year ended 31 March 2019 assuming the acquisition date had been at the beginning of the fiscal year : Immaterial

For the fiscal year ended 31 March 2020

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: A privately-held biotechnology company focused on immuno-oncology therapeutics

(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.

Through the acquisition, the Group will combine this technology with its capabilities in cell therapy that it has been working on so far, so that it can create next-generation high-function cells and maximize 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 above reflect provisional fair values based on reasonable information obtained at 31 March 2020 as the purchase price allocation is incomplete.

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: 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

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 focused on developing and commercializing 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 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)
Property, plant and equipment	8,964
Intangible assets	284,944
Financial assets at FVTOCI (debt instruments)	22,248
Cash and cash equivalents	9,320
Other assets	1,708
Trade and other payables	(6,092)
Deferred tax liabilities	(41,517)
Other liabilities	(6,488)
Fair value of assets acquired and liabilities assumed (net)	273,085
Goodwill	42,497
Total	315,582
Total fair value of purchase consideration transferred	315,582

Certain items above reflect provisional fair values based on reasonable information obtained at 31 March 2020 as the purchase price allocation is incomplete.

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 the payment for unvested share-based payments, such as share options from the business combination and recognized 7,744 million yen as other expense 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: (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

Segment information

The main activities of the Group are the 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 are as follows:

(Millions of yen)

	Fiscal year ended 31 March 2019	Fiscal year ended 31 March 2020
XTANDI	333,050	399,989
Prograf	195,706	192,926
Betanis/Myrbetriq/BETMIGA	147,178	161,564
Vesicare	94,974	44,721
Other	535,439	501,643
Total	1,306,348	1,300,843

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 2019	Fiscal year ended 31 March 2020
Japan	396,615	375,174
United States	427,772	448,083
Others	481,961	477,586
Total	1,306,348	1,300,843

(Note) Revenue by geographical areas is categorised by country or areas based on the geographical location of sellers, whereas it was previously categorised by that of customers. Accordingly, the amounts for the fiscal year ended 31 March 2019 have been reclassified. The effect of this change was immaterial.

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

(Millions of yen)

	As of 31 March 2019	As of 31 March 2020
Japan	408,922	462,132
United States	325,023	711,393
Others	95,108	101,092
Total	829,053	1,274,617

Information about major customers

External customer that accounts for 10% or more of consolidated Revenue of the Group is as follows:

(Millions of yen)

	Segment	Fiscal year ended 31 March 2019	Fiscal year ended 31 March 2020
McKesson Corporation	Pharmaceutical	151,260	162,361

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 2019	Fiscal year ended 31 March 2020
Basis of calculating basic earnings per share		
Profit attributable to owners of the parent	222,265	195,411
Profit not attributable to ordinary shareholders of the parent	—	—
Profit used to calculate basic earnings per share	222,265	195,411
Weighted average number of shares during the year (Thousands of shares)	1,931,882	1,876,193
Basis of calculating diluted earnings per share		
Profit used to calculate basic earnings per share	222,265	195,411
Adjustment	—	—
Profit used to calculate diluted earnings per share	222,265	195,411
Weighted average number of shares during the year (Thousands of shares)	1,931,882	1,876,193
Subscription rights to shares (Thousands of shares)	1,861	1,355
Weighted average number of diluted ordinary shares during the year (Thousands of shares)	1,933,743	1,877,548
Earnings per share (attributable to owners of the parent):		
Basic (Yen)	115.05	104.15
Diluted (Yen)	114.94	104.08

Significant subsequent events

Not applicable.