Supplementary Documents [IFRS]

Financial results for the first six months of the fiscal year 2020 (FY2020)

Astellas Pharma Inc.

- Q2/FY2020 Financial Results

For the year ended September 30, 2020

- > Three months ended September 30, 2020
- Pipeline list

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.

[Six months ended September 30, 2020]

1. Consolidated Results (Full Basis)

			Unit: B¥				Previous Forecasts	Latest Forecasts	
	FY19	FY20	Change	Change		FY19	FY20	FY20	
	APR SEP.	APR SEP.		(%)		Full Year	Full Year	Full Year	
Revenue	650.5	615.5	-35.0	-5.4%		1,300.8	1,256.5	1,256.5	Γ
Cost of sales	138.9	119.5	-19.3	-13.9%		276.7			Γ
Ratio to Revenue	21.3%	19.4%				21.3%			
Gross profit	511.6	495.9	-15.7	-3.1%		1,024.1			
SG&A expenses	226.1	242.1	16.1	7.1%		499.3			
Ratio to Revenue	34.8%	39.3%				38.4%			
Advertising and Sales Promotion	81.6	84.6	3.0	3.7%		172.4			
Personnel expenses	86.4	90.2	3.9	4.5%		179.8			
Other	58.1	67.3	9.2	15.8%		147.0			
R&D expenses	105.0	111.7	6.7	6.4%		224.2	233.5	233.5	
Ratio to Revenue	16.1%	18.1%				17.2%	18.6%	18.6%	
Amortisation of intangible assets	11.2	11.5	0.3	3.1%		21.2			
Share of profit (loss) of investments accounted for using equity method	-1.4	-0.3	1.1	-		-1.7			
Other income	7.2	4.3	-3.0	-41.2%		12.2			
Net foreign exchange gains	1.9	-	-1.9	-		-			
Fair value remeasurements on contingent consideration	-	3.9	3.9	-		0.4			
Other expense	13.0	47.7	34.7	266.6%		45.9			
Impairment losses	0.1	34.6	34.5	-		13.8			
Net foreign exchange losses	-	5.2	5.2	-		8.9			
Fair value remeasurements on contingent consideration	11.9	4.2	-7.6	-64.2%		11.2			
Operating profit	162.2	86.9	-75.3	-46.4%		244.0	246.5	210.5	ſ
Ratio to Revenue	24.9%	14.1%				18.8%	19.6%	16.8%	
Finance income	1.3	3.4	2.1	157.8%		4.4			Γ
Finance expense	1.9	1.2	-0.7	-37.1%		3.0			
Profit before tax	161.6	89.1	-72.5	-44.9%		245.4	245.5	209.5	T
Ratio to Revenue	24.8%	14.5%				18.9%	19.5%	16.7%	
Income tax expense	33.1	16.3	-16.8	-50.8%		49.9			Γ
Profit	128.5	72.8	-55.7	-43.3%		195.4	197.5	169.5	Γ
Ratio to Revenue	19.8%	11.8%				15.0%	15.7%	13.5%	
Comprehensive income	74.6	78.1	3.5	4.7%	I	156.7	·		

Change from FY19

Change (%)

-3.4%

4.1%

-13.7%

-14.6%

-13.3%

2. Consolidated Results (Core Basis)			Unit: B¥	
	FY19	FY20	Change	Change
	APR SEP.	APR SEP.	_	(%)
Revenue	650.5	615.5	-35.0	-5.4%
Cost of sales	138.9	119.5	-19.3	-13.9%
Ratio to Revenue	21.3%	19.4%		
Gross profit	511.6	495.9	-15.7	-3.1%
SG&A expenses	226.1	242.1	16.1	7.1%
Ratio to Revenue	34.8%	39.3%		
Advertising and Sales Promotion	81.6	84.6	3.0	3.7%
Personnel expenses	86.4	90.2	3.9	4.5%
Other	58.1	67.3	9.2	15.8%
R&D expenses	105.0	111.7	6.7	6.4%
Ratio to Revenue	16.1%	18.1%		
Amortisation of intangible assets	11.2	11.5	0.3	3.1%
Share of profit (loss) of investments accounted for using equity method	-1.4	-0.3	1.1	-
Operating profit	168.0	130.3	-37.7	-22.4%
Ratio to Revenue	25.8%	21.2%		
Finance income	1.3	3.4	2.1	157.8%
Finance expense	1.9	1.2	-0.7	-37.1%
Profit before tax	167.3	132.5	-34.8	-20.8%
Ratio to Revenue	25.7%	21.5%		
Income tax expense	31.4	26.3	-5.1	-16.2%
Profit	135.9	106.2	-29.7	-21.9%
Ratio to Revenue				

	Previous Forecasts	Latest Forecasts	Change from FY19
FY19	FY20	FY20	Change
Full Year	Full Year	Full Year	(%)
1,300.8	1,256.5	1,256.5	-3.4%
276.7			
21.3%			
1,024.1			
499.3			
38.4%			
172.4			
179.8			
147.0			
224.2	233.5	233.5	4.1%
17.2%	18.6%	18.6%	
21.2			
-1.7			
277.8	251.0	251.0	-9.6%
21.4%	20.0%	20.0%	
4.4			
3.0			
279.1			
21.5%			
55.9			
223.2	200.5	200.5	-10.2%
17.2%	16.0%	16.0%	

- The Company has left its business forecasts on a core basis unchanged from the consolidated full-year business forecasts announced in August 2020.

3. Exchange Rate				Unit: yen
	FY19	FY20	FY19	FY20
	APR SEP.Ave.	APR SEP.Ave.	End	Q2 End
USD/Yen	109	107	109	106
EUR/Yen	121	121	120	124

	Previous Forecasts	Latest Forecasts
FY19	FY20	FY20
Full Year	Full Year	Full Year
109	109	109
121	120	120

* Fx impacts: Net sales -5.3 billion yen and Core operating profit -6.5 billion yen

* Fx impact on elimination of unrealized gain: COGs ratio +1.0ppt

4. Reconciliation of Full Basis to Core Basis

						Unit: B¥
		FY19			FY20	
		APR SEP.			APR SEP.	
	Full basis	Adjustment	Core basis	Full basis	Adjustment	Core basis
Revenue	650.5	-	650.5	615.5	-	615.5
Cost of sales	138.9	-	138.9	119.5	-	119.5
Gross profit	511.6	-	511.6	495.9	-	495.9
SG&A expenses	226.1	-	226.1	242.1	-	242.1
R&D expenses	105.0	-	105.0	111.7	-	111.7
Amortisation of intangible assets	11.2	-	11.2	11.5	-	11.5
Share of profit (loss) of investments accounted for using equity method	-1.4	-	-1.4	-0.3	-	-0.3
Other income *	7.2	-7.2	-	4.3	-4.3	-
Other expenses *	13.0	-13.0	-	47.7	-47.7	-
Operating profit	162.2	5.8	168.0	86.9	43.4	130.3
Finance income	1.3	-	1.3	3.4	-	3.4
Finance expenses	1.9	-	1.9	1.2	-	1.2
Profit before tax	161.6	5.8	167.3	89.1	43.4	132.5
Income tax expense	33.1	-1.6	31.4	16.3	10.1	26.3
Profit	128.5	7.4	135.9	72.8	33.3	106.2

* "Other income" and "Other expenses" are excluded from Full basis results. "Other income" and "Other expenses" include gain/loss on sale and disposal of property, plant and equipment, impairment losses, restructuring costs, litigation costs and foreign exchange gains/losses, etc.

5. Revenue by F	Region				Unit: B¥	
			FY19	FY20	Change	Change
			APR SEP.	APR SEP.	-	(%)
Revenue			650.5	615.5	-35.0	-5.4%
	Japan		183.3	144.2	-39.1	-21.3%
		Ratio to Revenue	28.2%	23.4%		
	United States		216.7	236.7	20.0	9.2%
		Ratio to Revenue	33.3%	38.5%		
	Established Market		146.7	138.9	-7.9	-5.4%
		Ratio to Revenue	22.6%	22.6%		
	Greater China		29.4	29.6	0.1	0.5%
		Ratio to Revenue	4.5%	4.8%		
	International		63.4	56.7	-6.6	-10.5%
		Ratio to Revenue	9.7%	9.2%		
	Others		10.9	9.3	-1.6	-14.3%
		Ratio to Revenue	1.7%	1.5%		

	Previous Forecasts	Latest Forecasts	Change from FY19
FY19	FY20	FY20	Change
Full Year	Full Year	Full Year	(%)
1,300.8	1,256.5	1,256.5	-3.4%
345.4	281.7	281.7	-18.4%
26.6%	22.4%	22.4%	
443.5	486.4	486.4	9.7%
34.1%	38.7%	38.7%	
296.1	287.5	287.5	-2.9%
22.8%	22.9%	22.9%	
60.4	67.2	67.2	11.4%
4.6%	5.4%	5.4%	
134.8	117.1	117.1	-13.1%
10.4%	9.3%	9.3%	
20.7	16.5	16.5	-20.5%
1.6%	1.3%	1.3%	

- Established Market: Europe, Canada, Australia

- Greater China: China, Hong Kong, Taiwan

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

- The Company has left its revenue forecasts of each region unchanged from the full-year business forecasts announced in August 2020.

6. Per Share Information

	FY19	FY20
	APR SEP.	APR SEP.
The number of shares issued (thousand)	1,888,823	1,861,787
Treasury Shares (thousand)	3,394	4,313
The number of shares issued after deducting Treasury Shares (thousand)	1,885,430	1,857,473
Earnings per share (yen)	68.16	39.21
Earnings per share (yen) core base	72.07	57.15
Dividend per share (yen)	20	21

	Previous Forecasts	Latest Forecasts
FY19	FY20	FY20
Full Year	Full Year	Full Year
1,861,787		
4,276		
1,857,511		
104.15	106.32	91.25
118.95	107.94	107.94
40	42	42

7. Addition to Property, Plant and Equipment

Depreciation/Amortisation

			Unit: B¥	
	FY19	FY20	Change	Change
	APR SEP.	APR SEP.		(%)
Addition to Property, Plant and Equipment				
Consolidated	22.5	14.6	-7.9	-35.2%
Depreciation (PP&E)				
Consolidated	16.3	20.0	3.7	22.6%
Amortisation of Intangible Assets (incl. software, etc.)				
Consolidated	14.9	16.0	1.1	7.5%

Change from FY19 Previous Forecasts Latest Forecasts FY20 FY19 FY20 Change (%) Full Year Full Year Full Year 41.8 29.0 29.0 -30.6% 37.5 41.0 41.0 9.3% 28.9 30.0 30.0 3.9%

- Addition to Property, Plant and Equipment does not include right-of-use asset.

8. Sales of major products

1) Global				Unit: B¥	
		FY19	FY20	Change	Change
		APR SEP.	APR SEP.		(%)
XTANDI		195.0	225.5	30.5	15.6%
	United States	98.7	121.1	22.5	22.8%
	ex-US	96.3	104.4	8.1	8.4%
	Japan	18.7	19.9	1.2	6.5%
	Established Market	66.1	68.8	2.7	4.2%
	Greater China	1.0	2.3	1.2	120.5%
	International	10.5	13.4	2.8	27.1%
XOSPATA		5.7	11.0	5.2	91.9%
	Japan	1.3	1.8	0.6	46.6%
	United States	4.5	7.3	2.8	63.0%
	Established Market	-	1.8	1.8	
PADCEV		-	6.0	6.0	
	United States	-	6.0	6.0	
Betanis/Myrbetrie	q/BETMIGA	78.8	80.0	1.2	1.5%
	Japan	17.9	16.6	-1.2	-6.9%
	United States	42.5	44.0	1.6	3.7%
	Established Market	13.6	14.3	0.7	5.1%
	Greater China	0.7	0.9	0.3	40.8%
	International	4.1	4.0	-0.1	-3.2%
Vesicare		25.1	16.2	-8.9	-35.4%
	Japan	10.6	9.4	-1.2	-11.3%
	United States	2.7	1.6	-1.1	-40.6%
	Established Market	8.7	2.9	-5.8	-66.7%
	Greater China	0.9	0.5	-0.5	-48.6%
	International	2.2	1.8	-0.3	-15.4%
Prograf		96.2	89.6	-6.6	-6.9%
	Japan	22.9	21.1	-1.8	-8.0%
	United States	7.0	6.6	-0.5	-6.7%
	Established Market	34.4	30.4	-4.0	-11.5%
	Greater China	15.5	16.2	0.7	4.6%
	International	16.4	15.3	-1.0	-6.4%
Harnal/Omnic		22.2	20.2	-2.0	-9.0%
Funguard/MYCA	MINE	17.8	13.9	-3.8	-21.5%
Eligard		6.9	6.1	-0.8	-11.0%

FY19 Full YearFY20 Full YearFY20 Full YearChange (%) 400.0 464.6 464.6 16.1 203.5 249.5 2249.5 226.6 196.5 215.1 215.1 9.5 35.8 38.9 38.9 8.6 135.4 142.9 142.9 5.5 3.2 6.9 6.9 115.0 22.1 26.4 26.4 195.5 22.1 26.4 26.4 195.5 14.3 23.1 23.1 61.6 28.8 3.2 3.2 16.3 10.5 13.8 13.8 30.6 1.8 13.0 13.0 619.6 1.8 13.0 13.0 619.6 161.6 167.9 3.5 34.3 34.2 34.2 -0.5 89.2 90.8 90.8 1.7 28.2 30.5 30.5 8.4 1.4 3.1 3.1 125.0 44.7 30.0 30.0 -32.5 20.2 17.1 17.1 -15.4 5.4 2.2 2.2 -59.0 13.1 5.2 5.2 -60.3 1.8 1.2 1.2 -34.7	
Full Year Full Year Full Year (%) 400.0 464.6 464.6 16.1 203.5 249.5 249.5 22.6 196.5 215.1 215.1 9.5 35.8 38.9 38.9 8.6 135.4 142.9 142.9 5.5 3.2 6.9 6.9 115.0 22.1 26.4 26.4 195.5 3.2 6.9 6.9 115.0 22.1 26.4 26.4 195.5 3.2 3.2 16.3 30.8 10.5 13.8 13.8 30.8 0.9 5.5 5.5 486.2 1.8 13.0 13.0 619.6 1.8 13.0 13.0 619.6 1.8 13.0 13.0 619.6 1.8 13.0 13.0 619.6 1.8 13.0 30.5 8.4 9.3 90.8 90.8 1.7 <td></td>	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	
196.5 215.1 215.1 9.5 35.8 38.9 38.9 8.6 135.4 142.9 142.9 5.5 3.2 6.9 6.9 115.0 22.1 26.4 26.4 19.5 14.3 23.1 23.1 61.6 2.8 3.2 3.2 16.3 10.5 13.8 13.8 30.6 0.9 5.5 5.5 486.2 1.8 13.0 13.0 619.6 161.6 167.9 167.9 3.6 34.3 34.2 34.2 -0.5 89.2 90.8 90.8 1.7 28.2 30.5 30.5 8.4 1.4 3.1 3.1 125.0 8.4 9.3 9.3 10.6 44.7 30.0 30.0 -32.9 20.2 17.1 17.1 -15.4 5.4 2.2 2.2 -59.0 13.1 5.2 5.2 -60.3 1.8 1.2 1.2 -34.7	%
35.8 38.9 38.9 8.6 135.4 142.9 142.9 5.5 3.2 6.9 6.9 115.0 22.1 26.4 26.4 19.5 14.3 23.1 23.1 61.6 2.8 3.2 3.2 16.3 10.5 13.8 13.8 30.8 0.9 5.5 5.5 486.2 1.8 13.0 13.0 619.6 161.6 167.9 167.9 3.9 34.3 34.2 34.2 -0.5 89.2 90.8 90.8 1.7 28.2 30.5 30.5 8.4 1.4 3.1 3.1 125.0 84.4 9.3 9.3 10.6 44.7 30.0 30.0 -32.9 20.2 17.1 17.1 -15.4 5.4 2.2 2.2 -59.0 13.1 5.2 5.2 -60.3 1.8 1.2 1.2 -34.7	%
135.4 142.9 142.9 5.5 3.2 6.9 6.9 115.0 22.1 26.4 26.4 19.5 14.3 23.1 23.1 61.5 2.8 3.2 3.2 16.5 10.5 13.8 13.8 30.6 0.9 5.5 5.5 486.2 1.8 13.0 13.0 619.6 161.6 167.9 167.9 3.5 34.3 34.2 34.2 -0.5 89.2 90.8 90.8 1.7 28.2 30.5 30.5 8.4 1.4 3.1 3.1 125.0 8.4 9.3 9.3 10.6 44.7 30.0 30.0 -32.9 5.4 2.2 2.2 -59.0 13.1 5.2 5.2 -60.3 1.8 1.2 1.2 -34.7	%
3.2 6.9 6.9 115.0 22.1 26.4 26.4 19.5 14.3 23.1 23.1 61.9 2.8 3.2 3.2 16.3 10.5 13.8 13.8 30.8 0.9 5.5 5.5 486.2 1.8 13.0 13.0 619.6 1.8 13.0 13.0 619.6 161.6 167.9 167.9 3.9 34.3 34.2 34.2 -0.5 89.2 90.8 90.8 1.7 28.2 30.5 30.5 8.4 1.4 3.1 3.1 125.0 8.4 9.3 9.3 10.6 44.7 30.0 30.0 -32.9 20.2 17.1 17.1 -15.4 5.4 2.2 2.2 -59.0 13.1 5.2 5.2 -60.3 1.8 1.2 1.2 -34.7	%
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	%
$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	%
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	%
$ \begin{array}{c c c c c c c c c c c c c c c c c c c $	%
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	%
34.3 34.2 34.2 -0.5 89.2 90.8 90.8 1.7 28.2 30.5 30.5 8.4 1.4 3.1 3.1 125.0 8.4 9.3 9.3 10.6 44.7 30.0 30.0 -32.5 20.2 17.1 17.1 -15.4 5.4 2.2 2.2 -59.0 13.1 5.2 5.2 -60.3 1.8 1.2 1.2 -34.7	%
89.2 90.8 90.8 1.7 28.2 30.5 30.5 8.4 1.4 3.1 3.1 125.0 8.4 9.3 9.3 10.6 44.7 30.0 30.0 -32.9 20.2 17.1 17.1 -15.4 5.4 2.2 2.2 -59.0 13.1 5.2 5.2 -60.3 1.8 1.2 1.2 -34.7	%
89.2 90.8 90.8 1.7 28.2 30.5 30.5 8.4 1.4 3.1 3.1 125.0 8.4 9.3 9.3 10.6 44.7 30.0 30.0 -32.9 20.2 17.1 17.1 -15.4 5.4 2.2 2.2 -59.0 13.1 5.2 5.2 -60.3 1.8 1.2 1.2 -34.7	%
$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	
8.4 9.3 9.3 10.6 44.7 30.0 30.0 -32.5 20.2 17.1 17.1 -15.4 5.4 2.2 2.2 -59.0 13.1 5.2 5.2 -60.3 1.8 1.2 1.2 -34.7	%
44.7 30.0 30.0 -32.9 20.2 17.1 17.1 -15.4 5.4 2.2 2.2 -59.0 13.1 5.2 5.2 -60.3 1.8 1.2 1.2 -34.7	%
20.2 17.1 17.1 -15.4 5.4 2.2 2.2 -59.0 13.1 5.2 5.2 -60.3 1.8 1.2 1.2 -34.7	%
5.4 2.2 2.2 -59.0 13.1 5.2 5.2 -60.3 1.8 1.2 1.2 -34.7	%
13.1 5.2 5.2 -60.3 1.8 1.2 1.2 -34.7	%
1.8 1.2 1.2 -34.7	%
	%
	%
4.2 4.3 4.3 3.1	%
192.9 182.0 182.0 -5.7	%
44.3 40.5 40.5 -8.7	%
13.2 12.1 12.1 -8.2	
71.5 62.6 62.6 -12.4	%
32.2 35.1 35.1 9.2	%
31.7 31.6 31.6 -0.4	%
42.7 39.1 39.1 -8.3	
35.2 23.1 23.1 -34.4	%
14.2 12.3 12.3 -13.3	

Change from

- Sales of products in Japan are shown in a gross sales basis

- EM(Established Market): Europe, Canada, Australia

- Greater China: China, Hong Kong, Taiwan

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

- The Company has left its sales forecasts of each product unchanged from the full-year business forecasts announced in August 2020.

(1) Japan	Unit: B¥					
	FY19	FY20	Change	Change	Γ	FY
<global></global>	APR SEP.	APR SEP.	-	(%)		Full `
XTANDI	18.7	19.9	1.2	6.5%		
XOSPATA	1.3	1.8	0.6	46.6%		
Betanis	17.9	16.6	-1.2	-6.9%		
Vesicare	10.6	9.4	-1.2	-11.3%		
Prograf (Including Graceptor)	22.9	21.1	-1.8	-8.0%		
Harnal	2.2	1.6	-0.7	-29.3%		
Funguard	3.9	2.9	-1.0	-26.8%		
<main products=""></main>					·	
Suglat [Family]	11.7	13.8	2.1	18.2%		
Sujanu	4.2	5.5	1.4	32.5%		
Repatha	1.5	2.4	0.9	62.6%		
Linzess	2.7	3.1	0.4	13.5%		
BLINCYTO	2.2	2.2	-0.0	-0.5%		
EVENITY	9.5	12.7	3.2	33.9%		
Celecox	26.2	14.2	-12.0	-45.7%		
Symbicort	14.1	-	-14.1	-100.0%		
Geninax	4.1	1.1	-2.9	-72.6%		
Vaccines	5.1	2.8	-2.4	-45.8%		
Gonax	2.6	2.9	0.3	9.9%		
Cimzia	4.7	5.0	0.3	5.6%		
Micardis [Family]	9.6	-	-9.6	-100.0%		
Bonoteo	3.3	2.0	-1.3	-38.9%		
Lipitor	6.9	5.5	-1.4	-19.8%		
Myslee	4.8	4.0	-0.8	-16.3%		
Total Rx Sales In Japanese market	182.3	143.1	-39.3	-21.5%		

2)	Revenue	by	Region
----	---------	----	--------

Unit: B¥	Previous Forecasts	Latest Forecasts	Change from FY19
FY19	FY20	FY20	Change
⁻ ull Year	Full Year	Full Year	(%)
35.8	38.9	38.9	8.8%
2.8	3.2	3.2	16.3%
34.3	34.2	34.2	-0.5%
20.2	17.1	17.1	-15.4%
44.3	40.5	40.5	-8.7%
4.1	2.6	2.6	-36.2%
7.6	3.6	3.6	-53.0%
23.9	30.3	30.3	26.7%
8.9			
3.1			
5.6	6.6	6.6	19.4%
4.5			
23.6			
49.2	20.9	20.9	-57.4%
14.1	-	-	-
7.7	5.0	5.0	-35.6%
11.2	7.4	7.4	-34.0%
5.1	5.5	5.5	8.0%
9.3	9.4	9.4	1.6%
17.7	-	-	-
6.0	3.2	3.2	-46.3%
12.7	10.2	10.2	-19.3%
9.0	7.2	7.2	-20.3%
342.1	275.6	275.6	-19.5%
J 4 2.1	275.0	275.0	-19.370

Sales of products in Japan are shown in a gross sales basis.
 The Company has left its sales forecasts of each product unchanged from the full-year business forecasts announced in August 2020.

(2) United	States			Unit: M\$	
		FY19	FY20	Change	Change
		APR SEP.	APR SEP.	-	(%)
Revenue		1,995	2,214	219	11.0%
	XTANDI	908	1,133	225	24.7%
	XOSPATA	41	68	27	65.6%
	PADCEV	-	56	56	-
	Myrbetriq	391	412	21	5.3%
	VESIcare	25	15	-10	-39.7%
	Prograf	65	61	-3	-5.2%
	MYCAMINE	55	46	-9	-16.1%
	AmBisome	56	52	-4	-7.4%
	CRESEMBA	72	76	4	5.9%
	Scan	364	291	-73	-20.0%
	Tarceva	19	5	-14	-75.4%

	Previous Forecasts	Latest Forecasts	Change from FY19
FY19	FY20	FY20	Change
Full Year	Full Year	Full Year	(%)
4,078	4,446	4,446	9.0%
1,871	2,280	2,280	21.8%
97	126	126	30.0%
17	119	119	615.2%
821	830	830	1.1%
50	20	20	-59.3%
122	111	111	-8.7%
106	62	62	-41.8%
116	106	106	-8.7%
155	155	155	0.0%
694	626	626	-9.8%
30			

- The Company has left its sales forecasts of each product unchanged from the full-year business forecasts announced in August 2020.

(3) Established Market			Unit: M€	
	FY19	FY20	Change	Change
	APR SEP.	APR SEP.	-	(%)
Revenue	1,209	1,145	-64	-5.3%
XTANDI	544	567	23	4.3%
XOSPATA	-	15	15	-
BETMIGA	112	118	6	5.2%
Vesicare	71	24	-48	-66.6%
Prograf	283	251	-32	-11.4%
Omnic	34	32	-3	-7.6%
MYCAMINE	30	25	-5	-17.6%
Eligard	47	43	-5	-10.0%

	Previous Forecasts	Latest Forecasts	
FY19	FY20	FY20	Change
Full Year	Full Year	Full Year	(%)
2,451	2,403	2,403	-1.9%
1,121	1,195	1,195	6.6%
8	46	46	492.1%
233	255	255	9.4%
108	43	43	-59.9%
592	524	524	-11.5%
71	63	63	-11.1%
56	40	40	-27.9%
98	81	81	-17.1%

Previous Ecrecaste | atest Ecrecaste

Established Market: Europe, Canada, Australia
The Company has left its sales forecasts of each product unchanged from the full-year business forecasts announced in August 2020.

(4) Greater China	Unit: B¥				
	FY19	FY20	Change	Change	
	APR SEP.	APR SEP.	-	(%)	
Revenue	29.4	29.6	0.1	0.5%	
XTANDI	1.0	2.3	1.2	120.5%	
BETMIGA	0.7	0.9	0.3	40.8%	
Vesicare	0.9	0.5	-0.5	-48.6%	
Prograf	15.5	16.2	0.7	4.6%	
Harnal	6.8	6.7	-0.1	-1.8%	
MYCAMINE	1.7	1.2	-0.5	-27.8%	
Eligard	0.2	0.2	0.0	22.0%	
Feburic	1.2	1.2	-0.0	-2.9%	

	Previous Forecasts	Latest Forecasts	Change from FY19
FY19	FY20	FY20	Change
Full Year	Full Year	Full Year	(%)
60.4	67.2	67.2	11.4%
3.2	6.9	6.9	115.0%
1.4	3.1	3.1	125.0%
1.8	1.2	1.2	-34.7%
32.2	35.1	35.1	9.2%
13.1	11.4	11.4	-13.1%
3.8	3.7	3.7	-2.4%
0.3	0.4	0.4	19.3%
2.5	3.9	3.9	56.0%

- Greater China: China, Hong Kong, Taiwan - The Company has left its sales forecasts of each product unchanged from the full-year business forecasts announced in August 2020.

(5) Internatio	nal			Unit: B¥	
		FY19	FY20	Change	Change
		APR SEP.	APR SEP.	-	(%)
Revenue		63.4	56.7	-6.6	-10.5%
	XTANDI	10.5	13.4	2.8	27.1%
	BETMIGA	4.1	4.0	-0.1	-3.2%
	Vesicare	2.2	1.8	-0.3	-15.4%
	Prograf	16.4	15.3	-1.0	-6.4%
	Harnal	9.0	8.1	-0.9	-9.9%
	MYCAMINE	2.6	2.0	-0.6	-23.8%

	Previous Forecasts	Latest Forecasts	Change from FY19
FY19	FY20	FY20	Change
Full Year	Full Year	Full Year	(%)
134.8	117.1	117.1	-13.1%
22.1	26.4	26.4	19.5%
8.4	9.3	9.3	10.6%
4.2	4.3	4.3	3.1%
31.7	31.6	31.6	-0.4%
16.9	17.6	17.6	4.1%
5.5	4.2	4.2	-23.2%

International: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea, Export sales, etc.
The Company has left its sales forecasts of each product unchanged from the full-year business forecasts announced in August 2020.

9. Consolidated statements of financial position

			Unit: B
	FY19	FY20	Change
	End	Q2 End	Change
sets	2,315.2	2,237.0	-78.2
Non-current assets	1,447.7	1,417.1	-30.
Property, plant and equipment	268.6	265.7	-2.
Goodwill	278.3	273.4	-4.
Intangible assets	724.8	687.3	-37.
Trade and other receivables	34.0	34.0	0.
Investments accounted for using equity method	4.7	5.3	0.
Deferred tax assets	52.9	55.2	2.
Other financial assets	74.3	86.0	11.
Other non-current assets	10.2	10.2	0.
Current assets	867.5	819.9	-47.
Inventories	151.0	155.7	4.
Trade and other receivables	347.0	332.7	-14.
Income tax receivable	23.6	14.3	-9.
Other financial assets	9.5	7.7	-1.
Other current assets	18.0	22.7	4.
Cash and cash equivalents	318.4	286.7	-31.

			Unit: E
	FY19	FY20	Change
	End	Q2 End	Change
uity and Liabilities	2,315.2	2,237.0	-78.
Equity	1,289.2	1,329.6	40.
Equity attributable to owners of the parent	1,289.2	1,329.6	40
Share capital	103.0	103.0	
Capital surplus	177.5	177.5	-0
Treasury shares	-7.2	-7.3	-0
Retained earnings	905.9	941.8	36
Other components of equity	110.0	114.6	4
Liabilities	1,026.0	907.4	-118
Non-current liabilities	227.3	290.5	63
Trade and other payables	3.1	2.7	-0
Deferred tax liabilities	24.7	13.9	-10
Retirement benefit liabilities	38.1	40.4	2
Provisions	6.1	4.2	-2
Other financial liabilities	129.3	203.5	74
Other non-current liabilities	26.0	25.7	-0
Current liabilities	798.7	616.9	-181
Trade and other payables	172.0	113.5	-58
Income tax payable	4.0	19.7	15
Provisions	14.2	14.6	0
Other financial liabilities	345.7	205.7	-140
Other current liabilities	262.8	263.4	0

In the first three months of FY2020, the consolidated statement of financial position as of March 31, 2020 was retroactively revised due to adjustments of fair value of assets acquired and liabilities assumed for Audentes Therapeutics, Inc., which was acquired in January 2020. For the details, refer to Note "Business Combinations" in Financial Results.

10. Employees		Number of employee
	FY19	FY20
	2Q End	2Q End
Total	15,432	15,791

FY19
4Q End
15,883

11. Shareholders

	FY19	FY20
	2Q End	2Q End
Banks	34.3%	36.6%
Securities	4.2%	3.6%
Other companies	3.2%	3.2%
Foreign companies	49.2%	47.7%
Individuals and others	9.1%	8.8%
Treasury Stock*	0.1%	0.1%

* Treasury Stock does not include shares owned by the executive compensation BIP (Board Incentive Plan) trust and ESOP (Employee Stock Ownership Plan) trust.

[Three months ended September 30, 2020]

1. Consolidated Results (Full Basis)			Unit: B¥	
		FY	20	
	APRJUN.	Change	JULSEP.	Change
	(Quarterly)	(%)	(Quarterly)	(%)
Revenue	307.0	-8.1%	308.5	-2.5%
Cost of sales	59.7	-15.4%	59.9	-12.4%
Ratio to Revenue	19.4%		19.4%	
Gross profit	247.3	-6.2%	248.6	0.3%
SG&A expenses	120.8	2.8%	121.4	11.8%
Ratio to Revenue	39.3%		39.3%	
Advertising and Sales Promotion	42.0	1.8%	42.6	5.6%
Personnel expenses	45.7	4.8%	44.6	4.2%
Other	33.1	1.5%	34.2	34.2%
R&D expenses	57.3	7.1%	54.4	5.7%
Ratio to Revenue	18.7%		17.6%	
Amortisation of intangible assets	5.9	-18.4%	5.7	41.6%
Share of profit (loss) of investments accounted for using equity method	-0.0	-	-0.2	
Other income	2.2	-50.4%	3.2	19.0%
Net foreign exchange gains	1.1	131.6%	-	
Fair value remeasurements on contingent consideration	0.9	-	3.1	
Other expense	4.8	-60.6%	44.1	
Impairment losses	3.3	-	31.3	
Net foreign exchange losses	-	-	6.4	
Fair value remeasurements on contingent consideration	0.2	-98.5%	4.2	783.4%
Operating profit	60.8	-21.1%	26.1	-69.4%
Ratio to Revenue	19.8%		8.4%	
Finance income	0.4	-50.5%	3.1	437.8%
Finance expense	1.0	-27.8%	0.3	-56.7%
Profit before tax	60.2	-21.3%	28.9	-66.1%
Ratio to Revenue	19.6%		9.4%	
Income tax expense	9.8	-45.4%	6.4	-57.3%
Profit	50.4	-13.9%	22.4	-68.0%
Ratio to Revenue	16.4%		7.3%	
Comprehensive income	55.4	104.9%	22.7	-52.3%

2. Consolidated Results (Core Basis)

		Unit: B¥			
		FY20			
	APRJUN.	Change	JULSEP.	Change	
	(Quarterly)	(%)	(Quarterly)	(%)	
Revenue	307.0	-8.1%	308.5	-2.5%	
Cost of sales	59.7	-15.4%	59.9	-12.4%	
Ratio to Revenue	e 19.4%		19.4%		
Gross profit	247.3	-6.2%	248.6	0.3%	
SG&A expenses	120.8	2.8%	121.4	11.8%	
Ratio to Revenue	e 39.3%		39.3%		
Advertising and Sales Promotion	42.0	1.8%	42.6	5.6%	
Personnel expenses	45.7	4.8%	44.6	4.2%	
Other	33.1	1.5%	34.2	34.2%	
R&D expenses	57.3	7.1%	54.4	5.7%	
Ratio to Revenue	e 18.7%		17.6%		
Amortisation of intangible assets	5.9	-18.4%	5.7	41.6%	
Share of profit (loss) of investments accounted for using equity method	-0.0	-	-0.2	-	
Operating profit	63.4	-25.2%	66.9	-19.6%	
Ratio to Revenue	e 20.6%		21.7%		
Finance income	0.4	-50.5%	3.1	437.8%	
Finance expense	1.0	-27.8%	0.3	-56.7%	
Profit before Tax	62.8	-25.4%	69.7	-16.2%	
Ratio to Revenue	e 20.5%		22.6%		
Income tax expense	10.8	-36.7%	15.5	8.2%	
Profit	52.0	-22.5%	54.2	-21.3%	
Ratio to Revenue	e 16.9%		17.6%		

3. Revenue by Re	egion				Unit: B¥	
			FY20			
			APRJUN.	Change	JULSEP.	Change
			(Quarterly)	(%)	(Quarterly)	(%)
Revenue			307.0	-8.1%	308.5	-2.5%
	Japan		77.8	-21.0%	66.5	-21.7%
		Ratio to Revenue	25.3%		21.5%	
	United States		117.2	11.3%	119.6	7.39
		Ratio to Revenue	38.2%		38.8%	
	Established Market		64.0	-15.5%	74.8	5.49
		Ratio to Revenue	20.9%		24.3%	
	Greater China		14.2	-3.4%	15.3	4.4%
		Ratio to Revenue	4.6%		5.0%	
	International		30.2	-11.8%	26.5	-8.9%
		Ratio to Revenue	9.8%		8.6%	
	Others		3.6	-36.4%	5.8	9.3%
		Ratio to Revenue	1.2%		1.9%	

- Established Market: Europe, Canada, Australia

- Greater China: China, Hong Kong, Taiwan - International: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea, Export sales, etc

4. Addition to Property,Plant and Equipment

Depreciation/Amortisation

	Unit: B¥			
	FY20			
	APRJUN. Change JULSEP. Cha			Change
	(Quarterly)	(%)	(Quarterly)	(%)
Addition to Property, Plant and Equipment				
Consolidated	7.1	-43.8%	7.5	-24.2%
Depreciation (PP&E)				
Consolidated	10.0	24.5%	10.0	20.8%
Amortisation of Intangible Assets (incl. software, etc.)				
Consolidated	8.0	-10.9%	8.0	35.7%

- Addition to Property, Plant and Equipment does not include right-of-use asset

5. Sales of major products

1) Global				Unit: B¥	
			FY	-	
		APRJUN.	Change	JULSEP.	Change
		(Quarterly)	(%)	(Quarterly)	(%)
XTANDI		112.0	16.6%	113.5	14.7%
	United States	62.7	33.7%	58.4	12.8%
	ex-US	49.3	0.3%	55.1	16.7%
	Japan	10.1	9.1%	9.8	4.0%
	Established Market	31.5	-6.4%	37.4	15.1%
	Greater China	0.7	31.4%	1.6	219.0%
	International	6.9	22.7%	6.4	32.3%
XOSPATA		5.6	128.3%	5.3	64.4%
	Japan	1.0	70.3%	0.8	25.6%
	United States	3.6	92.3%	3.7	41.8%
	Established Market	1.0	-	0.8	
PADCEV		3.0	-	3.1	
	United States	3.0	-	3.1	
Betanis/Myrbetriq/BETMIGA		40.4	1.2%	39.5	1.8%
	Japan	8.4	-10.5%	8.2	-2.8%
	United States	22.9	7.7%	21.1	-0.3%
	Established Market	6.6	-2.3%	7.7	12.4%
	Greater China	0.4	12.3%	0.5	79.8%
	International	2.0	-2.5%	2.0	-3.9%
Vesicare		7.7	-43.0%	8.4	-26.5%
	Japan	4.9	-13.8%	4.4	-8.4%
	United States	0.4	85.7%	1.2	-51.4%
	Established Market	1.3	-79.2%	1.6	-37.4%
	Greater China	0.2	-52.9%	0.3	-44.19
	International	0.9	-14.3%	0.9	-16.5%
Prograf		45.3	-10.2%	44.3	-3.2%
Ŭ	Japan	11.1	-9.1%	10.0	-6.7%
	United States	3.6	10.1%	3.0	-21.0%
	Established Market	13.8	-21.9%	16.6	-0.5%
	Greater China	7.8	1.3%	8.4	7.99
	International	9.0	-6.0%	6.3	-7.09
Harnal/Omnic		10.6	-3.1%	9.6	-14.79
Funguard/MYCA	MINE	7.1	-21.6%	6.9	-21.49
Eligard		3.1	-16.0%	3.1	-5.49

- Sales of products in Japan are shown in a gross sales basis

- Established Market: Europe, Canada, Australia

- Greater China: China, Hong Kong, Taiwan

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

2) Revenue by Region

(1) Japan		Unit: B¥			
		FY20			
	APRJUN.	Change	JULSEP.	Change	
<global></global>	(Quarterly)	(%)	(Quarterly)	(%)	
XTANDI	10.1	9.1%	9.8	4.0%	
XOSPATA	1.0	70.3%	0.8	25.6%	
Betanis	8.4	-10.5%	8.2	-2.8%	
Vesicare	4.9	-13.8%	4.4	-8.4%	
Prograf (Including Graceptor)	11.1	-9.1%	10.0	-6.7%	
Harnal	0.8	-30.5%	0.7	-28.0%	
Funguard	1.5	-24.5%	1.4	-29.1%	
<main products=""></main>					
Suglat [Family]	7.1	18.3%	6.7	18.0%	
Sujanu	2.8	34.9%	2.7	30.0%	
Repatha	1.2	52.5%	1.3	73.1%	
Linzess	1.6	12.3%	1.5	14.6%	
BLINCYTO	1.2	12.0%	1.0	-12.0%	
EVENITY	6.9	96.1%	5.8	-3.0%	
Celecox	11.6	-11.9%	2.7	-79.5%	
Geninax	0.6	-72.6%	0.5	-72.7%	
Vaccines	0.0	-99.9%	2.8	49.0%	
Gonax	1.6	23.2%	1.2	-3.6%	
Cimzia	2.5	4.4%	2.4	6.9%	
Bonoteo	1.1	-40.4%	1.0	-37.2%	
Lipitor	2.9	-21.2%	2.6	-18.1%	
Myslee	2.1	-17.3%	2.0	-15.2%	
Total Rx Sales In Japanese market	76.9	-21.5%	66.2	-21.6%	

- Sales of products in Japan are shown in a gross sales basis.

(2) United	(2) United States				Unit: M\$	
		FY20				
			APRJUN.	Change	JULSEP.	Change
			(Quarterly)	(%)	(Quarterly)	(%)
Revenue	Revenue		1,089	13.6%	1,126	8.6%
	XTANDI		583	36.5%	550	14.2%
	XOSPATA		33	96.4%	35	43.8%
	PADCEV		27	-	29	-
	Myrbetriq		213	10.0%	199	0.8%
	Vesicare		4	89.6%	11	-50.5%
	Prograf		33	12.4%	28	-19.9%
	MYCAMINE		24	-10.5%	22	-21.5%
	Ambisome		22	-16.3%	29	0.8%
	CRESEMBA		36	-2.3%	40	14.7%
	Scan		111	-40.1%	180	0.6%
	Tarceva		3	-82.4%	2	-52.9%

(3) Established Market	Unit: M€					
		FY	20			
	APRJUN.	Change	JULSEP.	Change		
	(Quarterly)	(%)	(Quarterly)	(%)		
Revenue	540	-11.9%	604	1.6%		
XTANDI	266	-2.4%	302	10.9%		
XOSPATA	9	-	7	-		
BETMIGA	56	1.8%	62	8.5%		
Vesicare	11	-78.4%	13	-40.8%		
Prograf	117	-18.5%	134	-4.1%		
Omnic	15	-11.8%	17	-3.6%		
MYCAMINE	13	-10.0%	11	-25.0%		
Eligard	21	-13.3%	21	-6.4%		

- Established Market: Europe, Canada, Australia

(4) Greater China			Unit: B¥					
				FY20				
		A	APRJUN.	Change	JULSEP.	Change		
		(Quarterly)	(%)	(Quarterly)	(%)		
Revenue			14.2	-3.4%	15.3	4.4%		
	XTANDI		0.7	31.4%	1.6	219.0%		
	BETMIGA		0.4	12.3%	0.5	79.8%		
	Vesicare		0.2	-52.9%	0.3	-44.1%		
	Prograf		7.8	1.3%	8.4	7.9%		
	Harnal		3.7	12.6%	3.0	-15.3%		
	MYCAMINE		0.5	-45.6%	0.7	-6.6%		
	Eligard		0.1	16.8%	0.1	27.0%		
	Feburic		0.6	-2.6%	0.6	-3.2%		

- Greater China: China, Hong Kong, Taiwan

(5) Internat	ional	Unit: B¥					
		FY20					
		APRJUN.	Change	JULSEP.	Change		
		(Quarterly)	(%)	(Quarterly)	(%)		
Revenue		30.2	-11.8%	26.5	-8.9%		
	XTANDI	6.9	22.7%	6.4	32.3%		
	BETMIGA	2.0	-2.5%	2.0	-3.9%		
	Vesicare	0.9	-14.3%	0.9	-16.5%		
	Prograf	9.0	-6.0%	6.3	-7.0%		
	Harnal	4.2	-1.4%	3.9	-17.7%		
	MYCAMINE	1.0	-31.2%	1.0	-15.0%		

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

R&D Pipeline

The list shows the development status in the target diseases for which we aim to obtain approval in Japan, the United States, Europe and/or China.

As of Oct 2020

Underlined items indicate changes from the previous announcement on Aug 2020.

Key post-POC projects and projects to maximize their VALUE (1/2)

Therapeutic Area	Generic Name Code No. (Brand Name)	Modality / Technology	Classification	Target Disease	Pha	ase *	Licensor **	Remarks
0,5	MDV3100	Small molecule	Androgen receptor inhibitor			ved (Aug 2020)	Pfizer	
	(XTANDI [®])				,	Oct 2019)		
					Europe Filed (China P-III	Jul 2019)		
				Non-metastatic castration-sensitive prostate cancer	P-III			
	ASP2215	Small molecule	FLT3 inhibitor	Relapsed or refractory acute myeloid leukemia	China Filed (Mar 2020)	In-house	
	(XOSPATA [®])			Post-chemotherapy maintenance acute myeloid leukemia	P-III			
				Post-hematopoietic stem cell transplant maintenance acute myeloid leukemia	P-III			
				Newly diagnosed acute myeloid leukemia with low intensity induction of chemotherapy	P-III			
				Newly diagnosed acute myeloid leukemia with high intensity induction of chemotherapy	P-III			
				Acute myeloid leukemia in pediatric patients	P-III			
	enfortumab vedotin ASG-22ME (PADCEV [®])	Antibody-drug conjugate (ADC)	Nectin-4 targeted ADC	Metastatic urothelial cancer, PD-1/PD-L1 inhibitor and platinum-containing chemotherapy pretreated	P-III		In-house [Co-development with Seagen]	
	()			Metastatic urothelial cancer, previously untreated (first line; combo with pembrolizumab)	P-III			
				Muscle-invasive bladder cancer (combo with pembrolizumab)	<u>P-III</u>			
				Metastatic urothelial cancer, PD-1/PD-L1 inhibitor pretreated	P-II			
				Other solid tumors	P-II			

Key post-POC projects and projects to maximize their VALUE (2/2)

Therapeutic Area	Generic Name Code No. (Brand Name)	Modality / Technology	Classification	Target Disease	Phase *	Licensor **	Remarks
Oncology	zolbetuximab IMAB362	Antibody	Anti-Claudin 18.2 monoclonal antibody	Gastric and gastroesophageal junction adenocarcinoma	P-III	In-house (Ganymed)	
				Pancreatic adenocarcinoma	P-II		
Urology and Nephrology	roxadustat ASP1517/FG-4592	Small molecule		Anemia associated with chronic kidney disease in patients on dialysis	Europe Filed (Apr 2020)	FibroGen	Astellas has rights in Japan, Europe, the
				Anemia associated with chronic kidney disease in patients not on dialysis	Japan Filed (Jan 2020) Europe Filed (Apr 2020)		Commonwealth of Independent States, the
				Chemotherapy-induced anemia	P-II		Middle East, and South Africa.
Others	fezolinetant ESN364	Small molecule	NK3 receptor antagonist	Menopause-related vasomotor symptoms	P-III	In-house (Ogeda)	

* Compounds are developed globally unless noted. The list shows the most advanced stage if the stages are different depending on the region. The list specifies the area if the compound is developed in limited areas. ** Compounds with "In-house" in this column include ones discovered by collaborative research.

Updates from the previous announcement (Aug 2020):

enzalutamide (MDV3100): Removed the description of the approval in Japan for prostate cancer with distant metastasis in May 2020. Obtained the approval in US for tablet, a new formulation in Aug 2020. enfortumab vedotin (ASG-22ME): Initiated a Phase 3 study for muscle-invasive bladder cancer.

Projects with Focus Area approach (1/2)

Target (Biology)	Generic Name Code No. (Brand Name)	Modality / Technology	Therapeutic Area	Classification	Target Disease	Phase *	Licensor **	Remarks
oncology	ASP1948/PTZ-329	Antibody	Oncology	Anti-NRP1 antibody	Cancer	P-I	In-house (Potenza Therapeutics)	
	ASP1951/PTZ-522	Antibody	Oncology	GITR agonistic antibody	Cancer	P-I	In-house (Potenza Therapeutics)	
	ASP9801	Oncolytic virus	Oncology	Oncolytic virus carrying IL-7 and IL-12	Cancer	P-I	Tottori University [Discovered through collaborative research]	
	ASP7517	Cell therapy (artificial adjuvant vector cells)	Oncology	WT1 loaded artificial adjuvant vector cell	Cancer	P-I	RIKEN [Discovered through collaborative research]	
Regeneration	ASP7317	Cell therapy	Ophthalmology		Dry age-related macular degeneration, Stargardt disease	P-II	In-house (Astellas Institute for Regenerative Medicine)	
	FX-322	Small molecule	Otology	Inner ear progenitor cell activator (combination of GSK-3 inhibitor and HDAC inhibitor)	Sensorineural hearing loss	P-II	Frequency Therapeutics	Astellas has rights in Ex-US markets
	ASP0598	Recombinant protein	Otology	Recombinant human heparin-binding epidermal growth factor-like growth factor	Chronic tympanic membrane perforation	P-I	Auration Biotech	
Mitochondria	ASP1128/MA-0217	Small molecule	Nephrology	PPARδ modulator	Acute kidney injury	P-II	In-house (Mitobridge)	
	ASP0367/MA-0211	Small molecule	Muscle disease	<u>PPARδ modulator</u>	Primary mitochondrial myopathies	<u>P-II</u>	In-house (Mitobridge)	
					Duchenne muscular dystrophy	P-I		

Projects with Focus Area approach (2/2)

Target (Biology)	Generic Name Code No. (Brand Name)	Modality / Technology	Therapeutic Area	Classification	Target Disease	Phase *	Licensor **	Remarks
Genetic regulation	•	Gene therapy (AAV-based gene therapy)	Muscle disease	MTM1 gene replacement to express myotubularin	X-linked myotubular myopathy	P-II	In-house (Audentes)	
		Gene therapy (AAV-based gene therapy)	Muscle disease	GAA gene replacement to express GAA enzyme	Pompe disease	P-I	In-house (Audentes)	
		Next generation vaccine (MAPS technology)	Infectious disease	Pneumococcal vaccine based on a multiple antigen-presenting system (MAPS) platform	Prevention of pneumococcal disease	P-II	Affinivax	
	ASP0892	Next generation vaccine (LAMP- vax technology)	Immunology		Peanut allergy	P-I	Immunomic Therapeutics	
		New generation vaccine (LAMP- vax technology)	Immunology		House dust mite-induced allergic rhinitis	P-I	Immunomic Therapeutics [Discovered through collaborative research]	

* Compounds are developed globally unless noted. The list shows the most advanced stage if the stages are different depending on the region. The list specifies the area if the compound is developed in limited areas. ** Compounds with "In-house" in this column include ones discovered by collaborative research.

Update from the previous announcement (Aug 2020):

ASP0367/MA-0211: Initiated a Phase 2 study for primary mitochondrial myopathies.

ASP8374/PTZ-201: Discontinued Phase 1 program for cancer.

Others

Therapeutic Area	Generic Name Code No. (Brand Name)	Modality / Technology	Classification	Target Disease	Phase *	Licensor **	Remarks
Urology and Nephrology	mirabegron YM178	Small molecule	β_3 receptor agonist	Neurogenic detrusor overactivity in pediatric patients	<u>US</u> <u>Filed (Sep 2020)</u> Europe P-III	In-house	
				Overactive bladder in pediatric patients	Europe P-III	-	
	peficitinib ASP015K	Small molecule	JAK inhibitor	Rheumatoid arthritis	China P-III	In-house	
	bleselumab ASKP1240	Antibody	Anti-CD40 monoclonal antibody	Recurrence of focal segmental glomerulosclerosis in de novo kidney transplant recipients	P-II	Kyowa Kirin	
	ASP1617	Small molecule		Systemic lupus erythematosus	P-I	In-house	
	isavuconazole	Small molecule	Azole antifungal	Invasive aspergillosis and mucormycosis in pediatric patients	US P-II	Basilea	
	ASP8062	Small molecule	GABA _B receptor positive allosteric modulator	Substance use disorders	P-I	In-house	

* Compounds are developed globally unless noted. The list shows the most advanced stage if the stages are different depending on the region. The list specifies the area if the compound is developed in limited areas. "Filed" includes submission of application.

** Compounds with "In-house" in this column include ones discovered by collaborative research.

Update from the previous announcement (Aug 2020):

solifenacin (YM905): Removed the description of the approval in US for neurogenic detrusor overactivity in pediatric patients aged 2 years and older in May 2020.

mirabegron (YM178): Filed in US for neurogenic detrusor overactivity in pediatric patients in Sep 2020.

ASP1650: Discontinued the development for testicular cancer after Phase 2 study did not meet its primary endpoint.

ASP8302: Discontinued the development for underactive bladder after Phase 2 study did not meet its primary endpoint.

ASP1235/AGS62P1: Discontinued Phase 1 program for acute myeloid leukemia.

As of October 2020

Underlined item indicates changes from the previous announcement on August 2020

Sphere (Business area)	Project	Concept	Status	Partner	Remarks
		Offer smartphone application to support exercise using wearable device to people who needs regular exercise	1 5	BANDAI NAMCO Entertainment	
	Fitness service (Fit-eNce)	Scientifically evidenced exercise programs and systems which support regular exercise	Launched in limited areas		
	BlueStar	Digital therapeutics for adults with diabetes	Under development	Welldoc, Inc.	
Patient outcome maximization	ASP5354	Precision surgery-guide enabling identification of ureter in hysterectomy and colorectal surgery etc.	P-]]		

Update from the previous announcement (August 2020): Fitness service (Fit-eNce): Initiated service in limited areas from Sep. 1, 2020 through fitness clubs in Kanagawa Prefecture.