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Financial Results of Astellas for the First Nine Months of FY2018

Japan, January 31, 2019 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, “the Company”) today announced the financial results for the first nine months (April 1, 2018 – December 31, 2018) of the fiscal year 2018 (FY2018) ending March 31, 2019.

Consolidated financial results for the first nine months of FY2018 (core basis)

(Millions of yen)

	First nine months of FY2017	**First nine months of FY2018**	Change (%)
Sales	999,443	**1,005,028**	+5,585 (+0.6%)
Core operating profit	220,459	**243,984**	+23,526 (+10.7%)
Core profit for the period	167,877	**217,877**	+50,000 (+29.8%)

1. Qualitative information on consolidated financial results for the first nine months of FY2018

(1) Business performance

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

Consolidated financial results (core basis) in the first nine months of FY2018 are shown in the table below. Sales, core operating profit and core profit for the period increased across the board.

Consolidated financial results (core basis)

(Millions of yen)

	First nine months of FY2017	**First nine months of FY2018**	Change (%)
Sales	999,443	**1,005,028**	+5,585 (+0.6%)
Cost of sales	238,925	**227,711**	-11,214 (-4.7%)
Selling, general and administrative expenses	350,015	**355,784**	+5,769 (+1.6%)
R&D expenses	161,623	**149,959**	-11,664 (-7.2%)
Amortisation of intangible assets	26,995	**26,487**	-508 (-1.9%)
Share of profits/losses of associates and joint ventures	-1,427	**-1,103**	+323 (–)
Core operating profit	220,459	**243,984**	+23,526 (+10.7%)
Core profit for the period	167,877	**217,877**	+50,000 (+29.8%)
Basic core earnings per share (yen)	82.22	**112.20**	+29.98 (+36.5%)

(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 26 of the “Supplementary Documents for Results Q3/FY2018.”

Sales

Consolidated sales in the first nine months of FY2018 increased by 0.6% compared to those in the corresponding period of the previous fiscal year (“year-on-year”) to ¥1,005.0 billion.

- Sales of the mainstay products such as XTANDI for the treatment of prostate cancer, overactive bladder (“OAB”) treatments Vesicare and Betanis / Myrbetriq / BETMIGA, increased. Sales of Prograf, an immunosuppressant, remained largely unchanged year-on-year.

Core operating profit / Core profit for the period

- Gross profit increased by 2.2% year-on-year to ¥777.3 billion. The cost-to-sales ratio fell by 1.2 percentage points year-on-year to 22.7%, mainly owing to changes in product mix.
- Selling, general and administrative expenses were ¥355.8 billion (up 1.6% year-on-year), 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 were ¥150.0 billion, down 7.2% year-on-year 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-sales ratio was down 1.3 percentage points year-on-year to 14.9%.
- Amortisation of intangible assets decreased by 1.9% year-on-year to ¥26.5 billion.

As a result of the above, core operating profit increased by 10.7% year-on-year to ¥244.0 billion. Meanwhile, core profit for the period increased by 29.8% year-on-year to ¥217.9 billion due to one-off decline in corporate taxes rate.

<u>Impact of exchange rate on financial results</u>

The exchange rates for the yen in the first nine months of FY2018 are shown in the table below. The resulting impacts were a ¥0.3 billion decrease in sales and a ¥7.1 billion increase in core operating profit compared with if the exchange rates of the first nine months of FY2017 were applied.

Average rate	First nine months of FY2017	**First nine months of FY2018**	Change
US$/¥	112	**111**	¥1 (Strengthening of yen)
€/¥	129	**129**	¥1 (Weakening of yen)

Change from beginning to end of period	As of December 31, 2017	**As of December 31, 2018**
US$/¥	¥1 (Weakening of yen)	**¥5 (Weakening of yen)**
€/¥	¥15 (Weakening of yen)	**¥4 (Strengthening of yen)**

<Consolidated financial results (full basis)>

Consolidated financial results on a full basis in the first nine months of FY2018 are shown in the table below. Sales, operating profit, profit before tax and profit for the period increased across the board.

The full basis financial results include “Other income,” “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 in relation to the transfer of assets held by 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 and transfer of the Nishine Plant business as “Other expense.”
As a result of the above, “Other income” was ¥13.1 billion (¥10.4 billion in the same period of the previous fiscal year) and “Other expense” was ¥47.8 billion (¥51.2 billion in the same period of the previous fiscal year).

Consolidated financial results (full basis)

(Millions of yen)

	First nine months of FY2017	**First nine months of FY2018**	Change (%)
Sales	999,443	**1,005,028**	+5,585 (+0.6%)
Operating profit	179,751	**209,371**	+29,619 (+16.5%)
Profit before tax	184,605	**212,828**	+28,223 (+15.3%)
Profit for the period	142,614	**191,535**	+48,921 (+34.3%)
Basic earnings per share (yen)	69.84	**98.63**	+28.79 (+41.2%)
Comprehensive income	237,115	**196,167**	-40,948 (-17.3%)

<Sales of Main Products>

(Billions of yen)

	First nine months of FY2017	**First nine months of FY2018**	Change
XTANDI	219.9	**253.4**	+15.2%
OAB products in Urology	171.6	**184.3**	+7.4%
Vesicare	78.5	**74.4**	-5.2%
Betanis / Myrbetriq / BETMIGA	93.1	**109.9**	+18.0%
Prograf*	150.2	**150.0**	-0.1%

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

<XTANDI>

- Sales increased by 15.2% year-on-year to ¥253.4 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 18.0% year-on-year to ¥109.9 billion. Sales increased in all regions of Japan, the Americas, EMEA, and Asia and Oceania. Sales of Vesicare decreased by 5.2% year-on-year to ¥74.4 billion.

<Prograf>

- Sales decreased by 0.1% year-on-year to ¥150.0 billion. While sales grew mainly in the Asia and Oceania regions, sales decreased in Japan.

<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, the new products 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.

* EMEA: Europe, the Middle East, and Africa.

<Sales by region>

Sales by region are shown in the table below. Sales in Japan decreased, while in the Americas, EMEA, and Asia and Oceania increased.
As for the Japanese market, sales decreased largely due to effect of NHI drug price revisions implemented in April 2018, and the impact of generic drugs on the sales of long-listed products such as Micardis for the treatment of hypertension.

(Billions of yen)

	First nine months of FY2017	**First nine months of FY2018**	Change
Japan	337.3	**312.7**	-7.3%
The Americas	326.8	**352.0**	+7.7%
EMEA	260.0	**261.8**	+0.7%
Asia and Oceania	75.3	**78.5**	+4.3%

*Sales by region calculated according to locations of sellers.

(2) Financial position

i. Assets, equity and liabilities

An overview of the consolidated statement of financial position as of December 31, 2018 and the main changes from the end of the previous fiscal year are shown below.

Assets

Total assets as of December 31, 2018 saw an increase of ¥70.1 billion compared to the end of the previous fiscal year to ¥1,928.3 billion.

<Non-current assets> As of December 31, 2018: ¥1,038.1 billion (an increase of ¥25.5 billion)

- Goodwill increased by ¥13.6 billion to ¥226.6 billion, and other intangible assets increased by ¥16.0 billion to ¥432.9 billion compared to the end of the previous fiscal year.

<Current assets> As of December 31, 2018: ¥890.3 billion (an increase of ¥44.6 billion)

- Cash and cash equivalents decreased by ¥0.4 billion compared to the end of the previous fiscal year to ¥331.3 billion.

Equity

Total equity as of December 31, 2018 saw an increase of ¥23.9 billion compared to the end of the previous fiscal year to ¥1,292.2 billion, making the ratio of equity attributable to owners of the parent to gross assets 67.0%.

- While profit for the period stood at ¥191.5 billion, the Company paid ¥72.1 billion of dividends of surplus and executed a ¥100.4 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 ¥46.2 billion compared to the end of the previous fiscal year to ¥636.1 billion.

<Non-current liabilities> As of December 31, 2018: ¥139.6 billion (a decrease of ¥28.7 billion)

<Current liabilities> As of December 31, 2018: ¥496.5 billion (an increase of ¥74.9 billion)

ii. Cash flow

Cash flows from operating activities

Net cash flows from operating activities in the first nine months of FY2018 decreased year-on-year by ¥11.7 billion to ¥203.7 billion.

- Income tax paid was ¥55.1 billion.

Cash flows from investing activities

Net cash flows used in investing activities in the first nine months of FY2018 was ¥28.5 billion, a decrease in outflow of ¥65.4 billion year-on-year.

- There were cash outflow to acquire Potenza Therapeutics, Inc., in addition to acquire property, plant and equipment and intangible assets. On the other hand, the 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 the first nine months of FY2018 was ¥173.3 billion, an increase in outflow of ¥30.2 billion year-on-year.

- Dividends paid increased by ¥0.4 billion year-on-year to ¥72.1 billion. Other outflow included cash of ¥100.4 billion (an increase of ¥29.7 billion year-on-year) used for the acquisition of own shares.

As a result, cash and cash equivalents totaled ¥331.3 billion as of December 31, 2018, a decrease of ¥0.4 billion compared to the end of the previous fiscal year.

(3) Consolidated business forecasts for FY2018 and other forward-looking statements

The Company's business forecasts for FY2018 are presented on a core basis and full basis.
The consolidated full-year business forecasts for FY2018 are shown below. The Company has chosen to leave its business forecasts unchanged from the consolidated full-year business forecasts announced in October 2018 because it does not expect large deviations from the forecasts.

Consolidated full-year business forecasts (core basis)

(Millions of yen)

	FY2018 Initial forecasts	**FY2018 Revised forecasts**	Change	FY2017 Results
Sales	1,278,000	**1,300,000**	+22,000	1,300,316
R&D expenses	214,000	**216,000**	+2,000	220,781
Core operating profit	262,000	**270,000**	+8,000	268,698
Core profit for the year	210,000	**221,000**	+11,000	204,326
Basic core earnings per share (yen)	106.98	**114.11**	+7.13	100.64

Consolidated full-year business forecasts (full basis)

(Millions of yen)

	FY2018 Initial forecasts	**FY2018 Revised forecasts**	Change	FY2017 Results
Sales	1,278,000	**1,300,000**	+22,000	1,300,316
Operating profit	265,000	**234,000**	-31,000	213,258
Profit before tax	266,000	**236,000**	-30,000	218,113
Profit for the year	213,000	**195,000**	-18,000	164,679
Basic earnings per share (yen)	108.51	**100.69**	-7.82	81.11

Expected exchange rate for

FY2018 (Forecast) ¥110/US$ ¥130/€

(Expected exchange rate for the last six months of FY2018: ¥110/US$, ¥130/€)

FY2017 (Result) ¥111/US$ ¥130/€

2. Condensed Interim Consolidated Financial Statements and Notes
(1) Condensed Interim Consolidated Statement of Income

(Millions of yen)

	Nine months ended 31 December 2017	Nine months ended 31 December 2018
Sales	999,443	1,005,028
Cost of sales	(238,925)	(227,711)
Gross profit	760,519	777,317
Selling, general and administrative expenses	(350,015)	(355,784)
Research and development expenses	(161,623)	(149,959)
Amortisation of intangible assets	(26,995)	(26,487)
Share of losses of associates and joint ventures	(1,427)	(1,103)
Other income	10,448	13,140
Other expense	(51,155)	(47,754)
Operating profit	179,751	209,371
Finance income	6,052	4,356
Finance expense	(1,198)	(898)
Profit before tax	184,605	212,828
Income tax expense	(41,991)	(21,293)
Profit for the period	142,614	191,535
Profit attributable to:		
Owners of the parent	142,614	191,535
Earnings per share		
Basic (Yen)	69.84	98.63
Diluted (Yen)	69.76	98.53

(2) Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Nine months ended 31 December 2017	Nine months ended 31 December 2018
Profit for the period	142,614	191,535
Other comprehensive income		
Items that will not be reclassified subsequently to profit or loss		
Financial assets measured at fair value through other comprehensive income	–	734
Remeasurements of defined benefit plans	2,780	(1,034)
Subtotal	2,780	(300)
Items that may be reclassified subsequently to profit or loss		
Foreign currency translation adjustments	86,307	4,932
Fair value movements on available-for-sale financial assets	5,414	–
Subtotal	91,721	4,932
Other comprehensive income, net of tax	94,501	4,632
Total comprehensive income	237,115	196,167
Total comprehensive income attributable to:		
Owners of the parent	237,115	196,167

(3) Condensed Interim Consolidated Statement of Financial Position

(Millions of yen)

	As of 31 March 2018	As of 31 December 2018
Assets		
Non-current assets		
Property, plant and equipment	181,295	174,798
Goodwill	212,976	226,588
Other intangible assets	416,912	432,884
Trade and other receivables	25,282	25,409
Investments in associates and joint ventures	3,138	4,426
Deferred tax assets	97,237	94,293
Other financial assets	67,375	72,932
Other non-current assets	8,372	6,738
Total non-current assets	1,012,587	1,038,067
Current assets		
Inventories	147,626	145,167
Trade and other receivables	319,512	347,125
Income tax receivable	8,412	21,554
Other financial assets	13,517	21,877
Other current assets	14,448	18,998
Cash and cash equivalents	331,731	331,296
Subtotal	835,245	886,017
Assets held for sale	10,374	4,241
Total current assets	845,619	890,258
Total assets	1,858,205	1,928,325

(Millions of yen)

	As of 31 March 2018	As of 31 December 2018
Equity and liabilities		
Equity		
Share capital	103,001	103,001
Capital surplus	177,219	177,195
Treasury shares	(135,951)	(104,725)
Retained earnings	976,076	963,065
Other components of equity	147,945	153,673
Total equity attributable to owners of the parent	1,268,289	1,292,209
Total equity	1,268,289	1,292,209
Liabilities		
Non-current liabilities		
Trade and other payables	3,515	1,572
Deferred tax liabilities	26,426	5,255
Retirement benefit liabilities	36,673	38,564
Provisions	4,891	4,108
Other financial liabilities	49,422	52,806
Other non-current liabilities	47,370	37,314
Total non-current liabilities	168,296	139,618
Current liabilities		
Trade and other payables	140,909	191,627
Income tax payable	25,184	28,282
Provisions	126,231	23,386
Other financial liabilities	7,559	24,728
Other current liabilities	121,737	226,569
Subtotal	421,620	494,592
Liabilities directly associated with assets held for sale	—	1,906
Total current liabilities	421,620	496,498
Total liabilities	589,916	636,116
Total equity and liabilities	1,858,205	1,928,325

(4) Condensed Interim Consolidated Statement of Changes in Equity

(Millions of yen)

	Equity attributable to owners of the parent					
					Other components of equity	
	Share capital	Capital surplus	Treasury shares	Retained earnings	Subscription rights to shares	Foreign currency translation adjustments
As of 1 April 2017	103,001	177,091	(138,207)	1,013,923	1,784	99,590
Comprehensive income						
Profit for the period	—	—	—	142,614	—	—
Other comprehensive income	—	—	—	—	—	86,307
Total comprehensive income	—	—	—	142,614	—	86,307
Transactions with owners of the parent						
Acquisition of treasury shares	—	—	(70,712)	—	—	—
Disposals of treasury shares	—	(159)	724	(302)	(263)	—
Cancellation of treasury shares	—	—	132,150	(132,150)	—	—
Dividends	—	—	—	(71,634)	—	—
Share-based payments	—	284	—	—	—	—
Transfers	—	—	—	2,780	—	—
Total transactions with owners of the parent	—	125	62,163	(201,306)	(263)	—
As of 31 December 2017	103,001	177,217	(76,045)	955,231	1,521	185,897

As of 1 April 2018	103,001	177,219	(135,951)	976,076	1,477	128,179
Change in an accounting policy	—	—	—	—	—	—
As of 1 April 2018 (after adjustment)	103,001	177,219	(135,951)	976,076	1,477	128,179
Comprehensive income						
Profit for the period	—	—	—	191,535	—	—
Other comprehensive income	—	—	—	—	—	4,932
Total comprehensive income	—	—	—	191,535	—	4,932
Transactions with owners of the parent						
Acquisition of treasury shares	—	—	(100,440)	—	—	—
Disposals of treasury shares	—	(281)	1,247	(645)	(320)	—
Cancellation of treasury shares	—	—	130,419	(130,419)	—	—
Dividends	—	—	—	(72,066)	—	—
Share-based payments	—	258	—	—	—	—
Transfers	—	—	—	(1,416)	—	—
Total transactions with owners of the parent	—	(23)	31,226	(204,546)	(320)	—
As of 31 December 2018	103,001	177,195	(104,725)	963,065	1,157	133,111

(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 for the period	－	－	－	－	142,614	142,614
Other comprehensive income	5,414	－	2,780	94,501	94,501	94,501
Total comprehensive income	5,414	－	2,780	94,501	237,115	237,115
Transactions with owners of the parent						
Acquisition of treasury shares	－	－	－	－	(70,712)	(70,712)
Disposals of treasury shares	－	－	－	(263)	0	0
Cancellation of treasury shares	－	－	－	－	－	－
Dividends	－	－	－	－	(71,634)	(71,634)
Share-based payments	－	－	－	－	284	284
Transfers	－	－	(2,780)	(2,780)	－	－
Total transactions with owners of the parent	－	－	(2,780)	(3,043)	(142,061)	(142,061)
As of 31 December 2017	20,043	－	－	207,460	1,366,864	1,366,864
As of 1 April 2018	18,289	－	－	147,945	1,268,289	1,268,289
Change in an accounting policy	(18,289)	18,289	－	－	－	－
As of 1 April 2018 (after adjustment)	－	18,289	－	147,945	1,268,289	1,268,289
Comprehensive income						
Profit for the period	－	－	－	－	191,535	191,535
Other comprehensive income	－	734	(1,034)	4,632	4,632	4,632
Total comprehensive income	－	734	(1,034)	4,632	196,167	196,167
Transactions with owners of the parent						
Acquisition of treasury shares	－	－	－	－	(100,440)	(100,440)
Disposals of treasury shares	－	－	－	(320)	1	1
Cancellation of treasury shares	－	－	－	－	－	－
Dividends	－	－	－	－	(72,066)	(72,066)
Share-based payments	－	－	－	－	258	258
Transfers	－	382	1,034	1,416	－	－
Total transactions with owners of the parent	－	382	1,034	1,096	(172,247)	(172,247)
As of 31 December 2018	－	19,405	－	153,673	1,292,209	1,292,209

(5) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	Nine months ended 31 December 2017	Nine months ended 31 December 2018
Cash flows from operating activities		
Profit before tax	184,605	212,828
Depreciation and amortisation	48,354	47,756
Impairment losses and reversal of impairment losses	37,264	11,356
Finance income and expense	(4,852)	(3,457)
(Increase) decrease in inventories	46,440	1,999
(Increase) decrease in trade and other receivables	(20,206)	(26,946)
Increase (decrease) in trade and other payables	(51,755)	44,619
Other	26,738	(29,342)
Cash generated from operations	266,588	258,812
Income tax paid	(51,248)	(55,131)
Net cash flows from operating activities	215,340	203,681
Cash flows from investing activities		
Purchases of property, plant and equipment	(19,426)	(14,542)
Proceeds from sales of property, plant and equipment	420	16,656
Purchase of intangible assets	(9,268)	(19,946)
Proceeds from sales of available-for-sale financial assets	6,959	—
Acquisition of subsidiaries, net of cash acquired	(61,567)	(19,290)
Interest and dividends received	1,294	2,016
Other	(12,245)	6,646
Net cash flows used in investing activities	(93,832)	(28,461)
Cash flows from financing activities		
Acquisition of treasury shares	(70,712)	(100,440)
Dividends paid to owners of the parent	(71,634)	(72,066)
Other	(752)	(833)
Net cash flows used in financing activities	(143,097)	(173,340)
Effect of exchange rate changes on cash and cash equivalents	12,348	(478)
Cash and cash equivalents reclassified to assets held for sale	—	(1,837)
Net increase (decrease) in cash and cash equivalents	(9,240)	(435)
Cash and cash equivalents at the beginning of the year	340,923	331,731
Cash and cash equivalents at the end of the period	331,683	331,296

(6) Notes to condensed interim consolidated financial statements

Notes on going concern assumption

Not applicable.

Significant accounting policies

The significant accounting policies adopted for the condensed interim consolidated financial statements are the same as those applied for the consolidated financial statements for the fiscal year ended 31 March 2018 with exception of the items described below.

Astellas Pharma Inc. and its subsidiaries (collectively, the "Group") calculated income tax expense for the nine months ended 31 December 2018 based on the estimated average annual effective tax rate.

The Group has newly adopted the following standards from the three months ended 30 June 2018:

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 condensed interim 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 nine months ended 31 December 2018.

(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 condensed interim 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 three months ended 30 June 2018.

(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 condensed interim 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 three months ended 30 June 2018.

Business Combinations

For the nine months ended 31 December 2018

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 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
Other intangible assets	31,675
Cash and cash equivalents	803
Other assets	192
Deferred tax liabilities	(5,242)
Other liabilities	(1,583)
Fair value of assets acquired and liabilities assumed (net)	25,881
Goodwill	5,735
Total	31,616
Cash	18,668
Contingent consideration	7,080
Fair value of previously held equity interests in Potenza	5,868
Total fair value of purchase consideration transferred	31,616

Certain items above reflect provisional fair values based on reasonable information obtained at 31 December 2018 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.

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 5,868 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 condensed interim 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 (26,673 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	31,616
Fair value of contingent consideration included in purchase consideration transferred	(7,080)
Fair value of previously held equity interests in Potenza included in purchase consideration transferred	(5,868)
Cash and cash equivalents held by the acquiree	(803)
Acquisition of subsidiaries, net of cash acquired	17,865

(5) Acquisition-related costs

Immaterial

(6) Effect on the condensed interim consolidated statement of income

(i) Profit (loss) before tax of the acquiree since the acquisition date included in the condensed interim consolidated statement of income: Immaterial

(ii) Profit (loss) before tax of the combined entity for the nine months ended 31 December 2018 assuming the acquisition date had been at the beginning of the fiscal year: Immaterial