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## **Financial Results of Astellas for the First Three Months of FY2013**

Japan, August 1, 2013 – Astellas Pharma Inc. (hereinafter referred to as “the Company”) today announced the financial results for the first three months of the fiscal year 2013 (FY2013) ending March 31, 2014.

### **Consolidated financial results for the first three months of FY2013 (April 1, 2013 – June 30, 2013)**

(Millions of yen – fractions dropped)

	First three months of FY2012	<b>First three months of FY2013</b>	Change (%)
Net sales	243,232	<b>275,848</b>	+32,615 (+13.4%)
Operating income	52,891	<b>38,542</b>	-14,349 (-27.1%)
Ordinary income	55,735	<b>37,404</b>	-18,331 (-32.9%)
Net income	35,489	<b>22,121</b>	-13,368 (-37.7%)

**(Note) Comprehensive income** First three months of FY2013      **¥56,452 million** (-%)  
First three months of FY2012      ¥-4,094 million

#### **Cautionary statement regarding forward-looking information**

*This press release includes forward-looking statements based on a number of assumptions and beliefs in light of the information currently available to management and subject to significant risks and uncertainties. Consequently, any statements herein do not constitute assurances regarding actual results by the Company. Actual financial results may differ materially depending on a number of factors, including adverse economic conditions, currency exchange rate fluctuations, adverse legislative and regulatory developments, delays in new product launches, the pricing and product initiatives of competitors, the inability of the Company to market existing and new product effectively, interruptions in production, infringement of the Company's intellectual property rights and the adverse outcome of material litigation.*

## 1. Qualitative information on consolidated financial results for the first three months of FY2013

### (1) Information on business performance

Consolidated business performance in the first three months of FY2013 showed an increase in net sales, and decreases in operating income, ordinary income and net income, as follows.

#### Consolidated financial results

(Millions of yen – fractions dropped)

	First three months of FY2012	<b>First three months of FY2013</b>	Change (%)
Net sales	243,232	<b>275,848</b>	+32,615 (+13.4%)
Operating income	52,891	<b>38,542</b>	-14,349 (-27.1%)
Ordinary income	55,735	<b>37,404</b>	-18,331 (-32.9%)
Net income	35,489	<b>22,121</b>	-13,368 (-37.7%)

(Note) Comprehensive income First three months of FY2013 ¥56,452 million (-)  
First three months of FY2012 ¥-4,094 million

#### Research and development (R&D) expenses

(Millions of yen – fractions dropped)

	First three months of FY2012	<b>First three months of FY2013</b>	Change
R&D expenses	42,863	<b>52,055</b>	+9,192

#### Exchange rate

Average rate	First three months of FY2012	<b>First three months of FY2013</b>	Change
¥/US\$	¥80	<b>¥99</b>	¥19 Weakening of yen
¥/€	¥103	<b>¥129</b>	¥26 Weakening of yen

Change from beginning to end of period	As of June 30, 2012	<b>As of June 30, 2013</b>
¥/US\$	¥3 Strengthening of yen	<b>¥5</b> Weakening of yen
¥/€	¥11 Strengthening of yen	<b>¥8</b> Weakening of yen

### **Impact of exchange rate on financial results**

The exchange rates for the yen in the first three months of FY2013 are shown in the table above. The resulting impacts were a ¥28.3 billion increase in net sales and a ¥0.6 billion decrease in operating income. Due to the depreciation of the yen in the run-up to June 30, 2013, the effect of elimination of unrealized gains related to foreign currency-denominated inventories held by overseas subsidiaries in intra-group transactions put downward pressure on gross profit in the consolidated financial statements after these items were converted into yen. This is in contrast with the corresponding period of the previous fiscal year, when the exchange rates were moving in the direction of yen appreciation on June 30, 2012, and the effect of elimination of unrealized gains raised gross profit. Consequently, the impact of the exchange rates on financial results is to increase net sales but to decrease operating income.

### **Net sales**

Consolidated net sales in the first three months of FY2013 increased by 13.4% compared to those in the corresponding period of the previous fiscal year (“year-on-year”) to ¥275.8 billion.

- New products contributed to increased sales, including XTANDI for the treatment of prostate cancer, and Betanis / Myrbetriq / BETMIGA for the treatment of overactive bladder (OAB). In addition, sales of Vesicare, for the treatment of OAB, and other products continued to increase. There was also growth in sales of Prograf, the immunosuppressant, and Harnal for the treatment of functional symptoms of benign prostatic hyperplasia, partly due to the foreign exchange rate impact.

### **Sales by region**

\*Sales by region calculated according to locations of sellers.

#### **<Japan>**

Net sales in Japan decreased by 5.4% year-on-year to ¥130.3 billion. Sales in the Japanese market decreased by 5.5% year-on-year to ¥126.6 billion. Although sales of Betanis and others grew, the impact of generics and other factors caused overall sales to decline compared to those in the corresponding period of the previous fiscal year.

- In addition to Betanis, products such as Micardis, an antihypertensive drug (including its combination drugs, Micombi and Micamlo), Celecox, an anti-inflammatory and anti-pain drug, Symbicort for the treatment of bronchial asthma and Bonoteo for the treatment of osteoporosis showed growth in sales. Quattrovac, a combined vaccine for the prevention of pertussis, diphtheria, tetanus, and poliomyelitis that was launched in October 2012, also made a contribution to sales.
- Sales of products declined, including Lipitor for the treatment of hypercholesterolemia, Seroquel for the treatment of schizophrenia, Myslee for the treatment of insomnia, and Gaster for the treatment of peptic ulcer and gastritis, mainly due to the impact of generics.
- Micamlo BP (Combination Tablet) for the treatment of hypertension and Acofide for the treatment of functional dyspepsia were launched in May and June 2013, respectively.

## **<Outside of Japan>**

Net sales in the Americas increased by 48.4% year-on-year to ¥69.0 billion. The sales on a local currency basis increased by 20.5% year-on-year to US\$698 million.

- There was a contribution to the sales increase from XTANDI and Myrbetriq launched in the US in September and October 2012, respectively.
- In addition, products, such as VESicare, and Lexiscan, a pharmacologic stress agent, continuously grew. Also, income from anticancer drug Tarceva increased.
- Sales of Prograf declined mainly due to the impact of generics.

Net sales in Europe\* increased by 27.4% year-on-year to ¥62.5 billion. The sales on a local currency basis increased by 1.7% year-on-year to €485 million.

\* This category includes sales from the Middle and Near East, and Africa in addition to Europe.

- Sales of Vesicare and the Candin-type antifungal agent Mycamine grew, while sales of Prograf and Harnal through the Company's own distribution channel increased partly due to the foreign exchange rate impact.
- XTANDI was launched in the UK in July 2013.

Net sales in Asia\* increased by 40.5% year-on-year to ¥13.9 billion.

\* This category includes sales from Oceania in addition to Asia.

- Products such as Prograf, Harnal and Vesicare showed growth in sales, resulting in an increase in revenue.

## **Operating income**

Consolidated operating income in the first three months of FY2013 decreased by 27.1% year-on-year to ¥38.5 billion.

- Coupled with an increase in net sales, gross profit increased by 11.4% year-on-year to ¥189.2 billion. The cost-to-sales ratio, however, rose 1.2 percentage points year-on-year to 31.4%, owing to the foreign exchange rate impact related to the elimination of unrealized gains in intra-group transactions and other factors. Consequently, the rate of increase of gross profit was 2 percentage points lower than that of net sales (13.4%).
- Selling, general and administrative expenses, which included a foreign exchange rate impact, increased by 28.9% year-on-year to ¥150.6 billion.
- Research and development (R&D) expenses included therein were ¥52.0 billion, up 21.4% year-on-year, which in addition to the foreign exchange rate impact, was partly because of an increase in upfront and milestone payments associated with in-licensing. The R&D cost-to-sales ratio was up 1.2 percentage points year-on-year to 18.9%.
- Selling, general and administrative expenses, excluding R&D expenses, increased by 33.2% year-on-year to ¥98.6 billion, which in addition to the foreign exchange rate impact, was partly due to increased expenditures related to the oncology business in the US and Europe, including payment for co-promotion of XTANDI in the US.

### **Ordinary income**

Consolidated ordinary income in the first three months of FY2013 decreased by 32.9% year-on-year to ¥37.4 billion.

- Non-operating income decreased by ¥2.2 billion and non-operating expenses increased by ¥1.6 billion year-on-year. This was mainly due to the recording of exchange loss of ¥1.7 billion during the first three months of FY2013, compared to the ¥1.7 billion of exchange gain that was recorded during the corresponding period of the previous fiscal year.

### **Net income**

Consolidated net income in the first three months of FY2013 decreased by 37.7% year-on-year to ¥22.1 billion.

- Special losses of ¥6.9 billion was recorded. This included ¥4.6 billion of restructuring costs in connection with reshaping the research framework.

## (2) Information on financial conditions

### Assets, liabilities and net assets

An overview of the consolidated balance sheets as of June 30, 2013 and the main changes from the end of the previous fiscal year are shown below.

#### Assets

Total assets as of June 30, 2013 saw an increase of ¥25.5 billion compared to those as of the end of the previous fiscal year to ¥1,471.0 billion.

<Current assets> ¥846.0 billion (an increase of ¥18.8 billion)

- Marketable securities and inventories increased by ¥6.9 billion and ¥10.4 billion, respectively.

<Fixed assets> ¥624.9 billion (an increase of ¥6.6 billion)

- Property, plant and equipment decreased by ¥0.3 billion compared to those as of the end of the previous fiscal year to ¥218.1 billion.
- Intangible fixed assets increased by ¥4.4 billion compared to those as of the end of the previous fiscal year to ¥299.2 billion.

#### Liabilities

Liabilities decreased by ¥1.7 billion compared to those as of the end of the previous fiscal year to ¥381.7 billion.

<Current liabilities> ¥317.1 billion (an increase of ¥3.6 billion)

<Long-term liabilities> ¥64.6 billion (a decrease of ¥5.3 billion)

#### Net assets

Net assets increased by ¥27.2 billion compared to those as of the end of the previous fiscal year to ¥1,089.2 billion, making the equity ratio 73.9%.

- While net income stood at ¥22.1 billion, the Company paid ¥29.3 billion of dividends of surplus.
- Cancellation of treasury stock totaling ¥47.3 billion (11,000,000 shares) was carried out on May 31, 2013.
- In addition, the change in foreign currency translation adjustments of ¥31.6 billion had the effect of increasing net assets by the same amount.

**(3) Information on consolidated business forecasts for FY2013 and other forward-looking statements**

The forecasts for the first six months and full-year of the fiscal year ending March 31, 2014 (FY2013) are shown below. No changes have been made to the forecasts announced in May 2013.

**Consolidated first six months business forecasts**

(Millions of yen – fractions dropped)

	FY2012 First six months results	FY2013 First six months forecasts	Change (%)
Net sales	476,833	<b>567,000</b>	+90,166 (+18.9%)
Operating income	88,389	<b>83,000</b>	-5,389 (-6.1%)
Ordinary income	90,332	<b>83,000</b>	-7,332 (-8.1%)
Net income	57,405	<b>52,000</b>	-5,405 (-9.4%)

**Consolidated full-year business forecasts**

(Millions of yen – fractions dropped)

	FY2012 Full-year results	FY2013 Full-year forecasts	Change (%)
Net sales	1,005,611	<b>1,170,000</b>	+164,388 (+16.3%)
Operating income	153,867	<b>170,000</b>	+16,132 (+10.5%)
Ordinary income	157,156	<b>170,000</b>	+12,843 (+8.2%)
Net income	82,851	<b>110,000</b>	+27,148 (+32.8%)

(Notes)

- 1. Expected exchange rate for FY2013**

	<b>¥100/US\$</b>	<b>¥130/€</b>
Exchange rate for FY2012	¥83/US\$	¥107/€
Exchange rate for the first six months of FY2012	¥79/US\$	¥101/€
2. Although the Company will voluntarily adopt the International Financial Reporting Standards (IFRS) from the consolidated financial statements for the fiscal year ending March 31, 2014, the consolidated business forecasts presented here continue to be based on the Japanese Generally Accepted Accounting Principles.

# Consolidated Financial Statements

## (1) Consolidated Balance Sheets

*(All amounts are in millions of yen and amounts less than one million have been omitted.)*

	As of March 31, 2013	As of June 30, 2013
Assets		
Current assets		
Cash on hand and in banks	¥233,814	¥234,565
Trade notes and accounts receivable	286,068	285,621
Marketable securities	78,862	85,770
Inventories	128,180	138,677
Other	102,190	103,515
Allowance for doubtful receivables	(1,926)	(2,074)
Total current assets	827,189	846,077
Fixed assets		
Property, plant and equipment	218,478	218,139
Intangible fixed assets		
Goodwill	95,977	99,110
Patents	138,069	140,495
Other	60,793	59,653
Total intangible fixed assets	294,841	299,259
Investments and other assets		
Investment securities	61,646	64,893
Other	43,427	42,702
Allowance for doubtful receivables	(22)	(3)
Total investments and other assets	105,051	107,592
Total fixed assets	618,371	624,990
Total assets	¥1,445,561	¥1,471,067



(All amounts are in millions of yen and amounts less than one million have been omitted.)

	As of March 31, 2013	As of June 30, 2013
<b>Liabilities</b>		
Current liabilities		
Trade notes and accounts payable	¥102,834	¥106,638
Provision	4,474	4,148
Other	206,226	206,367
Total current liabilities	<u>313,536</u>	<u>317,154</u>
Long-term liabilities		
Accrued retirement benefits for employees	18,273	18,193
Other	51,726	46,431
Total long-term liabilities	<u>69,999</u>	<u>64,624</u>
Total liabilities	<u>383,535</u>	<u>381,779</u>
<b>Net assets</b>		
Shareholders' equity		
Common stock	103,000	103,000
Capital surplus	176,821	176,821
Retained earnings	917,511	862,920
Treasury stock	(72,284)	(24,815)
Total shareholders' equity	<u>1,125,048</u>	<u>1,117,927</u>
Accumulated other comprehensive income		
Unrealized holding gains on securities	15,966	18,614
Foreign currency translation adjustments	(80,925)	(49,242)
Total accumulated other comprehensive income	<u>(64,959)</u>	<u>(30,628)</u>
Stock subscription rights	1,936	1,989
Total net assets	<u>1,062,025</u>	<u>1,089,288</u>
Total liabilities and net assets	<u>¥1,445,561</u>	<u>¥1,471,067</u>

## (2) Consolidated Statements of Income and Consolidated Statements of Comprehensive Income

### (Consolidated Statements of Income)

(All amounts are in millions of yen and amounts less than one million have been omitted.)

	For the three months ended June 30, 2012	For the three months ended June 30, 2013
Net sales	¥243,232	¥275,848
Cost of sales	73,435	86,625
Gross profit	169,797	189,222
Selling, general and administrative expenses	116,905	150,680
Operating income	52,891	38,542
Non-operating income		
Interest income	302	182
Dividend income	518	409
Equity in earnings of affiliates	28	—
Exchange gain	1,792	—
Other	375	137
Total non-operating income	3,017	728
Non-operating expenses		
Equity in losses of affiliates	—	3
Exchange loss	—	1,738
Other	172	124
Total non-operating expenses	172	1,866
Ordinary income	55,735	37,404
Special gains		
Gain on sales of fixed assets	173	11
Gain on sales of investment securities	98	20
Other	15	2
Total special gains	286	35
Special losses		
Loss on sales and disposal of fixed assets	201	163
Loss on impairment of fixed assets	7,022	1,493
Restructuring costs	—	4,660
Other	1,103	626
Total special losses	8,327	6,944
Income before income taxes and minority interests	47,695	30,495
Income taxes	12,206	8,374
Income before minority interests	35,489	22,121
Net income	¥35,489	¥22,121

## (Consolidated Statements of Comprehensive Income)

*(All amounts are in millions of yen and amounts less than one million have been omitted.)*

	For the three months ended June 30, 2012	For the three months ended June 30, 2013
Income before minority interests	¥35,489	¥22,121
Other comprehensive income		
Unrealized holding gains on securities	(35)	2,648
Foreign currency translation adjustments	(39,547)	31,683
Total other comprehensive income	(39,583)	34,331
Comprehensive income	¥(4,094)	¥56,452
- attributable to owners of the parent	¥(4,094)	¥56,452
- attributable to minority interests	—	—

## Supplement Documents for Results 1Q/FY2013

### Astellas Pharma Inc.

- Financial Results of 1Q/FY2013
- Pipeline list

**Cautionary statement regarding forward-looking information**

*This material includes forward-looking statements based on a number of assumptions and beliefs in light of the information currently available to management and subject to significant risks and uncertainties. Actual financial results may differ materially depending on a number of factors, including adverse economic conditions, currency exchange rate fluctuations, adverse legislative and regulatory developments, delays in new product launches, the pricing and product initiatives of competitors, the inability of the company to market existing and new product effectively, interruptions in production, infringement of the company's intellectual property rights and the adverse outcome of material litigation.*

# 1. Consolidated Results

rounddown under 0.1 billion yen

Fiscal Year: From April to March

	billion yen		Forecast		Forecast		Change from FY12 (%)
	FY12 APR. - JUN.	FY13 APR. - JUN.	Change	Change (%)	FY13 Full Year	Change (%)	
Net Sales	243.2	275.8	32.6	13.4%	567.0	18.9%	16.3%
Cost of Sales	73.4	86.6	13.1	18.0%			
Ratio to Net Sales	30.2%	31.4%					
Gross Profit	169.7	189.2	19.4	11.4%			
SG&A	116.9	150.6	33.7	28.9%			
Ratio to Net Sales	48.1%	54.6%					
Research and Development	42.8	52.0	9.1	21.4%	105.0	25.6%	16.5%
SG&A excluding R&D	74.0	98.6	24.5	33.2%			
Advertising and Sales Promotion	15.9	25.6	9.6	60.6%			
Salaries, Bonuses and Allowances	33.4	40.0	6.6	19.8%			
Other	24.6	32.9	8.2	33.6%			
Operating Income	52.8	38.5	-14.3	-27.1%	83.0	-6.1%	10.5%
Ratio to Net Sales	21.7%	14.0%			14.6%		
Non-Operating Income	3.0	0.7	-2.2	-75.8%			
Exchange Gain	1.7	-	-1.7	-			
Non-Operating Expenses	0.1	1.8	1.6	980.2%			
Exchange Loss	-	1.7	1.7	-			
Ordinary Income	55.7	37.4	-18.3	-32.9%	83.0	-8.1%	8.2%
Ratio to Net Sales	22.9%	13.6%			14.6%		
Special Gains	0.2	0.0	-0.2	-87.8%			
Gain on sales of fixed assets	0.1	0.0	-0.1	-93.4%			
Gain on sales of investment securities	0.0	0.0	-0.0	-78.9%			
Special Losses	8.3	6.9	-1.3	-16.6%			
Loss on sale and disposal of fixed assets	0.2	0.1	-0.0	-18.9%			
Loss on impairment of fixed assets	7.0	1.4	-5.5	-78.7%			
Restructuring costs	-	4.6	4.6	-			
Income before Income Taxes	47.6	30.4	-17.2	-36.1%			
Income Taxes	12.2	8.3	-3.8	-31.4%			
Net Income	35.4	22.1	-13.3	-37.7%	52.0	-9.4%	32.8%
Ratio to Net Sales	14.6%	8.0%			9.2%		
Comprehensive income	-4.0	56.4	60.5	-			

## 2. Segment Information by Region

	billion yen			
	FY12 APR. - JUN.	FY13 APR. - JUN.	Change	Change (%)
Net Sales	243.2	275.8	32.6	13.4%
Japan	137.7	130.3	-7.3	-5.4%
Ratio to Net Sales	56.6%	47.3%		
Americas	46.4	69.0	22.5	48.4%
Ratio to Net Sales	19.1%	25.0%		
Europe	49.0	62.5	13.4	27.4%
Ratio to Net Sales	20.2%	22.7%		
Asia and Oceania	9.9	13.9	4.0	40.5%
Ratio to Net Sales	4.1%	5.1%		
Operating Income	52.8	38.5	-14.3	-27.1%
Japan	23.8	16.3	-7.5	-31.5%
Ratio to Net Sales	45.1%	42.4%		
Americas	5.8	5.1	-0.6	-11.1%
Ratio to Net Sales	11.0%	13.4%		
Europe	18.9	21.7	2.8	15.1%
Ratio to Net Sales	35.8%	56.5%		
Asia and Oceania	1.6	3.5	1.8	112.6%
Ratio to Net Sales	3.1%	9.1%		
Eliminations	2.6	-8.3	-10.9	

- Calculated according to locations of sellers.

- Europe: Including Middle and Near East and Africa

	Forecasts		Forecasts		Change from FY12 Change (%)
	FY13 1H	Change (%)	FY13 Full Year	Change (%)	
	567.0	18.9%	1,170.0	16.3%	
	279.8	3.9%	582.5	4.5%	
	49.4%		49.8%		
	134.5	43.7%	267.2	28.0%	
	23.7%		22.8%		
	123.5	32.4%	260.6	32.7%	
	21.8%		22.3%		
	28.9	42.3%	59.5	38.7%	
	5.1%		5.1%		
	83.0	-6.1%	170.0	10.5%	

### 3. Exchange Rate

	yen			
	FY12	FY13	FY12	FY13
	APR. - JUN.Ave.	APR. - JUN.Ave.	End	1Q End
Yen/USD	80	99	94	99
Yen/EUR	103	129	121	129

Forecasts	
FY13	FY13
1H	Full Year
100	100
130	130

\* Exchange rate fluctuations had positive impact by 28.3 billion yen on net sales and negative impact by 0.6 billion yen on operating income in 1Q/FY2013

### 4. Research and Development Expenses

	billion yen		
	FY12	FY13	Change
	APR. - JUN.	APR. - JUN.	(%)
Research and Development	42.8	52.0	21.4%
Ratio to Net Sales	17.6%	18.9%	9.1

Forecasts		Change from FY12	
FY13	Change (%)	FY13	Change (%)
1H		Full Year	
105.0	25.6%	212.0	16.5%
18.5%		18.1%	

### 5. Depreciation/Amortization

	billion yen		
	FY12	FY13	Change
	APR. - JUN.	APR. - JUN.	(%)
Depreciation(Tangible)			
Consolidated	4.0	5.4	33.1%
Amortization(Intangible)			
Consolidated	6.9	9.4	35.1%
Amortization of Goodwill	2.9	1.4	
Agensys	1.7	-	
OSI	1.1	1.4	

Forecasts		Change from FY12	
FY13	Change (%)	FY13	Change (%)
Full Year		Full Year	
21.0	18.8%		
37.0		37.0	24.3%
5.8		5.8	
-		-	
5.8		5.8	

6. Sales of major products

1) Sales of global products

	billion yen			Change (%)
	FY12 APR. - JUN.	FY13 APR. - JUN.	Change	
Prograf	39.7	44.2	4.5	11.5%
Sales by Astellas	38.6	43.0	4.4	11.5%
Japan (Including Graceptor)	12.4	12.5	0.1	1.2%
Americas	7.5	7.1	-0.4	-5.3%
Europe	14.1	17.2	3.1	22.2%
Advagraf	4.2	5.6	1.3	32.4%
Asia and Oceania	4.4	6.0	1.5	34.6%
Exports to third parties	1.1	1.2	0.1	11.8%
Harnal	13.8	15.3	1.4	10.8%
Sales by Astellas	12.9	13.9	1.0	8.0%
Japan	6.1	5.1	-0.9	-16.0%
Europe	4.0	5.0	1.0	26.3%
Asia and Oceania	2.5	3.5	0.9	37.5%
Bulk and Royalties	0.8	1.3	0.4	52.2%
Vesicare	26.7	31.7	5.0	18.8%
Japan	7.8	7.0	-0.8	-10.7%
Americas	10.6	13.4	2.8	26.5%
Europe	7.6	10.2	2.6	34.7%
Asia and Oceania	0.5	0.9	0.3	57.6%
Betanis/Mybetriq/Betmiga	0.6	4.6	4.0	656.7%
Japan	0.6	2.3	1.7	286.3%
Americas	-	2.1	2.1	-
Europe	-	0.1	0.1	-
Funguard/Mycamine	7.3	8.3	0.9	13.3%
Japan	3.2	2.8	-0.4	-14.7%
Americas	2.2	2.8	0.5	23.9%
Europe	1.2	2.0	0.7	57.2%
Asia and Oceania	0.5	0.7	0.1	37.1%
Protopic	4.4	6.1	1.7	39.0%
Japan	1.0	0.9	-0.0	-8.6%
Americas	1.7	2.8	1.1	67.3%
Europe	1.2	1.6	0.4	36.7%
Asia and Oceania	0.4	0.6	0.2	51.2%
XTANDI	-	8.5	8.5	-
US	-	8.1	8.1	-
ex-US	-	0.3	0.3	-
Americas (ex-US)	-	0.0	0.0	-
Europe*	-	0.3	0.3	-
Eligard	3.6	4.6	1.0	27.3%
Europe	3.6	4.6	1.0	27.3%
Asia and Oceania	-	0.0	0.0	-

\*Including "Temporary authorization for use" in France.

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

- Europe: Including Middle and Near East and Africa

Change from  
FY12

Forecasts

	FY13 Full Year	Change (%)
	182.3	12.7%
	177.7	13.0%
	53.4	8.1%
	29.1	-7.4%
	68.9	19.9%
	26.2	38.6%
	4.6	5.1%
	58.6	8.6%
	54.6	9.2%
	21.4	-6.7%
	17.7	15.0%
	14.4	32.6%
	3.9	1.1%
	131.7	19.8%
	32.4	8.8%
	53.5	14.4%
	40.8	35.7%
	4.6	56.2%
	22.9	229.9%
	10.9	107.0%
	10.2	529.3%
	1.6	-
	37.2	21.3%
	13.2	2.5%
	11.0	16.1%
	9.1	53.0%
	3.8	65.0%
	23.2	30.0%
	3.6	3.6%
	10.6	34.5%
	6.1	33.1%
	2.6	55.4%
	40.0	227.7%
	20.1	34.7%



2) Sales of products in Japan

	billion yen			Change (%)
	FY12 APR. - JUN.	FY13 APR. - JUN.	Change	
<Global products>				
Prograf (Including Graceptor)	12.4	12.5	0.1	1.2%
Harnal	6.1	5.1	-0.9	-16.0%
Vesicare	7.8	7.0	-0.8	-10.7%
Betanis	0.6	2.3	1.7	286.3%
Funguard	3.2	2.8	-0.4	-14.7%
Protopic	1.0	0.9	-0.0	-8.6%
<Domestic Products>				
Lipitor [Family]	18.9	15.7	-3.1	-16.9%
Caduet	2.3	2.5	0.2	10.2%
Micardis [Family]	22.6	23.6	1.0	4.5%
Micombi	2.9	2.9	-0.0	-1.6%
Micamllo	3.7	5.3	1.6	44.7%
Gaster	8.0	6.5	-1.5	-18.6%
Myslee	9.1	6.9	-2.1	-23.8%
Seroquel	7.7	5.2	-2.5	-32.8%
Vaccines	2.6	4.8	2.1	82.8%
Cefzon	1.7	1.5	-0.2	-15.4%
Frandol	2.3	2.0	-0.2	-12.1%
Celecox	9.2	9.9	0.6	6.8%
Geninax	2.9	2.9	-0.0	-1.4%
Bonoteo	2.2	3.0	0.8	38.1%
Symbicort	6.0	7.5	1.5	25.2%
Argamate	1.5	1.5	-0.0	-0.3%
Kiklin	0.0	0.2	0.2	634.5%
Gonax	-	0.4	0.4	-
Cimzia	-	0.5	0.5	-
Total Rx Sales In Japan	134.0	126.6	-7.3	-5.5%

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

3) Sales of products in Americas and Europe

	billion yen			Change (%)
	FY12 APR. - JUN.	FY13 APR. - JUN.	Change	
Scan* (Americas)	13.1	17.1	4.0	30.8%
Lexiscan	11.6	15.7	4.1	35.2%
AmBisome (Americas)	1.3	1.9	0.5	44.8%
Tarceva (US)	9.1	12.1	2.9	32.3%
(ROW)	5.7	8.1	2.3	41.8%
Qutenza (Europe)	3.4	4.0	0.5	16.6%
	0.2	0.3	0.1	65.2%

\* Adenoscan + Lexiscan

Forecasts

	FY13 Full Year	Change (%)
	53.4	8.1%
	21.4	-6.7%
	32.4	8.8%
	10.9	107.0%
	13.2	2.5%
	3.6	3.6%
	65.1	-7.8%
	100.6	12.3%
	27.3	-9.6%
	29.8	-7.3%
	22.9	-19.6%
	34.1	18.7%
	6.5	-8.3%
	8.2	-4.9%
	48.5	29.8%
	13.8	12.2%
	17.5	64.7%
	35.6	28.5%
	7.2	18.0%
	2.0	269.8%
	3.1	383.5%
	567.3	5.9%

Forecasts

	FY13 Full Year	Change (%)
	50.8	-4.2%
	6.8	8.6%

4) Sales in Americas and Europe (Local currency)

Americas	Unit: M\$			Change from FY12 (%)
	FY12 APR. - JUN.	FY13 APR. - JUN.	Change	
Net Sales	579	698	119	20.5%
Prograf	94	72	-21	-23.1%
Scan*	163	173	10	6.2%
Lexiscan	145	159	14	9.8%
AmBisome	16	19	2	17.6%
Protopic	21	29	7	35.9%
VESicare	132	135	3	2.7%
Myrbetriq	-	21	21	-
Mycamine	28	28	0	0.6%
Tarceva	114	123	8	7.4%
US	71	82	10	15.2%
ROW	43	40	-2	-5.3%
XTANDI	-	82	82	-
US Americas (ex-US)	-	82	82	-
Americas + Lexiscan	-	0	0	-

Europe	Unit: M€			Change from FY12 (%)
	FY12 APR. - JUN.	FY13 APR. - JUN.	Change	
Net Sales	477	485	7	1.7%
Harnal	47	49	2	4.5%
Sales by Astellas	39	39	0	0.8%
Capsule	17	17	0	4.2%
OCAS	22	21	-0	-1.9%
Bulk and Royalties	8	10	1	21.4%
Prograf	147	143	-4	-3.2%
Sales by Astellas	137	133	-3	-2.5%
Advagraf	41	43	2	5.7%
Exports to third parties	10	9	-1	-11.4%
Vesicare	74	79	5	7.5%
Beitmiga	-	1	1	-
Protopic	11	12	1	9.1%
Mycamine	12	15	3	25.5%
Eligard	35	36	0	1.6%
Quenza	1	2	0	31.8%
XTANDI*	-	2	2	-

\* Adenoscan + Lexiscan

\*Including "Temporary authorization for use" in France.

- Europe: Including Middle and Near East and Africa

## 7. Consolidated Balance Sheets

rounddown under 0.1 billion yen

	31-Mar-13		30-Jun-13		Change
	Amount	Amount	Amount	Amount	
<b>Assets</b>	<b>1,445.5</b>	<b>1,471.0</b>	<b>1,471.0</b>	<b>25.5</b>	
<b>Current assets</b>	<b>827.1</b>	<b>846.0</b>	<b>846.0</b>	<b>18.8</b>	
Cash on hand and in banks	233.8	234.5	234.5	0.7	
Trade notes and accounts receivable	286.0	285.6	285.6	-0.4	
Marketable securities	78.8	85.7	85.7	6.9	
Inventories	128.1	138.6	138.6	10.4	
Other	102.1	103.5	103.5	1.3	
Allowance for doubtful receivables	-1.9	-2.0	-2.0	-0.1	
<b>Fixed assets</b>	<b>618.3</b>	<b>624.9</b>	<b>624.9</b>	<b>6.6</b>	
Property, plant and equipment	218.4	218.1	218.1	-0.3	
Intangible fixed assets	294.8	299.2	299.2	4.4	
Goodwill	95.9	99.1	99.1	3.1	
Patents	138.0	140.4	140.4	2.4	
Other	60.7	59.6	59.6	-1.1	
Investments and other assets	105.0	107.5	107.5	2.5	
Investment securities	61.6	64.8	64.8	3.2	
Other	43.4	42.7	42.7	-0.7	
Allowance for doubtful receivables	-0.0	-0.0	-0.0	0.0	

Billion yen

rounddown under 0.1 billion yen

	31-Mar-13		30-Jun-13		Change
	Amount	Amount	Amount	Amount	
<b>Liabilities and Net assets</b>	<b>1,445.5</b>	<b>1,471.0</b>	<b>25.5</b>		
<b>Liabilities</b>	<b>383.5</b>	<b>381.7</b>	<b>-1.7</b>		
<b>Current liabilities</b>	<b>313.5</b>	<b>317.1</b>	<b>3.6</b>		
Trade notes and accounts payable	102.8	106.6	3.8		
Provision	4.4	4.1	-0.3		
Other	206.2	206.3	0.1		
<b>Long-term liabilities</b>	<b>69.9</b>	<b>64.6</b>	<b>-5.3</b>		
Accrued retirement benefits for employees	18.2	18.1	-0.0		
Other	51.7	46.4	-5.2		
<b>Net assets</b>	<b>1,062.0</b>	<b>1,089.2</b>	<b>27.2</b>		
Common stock	103.0	103.0	-		
Capital surplus	176.8	176.8	-		
Retained earnings	917.5	862.9	-54.5		
Treasury stock	-72.2	-24.8	47.4		
Unrealized holding gains on securities	15.9	18.6	2.6		
Foreign currency translation adjustments	-80.9	-49.2	31.6		
Stock subscription rights	1.9	1.9	0.0		

Billion yen



## R&D Pipeline (August 2013)

### 1. Global Development

#### (1) Approved

Code No. Generic Name	Product Name (Approval Date)	Classification	Target Disease	Area	Dosage Form	Origin	Remarks
erlotinib	Tarceva (May 2013)	HER1/EGFR tyrosine kinase inhibitor	First-line treatment of people with metastatic non-small cell lung cancer whose tumors have certain epidermal growth factor receptor activating mutations as detected by an FDA-approved test	US	Oral	In-house (co-development with Roche/ Genentech)	New indication
FK506 tacrolimus	Prograf (Jun. 2013)	Immunosuppressant	Interstitial pneumonia associated with polymyositis/dermatomyositis	Japan	Oral	In-house	New indication
	ASTAGRAF XL (Jul. 2013)		Prophylaxis of organ rejection in adult kidney transplant recipients (Extended release capsules)	US	Oral		New formulation
MDV3100 enzalutamide	XTANDI (Jun. 2013)	Androgen receptor inhibitor	Metastatic castration-resistant prostate cancer in patients whose disease has progressed on or after docetaxel therapy	Europe	Oral	Medivation	
FK463 micafungin	Mycamine (Jun. 2013)	Candin-type antifungal agent	Treatment of pediatric patients four months and older with Candidemia, acute disseminated candidiasis, Candida peritonitis and abscesses, esophageal candidiasis, prophylaxis of Candida infections in patients undergoing hematopoietic stem cell transplants	US	Injection	In-house	New indication

## (2) Filed

Stage in the most advanced territory

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks	
MDV3100 enzalutamide	Androgen receptor inhibitor	Prostate cancer	Japan Filed (May 2013)	Oral	Medivation		
		Prostate cancer (Chemotherapy-naive etc.)	US Phase-III Europe Phase-III Japan Phase-III Asia Phase-III				New indication
			Breast cancer			US/Europe Phase-II	

(3) Phase-III / Phase-II (1/2) Stage in the most advanced territory

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks
erlotinib	HER1/EGFR tyrosine kinase inhibitor	Non-small cell lung cancer (Adjuvant, combination with MetMab), Pediatric ependymoma*	US Phase-III	Oral	In-house (co-development with Roche/ Genentech)	New indication
isavuconazole	Azole antifungal	Invasive aspergillosis Candidemia / Invasive candidiasis	US/Europe Phase-III US/Europe Phase-III	Injection Oral	Basilea	
ASP0113 (VCL-CB01)	DNA vaccine for cytomegalovirus	Cytomegalovirus reactivation in hematopoietic cell transplant recipients Cytomegalovirus infection or reactivation in solid organ transplant recipients	US/Europe Phase-III Japan Phase-II US/Europe Phase-II	Injection	Vical	
YM905 solifenacin	Muscarine M <sub>3</sub> receptor antagonist	Neurogenic detrusor overactivity and idiopathic overactive bladder in pediatric patients	US/Europe Phase-III	Oral	In-house	New indication
EB178 solifenacin/ mirabegron	Concomitant use of solifenacin and mirabegron	Urinary frequency, urinary incontinence or urgency associated with overactive bladder	Europe/US/Asia Phase-III	Oral	In-house	
ASP1517 (FG-4592)	HIF stabilizer	Anemia associated with chronic kidney disease in patients not on dialysis and on dialysis	Europe Phase-III Japan Phase-II	Oral	FibroGen	
YM311 (FG-2216)	HIF stabilizer	Renal anemia	Europe Phase-II Japan Phase-I	Oral	FibroGen	
ASP4130 tivozanib	Inhibitor of vascular endothelial growth factor (VEGF) receptors 1, 2 and 3	Colorectal cancer, Breast cancer	US/Europe Phase-II	Oral	AVEO	

\*Pediatric ependymoma is not a new indication, rather a supplement whose results are planned to submit to the FDA.



(3) Phase-III / Phase-II (2/2) Stage in the most advanced territory

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks
ASP7487 (OSI-906) linsitinib	IGF-1R/IR tyrosine kinase inhibitor	Ovarian cancer, Non-small cell lung cancer	US Phase-II	Oral	In-house	
ASP015K	JAK inhibitor	Rheumatoid arthritis	Japan Phase-II (US/Europe Phase-II*)	Oral	In-house	
ASKP1240	Anti-CD40 antagonist	Prevention of organ transplant rejection	US Phase-II Japan Phase-I	Injection	Kyowa Hakko Kirin	
ASP3652	Inhibition of afferent nerve activity	Bladder pain syndrome / Interstitial cystitis	Europe Phase-II Japan Phase-I	Oral	In-house	
ASP1707	GnRH antagonist	Endometriosis	Europe/Japan Phase-II	Oral	In-house	
		Prostate cancer	Europe Phase-I			
ASP4901 (AKP-002)	PDE9 inhibitor	Lower urinary tract symptoms associated with benign prostatic hyperplasia	Japan Phase-II	Oral	ASKA	

\*A license agreement was executed with Janssen Biotech, Inc. for the development and commercialization worldwide except for Japan. Phase-IIb studies will be completed by Astellas.

## 2. Local Development: Japan

The most advanced stage

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks
YM060 ramosetron	5-HT3 receptor antagonist	Diarrhea-predominant irritable bowel syndrome in male (Orally-disintegrating tablet)	Japan Filed (Aug. 2012)	Oral	In-house	New formulation
		Irritable bowel syndrome Female patients	Japan Phase-III	Oral		New indication
midazolam	Benzodiazepine sedative	Conscious sedation in dentistry and dental surgery	Japan Filed (Feb. 2013)	Injection	Roche	New indication
ASP1941 ipragliflozin	SGLT2 inhibitor	Type 2 diabetes	Japan Filed (Mar. 2013)	Oral	In-house (co-development with Kotobuki)	

## (2) Phase-III / Phase-II

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks
YM533 beraprost sodium	Prostacyclin receptor stimulator	Chronic renal failure (primary, nephrosclerosis)	Japan/Asia Phase-III	Oral	Toray	New indication New formulation
FK949E quetiapine	Serotonin/dopamine antagonist	Depressive episode in bipolar disorders	Japan Phase-III	Oral	AstraZeneca	New indication New formulation
		Major depressive disorder	Japan Phase-II			
certolizumab pegol	PEGylated anti-tumor necrosis factor-alpha antibody	Methotrexate-naive rheumatoid arthritis	Japan Phase-III	Injection	UCB	New indication
ASP1585 (AMG223) bixalomer	Amine-functional polymer	Hyperphosphatemia in patients not on dialysis with chronic kidney disease	Japan Phase-III	Oral	Ilypsa/Amgen	New indication
nateglinide	Fast acting insulin secretion enhancer	Type 2 diabetes Combination with DPP-4 inhibitors	Japan Phase-III	Oral	Ajinomoto	New indication
ASP3550 degarelix	GnRH antagonist	Prostate cancer (Three-month formulation)	Japan Phase-III	Injection	Ferring	New formulation
AMG 785 romosozumab	Anti-Sclerostin monoclonal antibody	Osteoporosis	Japan Phase-III	Injection	Amgen (co-development with Amgen Astellas)	
ASP7374	Influenza vaccine	Prophylaxis of seasonal influenza	Japan Phase-III	Injection	UMN Pharma	
ASP7373	Influenza vaccine	Prophylaxis of H5N1 influenza	Japan Phase-II	Injection	UMN Pharma	
ASP0456 linaclofide	Guanylate cyclase type-C receptor agonist	Irritable bowel syndrome	Japan Phase-II	Oral	Ironwood	
AMG 145	Anti-PCSK-9 monoclonal antibody	Hyperlipidemia	Japan Phase-II	Injection	Amgen (co-development with Amgen Astellas)	

### 3. Local Development: Europe

#### (1) Approved

Code No. Generic Name	Product Name (Approval Date)	Classification	Target Disease	Area	Dosage Form	Origin	Remarks
EC905 solifenacin/ tamsulosin	VESOMNI (May 2013)	Fixed dose combination of solifenacin and tamsulosin	Moderate to severe storage symptoms (urgency, increased micturition frequency) and voiding symptoms associated with benign prostatic hyperplasia in men who are not adequately responding to treatment with monotherapy	Europe	Oral	In-house	

#### (2) Phase-III / Phase-II

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks
NGX-4010 capsaicin	TRPV1 agonist	Peripheral diabetic neuropathy	Europe Phase-III	Patch	NeurogesX	New indication

4. Phase-I

Code No. Generic Name	Target Disease	Dosage Form	Origin
AGS-16M8F/ AGS-16C3F	Cancer (ADC technology)	Injection	In-house (ADC technology in-licensed from Seattle Genetics)
ASP0306	Lower urinary tract symptoms associated with benign prostatic hyperplasia	Oral	In-house
ASP8477	Neuropathic pain	Oral	In-house
ASP2408	Rheumatoid arthritis	Injection	In-house
ASP3026	Cancer	Oral	In-house
ASG-22ME	Cancer (ADC technology)	Injection	In-house (co-development with Seattle Genetics)
ASP9226	Neuropathic pain	Oral	In-house
ASP7991	Secondary hyperparathyroidism	Oral	In-house
ASP2409	Prevention of organ transplant rejection	Injection	In-house
ASP6432	Lower urinary tract symptoms associated with benign prostatic hyperplasia	Oral	In-house
ASP9853	Cancer	Oral	In-house
ASP8232	Diabetic nephropathy	Oral	In-house
fidaxomicin*	Clostridium difficile associated diarrhea	Oral	Optimer
ASP3662	Alzheimer's disease	Oral	In-house
ASG-15ME	Cancer (ADC technology)	Injection	In-house (co-development with Seattle Genetics)
ASP2215	Cancer	Oral	In-house
ASP3325	Hyperphosphatemia	Oral	In-house
CK-2127107	Skeletal muscle disease (non-neuromuscular indications)	Oral	Cytokinetics
AMG 102 rilotumumab	Gastric cancer	Injection	Amgen (co-development with Amgen Astellas)

\*Japanese development

### 5. Project Discontinued

Code No. Generic Name	Area / Phase	Target Disease	Reason
YM155 sepantronium bromide	US Phase-II Europe Phase-II Japan Phase-I	Non-Hodgkin's lymphoma	Discontinued for strategic reasons after comprehensive consideration of prioritization of this product in our pipeline etc.
ASG-5ME	Phase-I	Cancer (ADC technology)	Discontinued for strategic reasons after comprehensive consideration of Phase-I study results and prioritization of this product in our pipeline etc.
ASP0777	Phase-I	Alzheimer's disease [Dementia]	Discontinued for strategic reasons after comprehensive consideration of prioritization of this product in our pipeline etc.

<Changes from the Previous Announcement on May 13, 2013>

Launched

-Amoxicillin: Removed the previous item below.

-Acotiamide: Removed the previous item below. Acotiamide was launched in Japan in June 2013.

Code No. Generic Name	Product Name (Approval Date)	Classification	Target Disease	Area	Dosage Form	Origin	Remarks
amoxicillin	Sawacillin (Feb. 2013)	Penicillin antibiotic	Helicobacter pylori eradication in patients with Helicobacter pylori gastritis by triple therapy with proton pump inhibitors and either clarithromycin or metronidazole	Japan	Oral	In-house	New indication
YM443 acotiamide	Acofide (Mar. 2013)	Acetylcholine esterase inhibitor	Postprandial fullness, upper abdominal bloating, and early satiation associated with functional dyspepsia	Japan	Oral	Zeria	

Approved

-Erlotinib: Approved for new indication in the US in May 2013.

Code No. Generic Name	Product Name (Approval Date)	Classification	Target Disease	Area	Dosage Form	Origin	Remarks
erlotinib	Tarceva (May 2013)	HER1/EGFR tyrosine kinase inhibitor	First-line treatment of people with metastatic non-small cell lung cancer whose tumors have certain epidermal growth factor receptor activating mutations as detected by an FDA-approved test	US	Oral	In-house (co-development with Roche/Genentech)	New indication

-Solifenacin/tamsulosin: Approved in Europe (Netherlands) in May 2013.

Code No. Generic Name	Product Name (Approval Date)	Classification	Target Disease	Area	Dosage Form	Origin	Remarks
EC905 solifenacin/ tamsulosin	VESOMNI (May 2013)	Fixed dose combination of solifenacin and tamsulosin	Moderate to severe storage symptoms (urgency, increased micturition frequency) and voiding symptoms associated with benign prostatic hyperplasia in men who are not adequately responding to treatment with monotherapy	Europe	Oral	In-house	

-Tacrolimus: Approved in Japan in June 2013 for new indication and in the US in July 2013 for new formulation.

Code No. Generic Name	Product Name (Approval Date)	Classification	Target Disease	Area	Dosage Form	Origin	Remarks
FK506 tacrolimus	Prograf (Jun. 2013)	Immunosuppressant	Interstitial pneumonia associated with polymyositis/dermatomyositis	Japan	Oral	In-house	New indication
	ASTAGRAF XL (Jul. 2013)		Prophylaxis of organ rejection in adult kidney transplant recipients (Extended release capsules)	US	Oral		New formulation

-Enzalutamide: Approved in Europe in June 2013.

Code No. Generic Name	Product Name (Approval Date)	Classification	Target Disease	Area	Dosage Form	Origin	Remarks
MDV3100 enzalutamide	XTANDI (Jun. 2013)	Androgen receptor inhibitor	Metastatic castration-resistant prostate cancer in patients whose disease has progressed on or after docetaxel therapy	Europe	Oral	Medivation	



-Micafungin: Approved in the US for pediatric patients in June 2013.

Code No. Generic Name	Product Name (Approval Date)	Classification	Target Disease	Area	Dosage Form	Origin	Remarks
FK463 micafungin	Mycamine (Jun. 2013)	Candin-type antifungal agent	Treatment of pediatric patients four months and older with Candidemia, acute disseminated candidiasis, Candida peritonitis and abscesses, esophageal candidiasis, prophylaxis of Candida infections in patients undergoing hematopoietic stem cell transplants	US	Injection	In-house	New indication

Filed

-Enzalutamide: Filed in Japan for prostate cancer in May 2013 and entered into Phase-II for breast cancer in US/Europe. (Changed underlined part)

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks
MDV3100 enzalutamide	Androgen receptor inhibitor	<u>Prostate cancer</u>	Japan Filed (May 2013)	Oral	Medivation	
			US Phase-III Europe Phase-III Japan Phase-III Asia Phase-III			New indication
			<u>US/Europe Phase-II</u>			New indication
		Breast cancer				

Phase-III / Phase-II

-Solifenacin/mirabegron: Entered into Phase-III in Europe/US/Asia. (Changed underlined part)

-ASP4901 (AKP-002): Entered into Phase-II in Japan. (Changed underlined part)

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks
EB178 solifenacin/ mirabegron	Concomitant use of solifenacin and mirabegron	Urinary frequency, urinary incontinence or urgency associated with overactive bladder	<u>Europe/US/Asia</u> <u>Phase-III</u>	Oral	In-house	
ASP4901 (AKP-002)	PDE9 inhibitor	Lower urinary tract symptoms associated with benign prostatic hyperplasia	<u>Japan Phase-II</u>	Oral	ASKA	

-AMG 785: Added to the list.

-AMG 145: Added to the list.

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks
AMG 785 romosozumab	Anti-Sclerostin monoclonal antibody	Osteoporosis	Japan Phase-III	Injection	Amgen (co-development with Amgen Astellas)	
AMG 145	Anti-PCSK-9 monoclonal antibody	Hyperlipidemia	Japan Phase-II	Injection	Amgen (co-development with Amgen Astellas)	

- Tivozanib: Deleted advanced renal cell carcinoma from the target disease.
- Erlotinib: Deleted colorectal carcinoma from the target disease.
- ASP3652: Deleted chronic prostatitis / chronic pelvic pain syndrome from the target disease.

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks
ASP4130 tivozanib	Inhibitor of vascular endothelial growth factor (VEGF) receptors 1, 2 and 3	Advanced renal cell carcinoma	US Filed (Sep. 2012) <del>Europe Phase-III</del>	Oral	AVEO	
		Colorectal cancer, Breast cancer	US/Europe Phase-II			
erlotinib	HER1/EGFR tyrosine kinase inhibitor	Non-small cell lung cancer (Adjuvant, combination with MetMab), <del>Colorectal carcinoma;</del> Pediatric ependymoma*	US Phase-III	Oral	In-house (co-development with Roche/ Genentech)	New indication
		Chronic prostatitis/ <del>Chronic pelvic pain syndrome</del>	Europe Phase-II Japan Phase-I			
ASP3652	Inhibition of afferent nerve activity	Bladder pain syndrome/ Interstitial cystitis	Europe Phase-II Japan Phase-I	Oral	In-house	

\*Pediatric ependymoma is not a new indication, rather a supplement whose results are planned to submit to the FDA.

#### Phase-I

- ASG-15ME [Cancer (ADC technology)]: Entered into Phase-I.
- ASP2215 [Cancer]: Entered into Phase-I.
- ASP3325 [Hyperphosphatemia]: Entered into Phase-I.
- CK-2127107 [Skeletal muscle disease (non-neuromuscular indications)]: Added to the list.
- AMG 102 [Gastric cancer]: Added to the list.

Project Discontinued

-Sepantronium bromide [Non-Hodgkin's lymphoma] in Phase-II in US/Europe and Phase-I in Japan: Discontinued the development.

-ASG-5ME [Cancer (ADC technology)] in the Phase-I: Discontinued the development.

-ASP0777 [Alzheimer's disease] in Phase-I: Discontinued the development.