Supplement Documents for Results FY2012

Astellas Pharma Inc.

- Financial Results of FY2012
- 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　　billion yen　　Forecasts　　Forecasts　　Change from FY12

	FY11 Full Year	FY12 Full Year	Change	Change (%)	FY12 Revised Forecasts	FY13 1H	Change (%)	FY13 Full Year	Change (%)
Net Sales	969.3	1,005.6	36.2	3.7%	972.0	567.0	18.9%	1,170.0	16.3%
Cost of Sales	318.6	324.1	5.4	1.7%					
Ratio to Net Sales	32.9%	32.2%							
Gross Profit	650.7	681.4	30.7	4.7%					
SG&A	519.2	527.6	8.3	1.6%					
Ratio to Net Sales	53.6%	52.5%							
Research and Development	189.8	181.9	-7.8	-4.2%	184.0	105.0	25.6%	212.0	16.5%
SG&A excluding R&D	329.3	345.6	16.2	4.9%					
Advertising and Sales Promotion	86.3	86.4	0.0	0.1%					
Salaries, Bonuses and Allowances	130.4	139.7	9.2	7.1%					
Other	112.5	119.4	6.9	6.1%					
Operating Income	131.5	153.8	22.3	17.0%	147.0	83.0	-6.1%	170.0	10.5%
Ratio to Net Sales	13.6%	15.3%			15.1%	14.6%		14.5%	
Non-Operating Income	4.1	4.0	-0.0	-1.4%					
Exchange Gain	1.0	1.4	0.4	45.8%					
Non-Operating Expenses	0.5	0.7	0.2	46.0%					
Ordinary Income	135.1	157.1	22.0	16.3%	149.0	83.0	-8.1%	170.0	8.2%
Ratio to Net Sales	13.9%	15.6%			15.3%	14.6%		14.5%	
Special Gains	14.0	5.8	-8.2	-58.7%					
Gain on sales of fixed assets	10.4	0.2	-10.1	-97.6%					
Gain on sales of investment securities	2.7	5.4	2.7	99.9%					
Special Losses	22.1	38.2	16.1	73.1%					
Loss on sale and disposal of fixed assets	5.9	0.7	-5.1	-87.6%					
Loss on impairment of fixed assets	9.2	34.7	25.5	276.7%					
Loss on disaster	3.1	-	-3.1	-					
Business integration expenses	0.6	-	-0.6	-					
Income before Income Taxes	127.0	124.6	-2.4	-1.9%					
Income Taxes	48.8	41.8	-7.0	-14.4%					
Net Income	78.2	82.8	4.6	5.9%	98.0	52.0	-9.4%	110.0	32.8%
Ratio to Net Sales	8.1%	8.2%			10.1%	9.2%		9.4%	
Comprehensive income	54.4	152.8	98.3	180.7%					

2.Segment Information by Region

billion yen

		FY11 Full Year	FY12 Full Year	Change	Change (%)
Net Sales		969.3	1,005.6	36.2	3.7%
	Japan	558.4	557.5	-0.8	-0.2%
	Ratio to Net Sales	57.6%	55.4%		
	Americas	183.5	208.7	25.1	13.7%
	Ratio to Net Sales	18.9%	20.8%		
	Europe	191.7	196.4	4.7	2.5%
	Ratio to Net Sales	19.8%	19.5%		
	Asia and Oceania	35.7	42.9	7.1	20.1%
	Ratio to Net Sales	3.7%	4.3%		
Operating Income		131.5	153.8	22.3	17.0%
	Japan	74.1	83.7	9.5	12.9%
	Ratio to Net Sales	56.4%	54.4%		
	Americas	8.6	23.2	14.6	168.6%
	Ratio to Net Sales	6.6%	15.1%		
	Europe	41.9	51.5	9.5	22.7%
	Ratio to Net Sales	31.9%	33.5%		
	Asia and Oceania	1.5	2.3	0.8	54.3%
	Ratio to Net Sales	1.2%	1.6%		
	Eliminations	5.1	-7.0	-12.2	

billion yen

FY12 Revised Forecasts
972.0
560.9
57.7%
185.8
19.1%
185.8
19.1%
39.3
4.0%
147.0

Forecasts / Forecasts / Change from FY12

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%	167.0	8.5%

- Calculated according to locations of sellers.
- Europe: Including Middle and Near East and Africa

3.Overseas Sales

billion yen

		FY11 Full Year	FY12 Full Year	Change	Change (%)
Overseas Sales		421.5	464.0	42.4	10.1%
	Ratio to Net Sales	43.5%	46.1%		
	Americas	182.6	215.5	32.9	18.0%
	Ratio to Net Sales	18.8%	21.4%		
	Europe	187.3	188.7	1.4	0.8%
	Ratio to Net Sales	19.3%	18.8%		
	Asia and others	51.5	59.6	8.1	15.7%
	Ratio to Net Sales	5.3%	5.9%		

- Calculated according to locations of buyers.

4.Exchange Rate

	FY11 Ave.	FY12 Ave.	FY11 End	FY12 End	FY12 Revised Forecasts	FY13 1H	FY13 Full Year
	yen				billion yen	Forecasts	Forecasts
Yen/USD	79	83	82	94	80	100	100
Yen/EUR	109	107	110	121	100	130	130

∗Exchange rate fluctuations had positive impact by 9.0 billion yen on net sales and negative impact by 7.5 billion yen on operating income in FY2012

5.Per Share Information

	FY11 Full Year	FY12 Full Year	FY12 Revised Forecasts	FY13 1H	FY13 Full Year
			billion yen	Forecasts	Forecasts
The number of share issued (thousand)	467,964	467,964			
Treasury Stock (thousand)	6,044	16,788			
The number of share issued after deducting Treasury Stock (thousand)	461,920	451,176			
Earnings per share (Yen)	169.38	180.40	212.15	115.25	243.81
Dividend per share (Yen)	125	130	130	65	135
Return on Equity (%)	7.7%	8.0%			
Dividend on Earnings (%)	5.7%	5.7%			

6.Research and Development Expenses

	FY11 Full Year	FY12 Full Year	Change	Change (%)	FY12 Revised Forecasts	FY13 1H	Change (%)	FY13 Full Year	Change from FY12 Change (%)
	billion yen		billion yen		billion yen	Forecasts		Forecasts	
Research and Development	189.8	181.9	-7.8	-4.2%	184.0	105.0	25.6%	212.0	16.5%
Ratio to Net Sales	19.6%	18.1%			18.9%	18.5%		18.1%	

7.Addition to Property, Plant and Equipment

Depreciation/Amortization

	FY11 Full Year	FY12 Full Year	Change	Change (%)	FY12 Revised Forecasts	FY13 Full Year	Change from FY12 Change (%)
	billion yen		billion yen		billion yen	Forecasts	
Addition to Property, Plant and Equipment							
Consolidated	45.0	32.0	-12.9	-28.8%	41.0	27.0	-15.8%
Depreciation (Tangible)							
Consolidated	28.6	17.6	-11.0	-38.4%	17.0	21.0	18.8%
Amortization (Intangible)							
Consolidated	24.9	29.7	4.8	19.3%	22.5	37.0	24.3%
Amortization of Goodwill	11.7	10.3			9.8	5.8	
Agensys	6.8	5.3			5.1	−	
OSI	4.8	4.8			4.6	5.8	

8.Employee

Number of employees

	FY11 End	FY12 End
Total	17,085	17,454
Japan	8,176	8,153
Americas	2,919	2,980
Europe	4,286	4,356
Asia and Oceania	1,704	1,965
Total Medical Representatives	6,190	6,350

- Europe: Including Middle and Near East and Africa

9.Shareholders

	FY11 End	FY12 End
Banks	33.6%	30.1%
Securities	7.8%	4.3%
Other companies	4.3%	3.8%
Foreign companies	43.6%	49.8%
Individuals and others	9.4%	8.5%
Treasury Stock	1.3%	3.6%

10. Sales of major products

1)Sales of global products

billion yen

	FY11 Full Year	FY12 Full Year	Change	Change (%)
Prograf	154.8	161.7	6.8	4.4%
Sales by Astellas	148.8	157.3	8.4	5.7%
Japan (Including Graceptor)	44.0	49.4	5.3	12.2%
Americas	29.2	31.4	2.2	7.6%
Europe	60.2	57.5	-2.7	-4.5%
Advagraf	15.7	18.0	2.2	14.6%
Asia and Oceania	15.2	18.9	3.6	23.7%
Exports to third parties	6.0	4.4	-1.6	-26.7%
Harnal	60.8	54.0	-6.8	-11.3%
Sales by Astellas	56.1	50.0	-6.0	-10.8%
Japan	27.4	22.9	-4.4	-16.2%
Europe	18.0	15.4	-2.6	-14.6%
Capsule	7.2	6.8	-0.4	-6.0%
Omnic OCAS	10.8	8.6	-2.2	-20.4%
Asia and Oceania	9.8	10.8	1.0	10.7%
Bulk and Royalties	4.7	3.9	-0.8	-18.0%
Vesicare	97.2	109.9	12.7	13.1%
Japan	28.0	29.8	1.7	6.2%
Americas	38.9	46.8	7.8	20.1%
Europe	27.5	30.1	2.5	9.2%
Asia and Oceania	2.4	2.9	0.5	20.7%
Betanis/Myrbetriq/Betmiga	0.9	6.9	6.0	641.1%
Japan	0.9	5.3	4.3	466.7%
Americas	-	1.6	1.6	-
Europe	-	0.0	0.0	-
Funguard/Mycamine	26.2	30.7	4.4	16.8%
Japan	12.5	12.9	0.3	2.6%
Americas	8.2	9.4	1.2	14.9%
Europe	3.7	5.9	2.1	58.3%
Asia and Oceania	1.6	2.3	0.6	38.9%
Protopic	16.9	17.8	0.9	5.3%
Japan	3.1	3.4	0.3	11.5%
Americas	7.4	7.9	0.4	6.1%
Europe	5.1	4.6	-0.4	-9.3%
Asia and Oceania	1.2	1.7	0.5	42.7%
XTANDI*	-	12.2	12.2	-
US	-	12.2	12.2	-
Eligard Europe	13.8	14.9	1.0	7.8%

billion yen

FY12 Revised Forecasts
150.7
147.1
49.8
26.5
53.4
17.4
3.5
52.1
48.7
23.2
14.7
6.6
8.1
9.9
3.4
106.8
30.9
43.6
29.1
3.0
3.6
29.2
12.1
9.1
5.8
2.1
17.3
3.7
7.5
4.4
1.5
7.9
14.3

Forecasts

Change from FY12

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%
8.3	22.9%
9.3	8.7%
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%

*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

2)Sales of products in Japan

billion yen

<Global products>	FY11 Full Year	FY12 Full Year	Change	Change (%)	billion yen FY12 Revised Forecasts	Forecasts FY13 Full Year	Change from FY12 Change (%)
Prograf（Including Graceptor）	44.0	49.4	5.3	12.2%	49.8	53.4	8.1%
Harnal	27.4	22.9	-4.4	-16.2%	23.2	21.4	-6.7%
Vesicare	28.0	29.8	1.7	6.2%	30.9	32.4	8.8%
Betanis	0.9	5.3	4.3	466.7%	3.6	10.9	107.0%
Funguard	12.5	12.9	0.3	2.6%	12.1	13.2	2.5%
Protopic	3.1	3.4	0.3	11.5%	3.7	3.6	3.6%
<Domestic Products>							
Lipitor [Family]	96.3	70.6	-25.7	-26.7%	71.8	65.1	-7.8%
Caduet	4.9	9.6	4.6	94.8%			
Micardis [Family]	85.3	89.6	4.2	5.0%	90.6	100.6	12.3%
Micombi	10.4	11.5	1.1	11.0%			
Micamlo	10.6	15.6	5.0	47.5%			
Gaster	37.5	30.2	-7.3	-19.5%	30.6	27.3	-9.6%
Myslee	35.2	32.2	-3.0	-8.6%	32.5	29.8	-7.3%
Seroquel	27.8	28.5	0.7	2.5%	27.7	22.9	-19.6%
Vaccines	26.5	28.8	2.2	8.3%	28.5	34.1	18.7%
Cefzon	8.2	7.1	-1.0	-13.0%	7.1	6.5	-8.3%
Frandol	9.4	8.6	-0.7	-8.3%	8.7	8.2	-4.9%
Celecox	33.0	37.4	4.4	13.3%	38.6	48.5	29.8%
Geninax	11.9	12.3	0.3	2.6%	12.1	13.8	12.2%
Bonoteo	5.0	10.6	5.5	110.1%	12.0	17.5	64.7%
Symbicort	20.0	27.7	7.6	38.2%	28.7	35.6	28.5%
Argamate	0.1	6.1	5.9	-	7.3	7.2	18.0%
Kiklin	-	0.5	0.5	-		2.0	269.8%
Gonax	-	0.6	0.6	-		3.1	383.5%
Total Rx Sales In Japan	539.9	535.7	-4.1	-0.8%	541.8	567.3	5.9%

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

3)Sales of products in Americas and Europe

billion yen

		FY11 Full Year	FY12 Full Year	Change	Change (%)	billion yen FY12 Revised Forecasts	Forecasts FY13 Full Year	Change from FY12 Change (%)
Scan*	(Americas)	49.0	53.1	4.0	8.3%	45.3	50.8	-4.2%
Lexiscan		42.4	47.5	5.1	12.2%			
AmBisome	(Americas)	5.5	6.3	0.7	14.4%	5.6	6.8	8.6%
Tarceva		33.7	36.5	2.8	8.3%			
	(US)	19.8	23.6	3.7	19.2%			
	(ex-US)	13.9	12.9	-0.9	-7.1%			
Qutenza	(Europe)	0.5	0.8	0.3	51.8%			

* Adenoscan + Lexiscan

4)Sales in Americas and Europe(Local currency)

Unit:M$ | Unit:M$ | Forecasts | Change from FY12

Americas	FY11 Full Year	FY12 Full Year	Change	Change (%)	FY12 Revised Forecasts	FY13 Full Year	Change (%)
Net Sales	2,320	2,511	190	8.2%	2,331	2,672	6.4%
Prograf	370	378	8	2.4%	332	291	-23.1%
Scan*	619	639	19	3.1%	568	508	-20.4%
Lexiscan	536	572	36	6.7%			
AmBisome	69	76	6	8.9%	70	68	-9.7%
Protopic	94	95	0	1.0%	94	106	11.8%
VESIcare	492	563	70	14.3%	547	535	-4.9%
Myrbetriq	-	19	19	-		102	423.0%
Mycamine	104	114	9	9.4%	115	110	-3.5%
Tarceva	426	439	13	3.1%			
US	250	284	33	13.4%			
ex-US	175	155	-20	-11.5%			
XTANDI	-	146	146	-	100	400	172.3%

* Adenoscan + Lexiscan

Unit:M€ | Unit:M€ | Forecasts

Europe	FY11 Full Year	FY12 Full Year	Change	Change (%)	FY12 Revised Forecasts	FY13 Full Year	Change (%)
Net Sales	1,759	1,833	74	4.2%	1,852	2,004	9.3%
Harnal	209	180	-29	-13.9%	181	166	-7.6%
Sales by Astellas	165	143	-21	-13.2%	147	136	-5.2%
Capsule	66	63	-2	-4.4%	66	64	1.3%
OCAS	99	80	-18	-19.1%	81	72	-10.4%
Bulk and Royalties	43	36	-7	-16.6%	34	30	-16.7%
Prograf	606	577	-29	-4.9%	566	565	-2.0%
Sales by Astellas	552	536	-15	-2.9%	532	530	-1.2%
Advagraf	144	168	23	16.6%			
Exports to third parties	54	40	-13	-25.7%	34	35	-12.5%
Vesicare	252	280	28	11.1%	291	314	11.8%
Betmiga	-	0	0	-		12	-
Protopic	46	43	-3	-7.7%	44	47	9.7%
Mycamine	34	55	21	61.0%	58	70	26.1%
Eligard	127	139	12	9.7%	143	155	11.0%
Qutenza	5	8	2	54.4%			

- Europe: Including Middle and Near East and Africa

11.Consolidated Balance Sheets

rounddown under 0.1 billion yen

Billion yen

	31-Mar-12 Amount	31-Mar-13 Amount	Change	Comments
Assets	**1,400.6**	**1,445.5**	**44.9**	
Current assets	**781.0**	**827.1**	**46.1**	
Cash on hand and in banks	210.9	233.8	22.8	
Trade notes and accounts receivable	264.6	286.0	21.3	
Marketable securities	88.1	78.8	-9.2	
Merchandise and finished goods	82.2	92.6	10.4	
Work in process	13.4	13.2	-0.1	
Raw materials and supplies	16.1	22.2	6.1	
Deferred tax assets	71.5	61.7	-9.8	
Other	36.8	40.4	3.6	
Allowance for doubtful receivables	-2.8	-1.9	0.9	
Fixed assets	**619.5**	**618.3**	**-1.1**	
Property, plant and equipment	**199.1**	**218.4**	**19.3**	
Buildings and structures	95.6	116.8	21.1	
Machinery, equipment and vehicles	25.2	28.8	3.6	
Tools, furniture and fixtures	10.7	15.4	4.6	
Land	31.0	30.1	-0.8	
Construction in progress	34.8	25.7	-9.0	
Other	1.5	1.3	-0.1	
Intangible fixed assets	**314.2**	**294.8**	**-19.4**	
Goodwill	94.1	95.9	1.7	
Patents	161.4	138.0	-23.4	・Patents
Other	58.5	60.7	2.2	OSI amortization(-13.0)
Investments and other assets	**106.1**	**105.0**	**-1.0**	Loss on impairment of IPR&D
Investment securities	60.5	61.6	1.1	
Deferred tax assets	33.8	27.1	-6.7	
Other	11.7	16.3	4.5	
Allowance for doubtful receivables	-0.0	-0.0	0.0	

rounddown under 0.1 billion yen

Billion yen

	31-Mar-12 Amount	31-Mar-13 Amount	Change	Comments
Liabilities and Net assets	**1,400.6**	**1,445.5**	**44.9**	
Liabilities	**382.5**	**383.5**	**1.0**	
Current liabilities	**314.1**	**313.5**	**-0.6**	
Trade notes and accounts payable	108.4	102.8	-5.5	
Other accounts payable	82.3	87.7	5.3	
Accrued expenses	80.9	94.3	13.4	
Accrued bonus for directors	0.0	0.0	0.0	
Allowance for sales rebates	3.9	4.3	0.4	
Other	38.4	24.1	-14.2	
Long-term liabilities	**68.3**	**69.9**	**1.6**	
Deferred tax liabilities	30.9	34.7	3.7	
Accrued retirement benefits for employees	16.9	18.2	1.2	
Other	20.4	17.0	-3.4	
Net assets	**1,018.1**	**1,062.0**	**43.9**	
Common stock	103.0	103.0	-	
Capital surplus	176.8	176.8	-	
Retained earnings	894.7	917.5	22.7	
Treasury stock	-23.1	-72.2	-49.1	
Unrealized holding gains on securities	12.2	15.9	3.7	
Foreign currency translation adjustments	-147.1	-80.9	66.2	
Stock subscription rights	1.6	1.9	0.3	

R&D Pipeline (May 2013)

1. Global Development

(1) Filed (1/2)

Stage in the most advanced territory

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks
MDV3100 enzalutamide	Androgen receptor inhibitor	Metastatic castration-resistant prostate cancer in patients who have received docetaxel-based chemotherapy	Europe Filed (Jun. 2012) Japan Phase-II	Oral	Medivation	
		Prostate cancer (Chemotherapy-naive etc.)	US Phase-III Europe Phase-III Japan Phase-III Asia Phase-III			New indication
		Breast cancer	US Phase-I			New indication
FK506 tacrolimus	Immunosuppressant	Prophylaxis of organ rejection in adult patients receiving kidney transplants (Extended release capsules)	US Filed (Sep. 2012)	Oral	In-house	New formulation
FK463 micafungin	Candin-type antifungal agent	Candidemia, acute disseminated candidiasis, Candida peritonitis and abscesses, esophageal candidiasis, prophylaxis of Candida infections in patients undergoing hematopoietic stem cell transplantation (Pediatric patients >= 4 months through 16 years of age)	US Filed (Sep. 2012)	Injection	In-house	New indication

(1) Filed (2/2)

Stage in the most advanced territory

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) Europe Phase-III	Oral	AVEO	
		Colorectal cancer, Breast cancer	US/Europe Phase-II			New indication
erlotinib (Tarceva)	HER1/EGFR tyrosine kinase inhibitor	First-line treatment of patients with locally advanced or metastatic non-small cell lung cancer whose tumors have epidermal growth factor receptor activating mutations	US Filed (Nov. 2012)	Oral	In-house (OSI)	New indication
		Non-small cell lung cancer (Adjuvant, combination with MetMab), Colorectal carcinoma, Pediatric ependymoma	US Phase-III			New indication

(2) Phase-lll / Phase-ll (1/2)

Stage in the most advanced territory

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks
isavuconazole	Azole antifungal	Invasive aspergillosis	US/Europe Phase-III	Injection Oral	Basilea	
		Candidemia / Invasive candidiasis	US/Europe Phase-III			
ASP0113 (VCL-CB01)	DNA vaccine for cytomegalovirus	Cytomegalovirus reactivation in hematopoietic cell transplant recipients	US/Europe Phase-III Japan Phase-II	Injection	Vical	
		Cytomegalovirus infection or reactivation in solid organ transplant recipients	US/Europe Phase-II			
YM905 solifenacin	Muscarine M_3 receptor antagonist	Neurogenic detrusor overactivity and idiopathic overactive bladder in pediatric patients	US/Europe Phase-III	Oral	In-house	New indication
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	
ASP7487 (OSI-906) linsitinib	IGF-1R/IR tyrosine kinase inhibitor	Ovarian cancer, Non-small cell lung cancer	US Phase-II	Oral	In-house (OSI)	
YM155 sepantronium bromide	Survivin suppressant	Non-Hodgkin's lymphoma	US Phase-II Europe Phase-II Japan Phase-I	Injection	In-house	
ASP015K	JAK inhibitor	Rheumatoid arthritis	Japan Phase-II (US/Europe Phase-II*)	Oral	In-house	

*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) Phase-lll / Phase-ll (2/2)

Stage in the most advanced territory

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks
ASKP1240	Anti-CD40 antagonist	Prevention of organ transplant rejection	US Phase-II Japan Phase-I	Injection	Kyowa Hakko Kirin	
EB178 solifenacin/ mirabegron	Concomitant use of solifenacin and mirabegron	Urinary frequency, urinary incontinence or urgency associated with overactive bladder	Europe Phase-II	Oral	In-house	
ASP3652	Inhibition of afferent nerve activity	Chronic prostatitis / Chronic pelvic pain syndrome	Europe Phase-II Japan Phase-I	Oral	In-house	
		Bladder pain syndrome / Interstitial cystitis	Europe Phase-II			
ASP1707	GnRH antagonist	Endometriosis	Europe/Japan Phase-II	Oral	In-house	
		Prostate cancer	Europe Phase-I			

2. Local Development: Japan

(1) Approved

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	

(2) Filed

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			New indication
midazolam	Benzodiazepine sedative	Conscious sedation in dentistry and dental surgery	Japan Filed (Feb. 2013)	Oral	Roche	New indication
ASP1941 ipragliflozin	SGLT2 inhibitor	Type 2 diabetes	Japan Filed (Mar. 2013)	Oral	In-house (co-development with Kotobuki)	

(3) Phase-lll / Phase-ll

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
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 linaclotide	Guanylate cyclase type-C receptor agonist	Irritable bowel syndrome	Japan Phase-II	Oral	Ironwood	

3. Local Development: Europe

(1) Filed

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks
EC905 solifenacin/ tamsulosin	Fixed dose combination of solifenacin and tamsulosin	Lower urinary tract symptoms associated with benign prostatic hyperplasia, with storage symptoms	Europe Filed (Mar. 2012)	Oral	In-house	

(2) Phase-lll / Phase-ll

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 (Agensys)
ASG-5ME	Cancer (ADC technology)	Injection	In-house (Agensys) (co-development with Seattle Genetics)
ASP0777	Alzheimer's disease [Dementia]	Oral	In-house
ASP0306	Lower urinary tract symptoms associated with benign prostatic hyperplasia	Oral	In-house
ASP4901 (AKP-002)	Lower urinary tract symptoms associated with benign prostatic hyperplasia	Oral	ASKA
ASP8477	Neuropathic pain	Oral	In-house
ASP2408	Rheumatoid arthritis	Injection	In-house (Perseid)
ASP3026	Cancer	Oral	In-house
ASG-22ME	Cancer (ADC technology)	Injection	In-house (Agensys) (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 (Perseid)
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

*Japanese development

5. Project Discontinued

Code No. Generic Name	Area / Phase	Target Disease	Reason
OSI-027	US Phase-II	Renal cell cancer	We have decided to discontinue the development based on the clinical data.
ASP9603	Phase-I	Prostate cancer	We have decided to discontinue the development for strategic reasons.

6. Deleted from the Pipeline List

Code No. Generic Name	Area / Phase	Target Disease	Reason
AC220 quizartinib	US/Europe Phase-II Japan Phase-I	Acute myeloid leukemia	Quizartinib was deleted from the pipeline list because we exercised our right to terminate the worldwide license agreement with Ambit for strategic reasons. The effective date of termination is September 3, 2013, at which time all right to quizartinib will revert to Ambit.
ASP7035	Phase-I	Nocturia	ASP7035 was deleted from the pipeline list because we decided not to develop it by ourselves. Tacurion, operated by Drais, has been granted an exclusive license of ASP7035 as a part of activities of "Multi-Track R&D".

<Changes from the Previous Announcement on February 1, 2013>

Launched

-Mirabegron: Removed the previous item below. Mirabegron was launched in Europe in February 2013.

-Certolizumab pegol: Removed the previous item below. Certolizumab pegol was launched in Japan in March 2013.

Code No. Generic Name	Product Name (Approval Date)	Classification	Target Disease	Area	Dosage Form	Origin	Remarks
YM178 mirabegron	BETMIGA (Dec. 2012)	Beta 3 receptor agonist	Symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder syndrome	Europe	Oral	In-house	
certolizumab pegol	Cimzia (Dec. 2012)	PEGylated anti-tumor necrosis factor-alpha antibody	Treatment of rheumatoid arthritis not responding to conventional therapy (including inhibition of progression of bone structural damage)	Japan	Injection	UCB	

Approved

-Amoxicillin: Approved for new indication in Japan in February 2013.

-Acotiamide: Approved in Japan in March 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	

Filed

-Tacrolimus: Withdrew the application for the indication of adult male patients receiving liver transplants in the US for extended release capsules.

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks
FK506 tacrolimus	Immunosuppressant	Prophylaxis of organ rejection in adult patients receiving kidney transplants ~~and in adult male patients receiving liver transplants~~ (Extended release capsules)	US Filed (Sep. 2012)	Oral	In-house	New formulation

-Midazolam: Filed in Japan for new indication in February 2013.

-Ipragliflozin: Filed in Japan in March 2013.

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks
midazolam	Benzodiazepine sedative	Conscious sedation in dentistry and dental surgery	Japan Filed (Feb. 2013)	Oral	Roche	New indication
ASP1941 ipragliflozin	SGLT2 inhibitor	Type 2 diabetes	Japan Filed (Mar. 2013)	Oral	In-house (co-development with Kotobuki)	

Phase-III / Phase-II

-ASP0113: Entered into Phase-II in Japan. (Changed underlined part)

-Degarelix: Entered into Phase-III for three-month formulation in Japan. (Changed underlined part)

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Origin	Remarks
ASP0113 (VCL-CB01)	DNA vaccine for cytomegalovirus	Cytomegalovirus reactivation in hematopoietic cell transplant recipients	US/Europe Phase-III Japan Phase-II	Injection	Vical	
		Cytomegalovirus infection or reactivation in solid organ transplant recipients	US/Europe Phase-II			
ASP3550 degarelix	GnRH antagonist	Prostate cancer (Three-month formulation)	Japan Phase-III	Injection	Ferring	New formulation

Phase-I

-ASP3662 [Alzheimer's disease]: Entered into Phase-I.

Project Discontinued

-OSI-027 [Renal cell cancer] in Phase-II in the US: Deleted from the list due to the development discontinuation.

-ASP9603 [Prostate cancer] in Phase-I: Deleted from the list due to the development discontinuation.

Deleted from the Pipeline List

-Quizartinib [Acute myeloid leukemia]: Deleted from the list because we exercised our right to terminate the worldwide license agreement with Ambit for strategic reasons. The effective date of termination is September 3, 2013, at which time all right to quizartinib will revert to Ambit.

-ASP7035 [Nocturia]: Deleted from the list because we decided not to develop it by ourselves. Tacurion has been granted an exclusive license of ASP7035 as a part of activities of "Multi-Track R&D".