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Financial Results of Astellas for Fiscal Year 2018

Japan, April 25, 2019 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, “the Company”) today announced the financial results for fiscal year 2018 (FY2018) ended March 31, 2019.

Consolidated financial results for FY2018 (April 1, 2018 – March 31, 2019) (core basis)

(Millions of yen)

	FY2017	FY2018	Change (%)
Revenue	1,300,316	1,306,348	+6,032 (+0.5%)
Core operating profit	268,698	278,514	+9,816 (+3.7%)
Core profit for the year	204,326	249,343	+45,017 (+22.0%)

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 FY2018

1) Overview of consolidated financial results for FY2018

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

Consolidated financial results (core basis) in FY2018 are shown in the table below.

Revenue, core operating profit and core profit for the year increased across the board.

Consolidated financial results (core basis)

(Millions of yen)

	FY2017	FY2018	Change (%)
Revenue	1,300,316	1,306,348	+6,032 (+0.5%)
Cost of sales	294,250	292,050	-2,200 (-0.7%)
Selling, general and administrative expenses	478,330	490,263	+11,933 (+2.5%)
R&D expenses	220,781	208,682	-12,099 (-5.5%)
Amortisation of intangible assets	35,838	35,212	-626 (-1.7%)
Share of profit (loss) of investments accounted for using equity method	-2,419	-1,627	+791 (-)
Core operating profit	268,698	278,514	+9,816 (+3.7%)
Core profit for the year	204,326	249,343	+45,017 (+22.0%)
Basic core earnings per share (yen)	100.64	129.07	+28.42 (+28.2%)

(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 on page 47 of the "Supplementary Documents for Results FY2018."

Revenue

Revenue in FY2018 increased by 0.5% compared to those in the previous fiscal year (“year-on-year”) to ¥1,306.3 billion.

- Sales of XTANDI for the treatment of prostate cancer, overactive bladder (“OAB”) treatments Vesicare and Betanis / Myrbetriq / BETMIGA, increased. Sales of Prograf, an immunosuppressant, decreased.

Core operating profit / Core profit for the year

- Gross profit increased by 0.8% year-on-year to ¥1,014.3 billion. The cost-to-revenue ratio fell by 0.3 percentage points year-on-year to 22.4%, mainly owing to changes in product mix.
- Selling, general and administrative expenses increased by 2.5% year-on-year to ¥490.3 billion, mainly due to increased XTANDI co-promotion fees in the United States, despite the continuous effort for effective use of expenses and the optimization of resource allocation.
- Research and development (R&D) expenses decreased by 5.5% year-on-year to ¥208.7 billion, due in part to the termination of research activities of Agensys, Inc., which had been carried out until March 2018, despite increased expenses related to key post-POC pipeline projects and enhanced investment in new opportunities such as new areas and technologies. The R&D cost-to-revenue ratio was down 1.0 percentage points year-on-year to 16.0%.
- Amortisation of intangible assets decreased by 1.7% year-on-year to ¥35.2 billion.

As a result of the above, core operating profit increased by 3.7% year-on-year to ¥278.5 billion and core profit for the year increased by 22.0% year-on-year to ¥249.3 billion.

Impact of exchange rate on financial results

The exchange rates for the yen in FY2018 are shown in the table below. The resulting impacts were a ¥4.6 billion decrease in revenue and a ¥0.3 billion decrease in core operating profit compared with if the exchange rates of FY2017 were applied.

Average rate	FY2017	FY2018	Change
US\$/¥	111	111	¥0 (Weakening of yen)
€/¥	130	128	¥1 (Strengthening of yen)

Change from beginning to end of period	As of March 31, 2018	As of March 31, 2019
US\$/¥	¥6 (Strengthening of yen)	¥5 (Weakening of yen)
€/¥	¥11 (Weakening of yen)	¥6 (Strengthening of yen)

<Consolidated financial results (full basis)>

Consolidated financial results on a full basis in FY2018 are shown in the table below. Revenue, operating profit, profit before tax and profit for the year increased across the board.

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 pertaining to Agensys, Inc. as “Other income.” In addition to that, with the acquisition of Potenza Therapeutics, Inc., the Company revalued its shares which had been held before the acquisition, and recorded a valuation gain. On the other hand, the Company recorded restructuring costs mainly in relation to business restructuring in Japan, litigation costs, and impairment losses in relation to the termination of a development project as “Other expense.”

As a result of the above, in FY2018, “Other income” was ¥14.2 billion (¥11.9 billion in the previous fiscal year) and “Other expense” was ¥48.8 billion (¥67.3 billion in the previous fiscal year).

Consolidated financial results (full basis)

(Millions of yen)

	FY2017	FY2018	Change (%)
Revenue	1,300,316	1,306,348	+6,032 (+0.5%)
Operating profit	213,258	243,912	+30,653 (+14.4%)
Profit before tax	218,113	248,967	+30,854 (+14.1%)
Profit for the year	164,679	222,265	+57,586 (+35.0%)
Basic earnings per share (yen)	81.11	115.05	+33.94 (+41.8%)
Comprehensive income	198,539	222,250	+23,710 (+11.9%)

<Sales of Main Products>

(Billions of yen)

	FY2017	FY2018	Change
XTANDI	294.3	333.1	+13.2%
OAB products in Urology	228.1	242.2	+6.2%
Vesicare	102.3	95.0	-7.2%
Betanis / Myrbetriq / BETMIGA	125.7	147.2	+17.0%
Prograf*	198.5	195.7	-1.4%

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

<XTANDI>

- Sales increased by 13.2% year-on-year to ¥333.1 billion. Sales grew in all regions of Japan, the Americas, EMEA*, and Asia and Oceania.

<OAB products in Urology>

- Sales of Betanis / Myrbetriq / BETMIGA increased by 17.0% year-on-year to ¥147.2 billion. Sales increased in all regions of Japan, the Americas, EMEA, and Asia and Oceania. Sales of Vesicare decreased by 7.2% year-on-year to ¥95.0 billion.

<Prograf>

- Sales decreased by 1.4% year-on-year to ¥195.7 billion. While sales grew in Asia and Oceania regions, sales decreased in other regions.

<Other new products and main products>

- In the Japanese market, sales of Suglat for the treatment of type 2 diabetes and Sujanu Combination Tablets launched in May 2018 increased. In addition, Repatha for the treatment of hypercholesterolemia and Linzess for the treatment of chronic constipation, among others, continued to grow.
- In the Americas, sales of azole antifungal CRESEMBA grew.
- In December 2018, the Company launched FLT3 inhibitor XOSPATA for the treatment of relapsed or refractory Acute Myeloid Leukemia(AML) with FLT3 mutations in Japan and the United States. In March 2019, the Company also launched EVENITY for the treatment of osteoporosis in Japan.

* EMEA: Europe, the Middle East and Africa.

<Revenue by region>

Revenue by region are shown in the table below. Revenue in the Americas, and Asia and Oceania increased, while in Japan and EMEA decreased.

Revenue in Japan were impacted by the NHI drug price revisions implemented in April 2018 and the effect of generic drugs on the sales of long-listed products such as Micardis for the treatment of hypertension.

(Billions of yen)

	FY2017	FY2018	Change
Japan	421.2	396.6	-5.8%
The Americas	433.3	461.5	+6.5%
EMEA	343.8	340.3	-1.0%
Asia and Oceania	102.0	107.9	+5.8%

*Revenue by region calculated according to locations of sellers.

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 FY2018:

<Maximizing Product VALUE and Operational Excellence>

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

- 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 OAB products in Urology, the Company focused on the promotion of Betanis / Myrbetriq / BETMIGA with the aim of mitigating the impact of the loss of exclusivity of Vesicare from 2019 onward. The Company worked to expand market share of Betanis / Myrbetriq / BETMIGA through education on its clinical profile featuring a balance of efficacy and safety. In addition, we obtained approval in the U.S. in May 2018 for the use of Betanis / Myrbetriq / BETMIGA in combination with Vesicare.

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 from FY2020 onward.

- With regard to XTANDI (generic name: enzalutamide) for the treatment of prostate cancer, in June 2018 the Company launched XTANDI Tablets in Japan as an additional dosage form. Also, based on the results from the Phase 3 PROSPER trial, the Company obtained approval for the additional indication for non-metastatic castration-resistant prostate cancer (nmCRPC) in the U.S. in July of the same year, and in October the Company obtained approval for the additional indication for high-risk nmCRPC in Europe. Additionally, in the Phase 3 ARCHES trial in men with metastatic hormone-sensitive prostate cancer, the Company achieved the primary endpoint of significantly improving radiographic progression-free survival.

- With regard to selective FLT3 inhibitor XOSPATA (generic name: gilteritinib fumarate), the Company obtained approval for the indication of relapsed or refractory acute myeloid leukemia (AML) with FLT3 mutation-positive in Japan in September 2018 and in the U.S. in November. It was launched in both countries in December. the Company also filed an application for approval in Europe in February 2019.
- With regard to roxadustat (generic name, development code: ASP1517/FG-4592), an orally administered small molecule inhibitor of hypoxia-inducible factor prolyl hydroxylase activity, the Company filed an application for approval for an indication of anemia associated with chronic kidney disease in patients on dialysis in Japan in September 2018. Also, all six of the Phase 3 studies being carried out with the aim of filing an application in Europe achieved their primary endpoints.
- In addition to these progresses, in the Phase 2b study of selective neurokinin-3 (NK3) receptor antagonist fezolinetant (generic name, development code: ESN364) targeting patients suffering postmenopausal vasomotor symptoms, all four co-primary endpoints were achieved. In the Phase 2 single-arm clinical trial of antibody-drug conjugate enfortumab vedotin (generic name, development code: ASG-22ME) targeting patients with locally advanced or metastatic urothelial cancer, positive results were achieved with the patient group that had received previous treatment with both platinum-containing chemotherapy and a PD-1 or PD-L1 inhibitor. The Company has embarked on Phase 3 trials in relation to zolbetuximab (generic name, development code: IMAB362), an anti-Claudin 18.2 monoclonal antibody, for patients with gastric and gastroesophageal junction adenocarcinoma.

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

- In May 2018, the Company launched SUJANU Combination Tablets for the treatment of type 2 diabetes mellitus, a combination drug of selective DPP-4 inhibitor JANUVIA (generic name, sitagliptin phosphate hydrate), manufactured and sold by MSD K.K., and a selective SGLT2 inhibitor Suglat (generic name: Ipragliflozin L-Proline), manufactured and sold by the Company.
- With regard to Repatha (generic name: evolocumab [Genetically Recombination]) for the treatment of hypercholesterolemia, joint development partner Amgen Astellas BioPharma K.K. filed an application for a supplemental indication for treating hypercholesterolemia patients with statin intolerance in August 2018.
- In August 2018, the Company obtained approval for an additional indication of chronic constipation (other than constipation associated with organic disorders) for Linzess (generic name: linaclotide) for the treatment of irritable bowel syndrome with constipation.

- In July 2018, the Company obtained approval for an indication of infectious enteritis (including pseudomembranous colitis) for the oral macrocyclic antimicrobial agent Dafclir (generic name: fidaxomicin) and it was launched onto the market in September.
- With regard to antineoplastic drug / bispecific antibody product BLINCYTO (generic name: blinatumomab [Genetically Recombination]), joint development partner Amgen Astellas BioPharma K.K. obtained approval for an indication of relapsed or refractory B-cell acute lymphoblastic leukemia in September 2018, and Amgen Astellas BioPharma K.K. and the Company launched it onto the market in November.
- In November 2018, the Company launched Cimzia 200mg AutoClicks for S.C. Injection as an additional dosage form of Cimzia (generic name: certolizumab pegol [Genetically Recombination]) for the treatment of rheumatoid arthritis.
- With regard to Suglat (generic name: lpragliflozin L-Proline) for the treatment of type 2 diabetes mellitus, the Company obtained approval for the additional indication of type 1 diabetes mellitus and for additional dosage and administration in December 2018.
- With regard to Gonax (generic name: degarelix acetate) for the treatment of prostate cancer, the Company obtained approval for partial changes for the additional dosage and administration of Gonax for the treatment of prostate cancer at 12-week intervals and obtained manufacturing and marketing authorization for Gonax 240 mg (additional dosage form) in January 2019.
- With regard to Biso Tape (generic name: bisoprolol) for the treatment of essential hypertension, manufacturing partner Toa Eiyo Ltd. obtained approval for the additional indication of atrial fibrillation and for Biso Tape 2 mg as an additional dosage form in January 2019.
- With regard to humanized anti-sclerostin monoclonal antibody EVENITY (generic name: romosozumab [Genetically Recombination]), joint development partner Amgen Astellas BioPharma K.K. obtained approval for an indication of osteoporosis in patients at high risk of fracture in January 2019, and Amgen Astellas BioPharma K.K., UCB Japan and the Company launched it onto the market in March.
- In May 2018, the Company filed an application for approval of an indication of rheumatoid arthritis (including prevention of structural joint damage) in patients who have an inadequate response to conventional therapies for oral Janus kinase (JAK) inhibitor Smyraf (generic name: peficitinib hydrobromide) and obtained said approval in March 2019.

In FY2018, the Company ceased transferred sale and distribution of products as below.

- In accordance with the expiration of an agreement concluded in 2009 by the Company and AstraZeneca AB (Sweden) concerning the sale and co-promotion of Symbicort Turbuhaler (generic name: budesonide / formoterol fumarate dihydrate) for the treatment of asthma and chronic obstructive pulmonary disease, the exclusive sale and distribution of the product in Japan conducted by the Company will be transferred to AstraZeneca K.K. and the co-promotion conducted by the Company and AstraZeneca K.K. will be terminated on July 30, 2019.
- In accordance with the expiration of an agreement with KM Biologics Co., Ltd. for the distribution of human vaccines, etc. and blood plasma products, distribution of the products and the provision and collection of information from medical institutions will be completed sequentially by July 31, 2019.

In pursuit of 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 FY2018:

- After reviewing its organizational capabilities, the Company restructured the Company and Group companies in Japan with the aim of further improving the quality of operations. The Company also offered an early retirement incentive program in accordance with this.
- In April 2018, the Company has transferred certain facilities and leasehold interests in land of Agensys, Inc. (U.S.), a consolidated subsidiary of the Company, to Kite (U.S.), a Gilead Company.
- In December 2018, Astellas Pharma Tech Co., Ltd. ("Astellas Pharma Tech"), the Company's production subsidiary in Japan, and CMIC CMO Co., Ltd. ("CMIC CMO") entered into a share transfer agreement where Astellas Pharma Tech split off the business of Nishine Plant and transfer all of the shares to CMIC CMO.
- Manufacturing and marketing approval and distribution of Anexate Injection 0.5mg (generic name: flumazenil), a benzodiazepine receptor antagonist manufactured and sold in Japan, were transferred to Aspen Japan K.K. in January 2019, and the Company agreed to transfer manufacturing and marketing approval for hypnotic Dormicum Injection 10mg (generic name: midazolam) to Maruishi Pharmaceutical Co., Ltd. on April 1, 2019.

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

The Company is focused on creating innovative healthcare products for patients with high unmet medical needs by combining biology with modalities and technologies based on emerging science, and it is taking a multifaceted approach to allocating management resources to specific fields.

Furthermore, the Company is carrying out capital expenditure with the aim of advancing and realizing the future commercialization of multiple development programs using new modalities such as antibodies and cell therapy. In Japan, the Company has started construction of facilities for the manufacture of active pharmaceutical ingredients for antibodies, as well as facilities for the manufacture of clinical trial materials for use in early-stage clinical trials with respect to gene therapies and cell therapies. In the United States, the Company is carrying out capital expenditure geared to accelerating research and development in the regenerative medicine and cell therapy fields, and enhancing manufacturing facilities.

In addition to this, the Company has been investing for new innovation while utilizing alliance opportunities with external partners. The following are the main initiatives during the FY2018:

- In August 2018, the Company acquired Quethera Limited (UK) and made it into a wholly owned subsidiary. Through this transaction, the Company acquired Quethera's ophthalmic gene therapy program, which uses a recombinant adeno-associated viral vector system (rAAV) to introduce therapeutic genes into target retinal cells for the treatment of glaucoma.
- In September 2018, the Company entered into an option agreement with Gene Therapy Research Institution Co., Ltd. involving exclusive negotiations worldwide, and accordingly acquired rights regarding the development and commercialization of the gene therapy program GT0001X for the treatment of sporadic amyotrophic lateral sclerosis.
- In November 2018, the Company concluded an exclusive worldwide (excluding China) option and license agreement with Juventas Therapeutics (United States), and accordingly acquired rights regarding the development and commercialization of JVS-100, a gene therapy program for fecal incontinence.
- In December 2018, the Company exercised an exclusive option to acquire immuno-oncology-focused biotechnology company Potenza Therapeutics, Inc. (U.S.) based on an exclusive collaboration agreement entered into in 2015 and made it into a wholly owned subsidiary. Through this transaction, the Company acquired multiple novel immuno-oncology programs that are in the clinical stage.

<Developing Rx+™ programs>

The Company is taking on the challenge of developing Rx+™ programs with the goal of realizing sustainable growth in the med 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 October 2018, as part of such efforts, the Company and BANDAI NAMCO Entertainment Inc. entered into an agreement for joint development of application for smartphone and other devices to support those who need regular exercise as a preventive measure against the onset and worsening of lifestyle diseases.

Enhancing and strengthening the corporate governance system

Following the Annual Shareholders Meeting of the Company held in June 2018, the Company made the transition from a company with an Audit & Supervisory Board to a company with an Audit & Supervisory Committee. Amid ongoing globalization and complication of the business environment, the Company has decided to make transition to a company with an Audit & Supervisory Committee, which enables the delegation of a substantial part of the Board of Directors' authority of the execution of business to executive Directors. In this way, the Company will further enhance deliberation on matters such as business strategy in the Board of Directors and further strengthen the functions of the Board of Directors. Furthermore, the transition will speed-up decision making regarding the execution of business, raising the agility of management.

(2) Financial position

1) Assets, equity and liabilities

An overview of the consolidated statement of financial position as of March 31, 2019 and the main changes from the end of the previous fiscal year are shown below.

Assets

Total assets saw an increase of ¥39.4 billion compared to the end of the previous fiscal year to ¥1,897.6 billion.

<Non-current assets> ¥1,040.5 billion (an increase of ¥27.9 billion)

- Goodwill increased by ¥12.9 billion compared to the end of the previous fiscal year to ¥225.9 billion, and intangible assets increased by ¥12.8 billion compared to the end of the previous fiscal year to ¥429.7 billion. These increases are due to the acquisition of Potenza Therapeutics, Inc. and other factor.

<Current assets> ¥857.2 billion (an increase of ¥11.5 billion)

- Cash and cash equivalents decreased by ¥20.7 billion compared to the end of the previous fiscal year to ¥311.1 billion.

Equity

Total equity as of March 31, 2019 saw a decrease of ¥9.9 billion compared to the end of the previous fiscal year to ¥1,258.4 billion, making the ratio of equity attributable to owners of the parent to gross assets 66.3%.

- While profit for the year stood at ¥222.3 billion, the Company paid ¥72.1 billion of dividends of surplus and executed a ¥160.4 billion acquisition of own shares.
- Cancellation of treasury shares totaling ¥130.4 billion (89 million shares) was carried out on May 31, 2018.

Liabilities

Total liabilities increased by ¥49.3 billion compared to the end of the previous fiscal year to ¥639.3 billion.

<Non-current liabilities> ¥141.6 billion (a decrease of ¥26.7 billion)

<Current liabilities> ¥497.7 billion (an increase of ¥76.0 billion)

2) Cash flow

Cash flows from operating activities

Net cash flows from operating activities in FY2018 decreased year-on-year by ¥54.0 billion to ¥258.6 billion.

- Income tax paid was ¥69.9 billion.

Cash flows from investing activities

Net cash flows used in investing activities in FY2018 was ¥41.8 billion, a decrease in outflow of ¥80.0 billion year-on-year.

- There were cash outflows including payments for acquisition of subsidiaries due to the acquisition of Potenza Therapeutics, Inc., in addition to purchases of property, plant and equipment and intangible assets. On the other hand, proceeds from sale of property, plant and equipment contributed to a cash inflow mainly from the transfer of assets owned by Agensys, Inc.

Cash flows from financing activities

Net cash flows used in financing activities in FY2018 was ¥233.7 billion, an increase in outflow of ¥30.3 billion year-on-year.

- Dividends paid increased by ¥0.4 billion year-on-year to ¥72.1 billion. Other outflow included cash of ¥160.4 billion (an increase of ¥29.7 billion year-on-year) used for the acquisition of treasury shares.

As a result, cash and cash equivalents totaled ¥311.1 billion as of March 31, 2019, a decrease of ¥20.7 billion compared to the end of the previous fiscal year.

Cash flow indicators

	FY2016	FY2017	FY2018
Ratio of owners' equity to gross assets (%)	70.1	68.3	66.3
Ratio of owners' equity to gross assets on a fair market value basis (%)	166.9	171.6	164.8
Cash flows to interest-bearing liabilities ratio (%)	0.0	0.0	0.0
Interest coverage ratio (times)	—	—	—

- Ratio of owners' equity to gross assets: equity attributable to owners of the parent / total assets
- Ratio of owners' equity to gross assets on a fair market value basis: market capitalization / total assets
- Cash flows to interest-bearing liabilities ratio: interest-bearing liabilities / cash flows
- Interest coverage ratio: cash flows / interest payment

(Notes)

1. Each indicator is calculated using financial data on a consolidated basis.
2. Market capitalization is calculated based on the total number of issued shares (after

eliminating treasury share).

3. Cash flows from operating activities are used as cash flows.
4. Of all liabilities included in the consolidated statement of financial position, those on which the Company pays interest are computed as interest-bearing liabilities.

(3) Consolidated business forecasts for FY2019 and other forward-looking statements

The Company's business forecasts for FY2019 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)

	FY2018 Results	FY2019 Forecasts	(Millions of yen) Change (%)
Revenue	1,306,348	1,224,000	-82,348 (-6.3%)
R&D expenses	208,682	211,000	+2,318 (+1.1%)
Core operating profit	278,514	240,000	-38,514 (-13.8%)
Core profit for the year	249,343	194,000	-55,343 (-22.2%)
Basic core earnings per share (yen)	129.07	102.87	-26.20 (-20.3%)

(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 FY2018.

Expected exchange rate for

FY2019 (Forecast)	¥110/US\$	¥125/€
FY2018 (Result)	¥111/US\$	¥128/€

Revenue, core operating profit and core profit for the year are anticipated to decrease compared with FY2018.

In FY2019, the loss of exclusivity for mainstay products and the expiration of the agreement related to licensed products in Japan are anticipated to be factors in the decrease in revenue and profits. The yen is anticipated to slightly strengthen against both the U.S. dollar and the euro compared with FY2018 result, and the fluctuations in the exchange rate is anticipated to cause a ¥12.7 billion decrease in revenue and a ¥4.7 billion decrease in core operating profit compared with if the exchange rates of FY2018 were applied.

Revenue

The revenue forecast is ¥1,224.0 billion (down 6.3% year on year).

XTANDI and Betanis / Myrbetriq / BETMIGA are anticipated to see continued growth, while sales of XOSPATA, which was launched in Japan and the United States in December 2018, are anticipated to contribute to earnings throughout the year. Furthermore, new product groups in Japan are also expected to grow. However, revenue is anticipated to decline, mainly due to the impact of the end of exclusivity for Vesicare in the United States and Europe and the anticancer drug Tarceva in the United States, and the impact of the expiration of an agreement regarding Symbicort in Japan and an agreement with KM Biologics Co., Ltd. regarding human vaccines etc. in Japan.

Core operating profit/ Core profit for the year

Gross profit is anticipated to decrease owing to a decrease in revenue.

Selling, general and administrative expenses are anticipated to remain at around the same level, with continued efforts to promote effective use of expenses and other measures balancing out an increase in co-promotion fees associated with sales expansion of XTANDI in the United States and an anticipated increase in expenses for maximizing the value of new products. The ratio of selling, general and administrative expenses to revenue is anticipated to rise, partly reflecting a decrease in revenue.

We project R&D expenses of ¥211.0 billion (up 1.1% year on year) due to steady progress in key post-POC pipeline projects and investment for the development of new technologies such as regenerative medicine and cell therapies, and an R&D expenses to revenue ratio of 17.2% (compared with 16.0% in FY2018).

As a result, we project a core operating profit of ¥240.0 billion (down 13.8% year on year).

Core profit for the year is forecasted at ¥194.0 billion (down 22.2% year on year) and basic core earnings per share is forecasted at ¥102.87 (down 20.3 % year on year).

<Sales of Main Products>

(Billions of yen)

	FY2018 Results	FY2019 Forecasts	Change
XTANDI	333.1	364.2	+9.3%
XOSPATA	2.5	15.1	-
OAB products in Urology	242.2	202.4	-16.4%
Vesicare	95.0	41.8	-56.0%
Betanis / Myrbetriq / BETMIGA	147.2	160.6	+9.1%
Prograf	195.7	187.7	-4.1%

<XTANDI>

- Sales of XTANDI are forecasted to increase by 9.3% year on year to ¥364.2 billion. Sales are anticipated to grow in all regions of Japan, the United States, Established Markets, Greater China, and International.

<XOSPATA>

- Sales of XOSPATA are anticipated to grow in Japan and the United States to ¥15.1 billion.

<OAB products in Urology>

- Sales of Betanis / Myrbetriq / BETMIGA are forecasted to increase by 9.1% year on year to ¥160.6 billion. Sales are anticipated to increase in all regions. On the other hand, sales of Vesicare are anticipated to decrease by 56.0% year on year to ¥41.8 billion, due to the end of exclusivity in the United States and Europe.

<Prograf>

- Sales of Prograf are forecasted to decrease by 4.1% year on year to ¥187.7 billion, and anticipated to continue to grow in Greater China and International.

<Other new products and main products>

- In Japan, continued sales growth is anticipated for Suglat, Sujanu, Linzess and Repatha, among others. Furthermore, sales of the new product EVENITY are anticipated to grow.
- In the United States, sales of CRESEMBA are anticipated to continue to grow.

Consolidated full-year business forecasts (full basis)

(Millions of yen)

	FY2018 Results	FY2019 Forecasts	Change (%)
Revenue	1,306,348	1,224,000	-82,348 (-6.3%)
Operating profit	243,912	229,000	-14,912 (-6.1%)
Profit before tax	248,967	230,000	-18,967 (-7.6%)
Profit for the year	222,265	182,000	-40,265 (-18.1%)
Basic earnings per share (yen)	115.05	96.51	-18.54 (-16.1%)

(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 FY2018.

Expected exchange rate for

FY2019 (Forecast)	¥110/US\$	¥125/€
FY2018 (Result)	¥111/US\$	¥128/€

(4) Capital allocation policy and dividends for FY2018 and FY2019

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 FY2018 is planned to be ¥38 per share (including a year-end dividend of ¥19 per share) to shareholders.

In addition, the Company implemented acquisition of own shares from the stock market of 90.84 million shares, which amounted to ¥160.0 billion, during FY2018.

The Company anticipates that the annual dividend in FY2019 will be ¥40 per share (composed of interim dividend of ¥20 per share and a year-end dividend of ¥20 per share).

(5) Risk factors

The main risks that could significantly impact the business results and financial position of the Astellas Group are outlined below.

Inherent Uncertainties in Pharmaceutical R&D

In general, the probability of discovering a promising compound through drug discovery research is not high. Further, it takes a large amount of investment and a great deal of time to successfully launch a new product after discovery of a new compound. However, it may be necessary to discontinue clinical development if the effectiveness of a drug is not proven as initially expected, or if safety issues arise. In addition, pharmaceuticals are subject to legal restrictions in each country, thus authorization from local regulatory authorities is a prerequisite for a product launch in each country. It is difficult to accurately foresee if and when approvals for new products can be obtained. The Astellas Group's research and development activities are subject to these inherent risks.

Sales-related Risk

The pharmaceutical industry operates in a highly competitive environment characterized by rapid technological innovation. The launch of competitive products by rivals could impact the Astellas Group's business results significantly.

Intellectual Property (IP) Risk

The Astellas Group's business benefits from the protection of many patents. Although the Astellas Group manages intellectual property rights properly and is vigilant against third-party violation of such rights, the adverse impact on the Astellas Group's business results of actual IP violations may still be substantial. The Astellas Group's business results are also subject to the outcome of litigation undertaken by the Astellas Group to protect patents where infringement has occurred. While the Astellas Group strives to ensure that its actions do not infringe the IP rights of other parties, there is a risk of litigation in the event of any inadvertent violations. Such litigation could also impact the Astellas Group's business results significantly.

Risks Relating to Product Side Effects and Safety

Any problems arising due to serious side effects or other safety issues that are caused by the Astellas Group's products could impact the Astellas Group's business results significantly.

Pharmaceutical Regulatory Risk

The ethical pharmaceutical business is governed by a wide variety of regulations in each country. In Japan, for example, the authorities periodically revise the NHI drug prices. Governments in developed countries in particular continue to adopt measures aimed at containing medical expenditures. Any trend toward stricter regulations governing the development, production and distribution of pharmaceuticals is a factor that could impact business results.

Environment-related Risks

The Astellas Group is careful to observe laws and regulations relating to environmental or health and safety issues, and has instituted internal standards that aim to exceed most statutory requirements. Despite such precautions, the costs involved in the unlikely event of a business-related incident causing a serious breach of compliance in this area could impact the Astellas Group's business results significantly.

Foreign Exchange Rate Fluctuations

The Astellas Group's business results and financial position are subject to the impact of exchange rate fluctuations due to the Astellas Group's extensive international operations.

In addition to the risks outlined above, the Astellas Group is exposed to a wide range of business-related risks, including but not limited to (1) general commercial litigation, (2) delays or suspension of manufacturing activities due to natural disasters or other factors, and (3) partial dependence on licensing or sales agreements relating to pharmaceuticals developed by other companies.

2. Basic rationale for selecting accounting standard

Since the consolidated financial statements for the fiscal year ended March 31, 2014, the Astellas Group adopts the International Financial Reporting Standards (“IFRS”), as a means of enabling capital market participants to more readily compare the financial information on an international basis.

2. Consolidated Financial Statements and Notes to Consolidated Financial Statements

(1) Consolidated Statement of Income

(Millions of yen)

	Fiscal year ended 31 March 2018	Fiscal year ended 31 March 2019
Revenue	1,300,316	1,306,348
Cost of sales	(294,250)	(292,050)
Gross profit	1,006,066	1,014,299
Selling, general and administrative expenses	(478,330)	(490,263)
Research and development expenses	(220,781)	(208,682)
Amortisation of intangible assets	(35,838)	(35,212)
Share of profit (loss) of investments accounted for using equity method	(2,419)	(1,627)
Other income	11,872	14,152
Other expense	(67,311)	(48,755)
Operating profit	213,258	243,912
Finance income	6,637	6,358
Finance expense	(1,782)	(1,302)
Profit before tax	218,113	248,967
Income tax expense	(53,434)	(26,702)
Profit	164,679	222,265
Profit attributable to:		
Owners of the parent	164,679	222,265
Earnings per share		
Basic (Yen)	81.11	115.05
Diluted (Yen)	81.02	114.94

(2) Consolidated Statement of Comprehensive Income

(Millions of yen)

	Fiscal year ended 31 March 2018	Fiscal year ended 31 March 2019
Profit	164,679	222,265
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
Remeasurements of defined benefit plans	1,611	(2,553)
Subtotal	1,611	2,508
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	28,590	(2,523)
Fair value movements on available-for-sale financial assets	3,660	—
Subtotal	32,250	(2,523)
Other comprehensive income	33,860	(15)
Total comprehensive income	198,539	222,250
Total comprehensive income attributable to:		
Owners of the parent	198,539	222,250

(3) Consolidated Statement of Financial Position

(Millions of yen)

	As of 31 March 2018	As of 31 March 2019
Assets		
Non-current assets		
Property, plant and equipment	181,295	173,483
Goodwill	212,976	225,864
Intangible assets	416,912	429,707
Trade and other receivables	25,282	25,248
Investments accounted for using equity method	3,138	3,653
Deferred tax assets	97,237	92,958
Other financial assets	67,375	81,457
Other non-current assets	8,372	8,121
Total non-current assets	1,012,587	1,040,489
Current assets		
Inventories	147,626	151,511
Trade and other receivables	319,512	342,628
Income tax receivable	8,412	20,113
Other financial assets	13,517	2,607
Other current assets	14,448	25,080
Cash and cash equivalents	331,731	311,074
Subtotal	835,245	853,012
Assets held for sale	10,374	4,147
Total current assets	845,619	857,159
Total assets	1,858,205	1,897,648

(Millions of yen)

	As of 31 March 2018	As of 31 March 2019
Equity and liabilities		
Equity		
Share capital	103,001	103,001
Capital surplus	177,219	177,301
Treasury shares	(135,951)	(164,629)
Retained earnings	976,076	991,957
Other components of equity	147,945	150,767
Total equity attributable to owners of the parent	1,268,289	1,258,396
Total equity	1,268,289	1,258,396
Liabilities		
Non-current liabilities		
Trade and other payables	3,515	1,572
Deferred tax liabilities	26,426	5,175
Retirement benefit liabilities	36,673	40,163
Provisions	4,891	5,416
Other financial liabilities	49,422	52,882
Other non-current liabilities	47,370	36,379
Total non-current liabilities	168,296	141,587
Current liabilities		
Trade and other payables	140,909	185,280
Income tax payable	25,184	17,587
Provisions	126,231	22,843
Other financial liabilities	7,559	14,136
Other current liabilities	121,737	255,913
Subtotal	421,620	495,759
Liabilities directly associated with assets held for sale	—	1,906
Total current liabilities	421,620	497,665
Total liabilities	589,916	639,252
Total equity and liabilities	1,858,205	1,897,648

(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 2017	103,001	177,091	(138,207)	1,013,923	1,784	99,590
Comprehensive income						
Profit	—	—	—	164,679	—	—
Other comprehensive income	—	—	—	—	—	28,590
Total comprehensive income	—	—	—	164,679	—	28,590
Transactions with owners						
Acquisition of treasury shares	—	—	(130,712)	—	—	—
Disposals of treasury shares	—	(159)	819	(353)	(307)	—
Cancellation of treasury shares	—	—	132,150	(132,150)	—	—
Dividends	—	—	—	(71,634)	—	—
Share-based payments	—	286	—	—	—	—
Transfers	—	—	—	1,611	—	—
Total transactions with owners	—	127	2,257	(202,526)	(307)	—
As of 31 March 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

(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 2017	14,629	—	—	116,002	1,271,810	1,271,810
Comprehensive income						
Profit	—	—	—	—	164,679	164,679
Other comprehensive income	3,660	—	1,611	33,860	33,860	33,860
Total comprehensive income	3,660	—	1,611	33,860	198,539	198,539
Transactions with owners						
Acquisition of treasury shares	—	—	—	—	(130,712)	(130,712)
Disposals of treasury shares	—	—	—	(307)	1	1
Cancellation of treasury shares	—	—	—	—	—	—
Dividends	—	—	—	—	(71,634)	(71,634)
Share-based payments	—	—	—	—	286	286
Transfers	—	—	(1,611)	(1,611)	—	—
Total transactions with owners	—	—	(1,611)	(1,918)	(202,060)	(202,060)
As of 31 March 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

(5) Consolidated Statement of Cash Flows

(Millions of yen)

	Fiscal year ended 31 March 2018	Fiscal year ended 31 March 2019
Cash flows from operating activities		
Profit before tax	218,113	248,967
Depreciation and amortisation	64,863	63,458
Impairment losses (reversal of impairment losses)	42,398	11,446
Finance income and expense	(4,854)	(5,055)
(Increase) decrease in inventories	37,830	(5,480)
(Increase) decrease in trade and other receivables	(6,634)	(25,640)
Increase (decrease) in trade and other payables	(43,804)	40,828
Other	69,723	20
Subtotal	377,635	328,543
Income tax paid	(65,021)	(69,913)
Net cash flows from operating activities	312,614	258,630
Cash flows from investing activities		
Purchases of property, plant and equipment	(25,077)	(25,190)
Proceeds from sales of property, plant and equipment	1,209	20,949
Purchase of intangible assets	(15,208)	(26,938)
Proceeds from sales of available-for-sale financial assets	6,970	—
Acquisition of subsidiaries, net of cash acquired	(83,723)	(19,292)
Interest and dividends received	1,849	2,798
Other	(7,818)	5,916
Net cash flows used in investing activities	(121,799)	(41,757)
Cash flows from financing activities		
Acquisition of treasury shares	(130,712)	(160,442)
Dividends paid to owners of the parent	(71,634)	(72,066)
Other	(1,083)	(1,173)
Net cash flows used in financing activities	(203,429)	(233,681)
Effect of exchange rate changes on cash and cash equivalents	3,421	(2,118)
Cash and cash equivalents reclassified to assets held for sale	—	(1,732)
Net increase (decrease) in cash and cash equivalents	(9,192)	(20,657)
Cash and cash equivalents at the beginning of the year	340,923	331,731
Cash and cash equivalents at the end of the year	331,731	311,074

(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 standards from the fiscal year ended 31 March 2019.

IFRSs		Summaries of new or amended IFRS standards and interpretations
IFRS 9	Financial Instruments	Amendments related to classification and measurement of financial assets and financial liabilities, impairment, and hedge accounting
IFRS 15	Revenue from Contracts with Customers	Comprehensive framework for revenue recognition

The nature and the effects of the changes in the significant accounting policies relevant to the consolidated financial statements are given below. With the application of IFRS 9 and IFRS 15, the Group adopts the method whereby the cumulative effect of initially applying these standards is recognised at the date of initial application as a transition measure. There is no impact on the beginning balance of retained earnings for the fiscal year ended 31 March 2019.

(IFRS 9 “Financial Instruments”)

1) Initial recognition and measurement

Financial assets and financial liabilities are recognised on the trade date when the Group becomes a party to the contractual provisions of the instruments.

Except for trade receivables which do not contain a significant financing component, financial assets and financial liabilities are measured at fair value at initial recognition. Transaction costs directly attributable to the acquisition or issue of the financial asset or financial liability, other than financial assets measured at fair value through profit or loss (“financial assets at FVTPL”) and financial liabilities measured at fair value through profit or loss (“financial liabilities at FVTPL”), are added to the fair value of the financial assets or deducted from the fair value of financial liabilities at initial recognition. Transaction costs directly attributable to the acquisition of financial assets at FVTPL and financial liabilities at FVTPL are recognised in profit or loss.

2) Financial assets

At initial recognition, all financial assets are classified as “financial assets measured at amortised cost”, “financial assets measured at fair value through other comprehensive income (“financial assets at FVTOCI”)” or “financial assets at FVTPL”.

(a) Financial assets measured at amortised cost

Financial assets are classified as financial assets measured at amortised cost if both of the following conditions are met:

- the financial asset is held within a business model whose objective is to hold financial assets in order to collect contractual cash flows and
- the contractual terms of the financial asset give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

After initial recognition, the financial assets are measured at amortised cost using the effective interest method, less any impairment loss. Interest revenue using the effective interest method is recognised in profit or loss.

(b) Financial assets at FVTOCI (debt instruments)

Financial assets are classified as financial assets at FVTOCI (debt instruments) if both of the following conditions are met:

- the financial asset is held within a business model whose objective is achieved by both collecting contractual cash flows and selling financial assets and
- the contractual terms of the financial asset give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

After initial recognition, the financial assets are measured at fair value, and any gain or loss resulting from changes in fair value is recognised in other comprehensive income, except for impairment gains or losses and foreign exchange gains or losses. When the financial asset is derecognised, the cumulative gain or loss recognised in other components of equity is reclassified from equity to profit or loss as a reclassification adjustment.

(c) Financial assets at FVTOCI (equity instruments)

The Group has made an irrevocable election for equity instruments, with some exceptions, to present subsequent changes in fair value in other comprehensive income, and classifies such instruments as financial assets at FVTOCI.

After initial recognition, the financial assets are measured at fair value, and any gain or loss resulting from changes in fair value is recognised in other comprehensive income. When the financial asset is derecognised or the fair value has significantly decreased, the cumulative gain or loss recognised in other component of equity is transferred to retained earnings. Dividends on such financial assets are recognised in profit or loss unless the dividend clearly represents a recovery of part of the cost of the investment.

(d) Financial assets at FVTPL

Financial assets not classified as financial assets measured at amortised cost or financial assets at FVTOCI are classified as financial assets at FVTPL.

After initial recognition, the financial assets are measured at fair value with subsequent changes recognised in profit or loss.

3) Impairment of financial assets

Loss allowances are recognised for expected credit losses on financial assets measured at amortised cost or debt instruments classified as financial assets at FVTOCI.

At the end of each quarter, the loss allowance is measured for a financial instrument at an amount equal to the lifetime expected credit losses if the credit risk on that financial instrument has increased significantly since initial recognition. The loss allowance is measured for a financial instrument at an amount equal to 12-month expected credit losses if the credit risk on that financial instrument has not increased significantly since initial recognition.

However, for trade receivables and contract assets, the loss allowance is always measured at an amount equal to lifetime expected credit losses.

4) Financial liabilities

At initial recognition, all financial liabilities are classified as “financial liabilities at FVTPL” or “financial liabilities measured at amortised cost”.

(a) Financial liabilities at FVTPL

Derivative financial liabilities, financial liabilities designated as financial liabilities at FVTPL and contingent consideration recognised in a business combination, that meets the definition of financial liabilities, are classified as financial liabilities at FVTPL.

After initial recognition, the financial liabilities are measured at fair value with subsequent changes recognised in profit or loss.

(b) Financial liabilities measured at amortised cost

Financial liabilities not classified as financial liabilities at FVTPL are classified as financial assets at amortised cost.

After initial recognition, the financial liabilities are measured at amortised cost using the effective interest method.

5) Derecognition

Financial assets are derecognised when the contractual rights to the cash flows from the financial asset expire or the contractual rights to receive the cash flows of the financial asset have been transferred and substantially all the risks and rewards of ownership of the financial asset are transferred or the contractual rights to receive the cash flows of the financial asset have been transferred but substantially all the risks and rewards of ownership of the financial asset are neither transferred nor retained and control of the financial asset has not been retained.

Financial liabilities are derecognised when a financial liability is extinguished, i.e., when the obligation specified in the contract is discharged or cancelled or expires.

There is no material impact on the Group's consolidated financial statements due to the application of IFRS 9. With the application of IFRS 9, the financial assets which were previously classified as available-for-sale financial assets are classified as financial assets at FVTOCI from the fiscal year ended 31 March 2019.

(IFRS 15 "Revenue from Contracts with Customers")

Revenue is recognised based on the following five-step:

Step 1: Identify the contract with a customer

Step 2: Identify the performance obligations in the contract

Step 3: Determine the transaction price

Step 4: Allocate the transaction price to the performance obligations in the contract

Step 5: Recognise revenue when (or as) the entity satisfies a performance obligation

1) Sales of pharmaceutical products

Revenue from sales of pharmaceutical products is recognised when control of the promised pharmaceutical product is transferred to the customer by the Group. The Group determines that control of a pharmaceutical product is usually transferred to the customer upon delivery. If the transaction price in a contract includes a variable amount, rebates, discounts and other consideration payable to a customer, the variable consideration is estimated by using either of the expected value method or the most likely amount method and is reduced from consideration received from the customer.

2) Royalty income

Revenue from royalty income is generated from contracts under which third parties have been granted rights to produce or market pharmaceutical products or rights to use technologies. Royalty income includes upfront payments and milestone payments received and running royalties. According to the nature of the related performance obligation, revenue is recognised at a point in time when the performance obligation is satisfied or revenue is recognised over time as the performance obligation is satisfied.

There is no material impact on the Group's consolidated financial statements due to the application of IFRS 15. With the application of IFRS 15, part of trade-related provisions which were previously included in "Provisions" are included in "Other non-current liabilities" and "Other current liabilities" as refund liabilities from the fiscal year ended 31 March 2019.

Business Combinations

For the fiscal year ended 31 March 2018

Acquisition of Ogeda SA

(1) Outline of the business combination

(i) Name and business description of the acquiree

Name of the acquiree: Ogeda SA ("Ogeda")

Business description: Development of small molecule drugs targeting G-protein coupled receptors (GPCR)

(ii) Acquisition date

16 May 2017, Central European Time

(iii) Percentage of voting equity interests acquired

100%

(iv) Acquisition method

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

(v) Primary reasons for the business combination

Ogeda is a formerly privately owned drug discovery company founded in 1994 and focuses on the discovery and development of small molecule drug candidates targeting GPCRs. Ogeda has fezolinetant in the clinical development stage. In addition, Ogeda has several small molecules targeting GPCRs in pre-clinical development in multiple therapeutic areas including inflammatory and autoimmune diseases. Through the acquisition, the Group will expand its late stage pipeline, thereby further solidifying its medium- to long-term growth prospects.

(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	560
Intangible assets	74,415
Cash and cash equivalents	519
Other assets	513
Deferred tax liabilities	(25,256)
Other liabilities	(1,883)
Fair value of assets acquired and liabilities assumed (net)	48,868
Goodwill	26,145
Total	75,014
Cash	62,086
Contingent consideration	12,928
Total fair value of purchase consideration transferred	75,014

Certain items had reflected provisional amounts as of 31 March 2018, however, the Group completed the purchase price allocation during the fiscal year ended 31 March 2019.

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 based on progress in the development of fezolinetant, Ogeda's clinical program. Maximum potential future cash outflows associated with the contingent consideration total 300 million euros (39,156 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	75,014
Fair value of contingent consideration included in purchase consideration transferred	(12,928)
Cash and cash equivalents held by the acquiree	(519)
Acquisition of subsidiaries, net of cash acquired	61,567

(5) Acquisition-related costs

Acquisition-related costs: 60 million yen

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

(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 2018 assuming the acquisition date had been at the beginning of the fiscal year (unaudited): Immaterial

Acquisition of Mitobridge, Inc.

(1) Outline of the business combination

- (i) Name and business description of the acquiree
Name of the acquiree: Mitobridge, Inc. ("Mitobridge")
Business description: Research and development in diseases associated with mitochondrial dysfunctions
- (ii) Acquisition date
23 January 2018, U.S. Time
- (iii) Percentage of voting equity interests
The Company had owned 26.4% of voting equity interests before the acquisition. As a result of the acquisition, the Company 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
Mitobridge is a biotechnology company founded in 2011 and discovering and developing compounds that target mitochondrial function. These drug candidates have the potential to treat genetic, metabolic or neurodegenerative disorders as well as conditions of aging. The transaction accelerates the Group's research and development in diseases associated with mitochondrial dysfunctions and will enable the delivery of innovative new treatment options to patients.

- (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	71
Deferred tax assets	1,594
Cash and cash equivalents	27
Other assets	27
Other liabilities	(339)
Fair value of assets acquired and liabilities assumed (net)	1,380
Goodwill	29,329
Total	30,708
Cash	17,951
Contingent consideration	7,048
Fair value of previously held equity interests in Mitobridge	5,709
Total fair value of purchase consideration transferred	30,708

Certain items had reflected provisional amounts as of 31 March 2018, however, the Group completed the purchase price allocation during the fiscal year ended 31 March 2019.

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 Company's previously held equity interests in Mitobridge at fair value as of the acquisition date, the Company recognised a 5,877 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 165 million U.S. dollars (17,582 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	30,708
Fair value of contingent consideration included in purchase consideration transferred	(7,048)
Fair value of previously held equity interests in Mitobridge included in purchase consideration transferred	(5,709)
Cash and cash equivalents held by the acquiree	(27)
Acquisition of subsidiaries, net of cash acquired	17,924

- (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 2018 assuming the acquisition date had been at the beginning of the fiscal year (unaudited): Immaterial

Acquisition of Universal Cells, Inc.

(1) Outline of the business combination

(i) Name and business description of the acquiree

Name of the acquiree: Universal Cells, Inc. ("Universal Cells")

Business description: Research and development of stem cell therapies that overcome immune rejection

(ii) Acquisition date

9 February 2018, U.S. Time

(iii) Percentage of voting equity interests acquired

100%

(iv) Acquisition method

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

(v) Primary reasons for the business combination

Universal Cells is a biotechnology company founded in 2013, which has a proprietary Universal Donor Cell technology to create cell therapy products that do not require Human Leukocyte Antigen (HLA) matching, potentially overcoming a huge treatment challenge by reducing the risk of rejection. The acquisition combines the Group's capability of establishing differentiated functional cells from pluripotent stem cells with Universal Cells' ability to produce pluripotent stem cells that have lower immunological rejection to further enable investigation of innovative cell therapy treatments for various diseases that currently have few or no treatment options.

(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)	
Intangible assets	6,485
Cash and cash equivalents	915
Other assets	82
Deferred tax liabilities	(1,354)
Other liabilities	(812)
Fair value of assets acquired and liabilities assumed (net)	5,315
Goodwill	2,814
Total	8,130
Cash	5,148
Contingent consideration	2,982
Total fair value of purchase consideration transferred	8,130

Certain items had reflected provisional amounts as of 31 March 2018, however, the Group completed the purchase price allocation during the fiscal year ended 31 March 2019.

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 specified clinical milestones. Maximum potential future cash outflows associated with the contingent consideration total 38 million U.S. dollars (3,984 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	8,130
Fair value of contingent consideration included in purchase consideration transferred	(2,982)
Cash and cash equivalents held by the acquiree	(915)
Acquisition of subsidiaries, net of cash acquired	4,233

(5) Acquisition-related costs

Acquisition-related costs: 64 million yen

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

(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 2018 assuming the acquisition date had been at the beginning of the fiscal year (unaudited): Immaterial

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. 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)

	Provisional fair value	Fair value adjustments	Provisional fair value (as adjusted)
Property, plant and equipment	36	—	36
Intangible assets	31,609	—	31,609
Cash and cash equivalents	802	—	802
Other assets	191	—	191
Deferred tax liabilities	(5,232)	—	(5,232)
Other liabilities	(1,580)	—	(1,580)
Fair value of assets acquired and liabilities assumed (net)	25,827	—	25,827
Goodwill	5,762	(244)	5,518
Total	31,589	(244)	31,345
Cash	18,668	—	18,668
Contingent consideration	7,065	(200)	6,865
Fair value of previously held equity interests in Potenza	5,856	(44)	5,812
Total fair value of purchase consideration transferred	31,589	(244)	31,345

During the fiscal year ended 31 March 2019, further facts came to light and additional analysis was performed on the fair value measurement of the purchase consideration transferred at the acquisition date. As a result, the provisional fair values were adjusted as above. The initial accounting for the business combination is incomplete as of 31 March 2019 as the Group is still in the process of finalizing the fair value measurement.

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 (unaudited): Immaterial

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 2018	Fiscal year ended 31 March 2019
XTANDI	294,302	333,050
Prograf	198,471	195,706
Betanis/Myrbetriq/BETMIGA	125,745	147,178
Vesicare	102,306	94,974
Other	579,492	535,439
Total	1,300,316	1,306,348

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 2018	Fiscal year ended 31 March 2019
Japan	406,414	376,157
Americas	435,108	459,646
U.S.A. (included in Americas)	404,409	428,776
EMEA	351,280	357,013
Asia and Oceania	107,513	113,532
Total	1,300,316	1,306,348

(Note) Revenue by geographical areas are categorised by country or areas based on the geographical location of customers.

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

(Millions of yen)

	As of 31 March 2018	As of 31 March 2019
Japan	424,603	408,922
Americas	240,566	325,312
U.S.A. (included in Americas)	240,313	325,023
EMEA	141,952	91,036
Asia and Oceania	4,061	3,783
Total	811,183	829,053

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 2018	Fiscal year ended 31 March 2019
McKesson Corporation	Pharmaceutical	148,962	151,260

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 2018	Fiscal year ended 31 March 2019
Basis of calculating basic earnings per share		
Profit attributable to owners of the parent	164,679	222,265
Profit not attributable to ordinary shareholders of the parent	—	—
Profit used to calculate basic earnings per share	164,679	222,265
Weighted average number of shares during the year (Thousands of shares)	2,030,203	1,931,882
Basis of calculating diluted earnings per share		
Profit used to calculate basic earnings per share	164,679	222,265
Adjustment	—	—
Profit used to calculate diluted earnings per share	164,679	222,265
Weighted average number of shares during the year (Thousands of shares)	2,030,203	1,931,882
Subscription rights to shares (Thousands of shares)	2,268	1,861
Weighted average number of diluted ordinary shares during the year (Thousands of shares)	2,032,472	1,933,743
Earnings per share (attributable to owners of the parent):		
Basic (Yen)	81.11	115.05
Diluted (Yen)	81.02	114.94

Significant subsequent events

Not applicable.