# Supplementary Documents [IFRS]

## Financial results for the first six months of the fiscal year 2016 (FY2016)

# Astellas Pharma Inc.

- Q2/FY2016 Financial Results
  - Six months ended September 30, 2016
  - Three months ended September 30, 2016
- 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, 2016]

1. Consolidated Results (Full Basis)

Unit: B¥

| | FY15 APR. - SEP. | FY16 APR. - SEP. | Change | Change (%) | FY15 Full Year | Initial Forecasts FY16 Full Year | Revised Forecasts FY16 Full Year | Change from FY15 FY16 Change (%) |
|---|---|---|---|---|---|---|---|---|
| Sales | 687.5 | 651.7 | -35.8 | -5.2% | 1,372.7 | 1,350.0 | 1,300.0 | -5.3% |
| Cost of sales | 168.4 | 146.2 | -22.2 | -13.2% | 335.6 | | | |
| Ratio to Sales | 24.5% | 22.4% | | | 24.4% | | | |
| Gross profit | 519.1 | 505.5 | -13.6 | -2.6% | 1,037.1 | | | |
| SG&A expenses | 239.7 | 220.8 | -18.9 | -7.9% | 500.4 | | | |
| Ratio to Sales | 34.9% | 33.9% | | | 36.5% | | | |
| Advertising and Sales Promotion | 83.3 | 69.2 | -14.1 | -16.9% | 169.1 | | | |
| Personnel expenses | 91.3 | 85.5 | -5.8 | -6.4% | 186.1 | | | |
| Other | 65.1 | 66.2 | 1.0 | 1.6% | 145.1 | | | |
| R&D expenses | 112.0 | 99.7 | -12.4 | -11.0% | 225.7 | 231.0 | 216.0 | -4.3% |
| Ratio to Sales | 16.3% | 15.3% | | | 16.4% | 17.1% | 16.6% | |
| Amortisation of intangible assets | 21.9 | 17.7 | -4.2 | -19.2% | 42.4 | | | |
| Share of profits/losses of associates and joint ventures | -0.3 | -0.8 | -0.5 | - | -1.2 | | | |
| Other income | 0.9 | 0.4 | -0.5 | -57.6% | 1.7 | | | |
| Gain on sales of property, plant and equipment | 0.2 | 0.0 | -0.2 | -89.7% | 0.3 | | | |
| Other expense | 13.4 | 9.8 | -3.6 | -27.2% | 20.2 | | | |
| Loss on sales and disposal of property, plant and equipment | 0.3 | 0.2 | -0.1 | -23.8% | 0.7 | | | |
| Impairment losses | 6.6 | 7.6 | 1.0 | 16.0% | 9.5 | | | |
| Net foreign exchange losses | 5.9 | 0.5 | -5.4 | -91.5% | 7.0 | | | |
| Operating profit | 132.6 | 157.1 | 24.4 | 18.4% | 249.0 | 267.0 | 267.0 | 7.2% |
| Ratio to Sales | 19.3% | 24.1% | | | 18.1% | 19.8% | 20.5% | |
| Finance income | 13.3 | 2.4 | -11.0 | -82.1% | 14.4 | | | |
| Gain on sales of available-for-sale financial assets | 12.1 | 1.6 | -10.5 | -86.9% | 12.3 | | | |
| Finance expense | 0.6 | 1.7 | 1.1 | 194.7% | 1.6 | | | |
| Impairment losses for available-for-sale financial assets | 0.1 | 0.4 | 0.3 | 263.1% | 0.4 | | | |
| Profit before tax | 145.4 | 157.8 | 12.4 | 8.5% | 261.8 | 268.0 | 268.0 | 2.4% |
| Ratio to Sales | 21.2% | 24.2% | | | 19.1% | 19.9% | 20.6% | |
| Income tax expense | 42.5 | 42.7 | 0.2 | 0.5% | 68.1 | | | |
| Profit for the period | 102.9 | 115.1 | 12.1 | 11.8% | 193.7 | 197.0 | 198.0 | 2.2% |
| Ratio to Sales | 15.0% | 17.7% | | | 14.1% | 14.6% | 15.2% | |
| Comprehensive income | 104.9 | 2.7 | -102.2 | -97.5% | 130.9 | | | |

## 2. Consolidated Results (Core Basis)

Unit: B¥

| | FY15 APR. - SEP. | FY16 APR. - SEP. | Change | Change (%) | FY15 Full Year | Initial Forecasts FY16 Full Year | Revised Forecasts FY16 Full Year | Change from FY15 FY16 Full Year (%) |
|---|---|---|---|---|---|---|---|---|
| Sales | 687.5 | 651.7 | -35.8 | -5.2% | 1,372.7 | 1,350.0 | 1,300.0 | -5.3% |
| Cost of sales | 168.4 | 146.2 | -22.2 | -13.2% | 335.6 | | | |
| Ratio to Sales | 24.5% | 22.4% | | | 24.4% | | | |
| Gross profit | 519.1 | 505.5 | -13.6 | -2.6% | 1,037.1 | | | |
| SG&A expenses | 239.7 | 220.8 | -18.9 | -7.9% | 500.4 | | | |
| Ratio to Sales | 34.9% | 33.9% | | | 36.5% | | | |
| Advertising and Sales Promotion | 83.3 | 69.2 | -14.1 | -16.9% | 169.1 | | | |
| Personnel expenses | 91.3 | 85.5 | -5.8 | -6.4% | 186.1 | | | |
| Other | 65.1 | 66.2 | 1.0 | 1.6% | 145.1 | | | |
| R&D expenses | 112.0 | 99.7 | -12.4 | -11.0% | 225.7 | 231.0 | 216.0 | -4.3% |
| Ratio to Sales | 16.3% | 15.3% | | | 16.4% | 17.1% | 16.6% | |
| Amortisation of intangible assets | 21.9 | 17.7 | -4.2 | -19.2% | 42.4 | | | |
| Share of profits/losses of associates and joint ventures | -0.3 | -0.8 | -0.5 | - | -1.2 | | | |
| Operating profit | 145.2 | 166.5 | 21.3 | 14.7% | 267.5 | 270.0 | 274.0 | 2.4% |
| Ratio to Sales | 21.1% | 25.5% | | | 19.5% | 20.0% | 21.1% | |
| Finance income | 1.3 | 0.8 | -0.5 | -37.8% | 2.1 | | | |
| Finance expense | 0.3 | 1.3 | 1.0 | 327.2% | 1.0 | | | |
| Profit before Tax | 146.2 | 166.0 | 19.8 | 13.6% | 268.6 | | | |
| Ratio to Sales | 21.3% | 25.5% | | | 19.6% | | | |
| Income tax expense | 42.2 | 45.4 | 3.2 | 7.5% | 69.8 | | | |
| Profit for the period | 103.9 | 120.6 | 16.6 | 16.0% | 198.8 | 199.0 | 202.0 | 1.6% |
| Ratio to Sales | 15.1% | 18.5% | | | 14.5% | 14.7% | 15.5% | |

## 3. Exchange Rate

Unit: yen

| | FY15 APR. - SEP.Ave. | FY16 APR. - SEP.Ave. | FY15 End | FY16 2Q End | FY15 Full Year | Initial Forecasts FY16 Full Year | Revised Forecasts FY16 Full Year |
|---|---|---|---|---|---|---|---|
| USD/Yen | 122 | 105 | 113 | 101 | 120 | 110 | 103 |
| EUR/Yen | 135 | 118 | 128 | 113 | 133 | 125 | 117 |

* Exchange rate fluctuations had negative impact by 64.1 billion yen on sales and negative impact by 12.5 billion yen on Core operating profit in Q2/FY2016

4. Reconciliation of Full Basis to Core Basis

Unit: B¥

| | FY15 APR. - SEP. | | | FY16 APR. - SEP. | | |
|---|---|---|---|---|---|---|
| | Full basis | Adjustment | Core basis | Full basis | Adjustment | Core basis |
| **Sales** | **687.5** | **-** | **687.5** | **651.7** | **-** | **651.7** |
| Cost of sales | 168.4 | - | 168.4 | 146.2 | - | 146.2 |
| **Gross profit** | **519.1** | **-** | **519.1** | **505.5** | **-** | **505.5** |
| SG&A expenses | 239.7 | - | 239.7 | 220.8 | - | 220.8 |
| R&D expenses | 112.0 | - | 112.0 | 99.7 | - | 99.7 |
| Amortisation of intangible assets | 21.9 | - | 21.9 | 17.7 | - | 17.7 |
| Share of losses of associates and joint ventures | -0.3 | - | -0.3 | -0.8 | - | -0.8 |
| Other income *1 | 0.9 | -0.9 | - | 0.4 | -0.4 | - |
| Other expense *1 | 13.4 | -13.4 | - | 9.8 | -9.8 | - |
| **Operating profit** | **132.6** | **12.5** | **145.2** | **157.1** | **9.4** | **166.5** |
| Finance income *2 | 13.3 | -12.1 | 1.3 | 2.4 | -1.6 | 0.8 |
| Finance expense *2 | 0.6 | -0.3 | 0.3 | 1.7 | -0.4 | 1.3 |
| **Profit before tax** | **145.4** | **0.7** | **146.2** | **157.8** | **8.2** | **166.0** |
| Income tax expense | 42.5 | -0.3 | 42.2 | 42.7 | 2.7 | 45.4 |
| **Profit for the period** | **102.9** | **1.0** | **103.9** | **115.1** | **5.5** | **120.6** |

*1. “Other income” and “Other expense” are excluded from Core results.
“Other income” and “Other expense” include gain/loss on sale and disposal of property, plant and equipment, impairment losses, loss on the restructuring, litigation costs and foreign exchange gains/losses, etc.

*2. Gain/loss on sale of available-for-sale (“AFS”) and impairment losses of AFS included in “Finance income” and “Finance expense” are excluded from Core results as non-core items.

## 5. Sales by Region

Unit: B¥

| | | FY15 APR. - SEP. | FY16 APR. - SEP. | Change | Change (%) | FY15 Full Year | Initial Forecasts FY16 Full Year | Revised Forecasts FY16 Full Year | Change from FY15 FY16 Full Year (%) |
|---|---|---|---|---|---|---|---|---|---|
| Sales | | 687.5 | 651.7 | -35.8 | -5.2% | 1,372.7 | 1,350.0 | 1,300.0 | -5.3% |
| | Japan | 247.1 | 237.2 | -10.0 | -4.0% | 497.2 | 480.8 | 483.7 | -2.7% |
| | Ratio to Sales | 35.9% | 36.4% | | | 36.2% | 35.6% | 37.2% | |
| | Americas | 232.9 | 206.6 | -26.2 | -11.3% | 455.1 | 441.2 | 409.1 | -10.1% |
| | Ratio to Sales | 33.9% | 31.7% | | | 33.2% | 32.7% | 31.5% | |
| | EMEA | 162.3 | 166.1 | 3.8 | 2.3% | 329.3 | 339.6 | 322.1 | -2.2% |
| | Ratio to Sales | 23.6% | 25.5% | | | 24.0% | 25.2% | 24.8% | |
| | Asia and Oceania | 45.2 | 41.8 | -3.4 | -7.6% | 91.1 | 88.3 | 85.1 | -6.6% |
| | Ratio to Sales | 6.6% | 6.4% | | | 6.6% | 6.5% | 6.5% | |

- Calculated according to locations of sellers.
- EMEA: Europe, Middle East and Africa

## 6 Per Share Information

| | FY15 APR. - SEP. | FY16 APR. - SEP. | FY15 Full Year | Initial Forecasts FY16 Full Year | Revised Forecasts FY16 Full Year |
|---|---|---|---|---|---|
| The number of shares issued (thousand) | 2,221,823 | 2,153,823 | 2,221,823 | | |
| Treasury Shares (thousand) | 64,020 | 29,169 | 96,844 | | |
| The number of shares issued after deducting Treasury Shares (thousand) | 2,157,802 | 2,124,653 | 2,124,978 | | |
| Earnings per share (yen) | 47.30 | 54.16 | 89.75 | 92.71 | 93.19 |
| Earnings per share (yen) core base | 47.76 | 56.75 | 92.12 | 93.65 | 95.07 |
| Dividend per share (yen) | 16 | 17 | 32 | 34 | 34 |

## 7. Addition to Property, Plant and Equipment

### Depreciation/Amortisation

Unit: B¥

| | | FY15 APR. - SEP. | FY16 APR. - SEP. | Change | Change (%) | FY15 Full Year | Initial Forecasts FY16 Full Year | Revised Forecasts FY16 Full Year | Change from FY15 FY16 Full Year (%) |
|---|---|---|---|---|---|---|---|---|---|
| Addition to Property, Plant and Equipment | | | | | | | | | |
| | Consolidated | 18.4 | 8.9 | -9.5 | -51.5% | 34.0 | 32.0 | 26.0 | -23.6% |
| Depreciation (PP&E) | | | | | | | | | |
| | Consolidated | 10.2 | 10.9 | 0.6 | 6.3% | 21.0 | 22.0 | 22.0 | 5.0% |
| Amortisation (Intangible Assets) * | | | | | | | | | |
| | Consolidated | 24.8 | 20.6 | -4.2 | -17.1% | 48.2 | 43.5 | 41.0 | -15.0% |

* Amortisation (Intangible Assets): Including amortisation of software, etc.

8. Sales of major products

1) Sales of global products

Unit: B¥

| | FY15 APR. - SEP. | FY16 APR. - SEP. | Change | Change (%) | FY15 Full Year | FY16 Full Year Initial Forecasts | FY16 Full Year Revised Forecasts | Change from FY15 (%) |
|---|---|---|---|---|---|---|---|---|
| XTANDI | 122.3 | 126.0 | 3.6 | 3.0% | 252.1 | 295.9 | 265.7 | 5.4% |
| US | 74.5 | 68.3 | -6.2 | -8.3% | 148.4 | 163.7 | 143.7 | -3.1% |
| ex-US | 47.9 | 57.7 | 9.8 | 20.4% | 103.7 | 132.2 | 122.0 | 17.6% |
| Japan | 13.1 | 11.8 | -1.3 | -9.9% | 26.2 | 25.7 | 24.3 | -7.2% |
| Americas (ex-US) | 2.3 | 3.5 | 1.3 | 56.6% | 4.5 | 6.1 | 7.2 | 59.9% |
| EMEA | 31.5 | 40.8 | 9.2 | 29.3% | 70.7 | 95.9 | 86.8 | 22.9% |
| Asia and Oceania | 1.0 | 1.6 | 0.6 | 53.8% | 2.4 | 4.5 | 3.7 | 54.9% |
| Eligard | 8.8 | 7.9 | -1.0 | -10.9% | 17.6 | 17.6 | 15.3 | -12.9% |
| EMEA | 8.7 | 7.7 | -1.0 | -11.5% | 17.4 | 17.3 | 15.0 | -13.5% |
| Asia and Oceania | 0.1 | 0.1 | 0.0 | 40.3% | 0.2 | 0.3 | 0.3 | 35.9% |
| Vesicare | 69.7 | 59.8 | -9.9 | -14.2% | 135.6 | 119.1 | 114.9 | -15.3% |
| Japan | 13.3 | 13.0 | -0.3 | -2.4% | 26.5 | 27.2 | 26.1 | -1.5% |
| Americas | 33.3 | 27.7 | -5.6 | -16.9% | 63.7 | 53.7 | 51.0 | -19.9% |
| EMEA | 20.3 | 16.6 | -3.8 | -18.5% | 39.8 | 32.4 | 32.5 | -18.4% |
| Asia and Oceania | 2.6 | 2.4 | -0.3 | -9.8% | 5.3 | 5.4 | 5.1 | -3.0% |
| Betanis/Myrbetriq/BETMIGA | 38.1 | 45.7 | 7.6 | 20.0% | 81.7 | 100.4 | 95.1 | 16.4% |
| Japan | 9.7 | 12.4 | 2.6 | 27.0% | 21.2 | 27.4 | 26.9 | 26.6% |
| Americas | 21.4 | 25.1 | 3.6 | 16.9% | 45.7 | 51.9 | 50.6 | 10.7% |
| EMEA | 6.6 | 6.9 | 0.2 | 3.6% | 13.4 | 18.3 | 14.5 | 8.5% |
| Asia and Oceania | 0.3 | 1.4 | 1.2 | 445.4% | 1.4 | 2.8 | 3.1 | 117.0% |
| Harnal/Omnic | 27.1 | 23.5 | -3.7 | -13.5% | 53.4 | 46.4 | 44.1 | -17.5% |
| Sales by Astellas | 25.7 | 22.5 | -3.2 | -12.3% | 50.4 | 44.2 | 42.1 | -16.4% |
| Japan | 6.7 | 4.8 | -1.9 | -27.8% | 12.7 | 9.4 | 9.0 | -28.7% |
| EMEA | 8.0 | 6.8 | -1.2 | -15.5% | 15.4 | 13.7 | 13.2 | -14.2% |
| Asia and Oceania | 10.6 | 10.5 | -0.1 | -1.2% | 21.5 | 20.5 | 19.9 | -7.7% |
| Bulk and Royalties | 1.5 | 1.0 | -0.5 | -33.9% | 3.0 | 2.2 | 1.9 | -35.5% |
| Prograf | 104.6 | 94.2 | -10.4 | -10.0% | 203.6 | 187.9 | 182.9 | -10.2% |
| Sales by Astellas | 103.1 | 92.6 | -10.5 | -10.2% | 200.7 | 185.4 | 180.5 | -10.1% |
| Japan (Including Graceptor) | 25.4 | 24.8 | -0.6 | -2.4% | 49.8 | 47.8 | 48.4 | -2.7% |
| Americas | 18.1 | 14.1 | -4.0 | -22.1% | 34.6 | 26.9 | 26.6 | -23.3% |
| EMEA | 40.1 | 35.7 | -4.5 | -11.1% | 77.9 | 73.6 | 68.7 | -11.8% |
| Advagraf | 15.8 | 15.0 | -0.8 | -5.1% | 31.1 | | | |
| Asia and Oceania | 19.4 | 18.0 | -1.4 | -7.4% | 38.4 | 37.1 | 36.8 | -4.3% |
| Exports to third parties | 1.5 | 1.6 | 0.1 | 6.5% | 2.8 | 2.5 | 2.4 | -14.9% |
| Funguard/MYCAMINE | 21.1 | 20.1 | -1.0 | -4.5% | 41.6 | 40.4 | 38.2 | -8.3% |
| Japan | 6.1 | 5.6 | -0.4 | -7.0% | 11.7 | 11.5 | 11.0 | -5.7% |
| Americas | 6.7 | 6.0 | -0.7 | -11.0% | 13.0 | 11.8 | 11.1 | -14.7% |
| EMEA | 5.6 | 5.6 | -0.0 | -0.9% | 11.2 | 11.2 | 10.3 | -8.5% |
| Asia and Oceania | 2.7 | 3.0 | 0.2 | 9.2% | 5.7 | 6.0 | 5.8 | 1.7% |

- Sales of products in Japan are shown in a gross sales basis.
- EMEA: Europe, Middle East and Africa

## 2) Sales of products in Japan

Unit: B¥

| <Global products> | FY15 APR. - SEP. | FY16 APR. - SEP. | Change | Change (%) | FY15 Full Year | Initial Forecasts FY16 Full Year | Revised Forecasts FY16 Full Year | Change from FY15 Change (%) |
|---|---|---|---|---|---|---|---|---|
| XTANDI | 13.1 | 11.8 | -1.3 | -9.9% | 26.2 | 25.7 | 24.3 | -7.2% |
| Vesicare | 13.3 | 13.0 | -0.3 | -2.4% | 26.5 | 27.2 | 26.1 | -1.5% |
| Betanis | 9.7 | 12.4 | 2.6 | 27.0% | 21.2 | 27.4 | 26.9 | 26.6% |
| Harnal | 6.7 | 4.8 | -1.9 | -27.8% | 12.7 | 9.4 | 9.0 | -28.7% |
| Prograf （Including Graceptor） | 25.4 | 24.8 | -0.6 | -2.4% | 49.8 | 47.8 | 48.4 | -2.7% |
| Funguard | 6.1 | 5.6 | -0.4 | -7.0% | 11.7 | 11.5 | 11.0 | -5.7% |
| <Local products in Japan> | | | | | | | | |
| Micardis [Family] | 48.5 | 46.8 | -1.7 | -3.5% | 97.2 | 90.8 | 94.7 | -2.6% |
| Micombi | 5.1 | 4.8 | -0.4 | -7.4% | 10.1 | | | |
| Micamlo | 12.7 | 13.0 | 0.3 | 2.0% | 26.0 | | | |
| Celecox | 23.4 | 24.1 | 0.7 | 3.0% | 46.6 | 50.4 | 48.3 | 3.8% |
| Symbicort | 17.5 | 18.7 | 1.1 | 6.5% | 37.4 | 41.1 | 40.1 | 7.2% |
| Bonoteo | 7.1 | 7.0 | -0.1 | -1.0% | 14.1 | 15.1 | 14.0 | -0.7% |
| Geninax | 4.8 | 4.2 | -0.5 | -11.2% | 10.8 | 10.2 | 10.0 | -7.7% |
| Vaccines | 14.0 | 11.1 | -2.9 | -20.7% | 41.1 | 25.9 | 30.2 | -26.6% |
| Argamate | 3.1 | 3.0 | -0.1 | -3.6% | 6.2 | 6.1 | 6.0 | -3.4% |
| Kiklin | 0.8 | 0.8 | -0.0 | -6.0% | 1.6 | 2.0 | 1.6 | -0.3% |
| Gonax | 1.9 | 2.2 | 0.2 | 12.7% | 3.9 | 4.6 | 4.5 | 15.5% |
| Cimzia | 3.2 | 3.9 | 0.6 | 19.6% | 6.6 | 9.6 | 8.0 | 21.9% |
| Suglat | 3.5 | 4.6 | 1.1 | 32.8% | 7.3 | 12.5 | 9.7 | 32.9% |
| Lipitor | 16.3 | 12.2 | -4.1 | -25.3% | 30.9 | 22.4 | 22.6 | -26.8% |
| Myslee | 9.2 | 7.6 | -1.6 | -17.9% | 17.9 | 14.6 | 14.6 | -18.3% |
| Gaster | 7.7 | 5.6 | -2.1 | -27.5% | 14.7 | 10.5 | 10.7 | -27.4% |
| Seroquel | 5.7 | 4.1 | -1.6 | -28.5% | 10.5 | 7.2 | 7.4 | -29.2% |
| Total Rx Sales In Japanese market | 240.0 | 221.8 | -18.2 | -7.6% | 483.0 | 456.6 | 453.0 | -6.2% |

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

## 3) Sales of products in Americas and EMEA

Unit: B¥

| | FY15 APR. - SEP. | FY16 APR. - SEP. | Change | Change (%) | FY15 Full Year | Initial Forecasts FY16 Full Year | Revised Forecasts FY16 Full Year | Change from FY15 Change (%) |
|---|---|---|---|---|---|---|---|---|
| Tarceva | 25.5 | 17.9 | -7.6 | -29.9% | 46.8 | | | |
| (US) | 18.6 | 13.2 | -5.5 | -29.3% | 33.8 | | | |
| (ex-US) | 6.9 | 4.7 | -2.2 | -31.4% | 13.0 | | | |
| Scan* (Americas) | 40.6 | 35.4 | -5.2 | -12.9% | 76.2 | 70.1 | 67.7 | -11.2% |
| AmBisome (Americas) | 5.5 | 4.8 | -0.8 | -13.7% | 10.9 | 9.8 | 9.7 | -10.9% |
| CRESEMBA (Americas) | 0.8 | 2.5 | 1.7 | 197.0% | 2.6 | 5.0 | 5.8 | 122.3% |
| Qutenza (EMEA) | 1.0 | 1.1 | 0.1 | 7.0% | 2.1 | | | |
| DIFICLIR (EMEA) | 1.3 | 1.1 | -0.2 | -17.5% | 2.6 | | | |

* Adenoscan + Lexiscan

- EMEA: Europe, Middle East and Africa

4) Sales in Americas and EMEA (Local currency)

Unit: M$

| Americas | FY15 APR. - SEP. | FY16 APR. - SEP. | Change | Change (%) | FY15 Full Year | Initial Forecasts FY16 Full Year | Revised Forecasts FY16 Full Year | Change from FY15 FY16 Change (%) |
|---|---|---|---|---|---|---|---|---|
| Sales | 1,912 | 1,963 | 51 | 2.6% | 3,788 | 4,011 | 3,986 | 5.2% |
| XTANDI | 630 | 682 | 52 | 8.3% | 1,272 | 1,544 | 1,470 | 15.5% |
| US | 611 | 649 | 37 | 6.1% | 1,235 | 1,488 | 1,400 | 13.4% |
| Americas (ex-US) | 19 | 34 | 15 | 81.2% | 37 | 56 | 70 | 87.1% |
| Tarceva | 210 | 170 | -40 | -18.9% | 389 | | | |
| US | 153 | 125 | -28 | -18.2% | 281 | | | |
| ex-US | 57 | 45 | -12 | -20.7% | 108 | | | |
| VESIcare | 273 | 263 | -11 | -3.9% | 530 | 488 | 497 | -6.3% |
| Myrbetriq | 176 | 238 | 62 | 35.2% | 380 | 472 | 493 | 29.6% |
| Prograf | 149 | 134 | -15 | -9.8% | 288 | 245 | 259 | -10.3% |
| Scan* | 333 | 336 | 3 | 0.8% | 634 | 637 | 660 | 4.0% |
| MYCAMINE | 55 | 57 | 2 | 3.0% | 109 | 107 | 108 | -0.2% |
| AmBisome | 45 | 45 | -0 | -0.2% | 91 | 89 | 95 | 4.3% |
| CRESEMBA | 7 | 24 | 17 | 243.5% | 22 | 45 | 56 | 160.2% |

* Adenoscan + Lexiscan

Unit: M€

| EMEA | FY15 APR. - SEP. | FY16 APR. - SEP. | Change | Change (%) | FY15 Full Year | Initial Forecasts FY16 Full Year | Revised Forecasts FY16 Full Year | Change from FY15 FY16 Change (%) |
|---|---|---|---|---|---|---|---|---|
| Sales | 1,201 | 1,406 | 204 | 17.0% | 2,484 | 2,717 | 2,763 | 11.3% |
| XTANDI | 233 | 345 | 112 | 47.9% | 533 | 767 | 745 | 39.8% |
| Eligard | 65 | 66 | 1 | 1.2% | 131 | 138 | 129 | -1.6% |
| Vesicare | 150 | 140 | -10 | -6.9% | 300 | 259 | 279 | -7.2% |
| BETMIGA | 49 | 58 | 9 | 18.4% | 101 | 146 | 125 | 23.4% |
| Omnic | 70 | 66 | -5 | -6.6% | 139 | 127 | 130 | -6.3% |
| Sales by Astellas | 59 | 57 | -2 | -3.4% | 116 | 109 | 114 | -2.4% |
| Bulk and Royalties | 11 | 8 | -3 | -24.4% | 23 | 18 | 17 | -26.6% |
| Prograf | 308 | 315 | 7 | 2.3% | 609 | 609 | 610 | 0.2% |
| Sales by Astellas | 297 | 302 | 5 | 1.6% | 588 | 589 | 590 | 0.3% |
| Advagraf | 117 | 127 | 10 | 8.5% | 234 | | | |
| Exports to third parties | 11 | 14 | 2 | 21.7% | 21 | 20 | 21 | -3.2% |
| MYCAMINE | 42 | 47 | 6 | 13.3% | 85 | 90 | 88 | 4.1% |
| Qutenza | 7 | 9 | 2 | 22.3% | 16 | | | |
| DIFICLIR | 10 | 9 | -1 | -5.7% | 20 | | | |

- EMEA: Europe, Middle East and Africa

9.Consolidated statements of financial position

Unit: B¥

| | | | 31-Mar-16 | 30-Sep-16 | |
|---|---|---|---|---|---|
| | | | Amount | Amount | Change |
| **Assets** | | | **1,799.3** | **1,713.2** | **-86.2** |
| | **Non-current assets** | | **901.8** | **838.5** | **-63.3** |
| | | Property, plant and equipment | 201.0 | 182.7 | -18.2 |
| | | Goodwill | 152.9 | 137.2 | -15.7 |
| | | Other intangible assets | 335.7 | 317.8 | -17.9 |
| | | Trade and other receivables | 24.1 | 28.0 | 3.9 |
| | | Investments in associates and joint ventures | 2.4 | 2.5 | 0.1 |
| | | Deferred tax assets | 81.5 | 74.2 | -7.3 |
| | | Other financial assets | 89.4 | 82.8 | -6.6 |
| | | Other non-current assets | 14.8 | 13.2 | -1.5 |
| | **Current assets** | | **897.5** | **874.7** | **-22.8** |
| | | Inventories | 161.7 | 157.4 | -4.2 |
| | | Trade and other receivables | 327.6 | 316.2 | -11.4 |
| | | Income tax receivable | 16.4 | 5.9 | -10.5 |
| | | Other financial assets | 14.4 | 12.0 | -2.4 |
| | | Other current assets | 17.2 | 16.8 | -0.4 |
| | | Cash and cash equivalents | 360.0 | 366.3 | 6.3 |
| | | Assets held for sale | 0.2 | - | -0.2 |

- Due to the adjustments of the provisional fair value for the acquisition of Ocata Therepeutics, Inc. (The company name was changed to Astellas Institute for Regenerative Medicine in May 2016.), consolidated statement of financial position as of 31 March, 2016 was retrospectively revised. For the details, refer to Financial Results P.22

Unit: B¥

| | 31-Mar-16 | 30-Sep-16 | |
|---|---|---|---|
| | Amount | Amount | Change |
| **Equity and Liabilities** | **1,799.3** | **1,713.2** | **-86.2** |
| **Equity** | **1,259.2** | **1,227.3** | **-32.0** |
| **Equity attributable to owners of the parent** | **1,259.2** | **1,227.3** | **-32.0** |
| Share capital | 103.0 | 103.0 | - |
| Capital surplus | 176.9 | 177.0 | 0.1 |
| Treasury shares | -157.1 | -47.3 | 109.8 |
| Retained earnings | 973.1 | 941.2 | -31.8 |
| Other components of equity | 163.4 | 53.4 | -110.0 |
| | | | |
| **Liabilities** | **540.1** | **485.9** | **-54.2** |
| **Non-current liabilities** | **126.8** | **102.4** | **-24.4** |
| Trade and other payables | 1.6 | 0.9 | -0.7 |
| Retirement benefit liabilities | 39.8 | 40.8 | 1.0 |
| Provisions | 7.1 | 4.9 | -2.2 |
| Other financial liabilities | 0.7 | 0.8 | 0.1 |
| Other non-current liabilities | 77.6 | 55.0 | -22.6 |
| **Current liabilities** | **413.4** | **383.5** | **-29.8** |
| Trade and other payables | 181.6 | 154.1 | -27.4 |
| Income tax payable | 19.3 | 9.7 | -9.6 |
| Provisions | 89.9 | 88.3 | -1.6 |
| Other financial liabilities | 1.5 | 34.6 | 33.1 |
| Other current liabilities | 121.1 | 96.9 | -24.2 |

10. Employees

Number of employees

| | FY15 2Q End | FY16 2Q End | FY15 FY End |
|---|---|---|---|
| Total | 17,352 | 17,215 | 17,217 |
| Japan | 7,300 | 7,070 | 7,056 |
| Americas | 2,957 | 2,936 | 3,062 |
| EMEA | 4,727 | 4,753 | 4,726 |
| Asia and Oceania | 2,368 | 2,456 | 2,373 |
| Total Medical Representatives | 6,220 | 5,980 | 6,000 |

- EMEA: Europe, Middle East and Africa

11. Shareholders

| | FY15 2Q End | FY16 2Q End |
|---|---|---|
| Banks | 30.5% | 32.0% |
| Securities | 3.6% | 3.0% |
| Other companies | 3.4% | 3.5% |
| Foreign companies | 51.4% | 51.6% |
| Individuals and others | 8.2% | 8.6% |
| Treasury Stock* | 2.9% | 1.3% |

* Treasury Stock does not include shares owned by the executive compensation BIP (Board Incentive Plan) trust

## [Three months ended September 30, 2016]

1. Consolidated Results (Full Basis)

Unit: B¥

| | FY16 | | | |
|---|---|---|---|---|
| | APR.-JUN. (Quarterly) | Change (%) | JUL.-SEP. (Quarterly) | Change (%) |
| Sales | 337.8 | -1.7% | 313.9 | -8.7% |
| Cost of sales | 71.5 | -20.7% | 74.7 | -4.6% |
| Ratio to Sales | 21.2% | | 23.8% | |
| Gross profit | 266.3 | 5.0% | 239.2 | -9.9% |
| SG&A expenses | 111.9 | -5.7% | 109.0 | -10.0% |
| Ratio to Sales | 33.1% | | 34.7% | |
| Advertising and Sales Promotion | 35.8 | -13.9% | 33.4 | -19.9% |
| Personnel expenses | 43.5 | -3.5% | 42.0 | -9.2% |
| Other | 32.6 | 1.9% | 33.6 | 1.3% |
| R&D expenses | 51.0 | -8.9% | 48.6 | -13.2% |
| Ratio to Sales | 15.1% | | 15.5% | |
| Amortisation of intangible assets | 9.0 | -17.5% | 8.7 | -20.8% |
| Share of profits/losses of associates and joint ventures | -0.4 | - | -0.3 | - |
| Other income | 0.2 | -81.8% | 0.1 | -44.0% |
| Gain on sales of property, plant and equipment | 0.0 | -89.6% | 0.0 | -89.8% |
| Other expense | 1.3 | -81.7% | 8.5 | 22.8% |
| Loss on sales and disposal of property, plant and equipment | 0.1 | 39.8% | 0.1 | -53.2% |
| Impairment losses | - | - | 7.6 | - |
| Net foreign exchange losses | 0.4 | - | 0.1 | -97.8% |
| Operating profit | 92.9 | 50.0% | 64.2 | -9.2% |
| Ratio to Sales | 27.5% | | 20.4% | |
| Finance income | 1.2 | -79.8% | 1.2 | -84.0% |
| Gain on sales of available-for-sale financial assets | 0.7 | -88.1% | 0.9 | -85.8% |
| Finance expense | 0.9 | 225.1% | 0.8 | 166.0% |
| Impairment losses for available-for-sale financial assets | 0.3 | 888.3% | 0.1 | 14.2% |
| Profit before tax | 93.2 | 37.7% | 64.6 | -16.9% |
| Ratio to Sales | 27.6% | | 20.6% | |
| Income tax expense | 26.6 | 15.3% | 16.1 | -17.0% |
| Profit for the period | 66.6 | 49.3% | 48.5 | -16.9% |
| Ratio to Sales | 19.7% | | 15.4% | |
| Comprehensive income | -34.0 | - | 36.7 | 11.0% |

2. Consolidated Results (Core Basis)

Unit: B¥

| | FY16 | | | |
|---|---|---|---|---|
| | APR.-JUN. (Quarterly) | Change (%) | JUL.-SEP. (Quarterly) | Change (%) |
| Sales | 337.8 | -1.7% | 313.9 | -8.7% |
| Cost of sales | 71.5 | -20.7% | 74.7 | -4.6% |
| Ratio to Sales | 21.2% | | 23.8% | |
| Gross profit | 266.3 | 5.0% | 239.2 | -9.9% |
| SG&A expenses | 111.9 | -5.7% | 109.0 | -10.0% |
| Ratio to Sales | 33.1% | | 34.7% | |
| Advertising and Sales Promotion | 35.8 | -13.9% | 33.4 | -19.9% |
| Personnel expenses | 43.5 | -3.5% | 42.0 | -9.2% |
| Other | 32.6 | 1.9% | 33.6 | 1.3% |
| R&D expenses | 51.0 | -8.9% | 48.6 | -13.2% |
| Ratio to Sales | 15.1% | | 15.5% | |
| Amortisation of intangible assets | 9.0 | -17.5% | 8.7 | -20.8% |
| Share of profits/losses of associates and joint ventures | -0.4 | - | -0.3 | - |
| Operating profit | 94.0 | 38.5% | 72.5 | -6.3% |
| Ratio to Sales | 27.8% | | 23.1% | |
| Finance income | 0.6 | 2.8% | 0.2 | -67.8% |
| Finance expense | 0.6 | 624.3% | 0.7 | 213.0% |
| Profit before Tax | 93.9 | 37.5% | 72.1 | -7.5% |
| Ratio to Sales | 27.8% | | 23.0% | |
| Income tax expense | 26.8 | 15.1% | 18.6 | -1.7% |
| Profit for the period | 67.1 | 49.1% | 53.4 | -9.3% |
| Ratio to Sales | 19.9% | | 17.0% | |

3. Sales by Region

Unit: B¥

| | | FY16 | | | |
|---|---|---|---|---|---|
| | | APR.-JUN. (Quarterly) | Change (%) | JUL.-SEP. (Quarterly) | Change (%) |
| Sales | | 337.8 | -1.7% | 313.9 | -8.7% |
| | Japan | 124.2 | -1.1% | 113.0 | -7.0% |
| | Ratio to Sales | 36.8% | | 36.0% | |
| | Americas | 107.6 | -6.3% | 99.1 | -16.1% |
| | Ratio to Sales | 31.8% | | 31.6% | |
| | EMEA | 85.3 | 4.4% | 80.8 | 0.3% |
| | Ratio to Sales | 25.3% | | 25.7% | |
| | Asia and Oceania | 20.7 | -3.8% | 21.1 | -11.0% |
| | Ratio to Sales | 6.1% | | 6.7% | |

- Calculated according to locations of sellers.

- EMEA: Europe, Middle East and Africa

4. Addition to Property, Plant and Equipment
Depreciation/Amortisation

Unit: B¥

| | | FY16 | | | |
|---|---|---|---|---|---|
| | | APR.-JUN. (Quarterly) | Change (%) | JUL.-SEP. (Quarterly) | Change (%) |
| Addition to Property, Plant and Equipment | | | | | |
| | Consolidated | 3.9 | -69.2% | 5.0 | -12.9% |
| Depreciation (PP&E) | | | | | |
| | Consolidated | 5.5 | 9.9% | 5.4 | 2.9% |
| Amortisation (Intangible Assets) * | | | | | |
| | Consolidated | 10.4 | -15.4% | 10.2 | -18.7% |

* Amortisation (Intangible Assets): Including amortisation of software, etc.

5. Sales of major products

1) Sales of global products

Unit: B¥

| | FY16 | | | |
|---|---|---|---|---|
| | APR.-JUN. (Quarterly) | Change (%) | JUL.-SEP. (Quarterly) | Change (%) |
| XTANDI | 64.2 | 8.7% | 61.7 | -2.4% |
| US | 35.7 | -1.4% | 32.6 | -14.8% |
| ex-US | 28.5 | 24.8% | 29.1 | 16.4% |
| Japan | 6.1 | -10.7% | 5.7 | -9.0% |
| Americas (ex-US) | 1.8 | 70.0% | 1.8 | 45.1% |
| EMEA | 20.0 | 37.0% | 20.8 | 22.8% |
| Asia and Oceania | 0.7 | 62.5% | 0.9 | 47.4% |
| Eligard | 4.4 | -0.1% | 3.4 | -21.8% |
| EMEA | 4.4 | -0.6% | 3.4 | -22.4% |
| Asia and Oceania | 0.1 | 59.5% | 0.1 | 27.9% |
| Vesicare | 30.4 | -14.0% | 29.4 | -14.5% |
| Japan | 7.0 | 1.7% | 6.0 | -6.7% |
| Americas | 13.6 | -20.5% | 14.1 | -13.3% |
| EMEA | 8.7 | -14.8% | 7.9 | -22.3% |
| Asia and Oceania | 1.2 | -3.3% | 1.2 | -15.7% |
| Betanis/Myrbetriq/BETMIGA | 23.6 | 30.1% | 22.1 | 10.9% |
| Japan | 6.4 | 32.5% | 5.9 | 21.5% |
| Americas | 12.9 | 31.4% | 12.1 | 4.5% |
| EMEA | 3.5 | 6.4% | 3.4 | 0.9% |
| Asia and Oceania | 0.7 | 606.9% | 0.7 | 351.4% |
| Harnal/Omnic | 12.1 | -14.6% | 11.3 | -12.3% |
| Sales by Astellas | 11.5 | -13.3% | 11.0 | -11.3% |
| Japan | 2.6 | -25.1% | 2.3 | -30.7% |
| EMEA | 3.7 | -22.5% | 3.1 | -5.4% |
| Asia and Oceania | 5.2 | 3.3% | 5.3 | -5.2% |
| Bulk and Royalties | 0.6 | -34.4% | 0.4 | -33.1% |
| Prograf | 49.4 | -1.9% | 44.8 | -17.4% |
| Sales by Astellas | 48.7 | -2.4% | 43.9 | -17.5% |
| Japan (Including Graceptor) | 12.9 | 1.4% | 11.9 | -6.2% |
| Americas | 7.7 | -8.4% | 6.4 | -33.8% |
| EMEA | 19.0 | -2.8% | 16.6 | -19.0% |
| Advagraf | 7.9 | 5.1% | 7.1 | -14.3% |
| Asia and Oceania | 9.0 | -1.3% | 9.0 | -12.9% |
| Exports to third parties | 0.8 | 45.6% | 0.9 | -13.7% |
| Funguard/MYCAMINE | 10.0 | -2.5% | 10.1 | -6.5% |
| Japan | 2.7 | -7.0% | 2.9 | -7.0% |
| Americas | 3.1 | -4.9% | 2.9 | -16.8% |
| EMEA | 2.8 | -2.8% | 2.8 | 1.1% |
| Asia and Oceania | 1.5 | 14.9% | 1.5 | 4.2% |

- Sales of products in Japan are shown in a gross sales basis.
- EMEA: Europe, Middle East and Africa

2) Sales of products in Japan

Unit: B¥

| | FY16 | | | |
|---|---|---|---|---|
| | APR.-JUN. | Change | JUL.-SEP. | Change |
| <Global products> | (Quarterly) | (%) | (Quarterly) | (%) |
| XTANDI | 6.1 | -10.7% | 5.7 | -9.0% |
| Vesicare | 7.0 | 1.7% | 6.0 | -6.7% |
| Betanis | 6.4 | 32.5% | 5.9 | 21.5% |
| Harnal | 2.6 | -25.1% | 2.3 | -30.7% |
| Prograf （Including Graceptor） | 12.9 | 1.4% | 11.9 | -6.2% |
| Funguard | 2.7 | -7.0% | 2.9 | -7.0% |
| <Local products in Japan> | | | | |
| Micardis [Family] | 24.7 | -0.4% | 22.1 | -6.8% |
| Micombi | 2.5 | -4.8% | 2.2 | -10.3% |
| Micamlo | 6.8 | 5.2% | 6.2 | -1.2% |
| Celecox | 12.4 | 4.9% | 11.7 | 1.2% |
| Symbicort | 9.8 | 9.3% | 8.8 | 3.6% |
| Bonoteo | 3.6 | -0.8% | 3.3 | -1.3% |
| Geninax | 2.5 | -12.5% | 1.8 | -9.3% |
| Vaccines | 3.8 | -42.4% | 7.3 | -1.5% |
| Argamate | 1.5 | -0.4% | 1.4 | -6.8% |
| Kiklin | 0.4 | -1.6% | 0.4 | -10.3% |
| Gonax | 1.1 | 14.7% | 1.1 | 10.7% |
| Cimzia | 1.9 | 20.8% | 1.9 | 18.4% |
| Suglat | 2.3 | 14.9% | 2.3 | 58.2% |
| Lipitor | 6.4 | -22.8% | 5.7 | -27.8% |
| Myslee | 3.9 | -15.8% | 3.7 | -19.9% |
| Gaster | 3.0 | -24.6% | 2.6 | -30.5% |
| Seroquel | 2.2 | -25.3% | 1.8 | -32.1% |
| Total Rx Sales In Japanese market | 114.8 | -6.1% | 107.0 | -9.1% |

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

3) Sales of products in Americas and EMEA

Unit: B¥

| | FY16 | | | |
|---|---|---|---|---|
| | APR.-JUN. | Change | JUL.-SEP. | Change |
| | (Quarterly) | (%) | (Quarterly) | (%) |
| Tarceva | 9.4 | -28.4% | 8.5 | -31.5% |
| (US) | 6.8 | -30.2% | 6.4 | -28.4% |
| (ex-US) | 2.6 | -23.3% | 2.1 | -39.5% |
| Scan* (Americas) | 19.3 | -7.3% | 16.1 | -18.8% |
| AmBisome (Americas) | 2.4 | -12.9% | 2.3 | -14.6% |
| CRESEMBA (Americas) | 1.3 | 346.4% | 1.2 | 120.7% |
| Qutenza (EMEA) | 0.6 | 10.3% | 0.5 | 3.4% |
| DIFICLIR (EMEA) | 0.6 | -6.9% | 0.5 | -27.6% |

* Adenoscan + Lexiscan

- EMEA: Europe, Middle East and Africa

4) Sales in Americas and EMEA (Local currency)

Unit: M$

| Americas | FY16 APR.-JUN. (Quarterly) | Change (%) | JUL.-SEP. (Quarterly) | Change (%) |
|---|---|---|---|---|
| Sales | 995 | 5.2% | 968 | 0.2% |
| XTANDI | 347 | 12.9% | 336 | 3.9% |
| US | 330 | 10.7% | 318 | 1.7% |
| Americas (ex-US) | 16 | 90.8% | 17 | 72.9% |
| Tarceva | 87 | -19.6% | 83 | -18.1% |
| US | 63 | -21.6% | 62 | -14.5% |
| ex-US | 24 | -13.9% | 21 | -27.4% |
| VESIcare | 126 | -10.7% | 137 | 3.3% |
| Myrbetriq | 119 | 47.5% | 119 | 24.7% |
| Prograf | 71 | 2.8% | 63 | -20.8% |
| Scan* | 178 | 4.0% | 158 | -2.7% |
| MYCAMINE | 29 | 6.7% | 28 | -0.6% |
| AmBisome | 23 | -2.2% | 23 | 1.9% |
| CRESEMBA | 12 | 400.9% | 12 | 162.7% |

* Adenoscan + Lexiscan

Unit: M€

| EMEA | FY16 APR.-JUN. (Quarterly) | Change (%) | JUL.-SEP. (Quarterly) | Change (%) |
|---|---|---|---|---|
| Sales | 699 | 14.8% | 706 | 19.3% |
| XTANDI | 164 | 50.6% | 181 | 45.5% |
| Eligard | 36 | 9.3% | 30 | -7.0% |
| Vesicare | 71 | -6.3% | 69 | -7.4% |
| BETMIGA | 29 | 16.9% | 29 | 20.0% |
| Omnic | 35 | -16.9% | 31 | 8.7% |
| Sales by Astellas | 30 | -14.8% | 28 | 13.2% |
| Bulk and Royalties | 5 | -27.8% | 3 | -18.6% |
| Prograf | 162 | 8.2% | 153 | -3.2% |
| Sales by Astellas | 156 | 6.8% | 146 | -3.4% |
| Advagraf | 65 | 15.6% | 62 | 2.1% |
| Exports to third parties | 6 | 59.8% | 7 | 1.8% |
| MYCAMINE | 23 | 6.9% | 24 | 20.0% |
| Qutenza | 5 | 21.3% | 4 | 23.4% |
| DIFICLIR | 5 | 2.4% | 4 | -13.5% |

- EMEA: Europe, Middle East and Africa

# R&D Pipeline (As of October 2016)

Underlined items indicate for changes from the previous announcement on July 29, 2016.

## 1. Global Development

### (1) Filed

*Compounds with "In-house" in this column include ones discovered by collaborative research. (The same applicable hereafter.)

| Code No. Generic Name | Classification | Target Disease | Area / Phase | Dosage Form | Licensor* | Remarks |
|---|---|---|---|---|---|---|
| MDV3100 enzalutamide | Androgen receptor inhibitor | Metastatic castration-resistant prostate cancer (Tablet) | Europe Filed (Mar. 2016) | Oral | Medivation | New formulation |
| | | Castration-resistant prostate cancer (Tablet) | Japan Filed (Sept. 2016) | | | |

### (2) Phase-III / Phase-II (1/4)

| Code No. Generic Name | Classification | Target Disease | Area / Phase | Dosage Form | Licensor | Remarks |
|---|---|---|---|---|---|---|
| MDV3100 enzalutamide | Androgen receptor inhibitor | Non-metastatic castration-resistant prostate cancer | US/Europe/Asia Phase-III | Oral | Medivation | New indication |
| | | Prostate cancer in patients with non-metastatic biochemical recurrence | US/Europe/Asia Phase-III | | | New indication |
| | | Metastatic hormone-sensitive prostate cancer | US/Europe/Japan/Asia Phase-III | | | New indication |
| | | Triple-negative breast cancer | US/Europe/Japan/Asia Phase-III | | | New indication |
| | | Breast cancer (ER/PgR positive, HER2 positive) | US/Europe Phase-II | | | New indication |
| | | Hepatocellular carcinoma | US/Europe/Asia Phase-II | | | New indication |

(2) Phase-III / Phase-II (2/4)

| Code No.<br>Generic Name | Classification | Target Disease | Area / Phase | Dosage Form | Licensor | Remarks |
|---|---|---|---|---|---|---|
| ASP0113<br>(VCL-CB01) | DNA vaccine<br>for cytomegalovirus | Cytomegalovirus reactivation<br>in hematopoietic cell<br>transplant recipients | US/Europe/Japan<br>Phase-III | Injection | Vical | |
| YM905<br>solifenacin | Muscarine $M_3$ receptor<br>antagonist | Neurogenic detrusor overactivity<br>in pediatric patients | US/Europe Phase-III | Oral | In-house | New indication<br>(pediatric) |
| EB178<br>solifenacin/<br>mirabegron | Concomitant use of<br>solifenacin and mirabegron | Urinary frequency,<br>urinary incontinence or urgency<br>associated with overactive bladder | US/Europe/Asia<br>Phase-III | Oral | In-house | |
| fidaxomicin | Macrocyclic antibiotic | Infectious enteritis<br>(bacterial target:<br>*Clostridium difficile* ) | Japan Phase-III | Oral | Merck | |
| | | *Clostridium difficile* infection<br>in pediatric patients | Europe Phase-III | | | New indication<br>(pediatric) |
| ASP015K<br>peficitinib | JAK inhibitor | Rheumatoid arthritis | Japan/Asia Phase-III<br>US/Europe Phase-II | Oral | In-house | |
| ASP1517<br>(FG-4592)<br>roxadustat | HIF stabilizer | Anemia associated with chronic<br>kidney disease in patients<br>not on dialysis and on dialysis | Europe Phase-III<br>Japan Phase-III | Oral | FibroGen | |

(2) Phase-III / Phase-II (3/4)

| Code No.<br>Generic Name | Classification | Target Disease | Area / Phase | Dosage Form | Licensor | Remarks |
|---|---|---|---|---|---|---|
| ASP2215<br>gilteritinib | FLT3/AXL inhibitor | Acute myeloid leukemia | US/Europe/Japan/Asia<br>Phase-III | Oral | In-house | |
| | | Non-small cell lung cancer | US/Japan/Asia<br>Phase-I | | | |
| ASP8273 | Mutant-selective irreversible EGFR inhibitor | Non-small cell lung cancer | US/Europe/Japan/Asia<br>Phase-III | Oral | In-house | |
| YM178<br>mirabegron | Beta 3 receptor agonist | Neurogenic detrusor overactivity in pediatric patients | Europe Phase-III | Oral | In-house | New indication (pediatric) |
| YM311<br>(FG-2216) | HIF stabilizer | Renal anemia | Europe Phase-II<br>Japan Phase-I | Oral | FibroGen | |
| ASKP1240<br>bleselumab | Anti-CD40 monoclonal antibody | Recurrence of focal segmental glomerulosclerosis in de novo kidney transplant recipients | US Phase-II | Injection | Kyowa Hakko Kirin | |
| ASP1707 | GnRH antagonist | Endometriosis | Europe/Japan<br>Phase-II | Oral | In-house | |
| | | Rheumatoid arthritis | Japan Phase-II | | | |
| ASP8232 | VAP-1 inhibitor | Diabetic nephropathy | Europe Phase-II | Oral | In-house | |

(2) Phase-III / Phase-II (4/4)

| Code No.<br>Generic Name | Classification | Target Disease | Area / Phase | Dosage Form | Licensor | Remarks |
|---|---|---|---|---|---|---|
| CK-2127107 | Fast skeletal troponin activator | Spinal muscular atrophy | US Phase-II | Oral | Cytokinetics | |
| | | Chronic obstructive pulmonary disease | US Phase-II | | | |
| ASP7962 | TrkA inhibitior | Osteoarthritis | Europe Phase-II | Oral | In-house | |
| AGS-16C3F | ADC targeting ENPP3 | Renal cell carcinoma | US/Europe Phase-II | Injection | In-house (ADC technology in-licensed from Seattle Genetics) | |
| RPE cell program | Cell therapy (Retinal pigment epithelium cell) | Dry age-related macular degeneration, Stargardt's macular degeneration | US Phase-II | Injection | In-house (Astellas Institute for Regenerative Medicine) | |
| ASP8062 | $GABA_B$ receptor positive allosteric modulator | Fibromyalgia | US Phase-II | Oral | In-house | |
| ASP0819 | Calcium$^{2+}$-activated $K^+$ channel opener | Fibromyalgia | US Phase-II | Oral | In-house | |

2. Local Development: Japan

(1) Approved

| Code No.<br>Generic Name | Product Name<br>(Approval Date) | Classification | Target Disease | Area | Dosage Form | Licensor | Remarks |
|---|---|---|---|---|---|---|---|
| ASP1585<br>(AMG 223)<br>bixalomer | Kiklin Granules<br>(Sept. 2016) | Amine-functional polymer | Treatment of hyperphosphatemia in patients with chronic kidney disease (granule formulation) | Japan | Oral | Amgen | New formulation |

(2) Filed

| Code No.<br>Generic Name | Classification | Target Disease | Area / Phase | Dosage Form | Licensor | Remarks |
|---|---|---|---|---|---|---|
| ASP7374 | Influenza vaccine | Prophylaxis of seasonal influenza | Japan Filed<br>(May 2014) | Injection | UMN Pharma | |
| ASP0456<br>linaclotide | Guanylate cyclase-C receptor agonist | Irritable bowel syndrome with constipation | Japan Filed<br>(Feb. 2016) | Oral | Ironwood | |
| FK949E<br>quetiapine | Serotonin / dopamine antagonist | Improvement of depressive symptoms associated with bipolar disorder (Extended-release tablet) | Japan Filed<br>(Aug. 2016) | Oral | AstraZeneca | |

(3) Phase-III / Phase-II

| Code No.<br>Generic Name | Classification | Target Disease | Area / Phase | Dosage Form | Licensor | Remarks |
|---|---|---|---|---|---|---|
| ASP3550<br>degarelix | GnRH antagonist | Prostate cancer<br>(3-month formulation) | Japan Phase-III | Injection | Ferring | New formulation |
| AMG 785<br>romosozumab | Anti-Sclerostin monoclonal antibody | Osteoporosis | Japan Phase-III | Injection | Amgen<br>(co-development with Amgen Astellas) | |
| ipragliflozin/<br>sitagliptin | Fixed dose combination of ipragliflozin and sitagliptin | Type 2 diabetes mellitus | Japan Phase-III | Oral | In-house<br>(co-development with MSD and Kotobuki) | |
| ASP1941<br>ipragliflozin | SGLT2 inhibitor | Type 1 diabetes mellitus | Japan Phase-III | Oral | In-house<br>(co-development with Kotobuki) | New indication |
| ASP0456<br>linaclotide | Guanylate cyclase-C receptor agonist | Chronic constipation | Japan Phase-III | Oral | Ironwood | New indication |
| ASP7373 | Influenza vaccine | Prophylaxis of H5N1 influenza | Japan Phase-II | Injection | UMN Pharma | |
| AMG 103<br>blinatumomab | Anti-CD19 BiTE | Acute lymphoblastic leukemia | Japan Phase-II | Injection | Amgen<br>(co-development with Amgen Astellas) | |

3. Phase-I

| Code No.<br>Generic Name | Target Disease | Dosage Form | Licensor |
|---|---|---|---|
| ASP3662 | Alzheimer's disease | Oral | In-house |
| ASG-22ME<br>enfortumab vedotin | Solid tumors, Urothelial cancer | Injection | In-house<br>(co-development with Seattle Genetics) |
| ASG-15ME | Urothelial cancer | Injection | In-house<br>(co-development with Seattle Genetics) |
| ASP5878 | Cancer | Oral | In-house |
| AGS67E | Lymphoid malignancies | Injection | In-house (ADC technology<br>in-licensed from Seattle Genetics) |
| ASP2205 | Stress urinary incontinence | Oral | In-house |
| ASP5094 | Rheumatoid arthritis | Injection | In-house |
| ASP4132 | Cancer | Oral | In-house |
| ASP4345 | Cognitive impairment associated with schizophrenia | Oral | In-house |
| ASP6282 | Underactive bladder | Oral | In-house |
| ASP4070<br>(JRC2-LAMP-vax) | Pollinosis caused by Japanese red cedar | Injection | Immunomic Therapeutics |
| ASP7398 | Nocturia | Oral | In-house |
| ASP6294 | Bladder pain syndrome / Interstitial cystitis | Injection | In-house |
| ASP7266 | Severe asthma | Injection | In-house |
| ASP0892 | Peanut allergy | Injection | Immunomic Therapeutics |
| AGS62P1 | Acute myeloid leukemia | Injection | In-house (ADC technology, EuCODE license from Ambrx) |
| ASP1807 (CC8464) | Neuropathic pain | Oral | Chromocell |
| ASP8302 | Underactive bladder | Oral | In-house |

4. Discontinued

(1) Discontinued in a part of indication

| Code No.<br>Generic Name | Target Disease | Area / Phase | Reason |
|---|---|---|---|
| ASP0113<br>(VCL-CB01) | Cytomegalovirus infection<br>or reactivation<br>in solid organ transplant recipients | US/Europe Phase-II | The Phase-II study did not meet its primary endpoint. |
| ASP8232 | Diabetic macular edema | US Phase-II | The Phase-II study did not meet its primary endpoint. |
| ASP3662 | Painful diabetic peripheral neuropathy | US Phase-II | The Phase-II study was terminated due to futility analysis for efficacy. |

5. Other items changed from the previous quarterly announcement on July 29, 2016

-Removed the description of solifenacin for overactive bladder in pediatric patients, for which review was completed in Europe.